Newer vaccines (measles-rubella, human papillomavirus, rotavirus, and pneumococcal conjugate vaccine) introduction: Experience from Northern India

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ABSTRACT

Vaccines are essential to ensure that the population is immune to certain diseases, and immunization is one of the most cost-effective interventions to prevent the occurrence of the diseases. Recently, new vaccines such as rotavirus, measles-rubella vaccine, and pneumococcal vaccines are introduced in the universal immunization program of some of the states in India. Human papillomavirus (HPV) vaccine is also introduced in Punjab through its own initiative. This paper documents the experience in terms of implementation plans, issues, and challenges in introducing these vaccines in North Indian states, including Haryana (rotavirus vaccine), Punjab (HPV vaccine), Himachal Pradesh (pneumococcal vaccine), and Chandigarh (measles and rubella vaccination campaign).

Keywords: Human papilloma virus vaccine, measles-rubella vaccine, newer vaccines, pneumococcal conjugate vaccine, rotavirus vaccine

Introduction

To meet its global commitment of achieving the sustainable development goal three, recently four new vaccines have been introduced in the India’s Universal Immunization Program (UIP), including rotavirus vaccine (RV), pneumococcal conjugate vaccine (PCV), measles-rubella (MR) vaccine, and human papillomavirus (HPV), by reducing the mortality and morbidity due to diarrhea, pneumonia, measles, rubella among under-five children, and cervical cancer among adults.¹ These diseases have been listed as major public health problems not only in India but also in other low- and middle-income countries as well. Globally, rotaviruses are the major cause of diarrhea among children under 5 years of age. India accounts for 23% of global rotavirus mortality in under-five children, with about 113,000 deaths every year (39% of diarrhea case). Annual expenditure on hospitalization due to RV diarrhea lies between $37.4 and $66.8 million.² Measles and rubella are highly contagious viral diseases that spread by contact with an infected person through coughing and sneezing. Rubella is a mild viral infection that occurs most often in children and young adults. Rubella infection during pregnancy can cause abortion, stillbirth, and may lead to multiple congenital disabilities in the newborn; such as blindness, deafness, and heart defects; known as congenital rubella syndrome (CRS). India accounts for...
around one-third of all children born worldwide with CRS.\textsuperscript{[3]} The HPV type 16 is found to be associated with 70%–90% of cervical cancer cases.\textsuperscript{[4]} Cervical cancer was the fourth leading cancer among women worldwide in 2012. It is the second most common cancer of women in India with age-standardized incidence rate of 22.0/100,000 women, and lead to 67,477 deaths in 2012. In Punjab, it is the second most prevalent cancer among women.\textsuperscript{[5,6]} Pneumococcal diseases are the leading causes of the vaccine-preventable deaths in children under 5 years of age globally and in India too. In 2015, India accounted for about 20% of all pneumonia deaths in this age group globally. More than 80% of pneumonia deaths occur in children under 2 years of age.\textsuperscript{[7]} In 2010, in children under 5 years of age, about 16% of all the severe pneumonia cases and 30% of the deaths due to pneumonia occurred in India were because of pneumococcal pneumonia. In India, pneumonia has a mortality rate of 7/1000 live births.\textsuperscript{[8,9]} The PCV provides gives protection against >2/3 of all the disease-causing strains.

