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NEWER VACCINE INTRODUCTION (PNEUMOCOCCAL CONJUGATE VACCINE) FROM THE STATE'S OWN RESOURCES IN HARYANA, INDIA: AN EXAMPLE OF ADVOCACY TO POLICY AND ACCELERATED PUBLIC HEALTH ACTION

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ABSTRACT: Introduction: Global pneumonia mortality (50%) caused by pneumococcus is responsible for invasive pneumococcal disease. Pneumococcal Conjugate Vaccine (PCV) has been introduced by the Government of India in a phased manner in selected states, but Haryana was not included. **Objective:** To draw key lessons learned from the process of newer vaccine introduction (PCV) in Haryana from the state's resources to inform future introductions of PCV and any other new vaccine in other states of India and internationally. **Methods** The process of PCV introduction in Haryana was introduced with the launch of "Atal Jeevan Rakshak Teekakaran Yojna," in 22 districts of the Haryana. The highest political and administrative leadership with a strong commitment to reducing the IMR and U5MR, approved the proposal and budget (~12 million USD). It was planned use of the of PCV13, and follow the National Immunization schedule *i.e.* 2 primary and 1 booster dose at 6, 14 weeks, and 9 months. The State-level launch ceremony of PCV introduction was organized in November 2018. **Findings:** Haryana became the first state of India to launch the PCV from state's own resources. More than 1 million doses of PCV are administered across the state with great success. The addition of PCV in state's EPI program is a step towards equity without creating undue and excessive additional burden on immunization systems. **Conclusion:** PCV introduction in Haryana is a brilliant example of state government ownership supported by MoHFW and development partners for health and immunization system strengthening.

INTRODUCTION: Globally, the under-5 deaths worldwide have declined from 12.6 million in 1990 to 5.2 million in 2019 [1].

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Despite this massive decline in the under-five mortality rates among children, pneumonia remains the leading cause of childhood mortality globally and in India. Pneumonia accounts for a significant disease burden among young children and one of the leading causes of childhood mortality [2]. Literature has reported that more than 50% of all global pneumonia mortality in children caused by a bacterial pathogen (pneumococcus) responsible for invasive pneumococcal disease [3].

As per the Million Death Study, approximately16% of under-five mortality is due to pneumonia, to which the contribution of pneumococcal pneumonia is 30% [4]. Southeast Asian region countries contribute more than 54% of global pneumonia cases, with 32% of the worldwide burden from India alone [5]. Pneumococcal pneumonia accounted for 30% of all pneumonia deaths under five years of age in India in 2010 [6]. That amounts to approximately 1 death every 6 minutes. The World Health Organization recommended that all countries introduce PCV and specify introduction in settings with under-5 mortality rates of more than 50 deaths per 1,000 live births [7]. Globally, 135 countries have already introduced PCV as part of the national immunization program (NIP) [8]. In India, PCV has been introduced by the Government of India in a phased manner in selected states (Uttar Pradesh, Himachal Pradesh, Rajasthan, Madhya Pradesh, and Bihar) and their districts. With the introduction of PCV, India's UIP now offer protection to children from 12 diseases (Polio, Diphtheria, Pertussis, Tetanus, Tuberculosis, Hepatitis B, Measles, Rotavirus diarrhea, Hemophilus influenza B (Hib), Japanese encephalitis (in endemic states), Rubella and Pneumococcal disease).

