A study to illustrate the use of data triangulation to estimate target population for immunization coverage in India

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A thesis submitted in partial fulfilment of the requirement for the degree of Master of Science in International Health

by

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Abbreviations

ANMOL	ANM Online
BCG	Bacille Calmette-Guérin (vaccine against tuberculosis)
CSSM	Child survival and safe motherhood programme
CES	Coverage Evaluation Survey
CRS	Civil Registration System
DLHS	District Level Household & Facility Survey
DTP3	Third dose of diphtheria and tetanus toxoid with pertussis containing vaccine
DVS	District Vaccine Stores
EPI	Expanded Programme on Immunization
JE	Japanese Encephalitis
GAVI	Global Alliance for Vaccines
GIS	Geographic information systems
GNSS	Global navigation satellite system
GMSD	Government medical store depots
HMIS	Health management information system
MCTS	Mother and Child Tracking System
MCV	Measles-containing vaccine
MoHFW	Ministry of health and family welfare
NFHS	National Family Health Survey
NHM	National health mission
NRHM	National Rural Health Mission
NTAGI	National Technical Advisory Group on Immunization
OPV	Oral Polio Vaccine
RCH	Reproductive and Child health programme
RI	Routine immunization
RSOC	Rapid Survey of Children
RVS	Regional Vaccine Stores
SDG	Sustainable development goals
SI	Surviving infants
SRS	Sample Registration System
SVS	State vaccine Stores
TT	Tetanus toxoid
UIP	Universal Immunization Programme
UNICEF	United Nations Children’s Fund
VPD	Vaccine preventable diseases
WHO	World Health Organization
WPP	World population prospects
WUENIC	WHO-UNICEF estimates of national immunization coverage

Abstract

Title: A study to illustrate the use of data triangulation to estimate target population for immunization coverage in India

Background: Immunization is one of the most powerful public health interventions currently available. It is becoming increasingly necessary to consider the consistency of reported target populations as countries seek to expand immunization coverage worldwide. It is therefore vital to determine accurate target populations for immunization using approaches like data triangulation which can serve as a cost-effective tool as the process involves the usage of multiple pre-existing data sources. With this background, the current study was done to illustrate the use of data triangulation in estimating denominator data for immunization in infants.

Methods: In this study, the application of data triangulation for target population estimation for India was illustrated using a case study. The study also involved a literature review of the Universal Immunization programme as well as the sources and methods of data used for denominator estimation.

Results and Discussion: Some of the sources of data available for target population estimation at national level include census, civil registration system and sample registration system. The target population estimates from various sources were flagged for inconsistencies at national and subnational level. Data inconsistencies were observed for various parameters.

Conclusion As advances in public health are dependent on accurate data and robust data systems, methods like data triangulation can be used to improve the accuracy of existing data sources. This approach of critical synthesis of existing data could serve as a valuable tool to track the progress made in the programme and guide further planning and decision-making.

Key words: Data triangulation, denominator, immunization coverage, Health information system
Word count: 9877

A.1 Introduction

1.1 Background: Study Area at a glance

Immunization is one of India's most notable public health achievements. The ‘Expanded Programme on Immunization’ (EPI) was first introduced in India in 1978.[1] In 1985, this programme was renamed as ‘Universal Immunization Programme’ (UIP) and was introduced in a phased manner to cover all the districts in the country.[1] The two major achievements under this programme include the elimination of polio in 2014 followed by elimination of maternal and neonatal tetanus in 2015.[2] Every year, this program aims to cover more than 26 million babies and 30 million pregnant women, totaling to around 300 million vaccine doses approximately.[3] This programme involves more than 2.5 million health care workers handling around 27,000 cold chain points.[3] These cold chain points are located at various levels in the state. About 3% of these cold chain points are established at district level and above while the remaining points are functional at primary and secondary level of healthcare.[3] The immunization programme in children underwent a sudden transition in India in the year 2014 with the launch of ‘Mission Indradhanush’ by the Ministry of Health and Family Welfare.[1] The main focus of this mission was to increase the immunization coverage by targeting the high focus areas with poor coverage as well as to accelerate the progress in areas with good coverage.[1]

India is a federal union and is divided into 29 states and 8 union territories for the purpose of administration.[4] The immunization coverage data is an important tool for monitoring and evaluation of the programme. According to NFHS-4, the national immunization coverage is 62 percent.[5] The coverage pattern across different states is quite diverse. The highest coverage was reported in Puducherry (95%) whereas Nagaland reported the lowest coverage (35%).[5-6] The larger states like Bihar, Madhya Pradesh, Uttar Pradesh and Rajasthan have the highest proportion of partially-immunized and non-immunized children.[7] The key challenges faced in achieving good coverage include shortage of healthcare field staff, gaps in predicting the accurate target population as well as logistics and cold chain management.[7]

The standard method of reporting the estimates of vaccine coverage (the proportion of a target population that received a given vaccine) at regional, national and global level serves as a tool for impact assessment of the National Immunization programme.[8] This data is obtained from administrative and survey coverage data which serves as a tool to guide the programme managers. The administrative coverage involves reporting of aggregated reports from healthcare providers on the total number of vaccines administered during a given period to a defined population while survey coverage involves data collected from population based household surveys based on documented evidence or caregiver recall.[9] Due to the availability of coverage data from numerous sources with varying levels of evidence, tracking the trends in immunization coverage remains challenging.[10]

The immunization program, which began three decades ago, has only partially achieved the reduction in the burden of vaccine-preventable diseases.[10] A major factor reflecting this is the huge discrepancy that exists due to the gap in the reported and evaluated coverage.[3] The consistency of administrative coverage estimates in India, is largely dependent on accurate recording of administered doses, information of the target population, regular reporting by the healthcare workers administering the vaccines, and appropriate data transfer through the healthcare system at all levels.[10,11] The indices like the numerator and denominators needed for estimation are often just available as rough estimates.[6,7,10] The ideal source of regular estimates would be the representative surveys conducted at national level providing information on immunization coverage.[10] However these surveys are expensive, cumbersome and time-consuming and are not done at regular intervals. Such a survey was last conducted in India in the year 2008.[10] As a result, administrative data coverage has served as a primary tool for monitoring and evaluation at various levels. This results in difficulties in estimating the accurate denominators for determining the size of the target population.[10]

1.2 Problem Statement & Justification

Immunization is one of the most powerful public health interventions currently available. It is one of the key component in achieving the progress towards attainment of the Sustainable Development Goals (SDG).[12] Good quality public health vaccination data is needed for a variety of purposes, including decision-making and planning at all levels of the health care, evaluating project outcomes, and justifying monetary assistance.[13–15] A reliable target population calculation is a crucial component of estimating vaccine coverage, given that administrative method is the most common method of calculating the vaccine doses administered to the target population.[13,15,16]

According to WHO's existing findings, the effect of a percent inaccuracy in target population estimates on the error in immunization coverage estimates increases as coverage increases.[17] The predicted coverage is overestimated when the target population considered as the denominator is underestimated, and vice versa.[17] The key problem is to get an accurate denominator for the estimation of vaccination coverage. Certain problems identified include the non-availability of population data, availability of redundant data, or data aggregation done at a higher administrative level; availability of inaccurate data due to technical reasons or data modification done to serve the interests of certain groups; data does not reflect reality due to the constant flux of people across administrative borders or catchment areas.[10,13–15,18] This has consequences for planning and evaluation of the vaccination efforts. Previous research studies have shown that administrative vaccine coverage denominators are often inaccurate, with vaccination coverage often exceeding

100%, unrealistic year-to-year variability, and disease outbreaks in these areas with high coverage.[8,10,11,17]

The solution to these existing denominator inaccuracies can be resolved with the use of data triangulation in immunization programmes. Data triangulation is defined as "an approach for critical synthesis of data from two or more sources to address relevant questions for program planning and decision-making" [19,20]. It can play a crucial role in guiding policies and strategies in immunization despite the data quality limitations from the existing individual sources. It also promotes deeper understanding of the phenomenon of interest by incorporating details of the deeper context and underlying mechanism involved.[20]

It is becoming increasingly necessary to consider the consistency of reported target populations as countries seek to expand immunization coverage worldwide. In order to control vaccine-preventable diseases, eligible populations must be detected and vaccinated. It would be difficult to eradicate or eliminate disease without understanding the accurate population estimates at risk, as well as who and where they are. It is therefore vital to determine accurate target populations for immunization using approaches like data triangulation which can serve as a cost-effective tool as the process involves the usage of multiple pre-existing data sources. With this background, the current study was done to illustrate the use of data triangulation in estimating denominator data for immunization in infants.

A.2 Study Objectives

Overall goal of the research

To describe the use of data triangulation in estimating denominator data for immunization of infants.

Specific objectives of the research:

- To provide a brief overview of the evolution of the Universal Immunization programme in India.
- To describe and explore the different types of methods & sources of data used to estimate population denominators in immunization of infants
- To illustrate the use of data triangulation to estimate target population for immunization of infants in India.
- To disseminate the findings obtained from the study to policy makers and public health officials involved in immunization activities.

