The beginning of the end for cervical cancer in India

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Taking a huge step towards the goal of elimination of cervical cancer, India is getting ready to roll out its indigenous quadrivalent human papillomavirus (HPV) vaccine named Cervavac as a part of the universal immunization program. This began with the National Technical Advisory Group on Immunization, the highest advisory body on immunization in India, which recommended incorporating the HPV vaccine into the universal immunization program in June 28, 2022. The vaccine was developed by the Serum Institute of India in partnership with the Department of Biotechnology under the Ministry of Science and Technology, the Biotechnology Industry Research Assistance Council, and the Bill and Melinda Gates Foundation. Based on a phase II/III randomized multicenter trial demonstrating non-inferior immune response of Cervavac compared with Gardasil, the drug controller general of India approved the marketing of Cervavac on July 12, 2022. The cost of a single dose of Cervavac is 200–400 Indian rupees (<US$5), which is a game changer for populations with limited resources for procurement. Launched officially on the September first 2023, Cervavac marks India's unrelenting march towards accelerating the global elimination of cervical cancer

With a plan to introduce the vaccine in a phased manner from 2013 to 2016, the vaccine demand for one-time catch up for girls aged 9–14 years would be around 23 million doses per year to effectively cover India's target age group. Following this, routine vaccination will be rolled out for the next cohort of girls aged 9 years. To ensure adequate coverage and to avoid drop-outs, it is planned to introduce the vaccine in schools with a grade/class-based approach, with both doses administered within the same academic calendar year. Outreach sessions and facility-based campaigns with an age-based approach will be planned for out-of-school vaccination and hard-to-reach areas. At present, the Serum Institute of India has a production capacity of 2–3 million doses of Cervavac, but is planning to expand the capacity to reach a target of 60–70 million doses.

In preparation for the vaccine roll-out, there is ample native experience with HPV vaccine implementation programs and demonstration projects to draw on. Demonstration projects through the efforts of the Indian Council of Medical Research and Program for Appropriate Technology in Health were initiated in the states of Andhra Pradesh and Gujarat in 2009 but were prematurely suspended owing to seven deaths, which were later proved to be unrelated. A cluster-randomized trial evaluating the efficacy of two versus three doses of quadrivalent vaccine initiated in 2009 by the International Agency for Research on Cancer was also terminated in 2010 owing to government suspension of the vaccine. These projects presented unique opportunities by providing data on immunogenicity of a single dose of quadrivalent vaccine in the defaulted cohort. Following this, subnational pilot vaccination efforts undertaken as a district-wide program implemented in Bathinda and Mansa districts of Punjab in 2016 and a state-wide program implemented in Sikkim in 2018 provided invaluable insights into cultural behavior, vaccine acceptance, advocacy efforts, communication strategies, and social mobilization, unique to Indian culture.

With 20% of the cervical cancer burden borne by India alone, Cervavac roll-out represents a giant step globally. With the support of theIndian Government and other stakeholders, Cervavac is our hope towards ensuring a cervical cancer-free future for India.

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