Rapid Situation Analysis—India

PREVENTING CERVICAL CANCER THROUGH VACCINATION

Situation Overview

1. Severity of crisis

One in five women dying from cervical cancer in the world today lives in India. While new cases of cervical cancer have declined in the past few years, projected trends show a rise in annual cases from just under 125,000 today to 148,624 by 2020.¹ Cervical cancer is the second-most common cancer affecting women between the ages of 15 and 44.

2. Status of HPV vaccine roll-out in India

After the suspension of the human papillomavirus (HPV) vaccine demonstration project in March 2010 involving nearly 23,500 girls in Vadodara, Gujarat and Khammam, Andhra Pradesh, the state governments of Delhi and Punjab have started pilots to vaccinate girls aged 11 to 13 years in 2016-17.

The Delhi State Cancer Institute, a state government organization, delivered over 4,500 doses in an opportunistic manner; approximately 1,200 girls received the second dose. The initiative is expected to continue.

The state government of Punjab focused on two districts, Bathinda and Mansa. Sixth graders in government schools were vaccinated during Phase 1, and six graders in all schools—government and private—were vaccinated in Phase 2. In total, around 9,000 girls received the first dose in Phase 1 and the second dose in Phase 2. An additional 6,000 girls received the first dose in Phase 2. All vaccinations were administered in district clinics. The effort is expected to expand in 2018 to include additional districts.

184
Number of women who die every day from cervical cancer in India

Fewer than 5%
Percent of eligible women in India who have ever been screened

HPV-related cancer incidence in India

<table>
<thead>
<tr>
<th>Cancer Site</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervix uteri</td>
<td>22.0</td>
</tr>
<tr>
<td>Other anogenital</td>
<td>1.0</td>
</tr>
<tr>
<td>Head &amp; neck</td>
<td>0.6</td>
</tr>
</tbody>
</table>

124,844
Estimated annual new cases of cervical cancer

67,477
Estimated annual deaths from cervical cancer

Top 5 cancers (# in thousands)

<table>
<thead>
<tr>
<th>Cancer Site</th>
<th>Incidence</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cervix uteri</td>
<td>2,387</td>
</tr>
<tr>
<td>Breast</td>
<td>1,658</td>
</tr>
<tr>
<td>Ovarian</td>
<td>597</td>
</tr>
<tr>
<td>Leukemia</td>
<td>483</td>
</tr>
<tr>
<td>Lip &amp; OC</td>
<td>452</td>
</tr>
</tbody>
</table>

Assessment registry: GlobalCan 2017 report
3. Priority barriers

AT THE SYSTEM LEVEL:

- **COST:** Even at the Gavi-negotiated price of US$4.50, the HPV vaccine is significantly costlier when compared with other vaccines included in the Universal Immunization Program (UIP).²

- **INCLUSION OF THE HPV VACCINE IN UIP:** The National Technical Advisory Group on Immunization (NTAGI) has reviewed the vaccine, but not recommended it be included in the UIP at this time.³ This implies that states need to allocate their own funds if they choose to deliver the vaccine, which is a significant barrier.

- **SUPREME COURT CASE:** A pending Supreme Court case from the 2008-10 HPV vaccination demonstration project continues to prompt caution from the government agencies and civil society organizations.

The next two barriers are not specific to the HPV vaccine but are occasionally cited as arguments in opposition to it.

- **VACCINE INJURY COMPENSATION FUND:** In India, there is no vaccine injury compensation program for investigating adverse events following immunizations and compensating vaccine-related injuries and disabilities.

- **CANCER REGISTRATION AND SURVEILLANCE SYSTEMS:** The population-based cancer registries and other vital registries are not representative and therefore limited in their ability to inform policy and recommendations for newer interventions.⁴,⁵

AT THE INDIVIDUAL LEVEL:

- **PUBLIC AWARENESS AND STIGMA:** Public awareness of cervical cancer and its risk factors is very low. The fact that HPV infection is acquired through sexual activity makes public discourse and engagement a challenge that has not yet been addressed.