The North Indian State of Haryana has an IMR of 30 and under 5 mortality rate of 35 [9]. Considering the health indicators of Haryana to be faring better than many empowered action group states, the introduction of PCV in Haryana did not fit into MoHFW, GoI plan. Until now, PCV was available only in the private sector of the state, putting it beyond the reach of most of the population. To ensure equitable access to those who need them the most – the underprivileged and underserved, Govt. of Haryana launched the ATAL JEEVAN RAKSHAK TEEKAKARAN YOJNA (AJRTY) [10] on the occasion of Golden Jubilee celebration (2017) of creation of Haryana state [11], where PCV introduction in public health facilities was conceptualized, implemented to enhance and accelerate the efforts to achieve the Sustainable Developmental Goals (reduce neonatal 12 per 1000 live births and under-5 mortality to 25 per 1000 live births). This paper draws key lessons learned from the introduction process of PCV in Haryana to inform future introductions of PCV in the rest of the country. The article distills the experiences of those actively involved in PCV introduction and review of communications from the state, national, and global task forces.

METHODS: Haryana is one of the wealthy States located in Northern India and surrounding the capital of India (Delhi) from three sides. It has a population of approximately 25 million [12]. Approximately the birth cohort in Haryana is 5,80,000 [13].

Desk reviews of communication from state, national, and global technical working groups involved in the introduction of PCV and interviews of the relevant stakeholders were conducted for the current study. Current immunization status was taken from the routine Health Management Information System (HMIS) portal of Haryana. Permission for the study was granted from concerned authorities of the Haryana State Health Resource Centre.

Findings: The PCV introduction in India started with the political will at the highest level through a letter of communication sent from the State Health Minister to the Union Health Minister. The evidence was already available, and MoHFW had already developed Operational Guidelines for introducing PCV in the country. The State adopted the National guidelines and modified them as per the state perspective.

The results structured into steps required for the introduction of PCV; Decision for the introduction of PCV, Selection of vaccine type, Financing the introduction, Constitution of the State Technical Advisory Group Immunization (STAGI), Composition of State and District AEFI committee (SD-AEFI), Capacity building of the health and paramedical staff, preparing the supply and cold chain management, media engagement, district workshops for awareness among masses and launch of PCV.

Decision for the Introduction of PCV: The highest political and administrative leadership of the state with a strong commitment to reducing the infant mortality rate and under 5 mortality, approved the proposal 'AJRTY', considering it as a high-impact intervention to reduce the mortality and disease burden of pneumococcal pneumonia and meningitis. Hence, the introduction of PCV

was in 22 districts was approved by the Government of Haryana in 2016 **Fig. 1**.

Selection of Vaccine Type: It was planned to use the 2 primary and 1 booster dose schedule at 6 weeks, 14 weeks, and 9 months of age in the national immunization schedule. It was 4 dose PCV vial and administered intramuscularly. The preferred site was the vastus lateralis muscle in the anterolateral thigh. Currently, PCV10 and PCV13 are two types of vaccines available in India **Fig. 1**. Haryana state decided to procure the PCV13 considering presentation, epidemiology, cost availability, and vaccine vial monitor, *etc*. The same vaccine is also being used in other states and districts where PCV has been introduced in the public health system.