The inclusion of RV vaccine is one of the major commitments of India against vaccine-preventable diseases (VPDs). India has introduced the indigenously developed RV (Rotavac) in its UIP during 2015. This vaccine was developed under a public–private partnership between the Ministry of health and family welfare, Ministry of science and technology, and Bharat Biotech. Recently, the eleven member states of the World Health Organization (WHO)-southeast Asia Region have committed to eliminate measles and control rubella/CRS by 2020, in the 66th session of the WHO Regional Committee.\textsuperscript{[10]} In line with this commitment, the Indian government had decided to provide measles-rubella (MR) vaccine in a campaign mode to all children of age 9 months to <15 years, and later replace measles vaccine with MR in universal immunization schedule (at 9–12 months and 16–24 months of age) in 2017. The vaccine being given in the MR campaign is produced in India by Serum Institute of India and is the WHO prequalified. There has been a proposal that a vaccine against the HPV, which causes cervical cancer, be introduced in India’s UIP. However, the medical community in India remains divided over the vaccine’s universal implementation. However, since health is a state subject, hence it is introduced by Punjab through the state funds. PCV vaccine provides protection against severe forms of pneumococcal disease such as meningitis and pneumonia. Millions of children in India will be protected against pneumonia because of administration of the PCV, which kills more under-five children than any other infectious disease in the world and in India. Until now, PCV was only available in the private sector in India, putting it beyond the reach of most of the population. By introducing in UIP, the Government of India is ensuring equitable access to those who need them the most, i.e., the underprivileged and underserved.

This paper documents the experience in terms of implementation, issues, and challenges in introducing these vaccines in the three Northern Indian states and one union territory, i.e., Haryana (RV), Punjab (HPV vaccine), Himachal Pradesh (pneumococcal vaccine), and Chandigarh (measles and rubella vaccination campaign). These states, first did the situational analysis regarding a number of beneficiaries for receiving the newer vaccines, estimated the vaccine storage capacity and transport requirement and training requirements at each level, formed the state and district level committees, prepared the reporting formats, did the information education activities, etc., and then proceeded with the introduction.

**Measles-Rubella Vaccination Campaign: Chandigarh Experience**

The first phase of MR vaccination campaign has been successfully completed during February 2017 in five states, namely, Tamil Nadu, Karnataka, Goa, Lakshadweep, and Puducherry in India. The next round was started in eight states/Union Territories (UTs) (Andhra Pradesh, Chandigarh, Dadra and Nagar Haveli, Daman and Diu, Himachal Pradesh, Kerala, Telangana, and Uttarakhand) from August 2017. The campaign aims to rapidly build up immunity against both measles and rubella infections in the community to knock out the disease. Therefore, all the children should receive MR vaccine during the campaign. To achieve maximum coverage during the campaign, multiple stakeholders were involved.\textsuperscript{[11]}

UT Administrator and Punjab Governor inaugurated the MR campaign on August 4, 2017, in Chandigarh. As many as 3 lakh children in the city were covered under the drive over 2 months period (75% of these children were covered in the schools). The vaccination was conducted in the schools during the first 2 weeks and later continued in the community sessions (Anganwadi centers) and fixed session sites (health facilities).

Preparation for MR vaccination campaign included the formation of specific committees involving stakeholders from the health sector, education sector, civil societies, nongovernmental organizations (NGOs) and communities, training of health and education staff, providing information to the parents in the schools,
arranging logistics, etc., Regarding informing the parents, in private schools, parents received a proper note from the school, seeking the parental consent, and also instructions on ensuring that child had proper breakfast on the day of the vaccination. In the government schools, the parents were just told verbally. Special parent teachers meeting were also held in this regard, and parents’ information sheet was distributed in both English and Hindi Language.

MR vaccine is a live attenuated vaccine, to be reconstituted with sterile water before administration. The dose is 0.5 ml which has to be administered in the right upper arm subcutaneously. It has to be stored at +2°C to +8°C and reconstituted vaccine to be used within 4 h of reconstitution. Vaccinations results in 95% seroconversion, and protection is generally assumed to be lifelong, although rubella antibodies may fall below detectable levels. Most children who receive the MR vaccine did not report to have any serious problems with it. Adverse reactions are generally mild and transient; slight pain, tenderness at injection site may occur within 24 h; fever (>39.4°C for 1–2 days) may occur 7–12 days after vaccination in 5% of recipients; febrile seizures may occur in 1 in 3000 vaccine recipients; transient rash may occur in about 2% of recipients; thrombocytopenic purpura occurs in approximately 1 in 30,000 vaccinated individuals; arthralgia/joint pain can also occur when given in adolescent children or adults. Risk of anaphylaxis due to measles vaccine is as low as 1 in 1 million children vaccinated. The evaluated coverage was reported to be 93% in Chandigarh (target was 95%). All children who have completed 9 months of age and are <15 years of age were administered with the additional MR dose during the campaign. Malnourished children should be vaccinated on a priority basis, as they are more likely to have complications such as diarrhea and pneumonia.