A.3 Methods

3.1 Literature review

A literature review was carried out to describe the different types of methods and sources of data used to estimate population denominators. The review was also done to provide a brief overview of the evolution of the Universal Immunization programme in India. PubMed, Embase and other search engines were used to procure the data. These databases were searched for obtaining the data using keywords (Annexure 1). Booleans used between the keywords were used to limit the number of articles reviewed. Snowballing was also used as a search technique in cases of interlinked articles.

3.2 Case Study

A case study was conducted to illustrate the use of data triangulation to estimate target population for immunization coverage in India.

3.2.1 Data Triangulation Methodology

The Data triangulation process aims to recognize and attempts to overcome the shortcomings of any single data source or data collection technique. The table below describes the steps that are involved in the data triangulation process. [20]

Table 2: Public health data triangulation process from Rutherford et al. 2010 [19]

Process	**Steps Involved**
Planning	**Step 1:** Identify key questions
	Step 2: Identify data sources and gather background information
	Step 3: Refine research questions
Conducting	**Step 4:** Gather data/reports
	Step 5: Assess data reliability and make observations from each data set
	Step 6: Note the trends across the data sets and hypothesize
	Step 8: Summarize findings and draw conclusions
Communicating	**Step 9:** Communicate results and recommendations
	Step 10: Outline next steps for public health action

3.2.2 Data Analysis

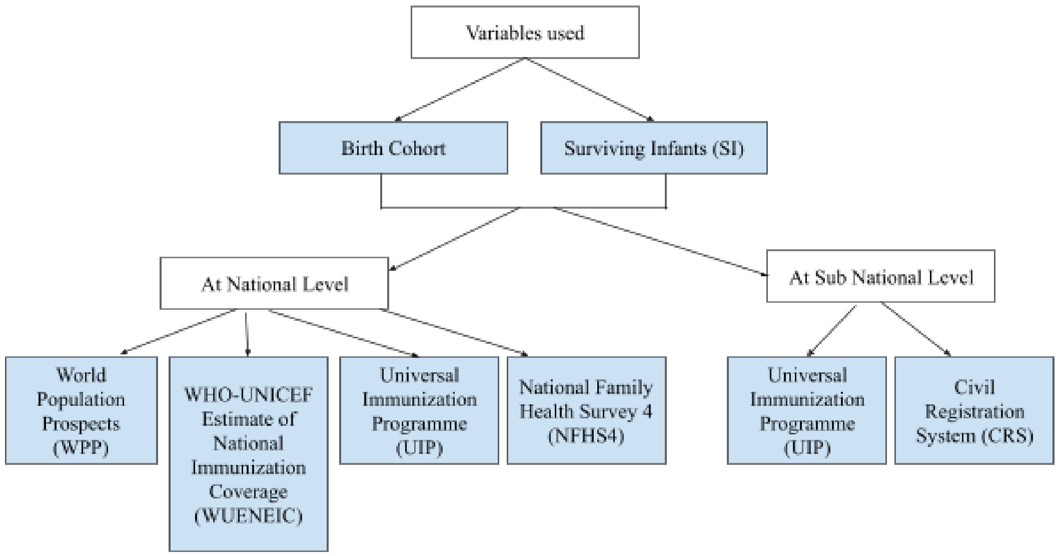


Figure 1: Source of the datasets along with the variables used for secondary data analysis

As a part of the data triangulation process in this study, secondary data analysis was done on the publicly available datasets. The analysis was done for a period of nine calendar years from 2011 to 2019. The target population included were the birth cohort and surviving infants (SI) for the following childhood vaccines given below one year of age i.e., BCG, DPT-3, OPV-3 and Measles. The Figure1 below shows the source of the datasets along with the variables to be used for secondary data analysis at national and subnational level. The WHO Guidelines on "Assessing and Improving the Accuracy of Target Population Estimates for Immunization Coverage" commonly referred to as the *WHO Denominator Guide*, was used as a guide to compare the target population estimates for Immunization coverage from various sources .[7]

The WHO method of assessing administrative immunization coverage was used in the study. The World Population Prospects (WPP) by the United Nations population Division provides an annual estimate of births and infant mortality rates at the national level, updated every two years. In India, there are two primary sources for annual numbers of births. They are the Civil registration system (CRS) and population projection estimates from a recent national population census. The current national annual estimates of births used by the immunization programme (UIP) were compared with estimates from World Population Prospects estimates and WHO-UNICEF estimates of immunization coverage (WUENIC) at national level. At state level, the UIP estimates were compared with the Civil Registration System (CRS) estimates. The comparison of the UIP data was made with NFHS-4 for internal consistency. The results were flagged if the difference between the estimates for any year was greater than 10% of the UIP estimate. The datasets were assessed for completeness of reporting and data quality (internal and external consistency).

3.2.3 Description of the datasets used at National level: WUENIC, WPP and UIP

WHO-UNICEF estimates of immunization coverage (WEUNIC) estimates: Every year, WHO and UNICEF jointly release immunization coverage reports at the country level. This report is collated based on the combined information obtained from national immunization coverage reports, survey reports as well as data obtained from published and grey literature. It is then reviewed jointly by the experts from WHO and UNICEF to provide the most likely estimate for immunization coverage. This data on the number of doses of vaccines administered (numerator) and the target population for each type of antigen (denominator) were used for comparison with the national immunization programme estimates. This is also called as the administrative method of reporting coverage.

World Population Prospects (WPP) estimates: The UNPD projections were used because of their standard and accurate methods of estimating population figures. It is often considered as a gold standard source for population prediction data.[21]

Universal Immunization Programme (UIP) estimates: The UIP programme utilizes HMIS (Health Management Information System) data. The HMIS data utilizes the population projection estimates from the SRS (Sample registration System) system with the base value from the most recent Census (2011).[22] The SRS reports are released every year.

National Family Health Survey (NFHS): The National Family Health Survey (NFHS) is a large-scale, multi-round survey conducted in a representative sample of households throughout India.[5] Five rounds of the survey have been conducted since the first survey in 1992-93. The survey collects data on fertility, infant and child mortality, maternal and child health indicators, reproductive health, nutrition, anemia, and measures the use of health and family planning services in India.[5] The data from the fourth round of the NFHS conducted in 2015-16 was used in the study.[5]

3.2.4 Description of datasets used at Subnational level: UIP and CRS

Civil Registration System (CRS): In India, the Civil Registration System (CRS), Sample Registration System (SRS) and Population Census are the primary sources of data on vital events. As the census is conducted as a decennial exercise, the yearly changes are not recorded. For the provision of regular yearly updates the SRS and CRS data is used to provide regular estimates at national and state level. The CRS provides information on the registration of births and deaths. [23] The Civil registration system provides reliable information at all the administrative levels. [23] However, these estimates are not being used in health programmes due to under reporting from states. To tackle this, the CRS was revamped in the year 2000 with a simplified pattern of reporting. This was implemented in all the states and Union Territories by the year 2009.[23]

3.2.5 Target populations: Birth cohort and surviving infants

The target population in this study were the number of births and the number of surviving infants. Births (Birth Cohort) was considered as the target population for BCG vaccination. Surviving infants (SI) as a target population was used for the DPT-3, OPV-3 and first dose of measles vaccine given in infancy.

Number of births are a traditional demographic metric that are used in official statistical reports. The number of surviving infants will be estimated using the formula given below:

$$\text{Surviving infants} = \text{Births} \times (1 - \text{Infant mortality rate}).$$

Infant mortality rates are also traditional demographic indicators that are found in official statistical reports.

3.3 Semi Structured Interviews

The last part of the case study involved qualitative interviews of the key informants to validate the study results. These interviews were semi structured, allowing for the capture of necessary information adapting to the respondent's line of reasoning. The interview covered questions about interpretation of the literature review findings of the existing field methods and sources of data for estimating target population, on issues they encounter in the programme from a professional perspective. This provided realistic insights to the case study. The semi- structured questionnaire was used for interviewing several respondents from different groups. The interviews were recorded in writing and audiotaped with the permission of the interviewee. Prior to the start of the interview, informed consent was taken from the participants.

3.3.1 Selection of Key Informants

A mix of respondents working around immunization planning strategies were considered to obtain a comprehensive qualitative response. Purposive sampling was used for selecting the participants based on their roles and experiences to obtain a diverse range of individuals. A total of four key informants were interviewed. Interviewees for the study included participants from each of the groups of UIP Programme Managers, Technical Partners and Surveillance Officers (E.g., WHO, UNICEF) from the states of Maharashtra, Uttar Pradesh, Rajasthan, and Delhi.

3.4 Dissemination of Results

The following publications will be prepared as part of the study for the dissemination of the study results: One policy brief and one article will be submitted in a peer reviewed journal after the completion of the study.

3.5 Ethical Considerations

The study was submitted to the Research Ethics Committee for a waiver at KIT, Royal Tropical Institute.

3.5.1 Informed consent

a) Open Data source: The datasets used in the study were publicly available. The available data was aggregated and did not reveal the identities of individuals. Complete confidentiality was maintained throughout the research process as patient information was encrypted for the researchers.

b) Key Informant Interview: The participants were asked for informed consent before the data collection, to make sure voluntary and informed participation was taking place. The informed consent and research information sheet were emailed to the participants. The participants were requested to fill the form and send a photograph/scanned copy of the filled form once they agreed to participate. The option of verbal recording of informed consent was also provided to the participants.