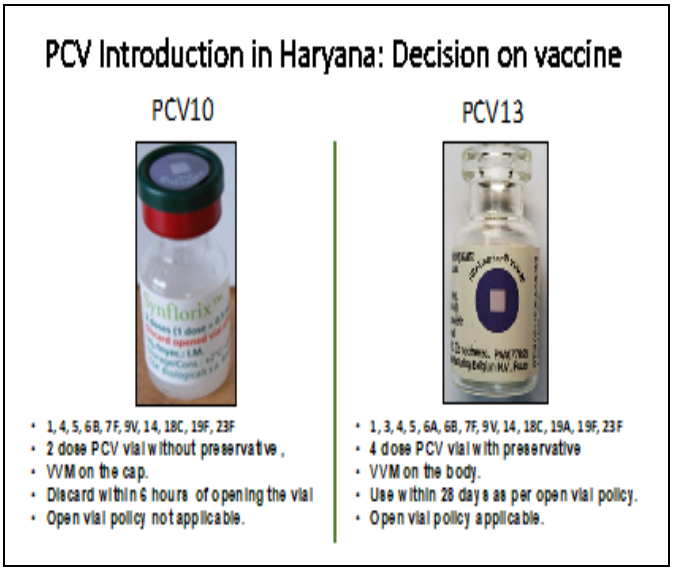

FIG. 1: COMPARISON OF PCV10 AND PCV13

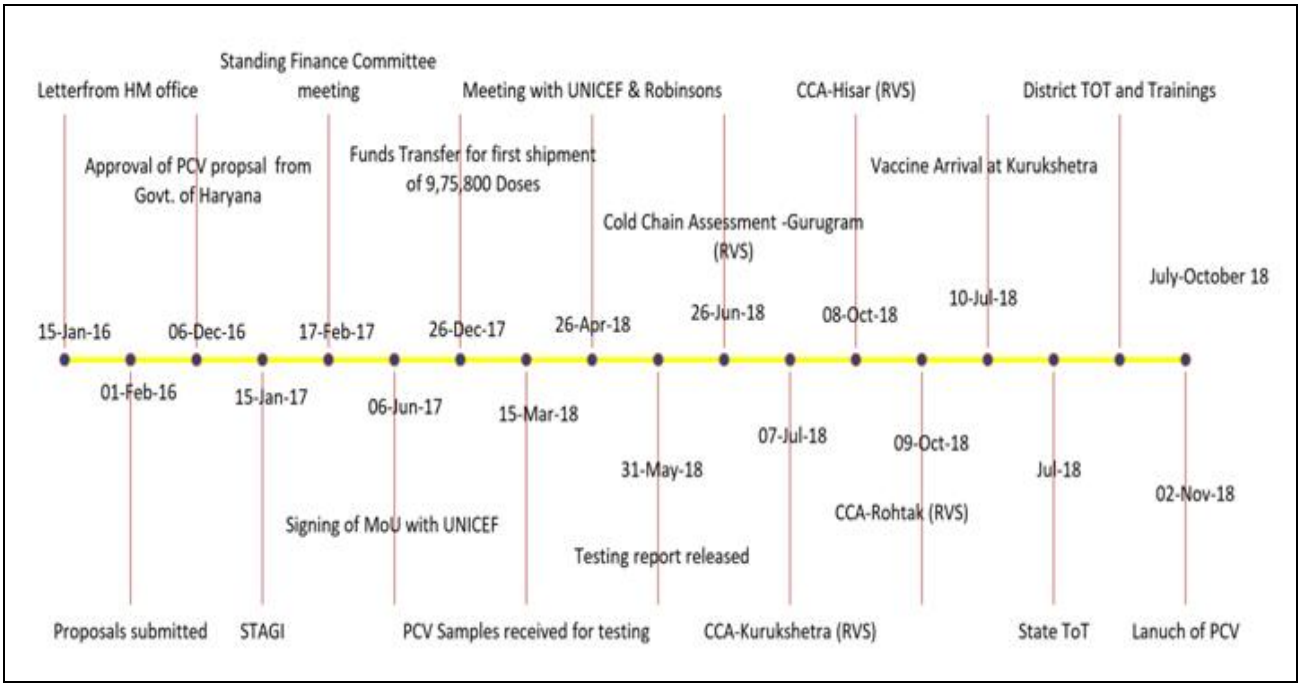

FIG. 2: TIMELINE FOR THE INTRODUCTION OF PCV IN HARYANA

Financing the Introduction of PCV: The necessary budget of ~840 million INR ($1,11,94,411) for vaccine procurement and strengthening the existing immunization system was committed and made available for two years. Global Alliance for Vaccine & Immunization (GAVI) supported the state's decision. GAVI decided to provide PCV @ subsidized rates of ~3$ per dose. In the financial year (2017-18), the state government signed a Memorandum of Understanding with UNICEF, for the procurement of PCV. States also liaised and succeeded in getting GST & customs duty waived off amounting to approximately 210 million INR ($27,98,602) from the Ministry of Finance through MOHFW, Government of India.

