Introduction of New Vaccines in State Immunization Schedule – Delhi's Experience

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Immunization is an established, cost-effective, preventive intervention to improve child survival. To provide protection against vaccine preventable diseases, all countries in the world have an immunization program that offers selected vaccines to the eligible beneficiaries. In India, Expanded Program of Immunization was started in 1978, and then Universal Immunization Program was launched in 1985 with six antigens. This article describes the experience with institutionalization of four state-specific vaccines by Delhi in its immunization schedule to enlarge the ambit of immunization services. It attempts to highlight the state's perspective in terms of the implementation policy, operational strategy adopted and evolution of immunization program in the state over 16 years.

Keywords: *Combination vaccines, Strategy of introduction,*

Immunization programs, one of the most cost-effective public health programs, have contributed immensely towards reducing infant and child mortality in developing countries, through provision of safe, economical and valuable means of preventing illness, disability and death from infectious diseases. Immunization also provides a range of indirect, often far-reaching supplementary benefits like disease control, eradication/elimination of disease, control of morbidity and mortality both at individual and community level, preventing emergence of drug resistance, improved child survival, and resultant overall economical and societal well-being. The strategic use of vaccines has led to successful eradication of smallpox and near elimination of polio [1].

RATIONALE FOR INTRODUCTION OF NEWER VACCINES

The aim of any immunization program is to bring down child mortality, especially Infant Mortality Rate (IMR) by reducing vaccine preventable disease (VPDs) associated morbidity and mortality by limiting numbers, clustering of cases and pooling of potentially susceptible children. Access to newer vaccines through immunization schedules has been a global health priority. Delhi has a population of 16.7 million (census 2011) and population density of 11,320 persons per square km – highest in the country [2]. Delhi attracts populace from adjoining states due to comparatively better infrastructure for employment, education and health [3]. This migratory population resides predominantly in urban slums and resettlement colonies with poor civic amenities adding to the pool of susceptible inhabitants. The ever increasing and dynamic population poses a serious challenge to universal access to health services. Considering the favorable role that new vaccines could play in reducing IMR and child mortality associated with childhood diseases peculiar to urban settings, their inclusion in state immunization schedule was planned in a phased manner. Keeping equity and accessibility in perspective, the aim was to bring new and relatively expensive vaccines within reach of the most vulnerable sections of under-five children. An annual birth cohort of approximately 0.30 to 0.32 million newborns is being protected against 11 life threatening diseases (Tuberculosis, Poliomyelitis, Hepatitis-B, Diphtheria, Pertussis, Tetanus, Hib-related diseases, Measles, Mumps, Rubella and Typhoid) by the immunization program in the state.

Scaling-up of immunization intervention is effective when the program is robust [4]. In 1999, immunization coverage of Delhi was about 69.8% [5], and the state also had a well-functioning Pulse Polio Program in place, ahead of rest of the country. This strength of immunization program was harnessed for enlarging the basket of childhood vaccines. Using scientific evidence, four childhood vaccines (Measles-Mumps-Rubella (MMR), Hepatitis B, Typhoid and Pentavalent) were introduced between 1999 and 2013. None of these vaccines were part of the then national UIP (except Pentavalent vaccine which was restricted to only six states of the country at that time).

MMR: Measles is one of the leading causes of under-five-

mortality-rate (U5MR). Single dose of measles vaccine confers protection up to 85%, while two doses protect up to 95% of the recipients [6]. Introduction of mumps vaccine into immunization programs by other countries and administration of MMR vaccine at high coverage levels has shown evidence of rapid decline in mumps-related morbidity [7]. To provide benefit of second dose of measles vaccine to eligible children and to reduce incidence of Mumps disease and Congenital Rubella Syndrome (CRS) in children, MMR Vaccine was introduced in 1999 in the state.

Available nationwide data regarding the prevalence of acquired and CRS is sketchy, particularly in absence of community-based assessment of prevalence of CRS in general population, but it is known that rubella is endemic in India. Time trends from Delhi have indicated a lowered susceptibility to rubella infection and steady increase in sero-prevalence in adolescent females over the years, which may be reflective of MMR vaccination started in 1999 [8].