Study Methodology Limitations - Purposive sampling was used in the study for the semi-structured interviews. As the sample size for these interviews was small, these results may not be regarded as a strong source of evidence.

A.4 Results

4.1 Universal Immunization programme in India

4.1.1 Overview

The eradication of smallpox ushered in an era of improved health systems, trained vaccinators, creation of cold chain systems, and a link for monitoring vaccine-preventable diseases. Globally, experts agreed to use this opportunity of having trained health personnel to improve health outcomes in children against vaccine preventable diseases.[18] This led to the launch of the Expanded Programme on Immunization (EPI) by the World Health Organization in 1974.[18]

The Expanded Programme of Immunization (EPI) was first implemented in India in 1978 after being declared as smallpox free in 1977. [18] In 1985, the programme was rolled out as 'Universal Immunization programme' to cover all the districts of the country in a phased manner in the next five years. [18] The target beneficiaries under the programme were pregnant women and children. In India, the initiation of the immunization programme is considered as one of the major public health interventions aimed at protecting children from preventable fatal childhood infections. It is recognized as one of the largest immunization programmes worldwide.[18] Currently, the programme provides protection against ten vaccine preventable diseases (VPDs) at the national level. This includes vaccines against diphtheria, pertussis, tetanus, polio, tuberculosis, measles, rubella, hepatitis B, meningitis, and rotavirus. In addition to these, Japanese encephalitis and pneumococcal pneumonia are currently being given only at subnational level. [18]

The UIP is managed under the Immunization Division of the Ministry of health and family welfare (MoHFW).[24] This division is a part of the Reproductive and Child health programme (RCH) of the National health mission (NHM). The division is responsible for providing technical assistance for the planning, coordination, and execution of immunization related activities under the UIP. The immunization division along with the National Technical Advisory Group on Immunization (NTAGI) take the programme related decisions taken under the UIP. [24]

The immunization programme in India has undergone a variety of changes to improve its coverage in different areas. This led to the launch of 'Mission Indradhanush' in 2014 targeting areas with low coverage.[25] Since the gains achieved by this mission were not sufficient, it led to further intensification of the initiative with the launch of ' Intensified Mission Indradhanush' in the year 2017.[25-26] The target was to achieve a 90% immunization coverage in all areas based on a district wise target approach.[26] However, this task continues to remain a challenge.

4.1.2 Major Milestones under UIP

The table below depicts the key milestones achieved by the programme chronologically in the past 43 years. The transition of the programme under the various government flagship initiatives including the addition of new vaccines and innovations have been highlighted.

Table 3: Key Achievements under UIP (1978-2020)

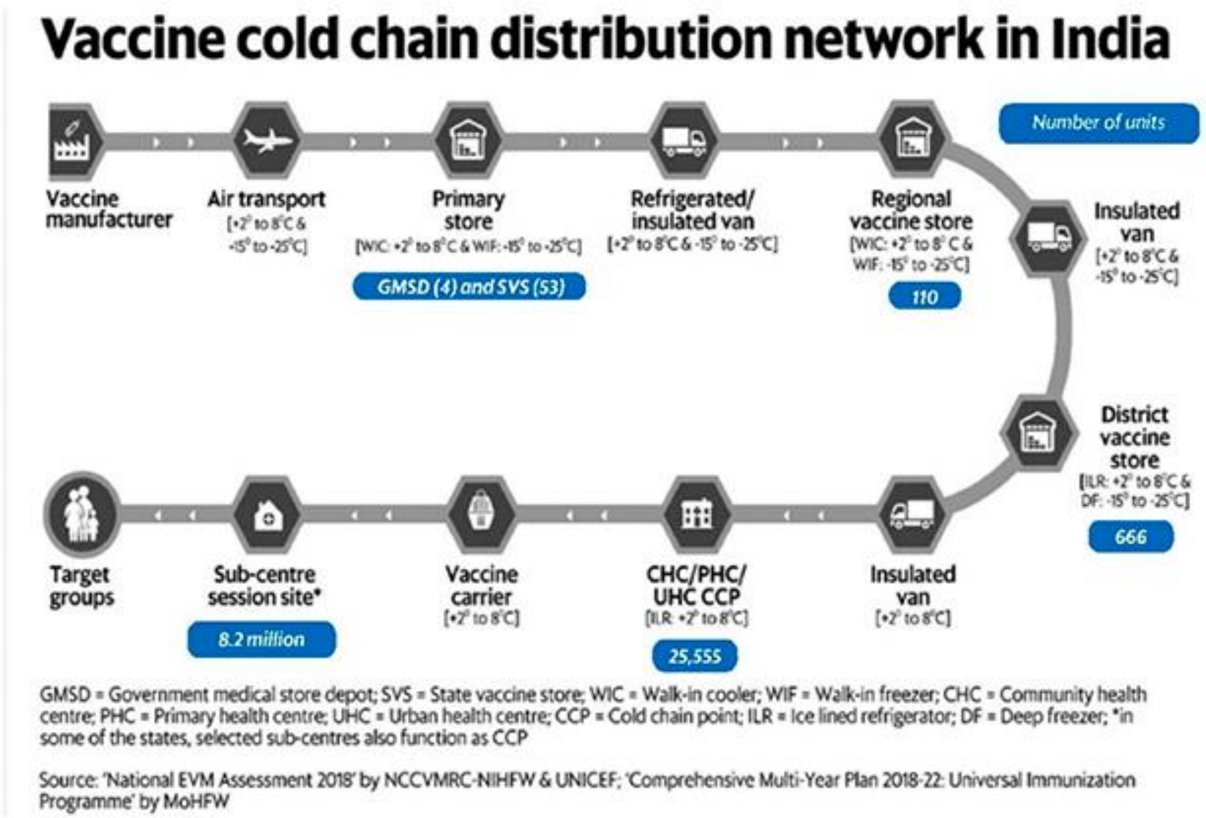
1978	Launch of Expanded programme of immunization with BCG, DPT, OPV, typhoid vaccines in urban areas
1983	Addition of TT (Tetanus toxoid) vaccine for pregnant women
1985	Programme renamed as 'Universal Immunization Programme' with addition of measles vaccine and removal of typhoid vaccine.
1990	Focus on children less than 1 yr of age for Vitamin-A supplementation
1992	UIP brought under the umbrella of Child survival and safe motherhood (CSSM) programme
1995	First national immunization day for polio eradication
1997	UIP was included under Reproductive and Child health (RCH) programme. Introduction of Vaccine vial monitor (VVM) on vaccines in UIP
2002	Hep B vaccine was introduced as pilot in 33 districts and cities of 10 states
2005	UIP Merged with National Rural Health Mission (NRHM). Introduction of Auto disable (AD) syringes into UIP.
2006	JE (Japanese Encephalitis) vaccine introduced after campaigns in endemic districts
2007-08	Hepatitis B expanded to all districts in 10 states and schedule revised to 4 doses from 3 doses
2010	Introduction of second dose of Measles in Routine immunization
2011	Introduction of Pentavalent vaccine in selected states Open Vial Policy for vaccines in UIP
2013	Expansion of Pentavalent vaccine to 9 states. Addition of second dose of JE vaccine in the UIP schedule
2014	Mission Indradhanush launched. India and Southeast Asia Region certified POLIO-FREE
2015	India validated for Maternal and Neonatal Tetanus elimination. Pentavalent vaccine expanded to all states. Introduction of IPV (Inactivated Polio Vaccine).
2016	Phase 1 introduction of Rotavirus vaccine in 4 states, **tOPV** (Trivalent oral polio vaccine) to **bOPV** (Bivalent oral polio vaccine) Switch. Switch to fractional IPV (Phased) Year of intensified Mission Indradhanush
2017	MR(Measles-Rubella) vaccine introduced PCV (Pneumococcal vaccine conjugate)-Phased launch
2019-20	Withdrawal of bOPV and routine OPV used

* *Adapted from: Immunization Handbook for Health Workers (2019)*[27]

Some of the major components associated with the programme have been discussed in detail below.

