

Rollout of Pneumococcal Conjugate Vaccine (PCV) in India

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Outline of Presentation

- Context of immunization program in India
- Gavi support & initial roll out
- Criteria for state/district selection
- Opportunity for accelerated expansion
 - National Nutrition Mission 2018
- Lessons

Context

Target beneficiaries for Routine Immunization in India

8 vaccines provided nationally; **4 vaccines** sub-nationally

26.7 million children



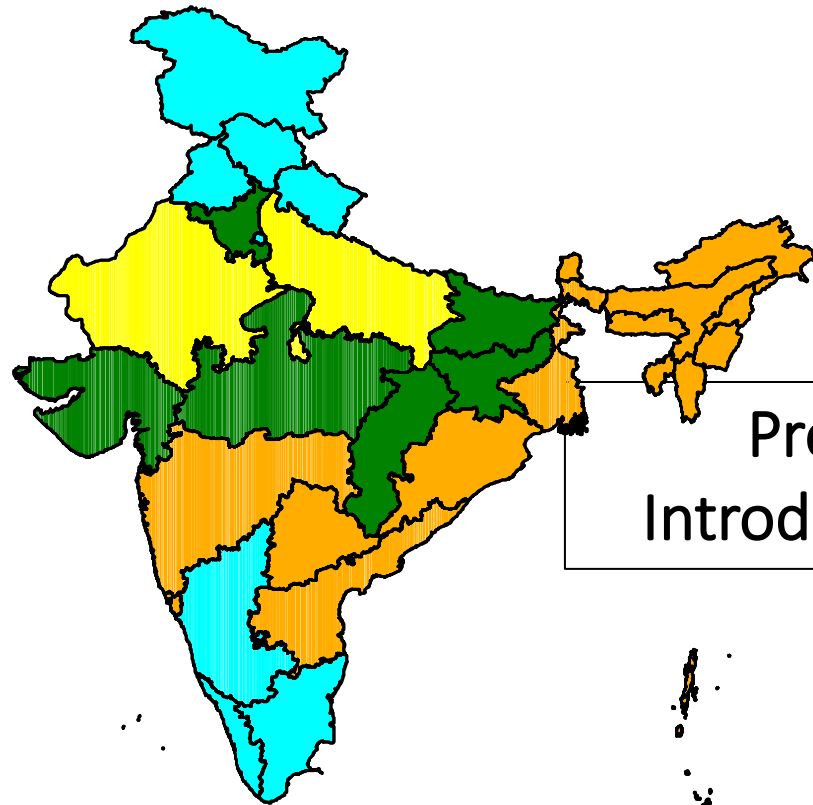
9 million session per annum

30 million pregnant women



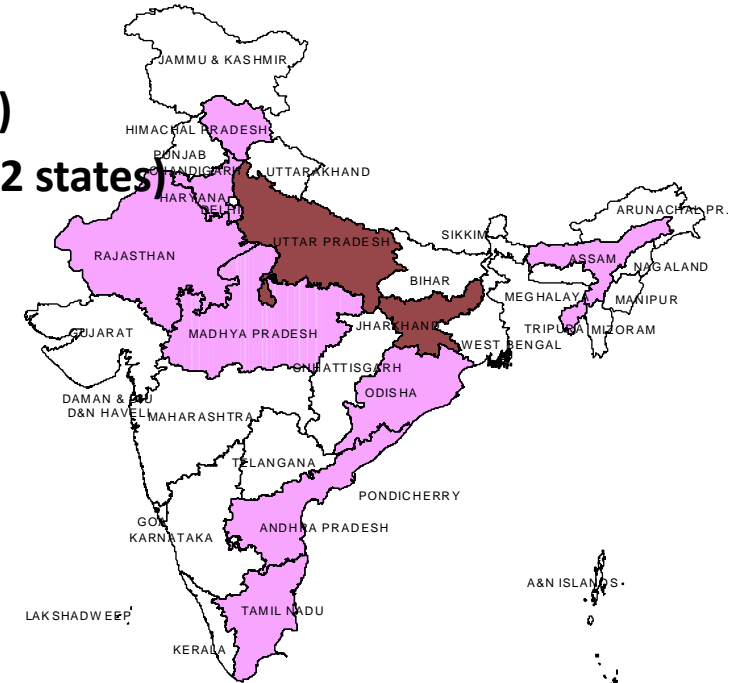
27,000 cold chain point

Simultaneous vaccine introductions (MR/RVV/PCV)



Proposed MR Vaccine Introduction Plan, 2016-2018

- RVV States (9 States)
- RVV States in 2018 (2 states)



Proposed PCV introduction plan (2017 onwards)

- Bihar
- UP
- MP
- Rajasthan
- HP

Phase	MR campaign Year	No. of States	No. of Districts	Estimated Target Population (9 m - 15 yrs)	MR vaccine required for campaign	Cumulative annual MR vaccine required for RI
Phase 1	2016	10	161	66,017,000	77,900,060	10,985,800
Phase 2	2017	18	212	111,100,000	131,098,000	29,057,840
Phase 3	2017	6	202	123,101,000	145,259,180	51,258,200
Phase 4	2018	2	108	108,582,000	128,126,760	70,053,760
Total	2016 – 2018	36	683	408,800,000	482,384,000	

Source: Projected Target population (9 months to 15 years) based of 2011 census data

Catalytic support of Gavi for initial roll out!