Hepatitis B vaccine: Hepatitis B disease poses serious 'silent epidemic' challenge to India with prevalence of 2 to 7% (intermediate endemic status) [9]. In absence of effective cure for hepatitis-B disease and its complications, prevention and control can be achieved through safe and effective vaccine. WHO also recommends routine infant vaccination with hepatitis B vaccine [10]. Delhi was pioneer state in the country to include hepatitis B vaccine in its immunization schedule in 2001.

Typhoid vaccine: Typhoid (Enteric fever) is a quintessential infectious water/food borne disease, rife in urban habitations primarily owning to compromised water and sanitation services coupled with poverty related malnutrition. High mortality, complication rates and multi-drug resistance is seen in paediatric population [11,12]. A baseline survey by Sinha, *et al*. [13] in Delhi's slums reported high prevalence of typhoid disease at 27.3/1000 in children below 5 years of age. In order to address these issues, typhoid vaccine was conceptualized for introduction in the state in 2004. Delhi remains the only state in the country that is providing typhoid *Vi* polysaccharide vaccine routinely to its children. A recent study [14] has recommended typhoid vaccine inclusion in national immunization schedule, supporting the rationality of its inclusion by the state.

Pentavalent vaccine: *Haemophilus influenzae type b* (Hib)-related infections are a major causes of morbidity and mortality in the country, estimated to account for 2.4 to 3.0 million cases and 72,000 deaths in under-five children [15]. In our country, Hib is the most common cause of meningitis (40-50%) and the second most common (25-30%) cause of pneumonia [16]. As per one study, nasopharyngeal Hib colonization among school children has been found to be 15% in Delhi, and 0.5-2.6% of all hospital admissions were attributable to bacterial meningitis, including Hib [17]. Continuing with successful inclusion of three new vaccines, Pentavalent vaccine containing Hib was introduced in 2013.

STRATEGY ADOPTED FOR INCORPORATING THE VACCINES INTO THE SYSTEM

The strategy of introducing a new vaccine has been shown to have bearing on the success of its absorption into the system. To ensure seamless and smooth incorporation, all the new vaccines were integrated into existing immunization schedule directly, as has been advocated by many studies [18-20]. Inclusion of Hepatitis-B and later Pentavalent vaccine were logistically more convenient, practical and least disruptive as these vaccines did not disturb the existing immunization schedule or route/dose of administration. Major thematic areas worked upon before introduction of each vaccine are described below:

Constitution of State-level expert group: A State-level expert group was constituted to examine and suggest feasibility, necessity, financial and logistical implications of introducing new vaccines. The group was drawn from medical colleges, professional bodies (IAP, Delhi) and National Centre for Disease Control (NCDC). Based on evidence and recommendations that these vaccines would be cost-effective and viable in a well-functioning immunization system, each of these vaccine(s) was included in the state schedule in the following years.

Administrative approvals: Introduction of new vaccines needs to be facilitated by political commitment as well as an enabling environment that leads to higher levels of immunization coverage and effectiveness [21,22]. Proposal for each vaccine was individually processed for policy and administrative approval to be obtained from competent authorities. A new dedicated budget line 'Special Immunization Scheme' was created for meeting the expenditure of these new vaccines.

Expansion of storage facilities: Augmentation of cold storage is prerequisite for introduction of new vaccines to ensure that cold chain is being strictly maintained to store vaccines at their recommended temperatures [23]. Cold storage capacity at the state-level store was expanded further by addition of second Walk-in-Cooler in 2009. Similarly, the cold chain storage at district stores and approximately 600 peripheral health facilities providing immunization services was strengthened with 249 Ice Lined Refrigerators and 352 Deep Freezers.

Capacity building and Quality assurance: Before the

introduction of each new vaccine, extensive training programs were conducted to adequately build capacity and knowledge of Medical Officers and Para-Medical Staff for smooth induction of the vaccine into the system. Based on the evidence [24,25] that on-the-job training before introduction of new vaccines is associated with improved vaccine coverage and better overall quality of service, ANMs were trained on safe immunization practices and use of auto-disabled single-use syringes. Training manual was also developed for doctors to serve day-to-day requirements on immunization activity. The adverse event reporting system was also strengthened.