4.1.3 Service Delivery

Supply chain and Logistics: The supply chain and logistics system serve as the backbone of the immunization programme. This ensures timely supply and delivery of vaccines and plays a critical role in immunization coverage. The distribution of the vaccine cold chain network in India is through 4 GMSD (Government medical store depots), 53 SVS (State vaccine Stores), 110 RVS (Regional Vaccine Stores), 666 DVS (District Vaccine Stores) and 25,555 sub-district stores involving around 8.2 million session.[3,28] (Figure 2) This system uses the paper based system of manual reporting and maintenance of logistics. However, there are several issues associated with this system like poor record keeping, frequent stock outs and irrational distribution of vaccines.[3] This often affects vaccine distribution leading to overstocking or understocking and in turn affecting coverage. [3]

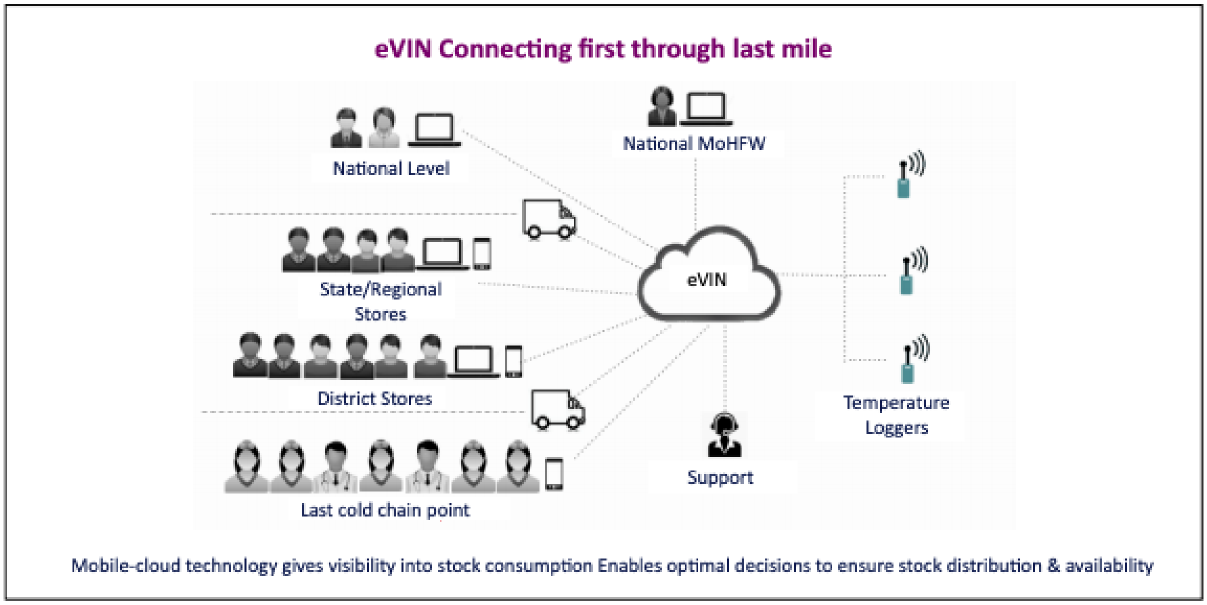


Source: Comprehensive Multi-Year Plan (cMYP) 2018-22, UIP [29]

Figure 2: Vaccine cold chain distribution network in India

In 2015, MoHFW successfully piloted the usage of indigenously built IT systems in 12 states for real-time tracking of vaccine stock availability to strengthen the logistic management. This innovation was named eVIN (Electronic Vaccine Intelligence Network) and was funded by GAVI.

(Figure 3) It is being scaled up to cover all the states of the country. This initiative ensures data-driven and efficient management of the vaccination supply chain and digitization of vaccine inventory.[30,31] This would in turn simplify and regularize vaccine flow networks. eVIN also provides real-time temperature information of all the cold chain equipment in the network. This helps in preventing vaccine wastage as well as vaccine stock out periods. [31] A high wastage in vaccines could lead to a false increase in vaccine demand as well as additional procurement costs. Thus, vaccine wastage can be a significant predictor for estimating vaccine doses. [31]



Source: Comprehensive Multi-Year Plan (cMYP) 2018-22, UIP [29]

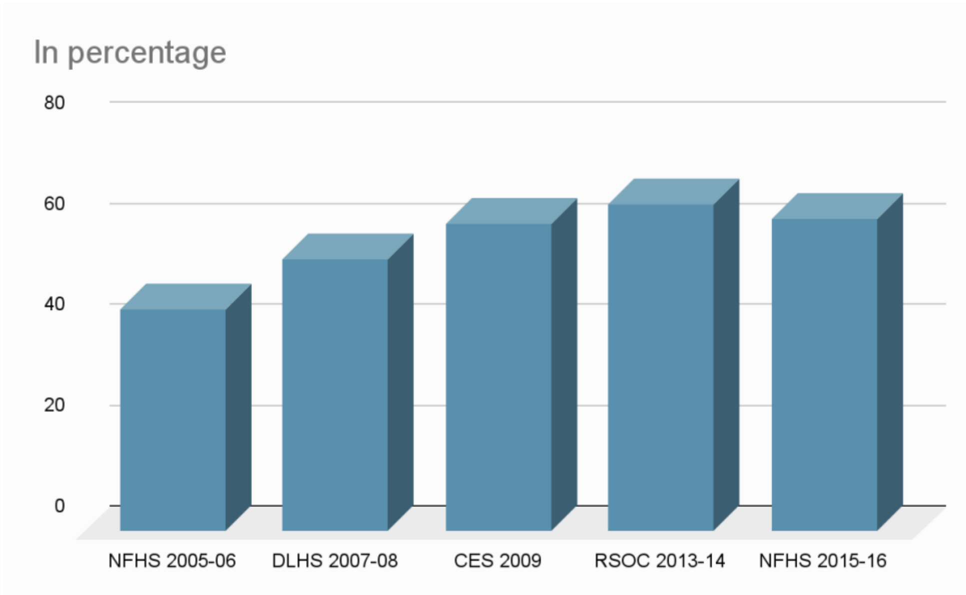
Figure 3: eVIN (Electronic Vaccine Intelligence Network)

There are certain limitations associated with the scaling of this initiative. This includes poor infrastructure, poor internet connectivity in hard to access areas and extended duration of power cuts in rural areas.[31]

Human resources: The immunization services provided under this programme are delivered through the existing cadre of health systems in the country.[3] As a result, UIP does not have a separate staffing structure. Several reviews and assessments have indicated the paucity of trained staff for the delivery of services at various levels in the system especially at the grass root level.[3]

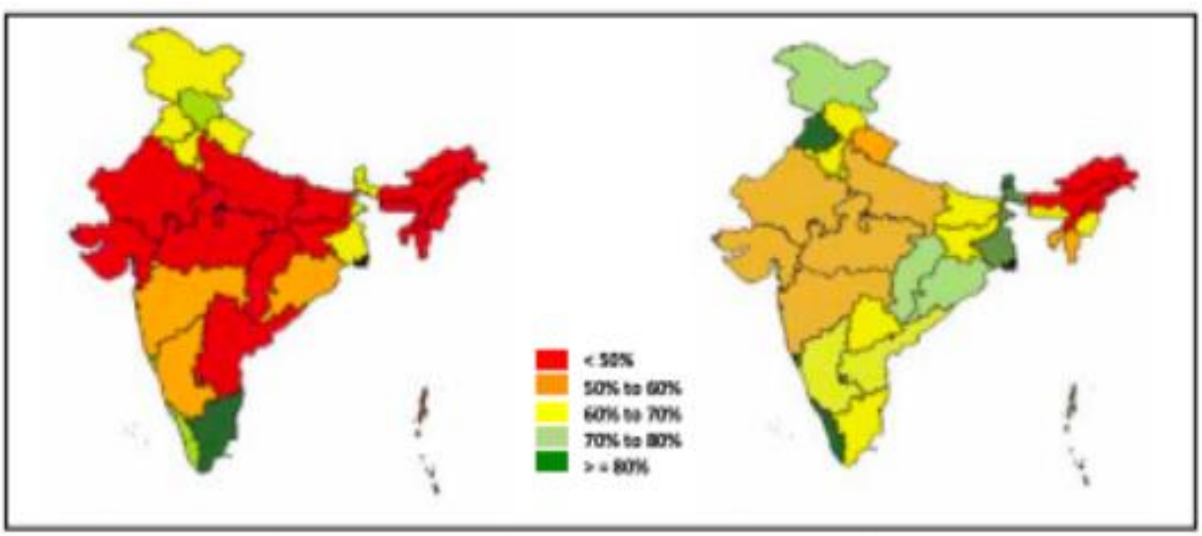
4.1.4 Trends in Immunization Coverage

Immunization coverage is a key criterion for determining the progress made in universal child health. According to the evaluated coverage from the NFHS data among children aged 12-23 months, the coverage has increased from 44% in NFHS-3, 2005-06 to 62% in NFHS-4, 2015-16.[5,32] The figure 2.1 below depicts a comparison of complete immunization coverage across various surveys conducted at national level.