- Gavi had committed commodity assistance for PCV introduction for an average of 20% birth cohort per year for a period of three years.
- Government of India proposed to introduce PCV under UIP in a phased manner in 2016-17
- Global PCV **vaccine supply constraints:**
 - Quantity & packaging (multi-dose vials)
- In the light of the above, the country decided
 - PCV for nearly **10%, 20% and 30%** of birth cohort for the years 2017, 2018 and 2019 respectively.

Criteria for state selection for initial phase of PCV introduction

- State-wise No. of Eligible Infants
- Infant mortality rate
- Under 5 mortality rate
- Estimated Mortality due to Pneumococcal pneumonia
- Immunization Coverage
- Simultaneous New Vaccine Introductions (Rotavirus, MR)
- Cold Chain Space Availability
- AEFI Surveillance System Preparedness
- Willingness of states

Estimation of impact of PCV

Parameters

- A. **Disease burden** (Estimated U-5 deaths due to pneumococcal pneumonia – Farooqui et al, PLoS One 2015)
- B. **Immunization coverage** (% Full Immunization Coverage* – AHS 3 / DLHS 4)
- C. **Effectiveness of vaccine** ~ 70% (Assumption)
- D. **No. of eligible infants** (Annual Birth cohort 2017-18 – Stat division, MoHFW)

Impact

- E. Potential Deaths averted by using PCV (at 100% coverage) = $A * C$
- F. Deaths averted by using PCV (at current coverage levels) = $A * B * C$
- G. Deaths averted by PCV per lakh eligible infants = $(E/D) * 1,00,000$

*Full Immunization Coverage in 12-23 month old children (definition)- one dose of BCG, three dose of DPT containing vaccine, three doses of OPV (excluding OPV 0) and one dose of Measles vaccine.

Mortality burden due to Pneumococcal Pneumonia* (1/3)

	A	E	F	G
State	Annual no. of U-5 deaths due to pneumococcal pneumonia*	Potential Deaths averted by using PCV (100% coverage) [=A*C]	Deaths averted by using PCV (current cov.) [=A*B*C]	Deaths averted by using PCV, per lakh eligible infants [=(F/D)*100,000]
Uttar Pradesh	27,800	19,460	10,255	182
Bihar	23,200	16,240	11,352	391
Madhya Pradesh	13,400	9,380	6,228	319
Rajasthan	11,900	8,330	6,181	342
Jharkhand	6,300	4,410	3,083	371
Odisha	3,400	2,380	1,637	203
West Bengal	2,900	2,030	1,614	117
Gujarat	2,600	1,820	1,030	77

B = State immunization coverage, C = 70% effectiveness of PCV (assumption), D = no. of eligible infants in the state

State selection scenarios with
potential impact

Summary of Scenarios

(Average of 20% National Cohort Covered Annually 2017-19)

S. No.	States	Avg. Annual no. of U-5 deaths averted by using PCV (100% coverage)	Avg. Annual no. of U-5 deaths averted by using PCV (current coverage)
Full State	Haryana, HP, MP, Bihar, Assam, Uttarakhand	23,287	15,721
Full State	Chhattisgarh, Haryana, Assam, Jharkhand, Jammu & Kashmir, Bihar, Punjab	19,838	13,725
Full State	Chhattisgarh, Haryana, Rajasthan, Madhya Pradesh, Jharkhand, Telangana	17,972	14,147
Partial	UP, Jharkhand (full-partial)	18,725	10,086
Partial	UP, Bihar, Jharkhand, Rajasthan (full-partial)	23,090	14,715
Partial	Bihar, Jharkhand, Rajasthan, MP (partial)	27,259	19,317
Partial	Bihar, MP, Rajasthan, UP (partial, all equal)	22,882	14,572
Partial	Bihar, MP, Rajasthan, UP, HP (partial, different)	26,131	17,681

Scenario Finally Selected

Year	States	No. of eligible infants	% of Annual birth cohort	Deaths averted (100% coverage)	Deaths averted (current coverage)
1	50% Bihar + 15% UP		9%	11,039	7,214
2	100% Bihar, 100% MP, 60% Rajasthan, 15% UP, + 100% HP	6,885,600	26%	33,677	22,915
3	100% Bihar, 100% MP, 60% Rajasthan, 15% UP +100% HP	6,885,600	26%	33,677	22,915
	Total	16,068,300	61%	78,393	53,044

Average Annual no. of deaths averted = 26,131 (100% cov); 17,681 (current)

Second Opportunity to accelerate PCV rollout?