Estimated total number of target beneficiaries between the ages of 9 months to 15 years in Chandigarh was 310,000, of which school beneficiaries were 226,406 from a total of 382 schools. The number of sessions planned in school was 1303 of which 713 outreach sessions were planned, and a total of 180 vaccinators were deployed. The evaluated coverage was reported to be 93% in Chandigarh against a target of 95%).

Some adverse events following immunization such as injection spot reactions (pain, redness, swelling, or a lump), fever, rash, headache, dizziness, joint or muscle pain, nausea, and vomiting were reported. Due to negative coverage by some of the media reports, some parents started refusing for the vaccine. These challenges were overcome by proactive media engagement and with UNICEF support, advisories issued to all schools regarding do’s and don’ts during the campaign, campaign achievements highlighted through print articles, parent-teacher meetings were repeated wherever needed with the support of education department.

Human Papillomavirus Vaccine Introduction: Experience from Punjab

The successful preventive strategies for cervical cancer are screening and early diagnosis and treatment of preinvasive lesions. However, screening rates are quite low (2.6%) among women in India. Hence, for primary prevention of cervical cancer, vaccination against HPV is an effective strategy. Three prophylactic vaccines are currently available: bivalent, quadrivalent, and nonavalent vaccine (Table 1). All three vaccines show high immunogenicity after administration of three doses. These vaccines have high efficacy, equally effective, and more cost-effective than treatment of cervical cancer.

HPV vaccination prevents 95% of the HPV infection with type 16 and 18.

On November 23, 2016, HPV vaccine was introduced in the state of Punjab, by state-level initiatives. UNICEF supported the Government of Punjab in the procurement of HPV vaccine. The technical expert group formed for introduction of HPV vaccine gave four major recommendations: endorsed Punjab’s plan to include HPV vaccination as part of routine immunization program in state; target girls studying in class 6th in schools-approximate age 11–12 years to be chosen; choice between bivalent or quadrivalent vaccine; asked to prepare operational guidelines, and to conduct cost-effectiveness/benefit analysis. The technical support

| Property                                | Bivalent vaccine | Quadrivalent vaccine | Nonavalent vaccine |
|-----------------------------------------|------------------|----------------------|--------------------|
| Protects against virus strain            | HPV: 16, 18      | HPV: 6, 11, 16, 18   | HPV: 6, 11, 16, 18, 31, 33, 45, 52, 58 |
| Vaccine efficacy against CIN 2+         | 80.8% (95% CI: 52.6-93.5) | 98.2% (95% CI: 93.3-99.8) | 96.7% (95% CI: 80.9-99.8) against high grade disease caused by HPV: 31, 33, 45, 52, 58 |
| Safety                                  | Safe             | Safe                 | Safe               |

HPV - Human papilloma virus, CI - Confidence interval, CIN - Cervical intraepithelial neoplasia
for implementation, capacity building and monitoring was provided by the WHO Country Office.\[21] The girls studying in the 6th standard in government and government-aided schools were targeted under the program. Two doses of quadrivalent vaccine were administered 6–12 months apart. Dose of the vaccine was 0.5 ml administered through intramuscular route in the deltoid region of the left arm. The vaccine was stored at a temperature of 2°C–8°C. In phase 1, about ten thousand girls were vaccinated in 448 schools. Overall, the vaccine coverage was 97.5% and 98.5% at Bathinda and Mansa, respectively. In phase 2, all districts having a reported incidence of >10 per 100,000 women will be covered. Gradually, the program will include the private schools and would cover the whole state. Both the school-based and facility-based approach will be adopted for the vaccination.\[22]

Delhi was the first state in India to implement an HPV vaccination program for girls (November 7, 2016).\[21] Vaccination was provided at East and West Delhi State Cancer Institute. Till March 2017, about 1200 doses of HPV vaccine have been administered to the target girls.