**NFHS- National Family health survey, DLHS- District Level Household & Facility Survey, CES-Coverage Evaluation Survey, RSOC- Rapid Survey of Children*

Figure 4: Trends in Full Immunization coverage over the last 15 years as shown in different surveys



Source: Comprehensive Multi-Year Plan (cMYP) 2018-22, UIP [29]

Figure 5: Map showing state wise variation in immunization coverage from *NFHS-3 (2005-06) to NFHS-4 (2015-16) survey.*

From the above figure, a wide state wise variation in immunization coverage is observed over the years. The immunization coverage has improved over the years. According to the NFHS-4 data, full immunization coverage, *[1] 62% of the children in the 12-23 months age group were fully immunized at national level. At subnational level, this ranged between 35.7% in Nagaland and 91.1% in Puducherry.[5,32] However, more than 90% full immunization coverage was only observed in Puducherry.[5,32]

4.1.5 VPD (Vaccine preventable diseases) Surveillance

A comprehensive surveillance system is essential to continuously identify and monitor the burden of diseases preventable by vaccination. The data captured at various levels generates evidence for informed decisions. There are different surveillance systems for VPD in India. These include the Integrated disease surveillance project (IDSP), Central and State Bureaus of Health Intelligence (CBHI and SBHI), Health Management Information System (HMIS), WHO supported laboratory based VPD surveillance, WHO supported AFP and Measles outbreak surveillance, Sentinel surveillance for Congenital Rubella Syndrome (CRS) and the Rotavirus Surveillance Network.[3,24] The existence of numerous sources of data for VPD surveillance has certain limitations. [24] A wide variation in data reporting exists across these systems while reporting for a particular disease.[3]

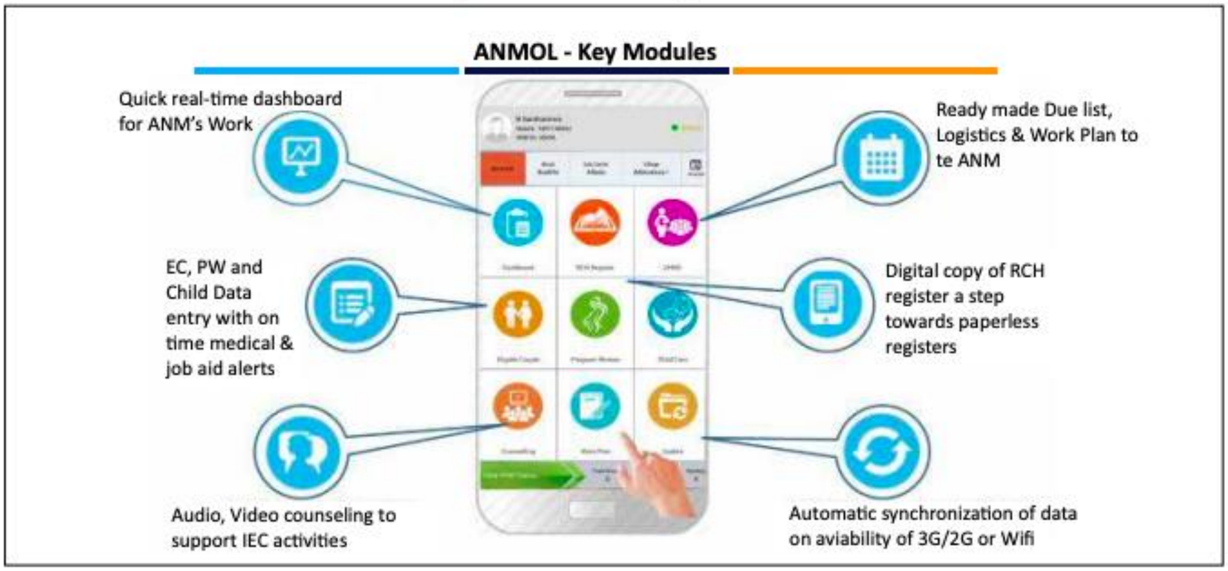
4.1.6 Monitoring & Evaluation and Data Quality

The administrative and survey coverage data serves as an indicator for measuring the progress of immunization programme in the country. However, the quality of the data reported from these sources is largely variable across states.[29] As a vertical program that is centrally managed, immunization has limited accountability at the facility level. In order to reduce the reporting discrepancies in coverage, facility-based reporting needs to be reinforced.[29] A separate robust cadre for monitoring and evaluation of the programme is currently deficient and needs to be established. [24] The monthly reporting pattern is from the Sub Centre to the primary health centre, district, state, and national level. This reporting has been digitized in the country as part of the Health Management Information System (HMIS), and data is made available monthly.[3]

In addition, a web enabled name-based system called the Mother and Child Tracking System (MCTS) was launched in 2009 to capture and track all the eligible newborn children for immunization from birth up to 5 years of age.[3,29] The government has recently launched a digital Tablet on a pilot basis in selected states with a newly launched software called ‘ANMOL’ (ANM Online) connected to the data portal at central level.[26,29] This would assist the field health care

[1] *Fully immunized: Bacillus Calmette-Guerin (BCG) vaccination; three doses of the Diphtheria, Pertussis, and Tetanus (DPT) vaccine; three doses of the polio vaccine; and a measles vaccine, within the first year of life amounts to being called as fully immunized.

workers to maintain a digital database of the beneficiaries of immunization and prompt updating of data on the field. (Figure 6)



Source: Comprehensive Multi-Year Plan (cMYP) 2018-22, UIP [29]

Figure 6: Key features of ANMOL (ANM Online)

4.1.7 Challenges

Some of the challenges associated with the programme include the stagnation in immunization coverage in recent years.[29,33,34] This could be attributed due to the programmatic challenges including gaps in the health system, shortage of manpower, poor microplanning etc.[29,33,34] The programme also lacks an effective monitoring and evaluation system. [24]

4.2 Sources of data used for denominator estimation for the immunization of infants

There are several sources of data for calculating denominators for the immunization of infants. The methods to estimate population differs in terms of their availability and consistency of the resources available. The sources of data like censuses, registration system, sample surveys, as well as recurrent data gathering like the Demographic Health Surveys or National family health survey, are all used to measure human populations.[35] A concise overview of some of the sources is given below.

4.2.1 Demographic Censuses

The census is a valuable source of health data. It is administered at regular intervals, usually every ten years, in the majority of countries around the world including India.[36] A census is a comprehensive enumeration of every resident within a country's national territory during a specified period of time, and is considered as the gold standard. The United Nations define census as " the total process of collecting, compiling, evaluating, analyzing and publishing or otherwise disseminating demographic, economic and social data pertaining, at a specified time, to all persons in a country or in a well-delimited part of a country".[36,37] The census includes a vast amount of information not only on the demographics, but also on the social and economic characteristics of the people, the conditions in which they thrive, grow, work and other fundamental information. This results in the collection of valuable data at household level from various parts of the country on important demographic parameters such as fertility, birth, death and migration.[36] In national health programmes, this data is used for the estimation of the denominators of health indicators. Population projections are applied to the census data to predict future estimates. The Indian Census is the most comprehensive single source of statistical data on the various characteristics of the population of the country. It is conducted once in ten years.[38] The next Census is planned for the year 2021 but has been delayed due to the current COVID-19 pandemic.[36]

The strengths associated with a large data repository like a census include complete representativeness since complete enumeration of the population is done. This data is publicly available and can be used for planning, action, and research.[35]

The use of census data has certain limitations, such as the likelihood of inaccurate estimates of population during the inter-censal years. The accuracy of these estimates tends to decline with each passing year due to significant changes in the factors influencing a country's changing demographic structure and distribution. The other aspects include the financial costs associated with running a huge country-wide survey.[37]

4.2.2 Civil Registration System (CRS)

The civil registration system is a system of “continuous recording of vital events such as births, deaths, marriages, divorce, adoptions etc”.[39] As a result, the most precise, current, and geographically comprehensive data is available to the user.[7] This system comes under the purview of the Registrar General of India. [23] It can be the most reliable and accurate source of information if reporting is done on a regular basis. [23] This system provides detailed information on births, including the time and location of birth, the sex and age of a child and the mother, as well as literacy, occupation, religion and other demographic details of the parents.[40] Currently, this system is in its transitional phase from the traditional reporting pattern of reporting to the online version.[39]

The disadvantages associated with this system is the underreporting or incomplete reporting of vital events which results in absence of recent data essential for planning and management at various levels.[40] A vast state wise variation is observed in reporting of data. However, this has shown improvement in reporting with time. [23]

4.2.3 Sample registration System (SRS)

The Sample Registration System (SRS) in India is a type of demographic survey with a unique feature of dual recording, which involves collection of data through two different procedures viz., continuous enumeration and retrospective half-yearly surveys.[23] It is primarily a dual recording system that records births and deaths in a nationally representative sample of villages and urban areas. It also records information on the causes of death. The SRS estimations are widely used in policy making and planning. Due to the lack of credible CRS estimates, this has become a valuable source for estimating vital events at the national and subnational levels.[7] The baseline SRS estimates are derived from the most recent census and updated with every census. [23]

Some of the limitations associated with the use of this data is that it does not provide estimates at lower administrative units. The adequacy of the sample size and the fixed sample units used in the SRS have been debated by researchers..[40] The line of argument is based on the fact that the de jure population estimation method used in SRS could be responsible for the lower prediction of births.[39,40]

4.2.4 Surveys

Surveys are an important tool for gathering health-related and socio-economic information from a standardized sample of people to truly comprehend a larger population. [37] This method enables the researchers to gather data in a relatively shorter period. However, there are certain constraints associated with the usage of survey data. The survey estimates are subject to sampling errors.[41] Also, the standard errors tend to be higher at the lower administrative units making the comparisons between regions difficult. Furthermore, surveys are conducted at irregular intervals.[37,40] The coverage estimates obtained from the samples tend to be biased based on the timing of the survey conducted due to simultaneous campaigns or immunization drives taking place. In addition, the survey results may be subjected to bias as the data is dependent on the interviewee's recall as well as the willingness to participate in the study. [37]