PCV and RVV scale up under National Nutrition Mission (NNM)

Joint meeting of the National Pneumococcal Vaccine Expert Committee and
Rotavirus Vaccine Expert Group

6th March, 2018

Objective

- To develop a roadmap for expansion of Pneumococcal conjugate vaccine (PCV) and Rotavirus vaccine (RVV) under National Nutrition Mission

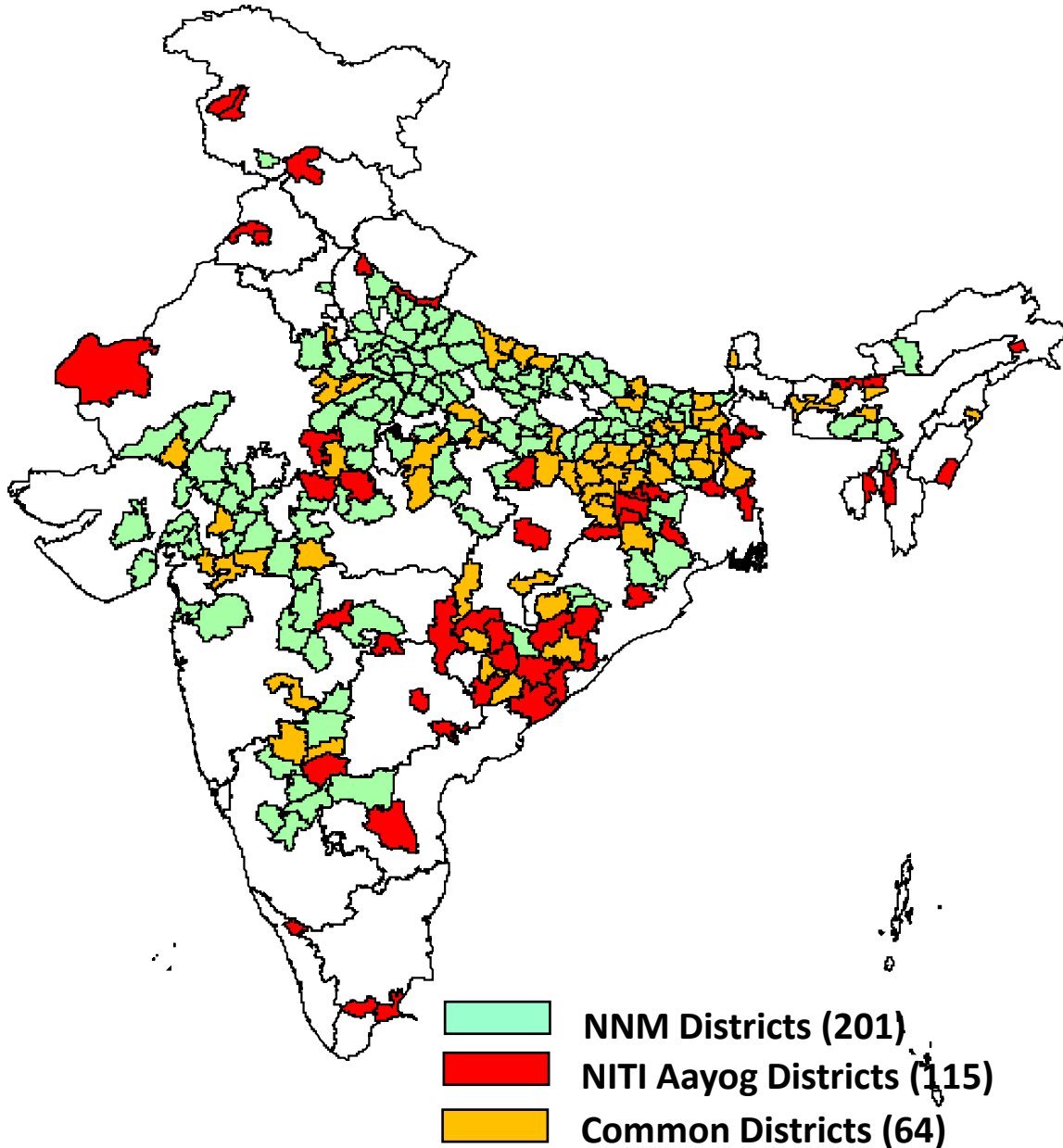
National Nutrition Mission

- The National Nutrition Mission (NNM) has been set up under the Ministry of Women & Child Development with aim to reduce the level of stunting, under-nutrition, anemia and low birth weight babies
- Why PCV and RVV under NNM?
 - Diarrhoea and pneumonia are key contributors to childhood malnutrition
 - PCV and RVV important interventions to reduce morbidity and mortality linked with under-nutrition
- Although childhood undernutrition is widespread, NNM has prioritized 201 NNM districts for immediate action.
- These 201 districts are spread across 19 states