Participation and role of stakeholders: State and district level information sharing, sensitization and priming on new vaccine introduction were completed through workshops, meetings and training before introducing these vaccines. Outreach component of immunization sessions conducted at Anganwadis was strengthened through coordination with Woman and Child Department (WCD). Ration cards were ubiquitous in the state about few years ago. Taking advantage of this situation the department coordinated with Food and Supply Department to disseminate message of immunization through this card.

Demand generation: In order to have political patronage and media advocacy, a ceremonial launch function was organized for launch of each vaccine with presence of political dignitaries like Chief Minister and Health Minister. Awareness generation and demand creation was done through extensive use of electronic and print media. Using services of House-to-House Pulse Polio Program teams established in 2000, pertinent information regarding the new vaccines, free-of-cost availability of these vaccines at government health facilities, and details of vaccinations sites were shared with families. The department also increased availability of immunization services by making it twice-a-week at primary health facilities and on all working days at hospitals.

OUTCOME

Lives saved: As per NFHS-2 survey (1998-99), IMR for Delhi was 46.8 and full immunization coverage was 69.8%. Corresponding data of NFHS-3 (2005-06) [26] documented IMR of 35 and full immunization coverage at 63%. Data from SRS 2014 [27] confirms IMR at 24 and U5MR at 26 (SRS 2013). State registered reduction in IMR from 46.8 (NFSH2) to 24 (SRS, 2014) and U5MR from 55.4 (NFHS2) to 26 (SRS,2013) (***Table* I**). The assured well-being and longevity of children is partly reflective of the plausible positive effects of new vaccines. The programmatic initiative of new vaccine introduction and translating them into implementation strategy can be one of the important factors that facilitated the demographic improvement seen in state despite a huge dynamic population load. The states with improved immunization services have been reported to register lower IMR and U5MR [28]. Inclusion of these newer vaccines also helped to promote better program management and perceptible boost in evenhanded access [29]. It also helped in better inter-sectoral co-ordination by providing platform for increased mutual interaction to strive better towards achieving higher immunization coverage.

Financial gains: Addition of new vaccines to state's immunization program has not only helped in saving lives of infants/children but has resulted in direct/indirect fiscal gains and resource-saving. The direct financial gains are in terms of cost saved by averting disease load in hospitals both as in-patient admissions and out-patient attendance and treatment expenses. The indirect monetary gains include money saved to families in terms of wages lost due to being away from work owing to the child's illness, aversion of potential deaths and long-term disability among children, reduced hospitalization and treatment resulting in improved quality of life of infants/children and their families (disability adjusted life year) leading to improved quality of life and societal well-being. The indirect benefits also include reduced patient load in already overburdened health system resulting in improved efficiency and quality care of other patients.

CONCLUSION

Immunization is one of the key interventions to reduce

TABLE I CHILD HEALTH INDICATORS FOR DELHI, INDIA

Year	*SRS (IMR)*	*Immunization coverage (%)*	*U5MR*
1998	46.8	69.8 (NHS II)	55.4 (NHS II)
2001	29		–
2002	30	–	–
2003	28	59.2 (DLHS II)	–
2004	32		–
2005	35	63.2 (NHS III)	–
2006	37	84.6 (CES 2006)	–
2007	36	67.3 (DLHS III)	–
2008	35	67.3 (DLHS III)	40 (SRS)
2009	33	71.5 (CES 2009)	37 (SRS)
2010	30	–	34 (SRS)
2011	28	–	32 (SRS)
2012	25	76 (HMIS)	28 (SRS)
2013	24	81.4 (HMIS)	26 (SRS)

NFHS: National Family Health Survey, DLHS: District level Household Survey [29], CES-Coverage Evaluation Survey, HMIS: Health Information Management system, Government of NCT Delhi.

IMR and U5MR. We believe that introduction of newer vaccines played an important role in strengthening the immunization system in Delhi. It also helped the state to achieve MDG-4. We also believe that a well conceptualized, well planned and properly executed introduction, integration, equitable distribution and enhanced coverage of newer vaccines remains the mainstay of a long-term mortality reduction strategy.

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