**Rotavirus Vaccine Introduction: Experience from Haryana**

Currently, two oral RVs are marketed worldwide, i.e., monovalent Rotarix (GlaxoSmithKline), and the pentavalent vaccine RotaTeq (Merck).\[23] Both vaccines are safe and efficacious with high efficacy in developed countries and lower efficacy reported from developing countries.\[24] In India, an indigenously developed vaccine Rotavac (Bharat Biotech International) was licensed for use in January 2014.\[26] The vaccine efficacy for severe nonvaccine rotavirus gastroenteritis was 56.4% (95% confidence interval [CI] 36.6, 70.1) in the first year of life and 49% [95% CI 17.5, 68.4] in the 2nd year [Table 2]. In this RV phase III efficacy study conducted in India, the prevalence of adverse events was similar in the vaccine and placebo groups. There were 11 confirmed cases of intussusceptions, but none of the cases occurred around the time of vaccination. The incidence of intussusception in the vaccine group was comparable to the placebo group (94/100,000 child-years vs. 71/100,000 child-years).\[26] RV vaccine has been proven to be a highly cost-effective vaccine.\[27]

Rotavac was included in the UIP in four states including Haryana, Himachal Pradesh, Odisha, and Andhra Pradesh on March 26, 2016.\[28] Haryana has a total population of 26 million, with an estimated targeted infant population of 5.8 lakhs to provide RV vaccination. The four pillars of the introduction of RV vaccine in Haryana were a political commitment, seamless partnership, evidence-based planning allowing for prioritization of activities, and optimization of resources at government and partner level, allowing for adequate preparation. Cascade model training method was adopted to train all the health care professionals involved including state officials, district immunization officers, medical officers, and health workers. All training was completed before the launch of the vaccine. Furthermore, RV introduction working group was formed to review the progress and plan for future activities and meeting with Panchayati Raj Institutions and NGOs was also held for RVV immunization. As it was a new vaccine, state AEFT workshop was conducted to train all districts on revised the AEFT guidelines and AEFT preparedness assessment was also done. For strengthening of the cold chain, 640 cold chain points were reviewed and the electronic database was used. The vaccine used was Rotavac, with each vial containing 10 doses. The vaccine was administered at 6, 10, and 14 weeks of life.

More than 1.5 million doses of RVV was administered till September 2017, with only 13 cases of AEFT reported with no case of intussusception. Commonly reported adverse events were fever, vomiting, spitting up, and diarrhea. Some of the challenges faced were maintaining a continuous supply of RVV, mixed of RVV dropper with OPV dropper, other competitive priorities like NIDs, tOPV to bOPV switch, mission Indradhanush, higher wastage of vaccine ranging from 35% to 40% and the problem of incoming children from other neighboring states. However, despite various challenges, Haryana successfully introduced RVV due to smooth coordination, efficient planning, synchronized implementation, continuous monitoring and support in the form of hand-holding by the Ministry of Health and Family Welfare, Government of India.

By the year 2016, RVV has been introduced in 90 countries with global coverage of 25%.\[29] In India, 65% coverage of Rotavac has been achieved in 6% of the national target population.\[29] Continued intussusception surveillance should be conducted for improving the safety profile of Rotavac in India.\[30]
Pneumococcal Conjugate Vaccine Introduction: Experience from Himachal Pradesh

Union Minister for Health and Family Welfare launched PCV under UIP on May 13, 2017, at Mandi, Himachal Pradesh. In the first phase, the vaccine is expected to benefit about 21 Lakh children of all 12 districts in Himachal Pradesh, six districts out of 75 of Uttar Pradesh, and 17 out of 38 districts of Bihar followed by introduction in Rajasthan and Madhya Pradesh next year, and the coverage will be expanded across the entire country in phased manner in the coming years.