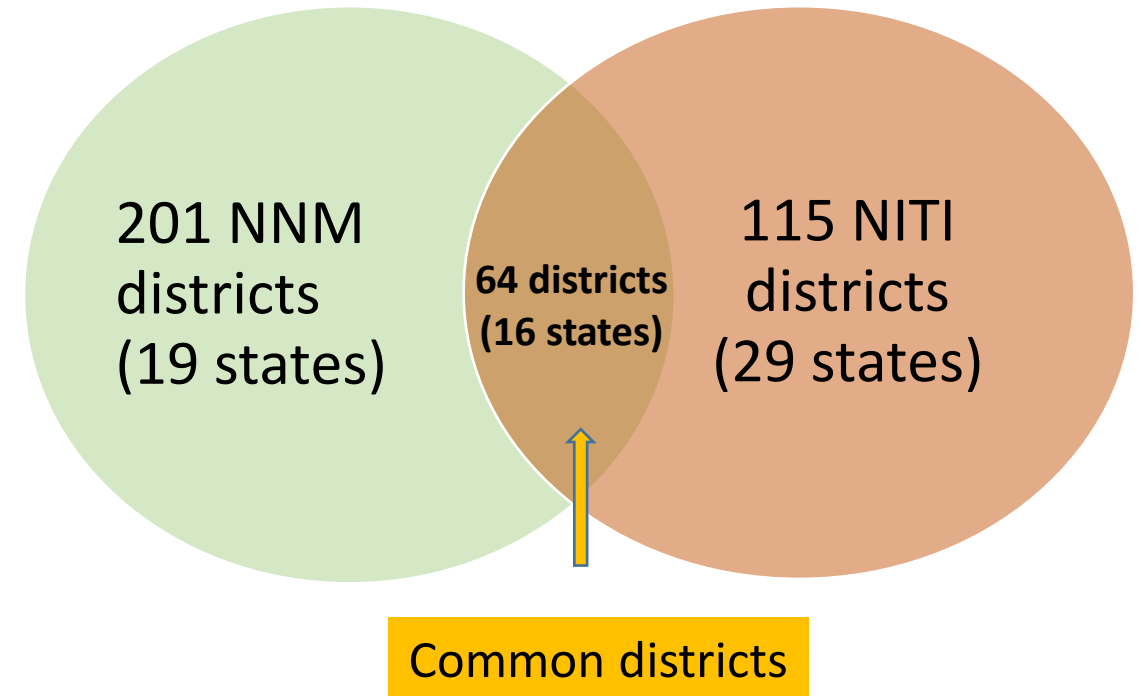
Districts identified by NITI Aayog

- 115 backward districts have been identified by NITI Aayog on composite index of poverty, health, education and infrastructure
- These 115 districts are spread across 29 states