4.2.5 Hospital Records and Registries

In the absence of a robust vital registration system, hospital data can serve as a primary source of vital information. The eighth WHO statistical report proposed the use of hospital records to be an inclusive part of the country's national statistical report.[42] The drawbacks associated with the use of hospital data are that they provide selective information of individuals who seek care and do not present a representative sample of the population. For example, this type of data would only report the institutional births and miss the births at home. The hospital records and registries also provide a biased record of individuals based on socio-economic status representing the government and private cadre divide.[37] This type of data also lacks the precise boundaries of the area during reporting. Individuals can seek care irrespective of the boundaries and approach health care facilities. In addition, private hospital records can only provide the numerator and not the denominator for the estimation of coverage. In spite of the above limitations, hospital records can still serve as a valuable tool for providing data on births, infant deaths and number of vaccinations conducted.[37] With the digital initiatives in progress in the country, digitalization of medical records could ensure effective healthcare planning and service delivery with regular evaluations.[43]

4.2.6 Health management information system (HMIS)

The Health management information system is a web based portal capturing data for health service delivery at all the levels in the healthcare delivery system.[39] The data is reported on a monthly basis and is used for planning and management in health programmes.[44] The HMIS uses the SRS estimate for the estimation of target population for immunization of children The immunization data is reported from collated reports at district, state and national level. The reporting system is currently transitioning towards paperless reporting at all levels. The HMIS enables reporting from public as well as private health facilities.[39] The reporting from private facilities is being included in a phased manner. The monitoring and evaluation system of the HMIS is in process of being revamped. Under the new initiatives, the validation of data by triangulation will be done to improve the quality of data reporting as well as to enable comparisons with time trend analysis.[39,45]

The data generated in the HMIS portal is dependent on the regular reporting of the lower administrative units. The mechanisms for quality control of the reported data are still in its transitioning phase and requires to be strengthened.[46] The surveillance data on vaccine preventable diseases is a part of a separate surveillance portal and is currently not being included in the HMIS portal. This linkage is vital as it is an indirect indicator of the immunization services provided in the country. [39]

4.2.7 Global Level: WPP (World Population Prospects)

The World Population prospects are estimates provided by the United Nations population Division for all the countries. These estimates provide an annual estimate of births and infant mortality rates at the national level and are updated every two years based on the changes reported by countries.[47] These projections use probabilistic methods for future predictions of trends in mortality, fertility etc. This method utilizes the past reporting pattern of each country as well as considers the uncertainty associated with the future trends.[47] The medium-variant projection is the most common probabilistic model of prediction used. The strengths associated with use of this method include the robust probabilistic modelling used for the accurate predictions. However, one of the challenges associated with use of this method is the dependence on the baseline data reported from countries to be used for projection. The accuracy of the projections would be indirectly linked to the country's reporting quality pattern and standards. [47]

4.2.8 Global Level: WHO-UNICEF estimates of immunization coverage (WUENIC)

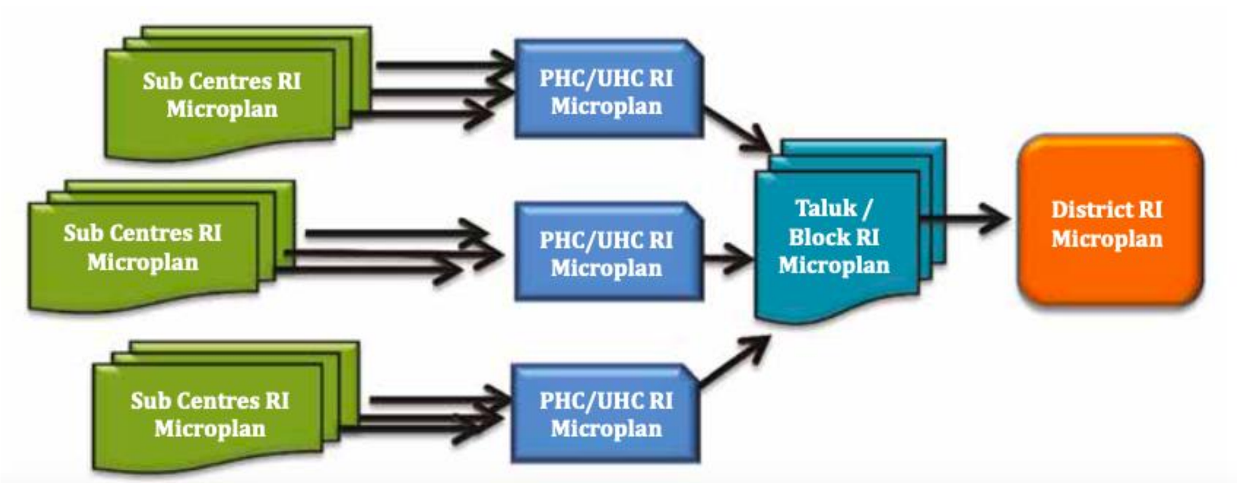
Every year, WHO and UNICEF jointly release immunization coverage reports at country level. This report is collated based on the combined information obtained from national immunization coverage reports, survey reports as well as data obtained from published and grey literature.[48] It is then reviewed jointly by the experts from WHO and UNICEF to provide the most likely estimate for immunization coverage.[48] This review takes into consideration the potential anticipated biases to avoid a misleading coverage estimate. This data is comparable across countries. The coverage estimates provided by this method are robust in nature due to the usage of multiple datasets which are critically analyzed and collated to provide the best estimate.[48]

4.3 Methods of denominator estimation in the immunization of infants

4.3.1 Local level: Routine Immunization (RI) Microplanning

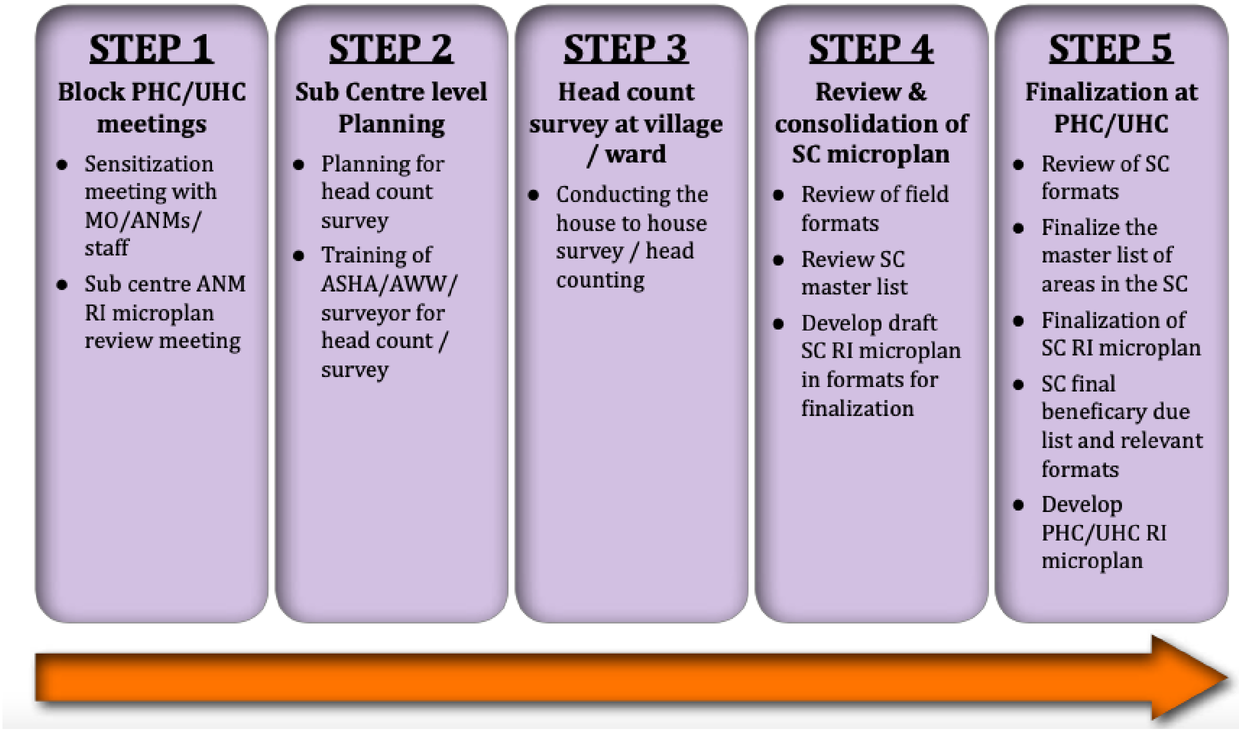
This is the most important component and forms the base for the planning and management of immunization services. A through microplanning can ensure a smooth delivery of services. The microplans generated need to be updated on a regular basis.[49] The microplans are planned at the lowest administrative health unit (sub centre) and compiled in a hierarchical pattern. Microplans from the sub centres (SC) are compiled to prepare the primary health centre (PHC) microplan.[50] Information from PHCs is consolidated at the district or may be at the taluk and then to the district level in some states.[50] The various steps involved in microplanning are shown in the figures below.