Constitution of STAGI: It was constituted for providing technical assistance on PCV and comprised of an eminent pediatrician from a PGIMER, Rohtak, State immunization officer, and resource persons from different specialties, *i.e.*, Health Economics and Community Medicine in 2017. STAGI recommended Dos and Don'ts and played a role in making decisions, *e.g.*, post-implementation evaluation after one year.

Composition of State and District AEFI Committees: For the investigation of any reported Adverse Event Following Immunization (AEFI) the state and district AEFI committees were re-constitutes. The committees included members *viz*.; pediatricians, state immunization officers, microbiologists, Forensic Medicine, and a representative from an NGO, *etc*.

Capacity Building of the Staff: State Training of Trainers (ToT) was organized in July 2018 with technical support from WHO, UNICEF, ITSU, BMGF, and other technical partner agencies. District level ToT and training sessions were held in August- September 2018. Further, Block level training sessions of ANMs, AWWs, ASHAs, and Community Mobilizers were completed in October 2018 in all the districts **Table 2**.

Preparing the Supply and Cold Chain: The vaccine has to be stored in 2 to 8 degrees Celsius (in WICs/ ILRs) at every level of the immunization supply chain. Cold chain assessments for state and regional vaccine store were done using WHO-UNICEFs Effective Vaccine Management (EVM) checklists, and volume needed to store additional PCV vials and existing vaccines storage were calculated. Before-hand preparations, including cold chain points assessments, volume needed to store additional vials of PCV and existing vaccine storage, *etc*., were started.

Through the National cold chain management information system (NCCMIS) all 620 cold chain points were assessed. Additional equipment (Ice lined refrigerators, deep refrigerators, voltage stabilizers, cold boxes, *etc*.) was provided following the gap analysis. Repair drives, float assembly (a stock of spare units of cold chain equipment), rational distribution of the same, and buffer stock (not specifically for PCV) provided by GOI were utilized. Necessary modifications were also done in the recording and reporting formats like Mother and Child Protection (MCP) Cards, RCH/Immunization registers, immunization monitoring formats, and HMIS formats to accommodate additional information about PCV.

Haryana State received the first consignment of 9,75,000 doses in July 2018, which was distributed to all cold chain and vaccine storage points through 4 regional vaccine stores and 22 district vaccine stores.

Media Engagement, District Workshops for Awareness among Masses: Public engagement strategies for trust-building among the community varied from community meetings, social mobilization activities, and engaging with religious leaders for awareness, dialogue, and trust-building. Media engagement and sensitization workshops were conducted in each of the 22 districts of Haryana.

Launching the PCV: Preparations regarding the PCV launch were initiated in 2017. Low-scale pilot implementation in a selected district was conducted before the full-scale launch in November 2018. The state-level launch ceremony of PCV introduction was organized at Panchkula, Haryana on dated 2nd November 2018, and Hon'ble Health Minister Haryana presided over the state-level function. After state launch, district-level launch ceremonies were organized in all 22 districts on subsequent days. With considerably good visibility of PCV introduction and huge difference of cost *i.e.* free of cost vaccination in public health institutions in comparison with ~10,000 INR for three doses in the private sector, the uptake of immunization services from the government sector was very encouraging. **Table 2** shows that total PCV doses administered till March 2020were approximately 1 million. PCV, being the new vaccine, is still getting stabilized in the system. The coverage (till March 2020) of 1st dose is 70%, 2nd dose is 58%, and the ninth-month booster dose is 41%.