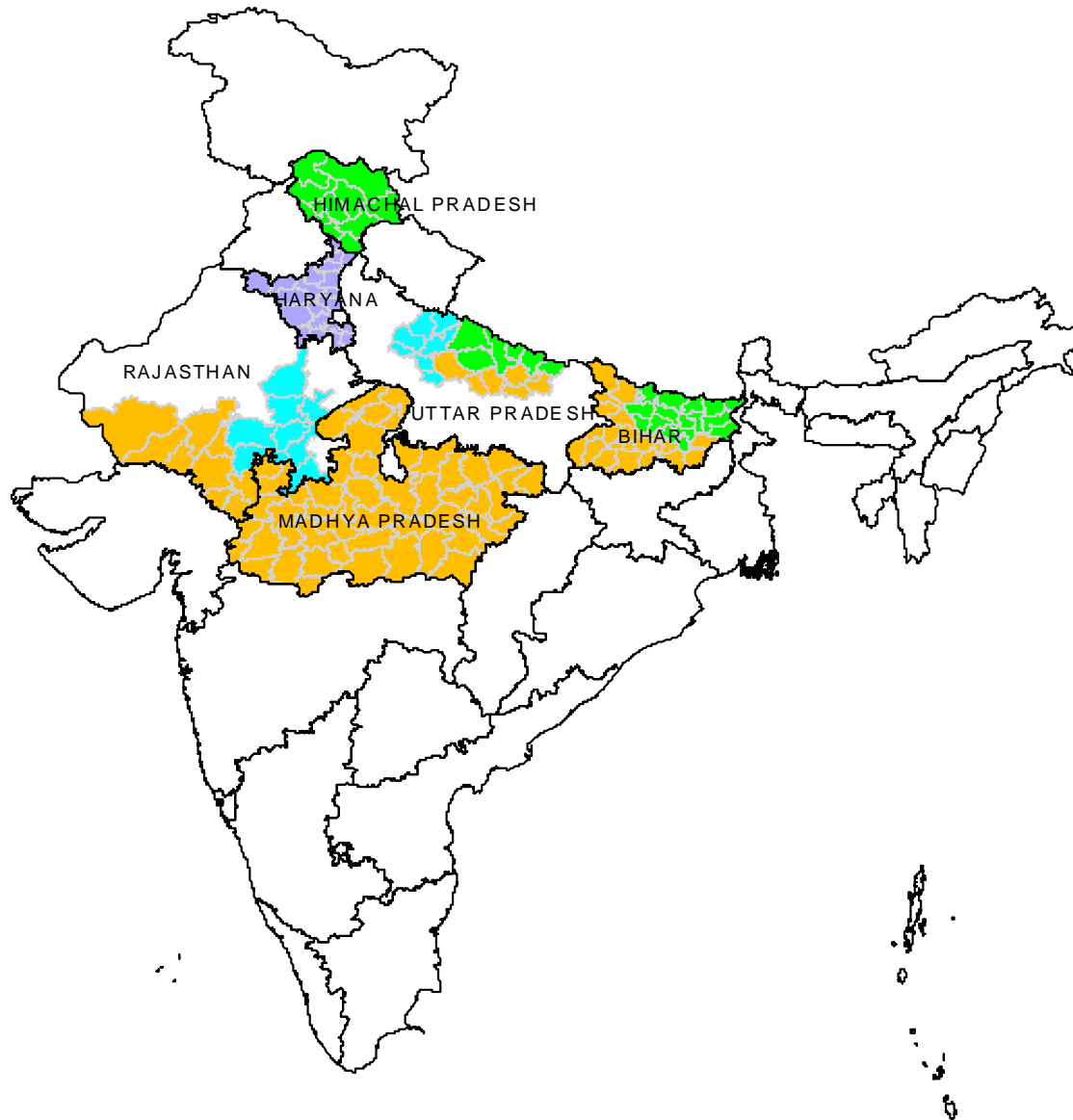
Districts under NNM and NITI Aayog



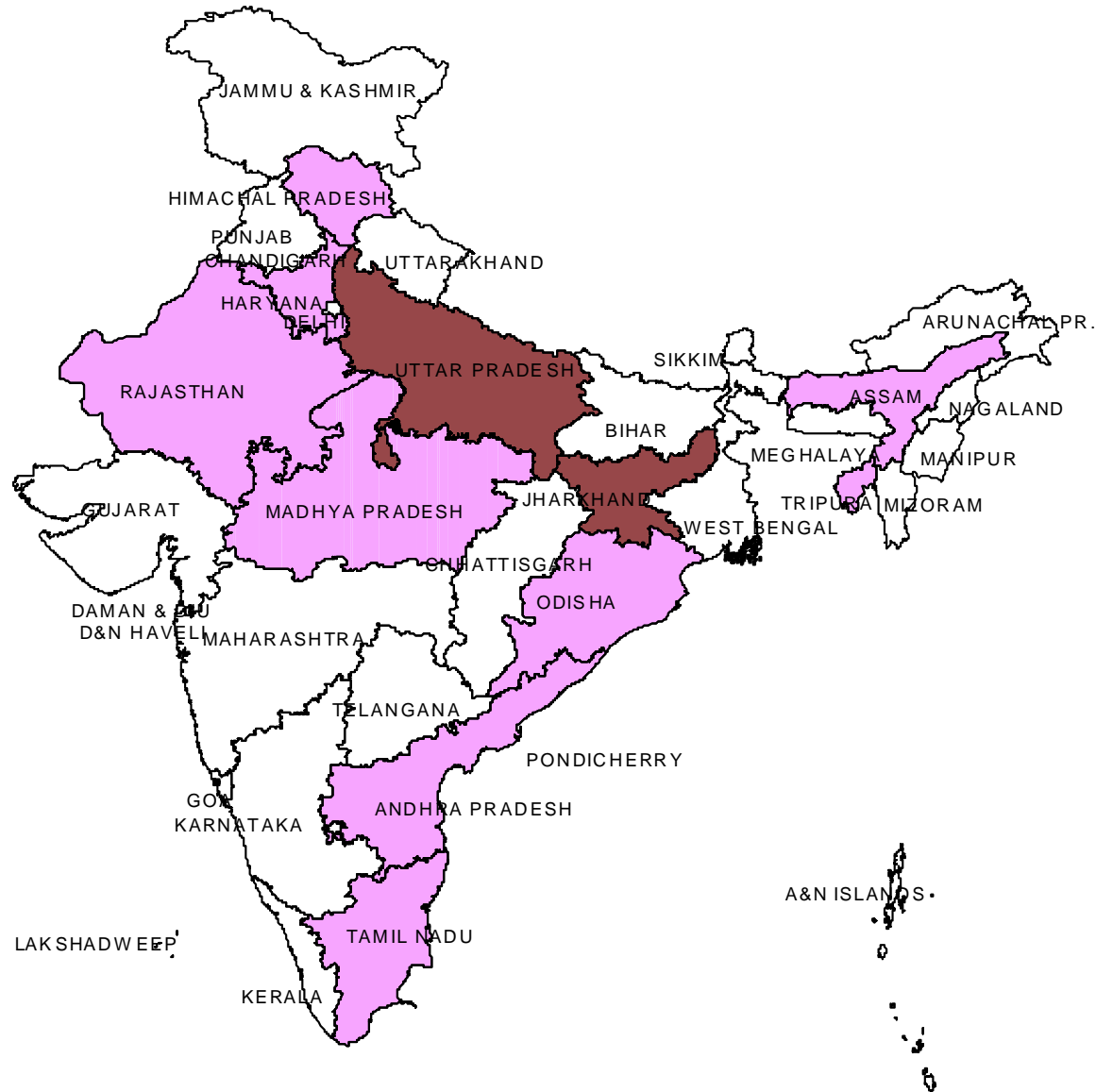
- 201 districts under NNM
- 115 backward districts identified by NITI Aayog on composite index of poverty, health, education and infrastructure





