

India Country Profile

2023



- a. Immunization program overview
- b. Vaccine spending
- c. Product selection and opportunities
- d. Market access



Country overview

Indicators	Status (2022)
Population	1.4B
Birth Cohort (M)	23M
Under 5 Mortality Rate (# per 1,000 live births)	31
EPI Coverage	80-90% for most vaccines except HepB and PCV which have low coverage per WUENIC estimates
National EPI Manager	National Health Mission
GNI per capita (USD)	\$2150
Government Health Spend (% per GDP)	2.1% - Government's ambition is to achieve 2.5% by 2025
Gavi Country Status (Y/N, Year of Transition)	Self-financing but continues to receive some support across selective programmes
Contribution to Gavi (USD)	 3M (2011-2015) 9M (2016-2020) 15M (2021-2025)
COVAX country (Y/N)	Υ



India's UIP is 100% funded by central government

Title of the Scheme	Universal Immunization Programme (UIP)		
Funding Pattern of Scheme	100% funded by the central government		
Beneficiaries & Eligibility Criteria	All children and pregnant women		
Types of Benefits	Material & Services		
How to Avail Benefits	In nearest government/PSU/Local body/Autonomous body health facility		
Website of the Scheme	Website; Detailed Document		

- ~90% of vaccination in India is provided through public sector while private sector contributed to only ~9%
- Only ~1M annual birth cohort potential for the private sector compared to ~27M annual Indian birth cohort overall
- Private sector means getting the vaccines at own personal cost in private clinics/hospitals compared to free of cost public funded vaccines available in government immunization centers

12 vaccines in Universal Immunization Program (UIP) target close to 26M newborns and 30M pregnant women annually



Immunization scheduled based on child age

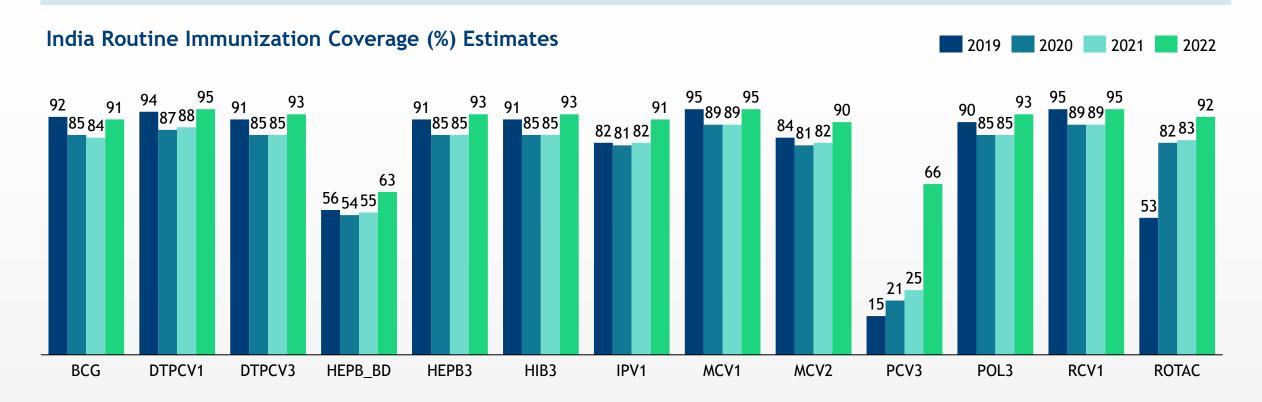
Birth	6 weeks	10 weeks	14 weeks	9-12 months	16-24 months	5-6 years	10 years	16 years	Pregnant Women
BCG	OPV-1	OPV-2	OPV-3	MR-1	MR-2	DPT booster-2	Tetanus & adult Diphtheri a (Td)	Tetanus & adult Diphtheri a (Td)	Td-1
OPV 0 dose	Penta-1	Penta-2	Penta-3	JE-1	JE-2				Td-2
HepB birth dose	Rota virus vaccine (RVV)-1	RVV-2	fIPV-2	PCV- booster	DPT booster-1				Td- Booster
	Fractional (f)IPV-1		RVV-3		OPV booster				
	PCV-1		PCV-2						

Under UIP, immunization is provided free of cost against 12 vaccine-preventable diseases

- Nationally against 11 diseases: Diphtheria, Pertussis, Tetanus, Polio, Measles, Rubella, severe form of Childhood Tuberculosis, Hepatitis B and Meningitis & Pneumonia caused by Hemophilus Influenza type B, PCV and Rotavirus
- Sub-nationally against 1 additional disease: Japanese encephalitis vaccine is provided only in endemic districts

2022 coverage figures have surpassed the pre-covid levels across most of the routine vaccines