PCV is available as PCV10 and PCV13. PCV13 is the vaccine that has been introduced in the UIP. It is available in a 4 doses vial, with vaccine vial monitor on the body. It is a freeze sensitive vaccine, to be stored at +2°C to +8°C, and used within 28 days as per open vial policy. PCV should be transported to session sites along with other vaccines in vaccine carrier with conditioned ice packs. It is an expensive vaccine and open vial policy prevents its wastage. The cost of PCV in the private sector is approximately INR 3,000–4,000 per dose. A child requires at least 3 doses, including 2 primary doses at 6 weeks and 14 weeks and 1 booster dose at 9 months of age, with a dose of 0.5 ml to be injected intramuscularly in the anterolateral aspect of right mid-thigh using an auto-disabled syringe. Minimum 2 months gap is must between 2 doses of PCV; 6 months gap is ideal for booster but a gap of at least 2 months in late cases. It is safe to administer PCV along with other vaccines such as pentavalent/IPV/measles or MR during the same immunization session. PCV 13 covers most of the common serotypes of pneumococcus in circulation. After receiving all the three doses of pneumococcal vaccine, a child is protected against infections due to strains of pneumococcus in the vaccine but may still get meningitis, pneumonia, or bacteremia since these can also be caused by other organisms. PCV is a safe and well-accepted vaccine. PCV can be safely administered to a child with immunodeficiency (e.g., HIV/AIDS, congenital or acquired immunodeficiency, sickle cell disease), malnutrition, or other underlying illnesses, using the same schedule as for any other child. These children are in particular need of PCV because their risk of pneumococcal disease is high. Most common reported side effects of PCV are irritability, crying, tenderness and swelling at injection site, transient fever >39°C (102°F). PCV should not be given to a child with any severe illness. However, it may be given in children with mild respiratory illness with or without low-grade fever. Contraindications to PCV are severe allergic reactions to a prior dose or to another vaccine containing diphtheria toxoid. Those people who have a severe illness; vaccination should be delayed until the condition improves.[31]

Ministry of Health and Family Welfare, Government of India, shared a state and district preparedness assessment checklists for PCV developed by the WHO. These checklists aimed to support the state and district program managers in assessing critical information before the introduction of PCV. Broad steps taken for the introduction of PCV in Himachal Pradesh were preparedness assessment at state and district, formulation of State and District Task Forces and conduct of meetings of these task forces, dissemination of guidelines, revised formats and information education and communication materials, cascaded training for health staff and mobilizers, track preparation in high priority districts/blocks, strengthening routine immunization microplans and tracking beneficiaries, indenting and delivery of vaccines and logistics, intensifying monitoring and supervision and communication planning.

Conclusion

The introduction of four newer vaccines in northern states of India was successful in terms of coverage of these vaccines due to excellent preparedness level by the respective states. Only existing infrastructure and workforce were involved in the implementation, which reflects no additional cost implications for the introduction of these vaccines. The success story also tells about the strong political commitment shown by the respective states, which is appreciable and is required for the success of any health program or intervention. However, states need to be cautious about the news about the side effects of the vaccine in the media, as it may hamper the progress of campaigns or coverage of new vaccines. Media should be involved as a key partner or stakeholder in the successful introduction of the newer vaccines in the states. The involvement of school teachers and community members was another key aspect for the success. However, certain challenges like the problem of migratory population and stock out of situations were faced which needs to be addressed for the successful rollout of the vaccines. Lesson learnt from the introduction of these four newer vaccines were requirement of strong political commitment and involvement of community members including school teachers and community leaders are two most important factors for successful introduction any health-care intervention including the introduction of any newer vaccine.
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