PCV introduction in Universal Immunization Programme – current status



RVV introduction in Universal Immunization Programme – current status



-  **RVV States (9 States)**
-  **RVV States in 2018 (2 states)**

NNM States Profile

Profile of NNM states

#	NNM state	IMR (SRS, 2016)	USMR (SRS, 2016)	Total districts in the State	NNM districts	Backward districts under NITI	Common NNM & NITI	NNM districts with PCV	NNM districts with RVV	Additional NNM districts for PCV scale up	Additional NNM districts for RVV scale up	NITI districts with PCV	NITI districts with RVV	Additional NITI districts for PCV scale up	Additional NITI districts for RVV scale up
1	Andhra Pradesh	34	37	13	1	3	0	0	1	1	0	0	3	3	0
2	Arunachal P	36	33	20	1	1	0	0	0	1	1	0	0	1	1
3	Assam	44	52	27	5	7	4	0	5	5	0	0	7	7	0
4	Bihar	38	43	38	36	13	13	36	0	0	36	13	0	0	13
5	Chhattisgarh	39	49	27	5	10	5	0	0	5	5	0	0	10	10
6	Gujarat	30	33	33	10	2	2	0	0	10	10	0	0	2	2
7	Haryana	33	37	21	2	1	1	2	2	0	0	1	1	0	0
8	J&K	24	26	22	1	2	0	0	0	1	1	0	0	2	2
9	Jharkhand	29	33	24	17	19	13	0	17	17	0	0	19	19	0
10	Karnataka	24	29	30	9	2	1	0	0	9	9	0	0	2	2
11	Madhya Pradesh	47	55	51	27	8	5	27	27	0	0	8	8	0	0
12	Maharashtra	19	21	35	7	4	2	0	0	7	7	0	0	4	4
13	Meghalaya	39	40	11	4	1	1	0	0	4	4	0	0	1	1
14	Nagaland	12	37	11	1	1	1	0	0	1	1	0	0	1	1
15	Odisha	44	50	30	8	8	3	0	8	8	0	0	8	8	0
16	Rajasthan	41	45	33	11	5	3	7	11	4	0	2	5	3	0
17	Sikkim	16	32	4	1	1	1	0	0	1	1	0	0	1	1
18	Uttar Pradesh	43	47	75	53	8	8	18	53	35	0	4	8	4	0
19	West Bengal	25	27	20	2	5	1	0	0	2	2	0	0	5	5
	India	34	39	525	201	101	64	90	124	111	77	28	59	73	42

Expansion of Vaccines to New States

- Past experience has shown that state-wise introduction/ expansion is a better idea than district-wise expansion owing to:
 - Equity
 - Operational feasibility
 - Vaccine logistics supply management
 - Migration
 - Epidemiological impact
 - Uniform reporting
 - Better ownership and accountability
- E.g. Hepatitis B pilot in 2002 and JE vaccine introduction in selected districts- state ownership and focus was missing with low coverage

Prioritization of states for expansion under NNM

- Prioritization based on:
 - ✓ Potential pneumococcal and rotavirus deaths averted [at MCV1 and Penta3 (NFHS-4) coverage, respectively*]
 - ✓ Number of additional NNM districts to be covered in state
- PCV impact is given higher ranking than RVV impact as pneumonia is a greater contributor to childhood mortality

*Assessment of potential deaths averted also done considering states achieve 90% full immunization coverage under Intensified Mission Indradhanush (IMI)

States prioritization based on selection criteria

#	NNM state	IMR (SRS,2016)	U5MR (SRS,2016)	Addl. NNM districts		Addl. NITI districts		Pneumo deaths averted		Rota deaths averted		
				PCV	RVV	PCV	RVV	90% FIC	MCV1 coverage	90% FIC	DPT3 coverage	
1	Uttar P	43	47	35	0	4	0	17514	13778	8714	6438	Phase I
2	Bihar	38	43	0	36	0	13	14616	12895	3597	3201	
3	Rajasthan	41	45	4	0	3	0	7497	6506	2458	1955	
4	Jharkhand	29	33	17	0	19	0	3969	3643	919	840	
5	Odisha	44	50	8	0	8	0	2142	2092	1288	1277	
6	West Bengal	25	27	2	2	5	5	1827	1884	1226	1263	
7	Chhattisgarh	39	49	5	5	10	10	1323	1380	775	787	
8	Gujarat	30	33	10	10	2	2	1638	1365	1364	1102	
9	Maharashtra	19	21	7	7	4	4	1260	1159	1194	992	Phase II
10	Assam	44	52	5	0	7	0	1386	1100	1232	910	
11	Andhra P	34	37	1	0	3	0	1008	1001	1306	1292	
12	Karnataka	24	29	9	9	2	2	882	808	933	808	
13	J&K	24	26	1	1	2	2	378	362	202	198	
14	Meghalaya	39	40	4	4	1	1	63	50	75	62	
15	Nagaland	12	37	1	1	1	1	63	35	41	24	
16	Arunachal P	36	33	1	1	1	1	0	0	29	17	
17	Sikkim	16	32	1	1	1	1	0	0	13	13	
	India	34	39	111	77	73	42	66213	59665	30828	26855	