TABLE 1: STATUS OF TRAINING SESSIONS FOR PVC LAUNCH

Designation	Expected	Attended	%Trained
Medical officers I/C	797	770	96.6
Data handlers	37	36	97.3
Vaccine & cold chain handlers	21	21	100.0
Medical officers (supervisors)	653	598	91.6
Health Supervisors (LHV/Sup)	472	440	93.2
ANMs	3741	3589	95.9
Mobilisers (ASHA/AWW/Others)	27729	24264	87.5

TABLE 2: DISTRICT WISE PCV COVERAGE IN THE STATE OF HARYANA FROM APRIL 2019 TO MARCH 2020

S. no.	Name of District	Estimated Infants	No. of Infants vaccinated with PCV					
			PCV-1	% PCV1	PCV-2	% PCV-2	PCV-3	% PCV-3
1	Ambala	20081	16808	83.70	14112	70.28	9562	47.62
2	Bhiwani	22186	19646	88.55	14847	66.92	13347	60.16
3	Faridabad	62251	33706	54.15	29165	46.85	18848	30.28
4	Fatehabad	18676	13396	71.73	11220	60.08	9741	52.16
5	Gurgaon	43859	30644	69.87	26165	59.66	15165	34.58
6	Hissar	34983	26553	75.90	21903	62.61	19451	55.60
7	Jhajjar	16780	14059	83.78	11395	67.91	6587	39.26
8	Jind	26009	17006	65.39	14454	55.57	9750	37.49
9	Kaithal	19640	15803	80.46	14279	72.70	10384	52.87
10	Karnal	29904	24573	82.17	20954	70.07	14835	49.61
11	Kurukshetra	18184	14204	78.11	11760	64.67	10884	59.85
12	Mewat	49195	27403	55.70	17822	36.23	8656	17.60
13	Narnaul	16333	10058	61.58	8938	54.72	5446	33.34
14	Palwal	30672	21045	68.61	18565	60.53	9593	31.28
15	Panchkula	9970	7885	79.09	7107	71.28	5932	59.50
16	Panipat	30870	17614	57.06	13343	43.22	8973	29.07
17	Rewari	22782	13207	57.97	10408	45.69	8179	35.90
18	Rohtak	21475	12932	60.22	11350	52.85	8985	41.84
19	Sirsa	24266	18150	74.80	15719	64.78	9954	41.02
20	Sonipat	32967	28214	85.58	25012	75.87	22643	68.68
21	Yamunanagar	24517	18150	74.03	15566	63.49	13319	54.33
	State	575600	401056	69.68	334084	58.04	240234	41.74

CONCLUSION: Although the Government of India decided to introduce PCV in a phased manner in selected states and districts in 2017-18, the progress remained slow due to the high cost of PCV compared with other vaccines provided in NIP8. Haryana became the first state of the country to take the initiative (2018) to launch the PCV from state resources. PCV introduction in Haryana is a landmark achievement and an illustration of the highest state-level political will and meticulous planning. It is a unique example in our country where a large state decided to introduce a newer vaccine for all beneficiaries in the state from its resources. PCV introduction in Haryana was possible only because of the well-defined plan and meticulous implementation with support from various stakeholders.

PCV introduction in the state has also provided an opportunity to strengthen the health systems and give a hands-on experience to inform other states and countries who might be looking for any new vaccine introduction in their system from their resources.

PCV vaccine introduced in all districts of Haryana, and all infant's cohort of approx 575,000 included for free of cost vaccination. This endeavor of state had proven the commitment for equity in immunization services.

Keeping the success story of Haryana, other states of India and other countries can also take the initiative to introduce newer vaccines-like PCV, in their immunization schedule. There is not much enhancement of the overall cost of vaccination as the procedural costs of immunization service delivery like infrastructure, human resources, and equipment remain the same. Only the additional cost of vaccine has to be borne by the State

Way Forward: The state of Haryana is determined to sustain the PCV through its resources and ensure fair access to those in need *i.e.,* the poorest, underprivileged and underserved. The state will be conducting post-introduction evaluation and impact assessment of PCV in 2020 as per WHO guidelines. It is planning to further expand the list of vaccines in the State Immunization Schedule by introducing vaccines of epidemiological significance like HPV, Typhoid vaccine, etc. as approved by STAGI and NTAGI

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