The various challenges associated with microplanning include the lack of updated mapping and area demarcation among various health facilities and incomplete microplanning due to shortage of healthcare staff at grass root level.[50] In addition, the microplanning process is labor intensive and requires adequate resources and manpower at the field level for the headcount survey making it challenging.[49,50] Also, the geographical terrains and climate conditions can be additional hurdles in the process. Due to these challenges, the microplanning data is not available or updated and is being carried out on a pilot basis in several states.



Source: *Immunization Handbook for Health Workers (2018)*[27]

Figure 7: Schematic diagram showing the collation of Routine Immunization (RI) microplanning from sub centre to district level



Source: *Immunization Handbook for Health Workers (2018)*[27]

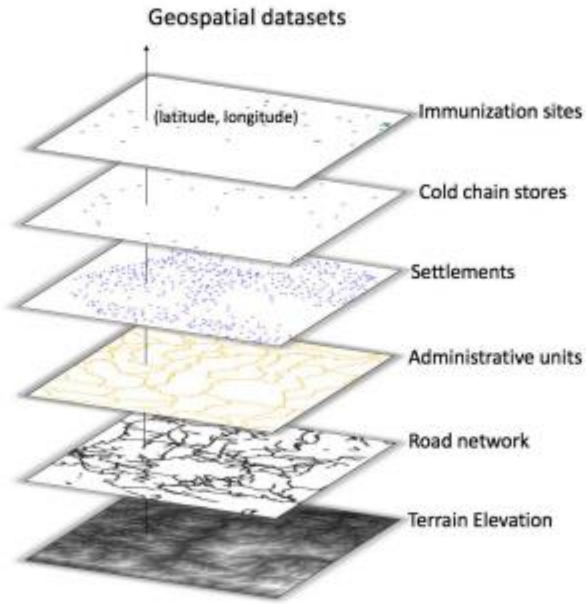
(*MO-Medical Officer, ANM-Auxiliary nurse midwife, ASHA- Accredited Social Health Activist & AWW-Anganwadi worker (Health workers at sub centre/village level); PHC-Primary healthcare centre, SC-Sub centre, UHC- Urban health centre)

Figure 8: Overview of major activities in RI microplanning

4.3.2 Target population estimation from different sources

The target population can be estimated from population databases and survey data based on the application of its future projection estimates. Data from the census, CRS and SRS are used for these projections.[7,39] The data obtained from the CRS is considered as the most accurate method. However, this is dependent on the strength of the CRS reporting system.[7] This method is currently being followed in the country.

4.3.3 Newer Methods: Geospatial Technologies



Source: Guidance on the use of Geospatial data and technologies in Immunization programmes, UNICEF (2018)[51]

Figure 9: Connection of geospatial datasets through geography in a GIS

Globally, geospatial technologies are being used to collect, depict, and link various elements of the immunization programme. The different types of geospatial technologies being used in immunization programmes include global navigation satellite system (GNSS), geographic information systems (GIS) and remote sensing. These technologies can be used for the estimation of target population using statistical modelling. Two different types of approaches can be used for this estimation.[52,53] The 'bottom up approach' for the estimation of the target population includes the use of micro-census data collected at household level along with identification of the surrounding topographical features from satellite imagery.[52,53] The other approach is the 'top-down' method that utilizes covariate datasets for the creation of population estimates in a grid pattern with absolute precision and accuracy. The use of geospatial mapping for the linkage of immunization registries to the civil registration and vital statistics system to improve target population estimation has shown promising results.[51] The usage of digital maps for microplanning are also being explored. These technologies are being tested in various countries on a pilot basis. Currently, the Global Alliance for Vaccines (GAVI), in association with UNICEF (United Nations Children's fund) is assisting countries in the use of GIS to strengthen the immunization services.[54] Numerous challenges exist in the system for the scale up of these initiatives for short term gains. However, these could be potential solutions in the long term.

4.4 Case Study Findings

4.4.1 Data Quality Dimension: Completeness

Data Completeness for target population estimates at National and Subnational Level:
The data reported at national level from all the sources revealed no missing data. However, at subnational level, missing data was found in the CRS database. It was also observed that provisional figures were used for some states in the CRS data. It was also noted that the registration of births in the CRS had increased to 92.7% in 2019 from 82.4% in 2011. [23] In the year 2019, about 14 states had achieved the status of 100% reporting while 10 states crossed the 90% mark.[23] The registration of infant deaths had also increased from 66.4% in 2011to 92% in 2019. [23]

4.4.2 Data Quality Dimension: External Consistency

A) External Consistency at National level *(Denominator comparison with UIP, WUENIC & WPP data sources)*

The target population estimates were assessed for a ten-year series from April 1, 2010 to March 31, 2020. In India, the calendar year for reporting the health parameters commences from April 1 to March 31of the next year. The table below illustrates the target population comparison between the UIP, WUNEIC and WPP estimates. During this period, it was observed that the data reported for the target population predictions of the birth cohort and surviving infants (SI) at national level by the WPP and WHO/UNICEF estimates were the same. The target population estimation for the birth cohort and surviving infants were noted to be the same under the UIP. The first two columns show the UIP and WPP estimates of births and the ratio of the WPP estimate to the UIP estimate. The next two columns provide the same information for surviving infants. The column in the centre of the table gives the WPP Infant mortality rate estimate. Using this, the estimate on surviving infants (SI) was calculated.

The last row of the table shows total births and surviving infants over the years (2011-2019). The ratios hint at the difference in level between the UIP and WPP estimates. The UIP estimates of SI are higher than the WPP estimates from the year 2016 to 2019 (11-12%). These differences observed are greater than 10% and warrants a further investigation. It was further noticed that the estimate for births and SI by the UIP was the same. This could explain the higher estimates as IMR was not taken into consideration for the estimation of SI in the UIP estimate.

Table 4: Comparison of Target population from UIP, WUENIC & WPP estimates at national level

Year	Birth Cohort (UIP)	Birth Cohort WUENIC & WPP	Birth Cohort Ratio	WPP IMR (Infant deaths per 1,000 live births)	Surviving Infants (SI) (UIP)	Surviving Infants (SI) WUENIC and WPP	Ratio
2011-12	2,53,01,000	2,55,92,000	0.99	42.0	2,53,01,000	2,45,15,000	1.03
2012-13	2,54,21,000	2,51,97,000	1.01	40.1	2,54,21,000	2,41,85,000	1.05
2013-14	2,55,94,000	2,48,62,000	1.03	38.3	2,55,94,000	2,39,10,000	1.07
2014-15	2,59,28,000	2,46,00,000	1.05	36.7	2,59,28,000	2,36,99,000	1.09
2015-16	2,58,70,000	2,44,14,000	1.06	35.2	2,58,70,000	2,35,58,000	1.10
2016-17	2,62,52,000	2,42,97,000	1.08	33.8	2,62,52,000	2,34,78,000	1.12
2017-18	2,63,11,000	2,42,21,000	1.09	32.5	2,63,11,000	2,34,36,000	1.12
2018-19	2,60,09,790	2,41,64,000	1.08	31.3	2,60,09,790	2,34,09,000	1.11
2019-20	2,62,97,590	2,41,16,000	1.09	30.2	2,62,97,590	2,33,90,000	1.12
2011-19	22,14,63,000	23,29,84,380	1.05		21,35,80,000	232984380	1.09

⁎BCG Target Population= Birth Cohort, Target Population for DPT3,OPV3, MCV1- Surviving Infants Surviving Infants for WUENIC/WPP estimates is calculated as = Births × (1 − Infant mortality rate).

The difference in the trend of the UIP and WPP estimates in Figure 10 is quite contrasting. The figure shows that the UIP estimates show an upward trend, whereas UNPD and WPP estimates show a downward trend. The two estimates coincide in the year 2012. The difference between the two estimates is quite large towards the end.

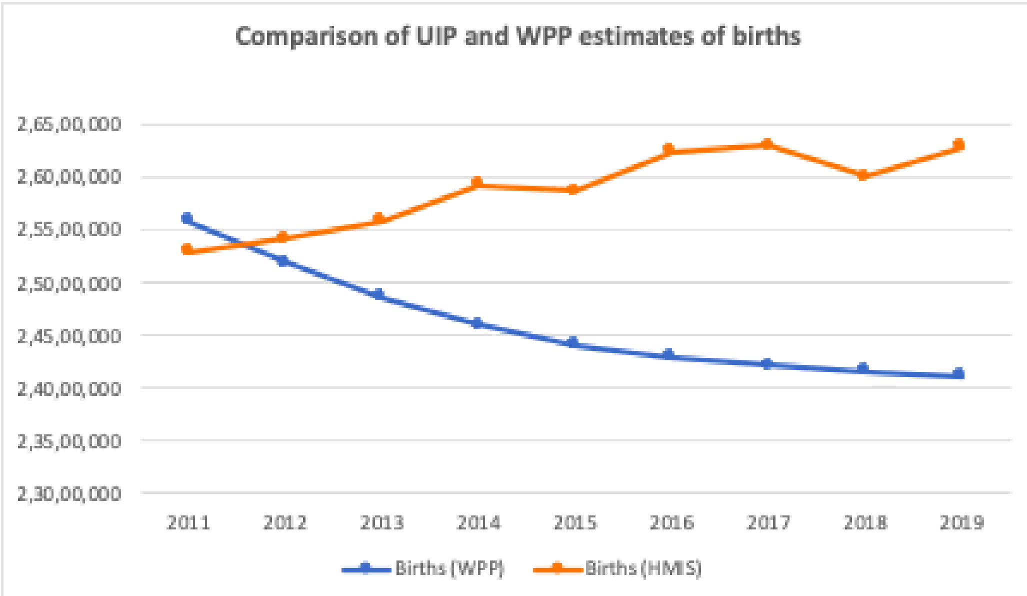


Figure 10: UIP and WPP estimates of births compared at national level

Growth Rates in Target population at National Level

The annual growth rates of the birth cohorts were calculated for the UIP and WUENIC estimates at national level. It is a sensitive indicator of year-to-year fluctuations in target population estimates. A growth rate difference of more than 10% or less than -10% indicated an error in the estimated target population. The calculated growth rate did not show a difference of more than 10% between any two consecutive years for each dataset calculated. No major spike or variability was observed in the annual growth of births. (Table 4)