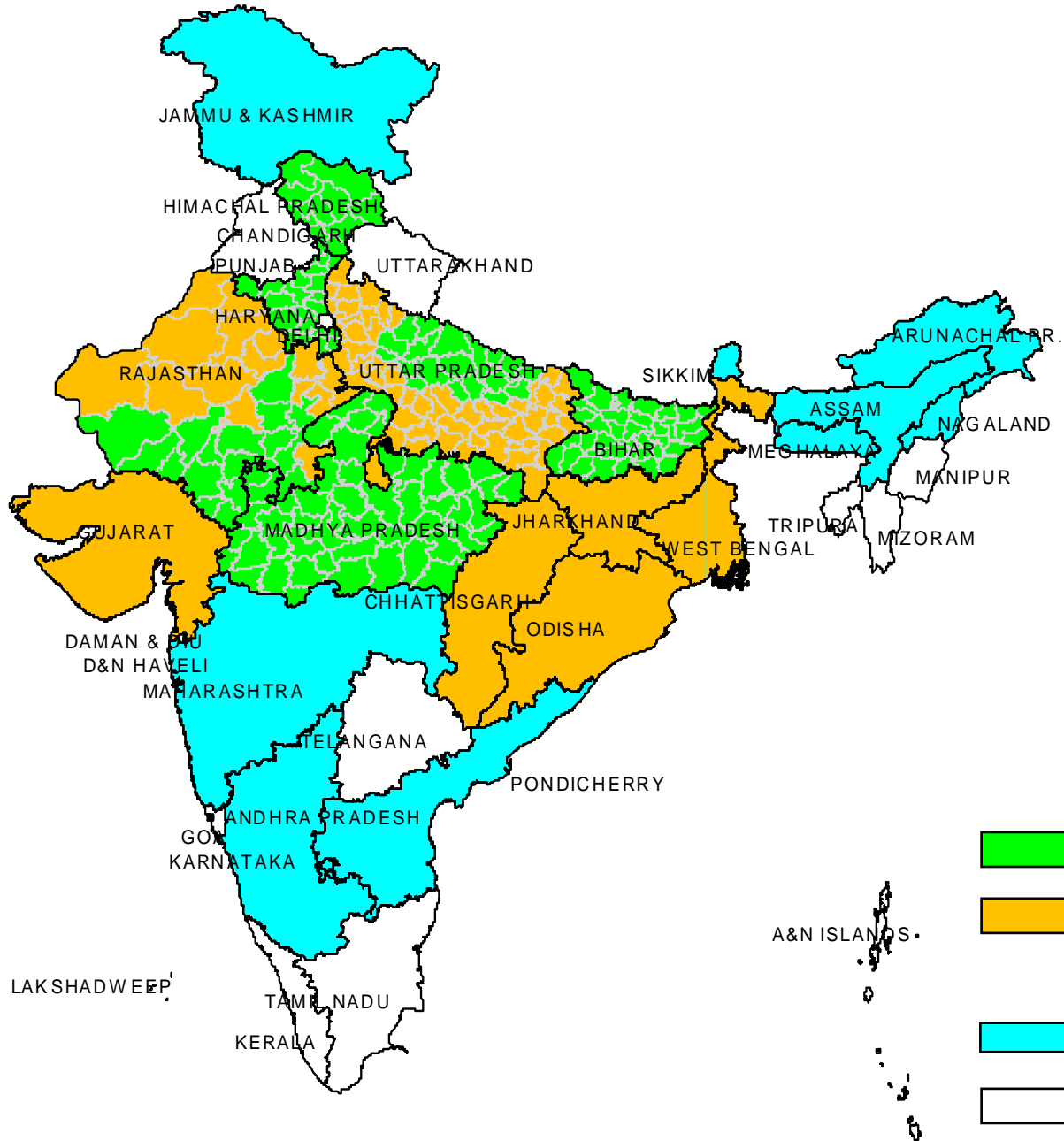
Source: Pneumococcal deaths: Farooqui et al; Rotavirus deaths: Kang et al; MCV1 & DPT3: NFHS4

- PCV and RVV expansion in a given year is subject to:
 - **Availability of budgetary resources**
 - **Availability of vaccine**



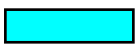
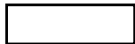
Summary of Phasing Decision

- Top 4 states with maximum pneumococcal and rotavirus deaths averted- Uttar Pradesh, Bihar, Madhya Pradesh, Rajasthan
- Consideration given if any state with high potential impact already has introduced one of the 2 said vaccines
- States, namely, Madhya Pradesh and Haryana, have both PCV & RVV and therefore not considered in this roll out plan