- **CLINICIAN EDUCATION AND AWARENESS:** Even though the Indian Academy of Pediatrics (IAP) has a formal recommendation for the HPV vaccine, the fact that it is not included in the UIP continues to cause confusion among clinicians in the private sector. Furthermore, ongoing unsupportive comments from oncologists and discussions taking place at professional conferences on different target age groups for the vaccine add to the confusion.

4. Potential Facilitators

- The IAP and the Federation of Obstetric and Gynecological Societies of India strongly recommend the use of the HPV vaccine to protect against cervical cancer.⁶

- During their December 19, 2017 meeting, the NTAGI endorsed the Standing Technical Sub-Committee (STSC) recommendation for introduction of HPV vaccine. The Group further recommended an effective communication strategy be put in place and additional studies and research be done to understand the protective efficacy of the vaccine among married versus unmarried women, particularly in Punjab, which has included HPV vaccine in its immunization program.⁷
• Also presented during the meeting were the results of an assessment done by the NTAGI secretariat using India-specific data on the cost effectiveness of HPV vaccination in girls. “The incremental cost averted is US$137/DALY which make the HPV vaccination of girls very cost-effective intervention, per the WHO definition, for inclusion in the UIP.”

5. Government capacity to respond

• India’s UIP has created the necessary infrastructure, human resources and systems for the procurement and delivery of vaccines at state and national levels.

• There are two vaccines currently included in the UIP that may be delivered in some schools in Punjab: Tetanus Toxoid (TT) vaccine (two doses at 10 years and 16 years of age) and DPT booster (one dose at 5-6 years). It is therefore likely that states have processes in place for delivering vaccinations to children and adolescents in schools. The coverage of these vaccines is however not clear.

• The Government of India has a funding shortfall that has increased from approximately US$550 million in 2013 to US$35 billion in 2017, without the inclusion of the HPV vaccine into the UIP. This funding gap has arisen for several reasons, including the rising costs of personnel and inclusion of rotavirus and PCV vaccines in the program.

6. Other relevant developments and trends

• NEW HPV VACCINE MANUFACTURERS IN INDIA AND CHINA: The Serum Institute of India is developing a tetravalent HPV vaccine that includes L1 VLPs of serotypes 6,11,16,18, which is expected to give a coverage of approximately 90% against the papilloma virus prevalent in the developing world. The vaccine is currently going through Phase II clinical trials. Additionally, the National Institute of Diagnostics and Vaccine Development in Infectious Diseases in China is also in the final stages of locally developed HPV vaccine trials. These vaccines are expected to be available sometime between 2018 and 2020 at a substantially lower cost than the Gavi-negotiated price.

• CERVICAL CANCER INCIDENCE, GLOBALLY AND IN INDIA: Congruent to the global trend in cervical cancer cases, urban population-based cancer registries in India show declining trends in new cases which may be attributable to changing risk profiles. Globocan projections, however, estimate that new cases for cervical cancer in India will increase by 21 percent between now and 2020, from 122,844 to 148,624 cases.

• POPULATION-LEVEL SCREENING: Screening among eligible women between the ages of 18 and 69 remains at less than 5%. Only one state, Tamil Nadu, has been successful in implementing cervical cancer screening at a population level.
Final Thoughts

India is at a tipping point with the HPV vaccine. Two key milestones, the Serum Institute making the HPV vaccine available at a much lower cost and NTAGI recommending that the HPV vaccine be included in the UIP, would change the momentum and shift the debate from if India should implement to how India should implement the HPV vaccine.

Endnotes


7 Minutes of the Meeting of the National Technical Advisory Group on Immunization (NTAGI), December 19, 2017. https://mohfw.gov.in/sites/default/files/Approved%20Minutes%20of%20NTAGI%20meeting%20held%20on%20December%202017.pdf

8 Minutes of the Meeting of the National Technical Advisory Group on Immunization (NTAGI), December 19, 2017. https://mohfw.gov.in/sites/default/files/Approved%20Minutes%20of%20NTAGI%20meeting%20held%20on%20December%202017.pdf