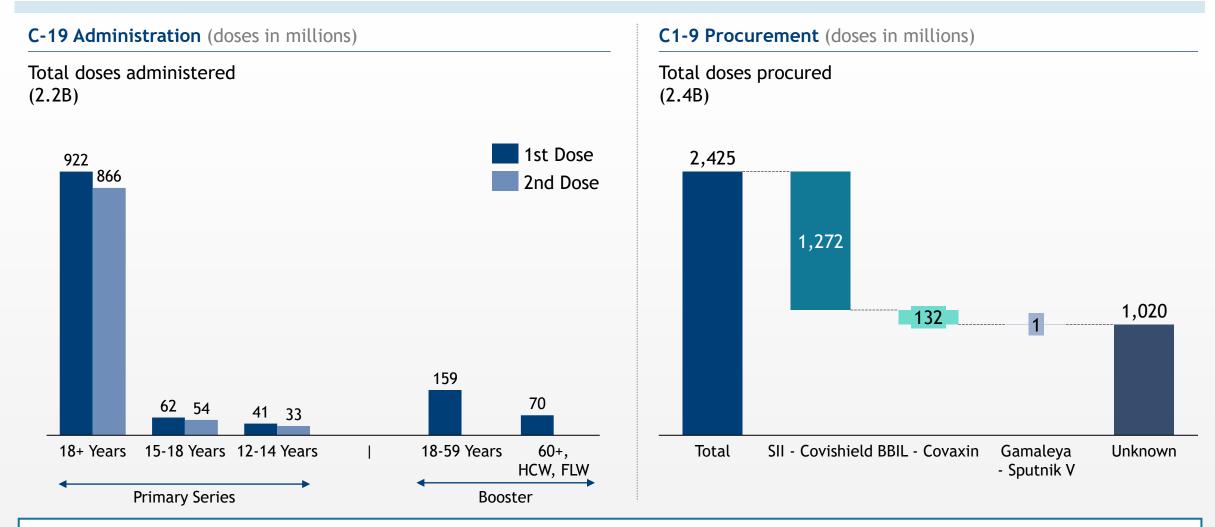


COVID-19 Impact on program

- Coverage was impacted significantly during H2 2020, and the impact continued in 2021 as many resources were repurposed to enhance COVID vaccination coverage
- Outbreaks of diphtheria, pertussis and measles in small pockets have been an indicator of risk due to declining coverage during the period

India has achieved ~72% primary series coverage for COVID-19 while the booster coverage stands at 16%





~80% of the vaccines administered estimated to be SII Covishield while BBIL Covaxin accounts for ~16%

Three new vaccine introductions are planned for India beyond 2023; OCV to be delivered in campaigns¹



Demand forecast for expected introductions (in million doses)

Vaccine	2024	2025	2026	2027	2028	2029	2030
HPV	45.0	59.0	24.0	9.9	9.8	9.6	9.5
TCV			20.5	24.6	32.3	31.5	40.4
OCV (campaign)			43.9	70.3	83.7	83.5	83.4

Service delivery priorities

- To catch up on gaps that might have emerged due to the COVID-19 pandemic, a targeted program
 called Intensified Mission Indradhanush 4.0 has been planned to reach out to unvaccinated and
 partially vaccinated children and pregnant women
- Additionally, a focus on expanding cold chain, strengthening supply chain, and ensuring safe waste disposal is also part of the current program priorities



a. Immunization program overview

b. Vaccine spending

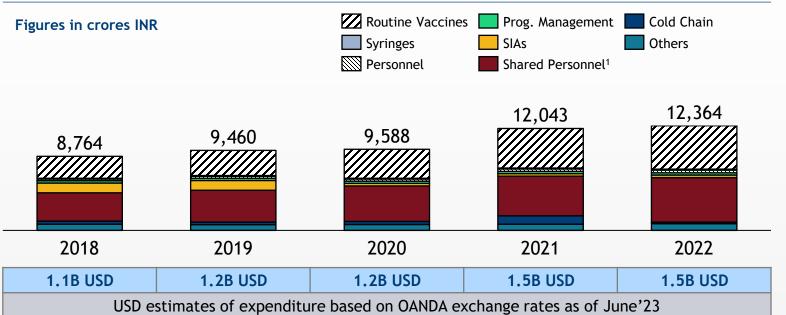
c. Product selection and opportunities

d. Market access

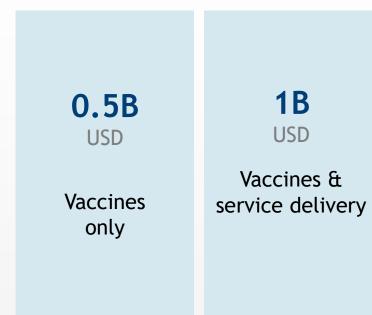
Total vaccine expenditure for 2021/2022 estimated to be ~1.5B USD; key drivers are procurement costs and service delivery personnel costs