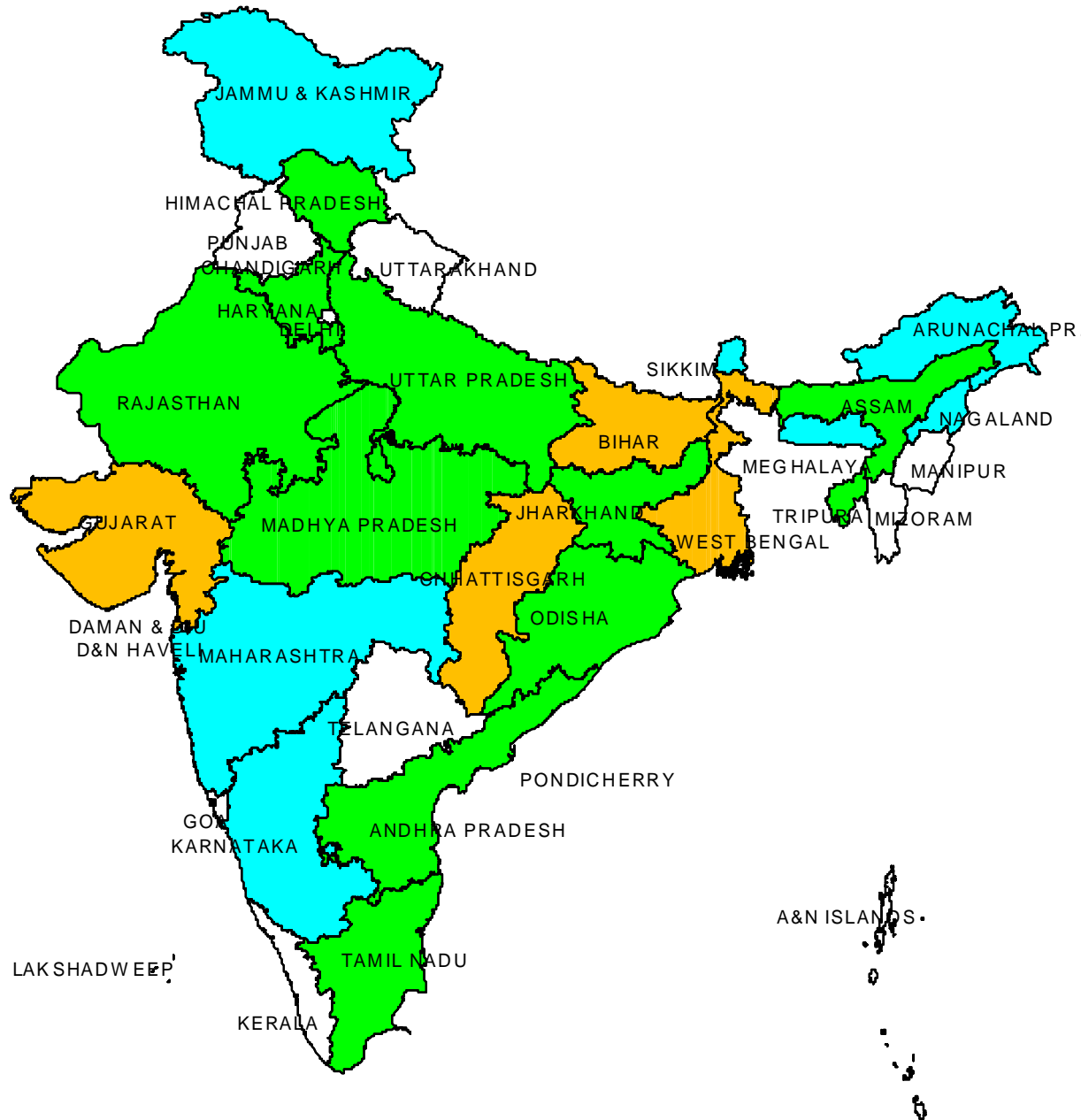
Proposed PCV scale up under NNM



Years mentioned are indicative

-  PCV introduced or in pipeline 2017-2019 (6 States)
-  PCV scale up in 2018 (7 NNM States- complete scale up in 2 partially covered states)
-  PCV scale up in 2019 (9 NNM States)
-  PCV scale up in 2020 (Remaining 16 States)

Proposed RVV scale up under NNM



-  RVV scale up in 2016-2018 (11 States)
-  RVV scale up in 2018 (4 NNM States)
-  RVV scale up in 2019 (7 NNM States)
-  RVV scale up in 2020 (Remaining 14 states)

Years mentioned are indicative

Summary : PCV and RVV expansion road map

	Number of States		
Year	PCV scale up	RVV scale up	
Introduced or in pipeline*	6 (90 NNM districts)	11 (124 NNM districts)	201 NNM districts
2018*	7 (81 NNM districts)	4 (53 NNM districts)	
2019*	9 (30 NNM districts)	7 (24 NNM districts)	
2020	16 (163 districts)	14 (123 districts)	Total districts in states

*All districts in states will be covered; within parenthesis is number of NNM districts only

Lessons

- Phased roll out of new vaccine
 - Handling by the system in the context of its capacity, resilience and state ownership
- Pre-defined criteria
 - Transparent, explicit and linked with potential impact assessment
 - Minimizes the political interference
- Financial and vaccine security sustainability
 - Avoidable interruptions once vaccine is launched
- Helps industry to plan production lines

Acknowledgements

- National Vaccine Roll-out Expert Group
- Development Partners
- Vaccine Division, Ministry of Health & Family Welfare, Government of India

Thank You

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