Government estimation on resource requirements for India's immunization programme based on current coverage



Incremental cost: current coverage to 90% coverage in all districts



- India's UIP had an estimated annual expenditure of ~1.5B USD for 2021 and 2022
- For 2022, the government contributed around 97% of the expenditure while remaining was expected to be covered under different grants for health system strengthening, monitoring & evaluation, etc. through partners like WHO, Gavi, BMGF, JSI, UNDP and UNICEF



- a. Immunization program overview
- b. Vaccine spending
- c. Product selection and opportunities
- d. Market access

New vaccine introductions (NVIs), switches, and procurement are decided by the central government



State governments are generally responsible for health policy design and implementation in India

Immunization programs are an exception - NVIs and product switches are decided at the central government level

The Ministry of Health and Family Welfare (MoHFW) at the central government level approves new vaccines for the country's immunization program and supports implementation planning

Central government typically covers the vaccine commodity cost through a central procurement process, while states take on part of the program rollout cost

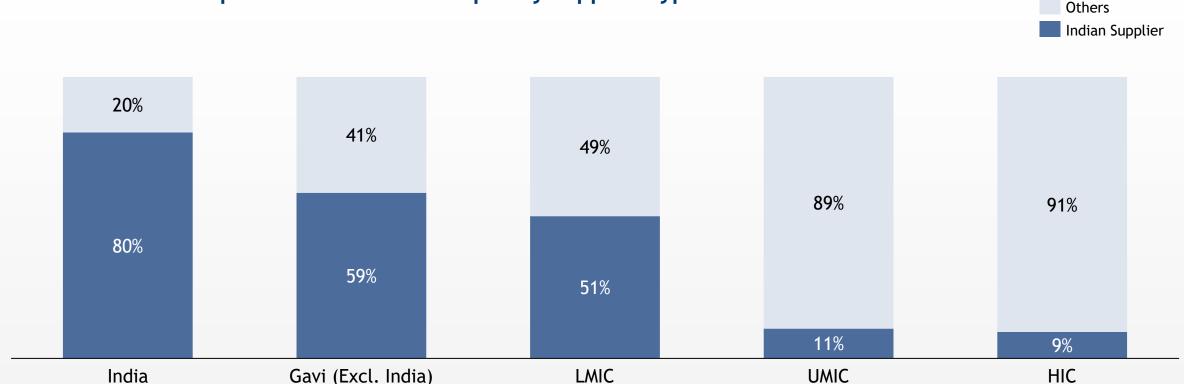
In some instances, states may act independently to accelerate new introductions that are stalled or delayed at the federal level

SOURCE: VIAL study 2019

India country procurement is dominated by Indian suppliers with one non-Indian supplier for bOPV vaccine in 2021



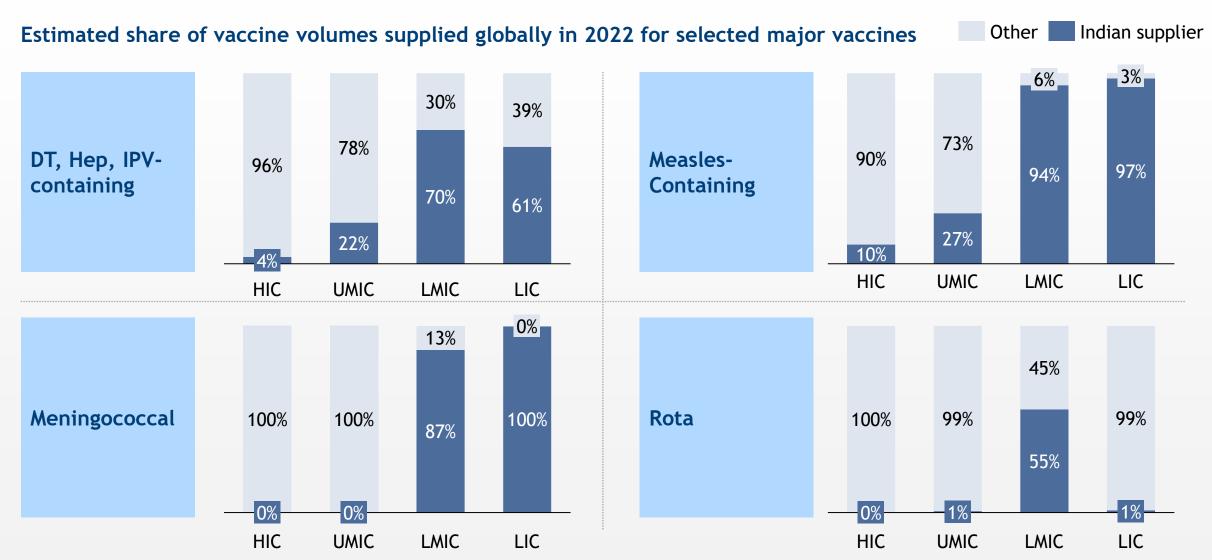
Estimation of 2021 procurement volume spilt by supplier type



- ~80% of the Indian domestic procurement is coming from 6 Indian suppliers
- ~60% of Gavi and ~50% of LMIC procurement volumes is estimated coming from Indian suppliers
 - Indian supply to these markets is driven by 3 suppliers who also account for ~33% of the domestic procurement

LMICs and LICs have significant dependence on Indian suppliers across several major vaccines





SOURCE: Linksbridge GHMH

Note: 'Other' category consists of non-Indian suppliers including MNCs



- a. Immunization program overview
- b. Vaccine spending
- c. Product selection and opportunities
- d. Market access

First two steps of the Indian NVI approval process involve evaluating the disease burden and preferred product profile based on local context





2

Standard Technical Sub-committee (STSC)

• Immunization and virology researchers from public sector medical and research institutes

 Co-chaired by the Secretary of the Indian Council for Medical Research (ICMR) and the Secretary of the Department of Biotechnology (DBT)

National Technical Advisory Group on Immunization (NTAGI)

- Medical and health policy experts from government agencies, national institutes, professional organizations
- Same co-chairs as the STSC

Activities

Membership

- Gathers epidemiological data and health burden evidence; ICMR will conduct new studies if data has not been collected before
- Prepares initial NVI proposal to present to the full NTAGI
- Assesses STSC proposal and makes a recommendation to the EPC (see next page)
- Indicates minimum efficacy or valency thresholds based on local context; does not express a preference for a specific products

Linkages

- STSC and NTAGI share information regularly as the STSC's core function is to support the NTAGI in developing the NVI proposal; they have the same co-chairs which guarantees alignment in workstream objectives
- As a result of their close alignment, STSC proposals do not typically face NTAGI resistance and are approved swiftly

SOURCE: VIAL study 2019; CHAI insight

The next steps of the NVI approval process focus on budget considerations and evaluation of its fit to overall public health priorities



3

Empowered Program Committee (EPC)



Mission Steering Group (MSG)

Membership

- Inter-ministerial technical body of ~15
 representatives, chaired by the Secretary of
 the MoHFW
- Convenes secretaries from other relevant ministries, including Women and Child Development, Social Justice, etc.
- Inter-ministerial political body of ~20 members, chaired by the Minister of the MoHFW (sits once a year)
- Includes broader range of stakeholders, including advocacy groups, and professional organizations, in addition to government ministers

Activities

- Considers NVI budget implications and weighs ROI against other health priorities
- Approves, rejects, or asks for revisions to the recommendation presented by the NTAGI
- Evaluates all aspects of the NVI, including competing public health priorities
- Makes final approval decision; may require the NTAGI to make additional revisions to their initial recommendation

Linkages

- Policy objectives and priorities are generally aligned between the two groups as they both fall within the National Health Mission (NHM) within MoHFW, which sets health policy objectives for the country and is under the purview of the Minister of Health
- NITI Aayog, chaired by prime minister, acts as the central think tank across these bodies and ends up being the interim decision maker right from step 1 to 4. Generally, members of NITI Aayog are present in each of these bodies and therefore these bodies work in sync with recommendations from NITI Aayog at each step.

Following the NVI approval, MoHFW defines product specifications and opens a price-driven tender process



Procurement

Product specifications



- MoHFW provides vaccine specifications for the tender in consultation with an independent expert group
- Criteria include
 - Impact valency and efficacy should be in line with NTAGI recommendations;
 - Feasibility all programmatic requirements (e.g. cold chain capacity, training, etc.) must be addressable and
 - Safety product license is required
- Goal of specification criteria is to limit implementation challenges and consider interchangeability issues in the case of multiple products being introduced
- Specifications are typically kept broad so that bidders compete mainly on price
- Each tender has certain percentage of volume fixed to promote the locally manufactured products in line with the Make in India initiative

- Tender is opened for all interested manufacturers but only those registered on the e-procurement portal and having completed the prescribed assessment (regulatory audit, manufacturing facility audit, etc.) are eligible for participating. It usually takes 3-4 months to get the registration process completed
- Procurement division conducts two review processes:
 - Compliance with product specification
 - Cost review, focused on pricing considerations
- Lowest price bidder is selected (60/40 split considered if second bidder matches winner's price).
 Recently the process has been flexible to even accommodate more than 2 suppliers to promote a healthy market in line with UNICEF tendering process
- Central budget covers the commodity cost of the immunization program

NVI approval complete

SOURCE: VIAL study 2019; CHAI insight



www.clintonhealthaccess.org