Table 5: Growth rates of Birth Cohort (UIP and WUENIC estimates)

Year	Birth Cohort UIP	Birth Cohort WUENIC	Surviving Infants UIP	Surviving Infants WUENIC
2011-12	0.47	-1.54	0.47	-1.35
2012-13	0.68	-1.33	0.68	-1.14
2013-14	1.30	-1.05	1.30	-0.88
2014-15	-0.22	-0.76	-0.22	-0.59
2015-16	1.48	-0.48	1.48	-0.34
2016-17	0.22	-0.31	0.22	-0.18
2017-18	-1.14	-0.24	-1.14	-0.12
2018-19	1.11	-0.20	1.11	-0.08
2019-20	NA	NA	NA	NA

**Growth rate was calculated as = (Births in year 2/ Births in year 1) - 1.The same formula was applied to the target population numbers of other vaccines for successive years.*

B) External Consistency at National level: Immunization coverage over time

(Coverage comparison of UIP and WUNEIC data estimates)

The time series assessments from 2011-19 provides an overall assessment of the consistency and quality of data with time. The coverage estimates for the individual vaccines are discussed below. A difference in coverage of more than 10 % was flagged when observed.

1) **BCG Coverage at National Level**

The BCG coverage estimates were comparable across the two sources. No major discrepancies in the trends were noted.

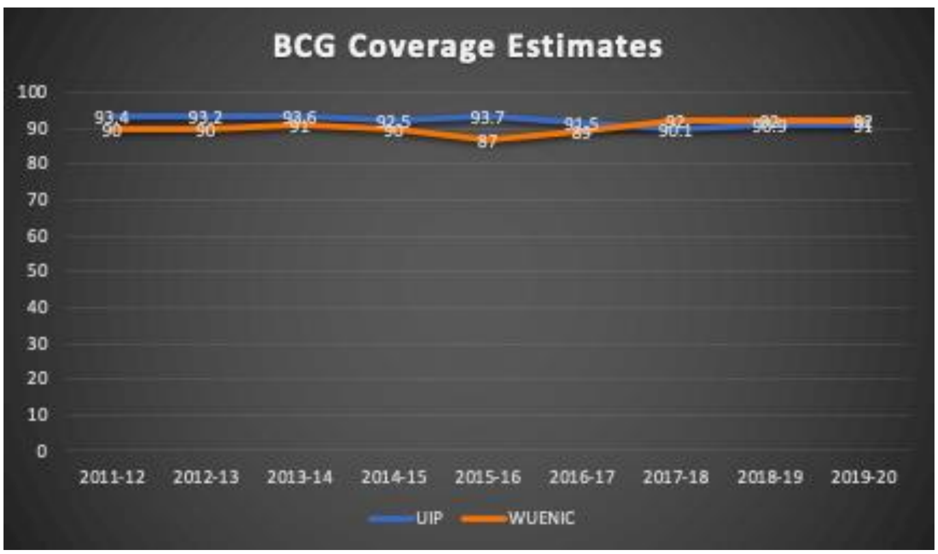


Figure 11: Depiction of administrative BCG Coverage estimates from UIP & WUENIC data sets

DTP3 Coverage

It was also observed that DPT3 coverage reported by the UIP during three consecutive years showed a major dip in coverage. This was due to the introduction of the pentavalent vaccine in a phased manner in the country. As pentavalent vaccine includes the DPT antigens along with HepB and H. influenzae, this variation could be explained.

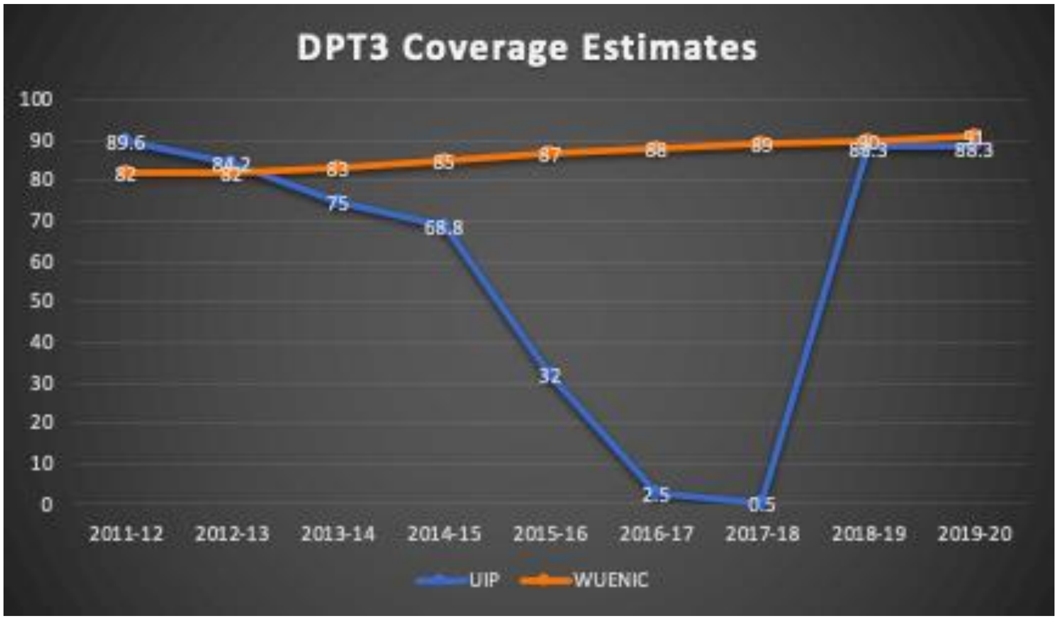


Figure 12: Depiction of administrative DPT3 coverage estimates from UIP & WUNEIC data sets

OPV3 Coverage

The OPV3 coverage estimates are comparable across the two sources. No major discrepancies in the trends were noted.

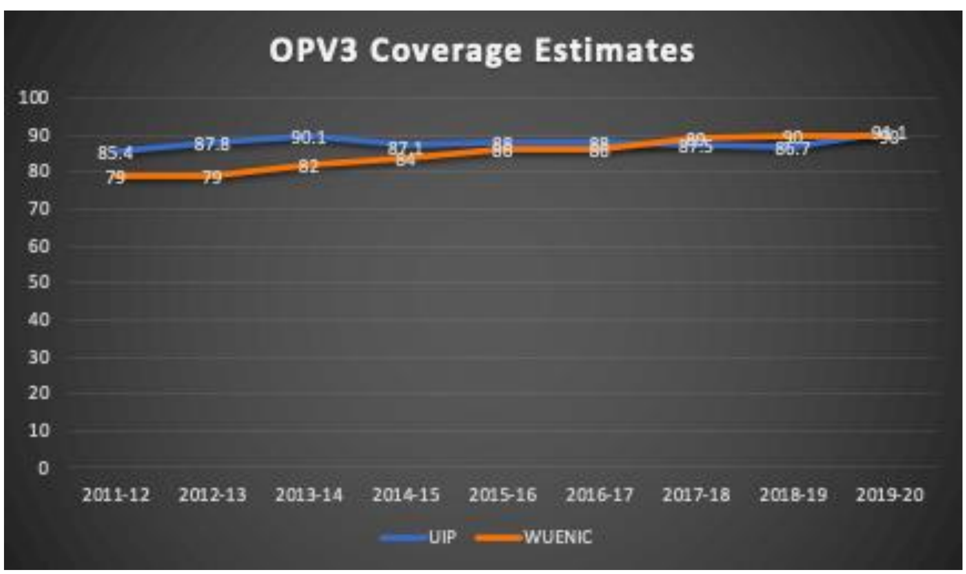


Figure 13: Depiction of administrative OPV3 Coverage estimates from UIP & WUENIC data sets

Measles Coverage

The coverage estimates from the two sources are comparable during the assessment period from 2011-19. However, a dip of more than 10.7% is seen in the UIP estimates. This can be explained due to the introduction of Measles Rubella (MR) campaign*[2] in the year 2017.[55] This resulted in children getting vaccinated during the campaign rather than the routine immunization sessions which resulted in a drop. As WUENIC estimates are a combination of routine as well as coverage data, this change was not reflected. The completion of the campaign resulted in the introduction of the MR vaccine instead of measles in the UIP schedule.

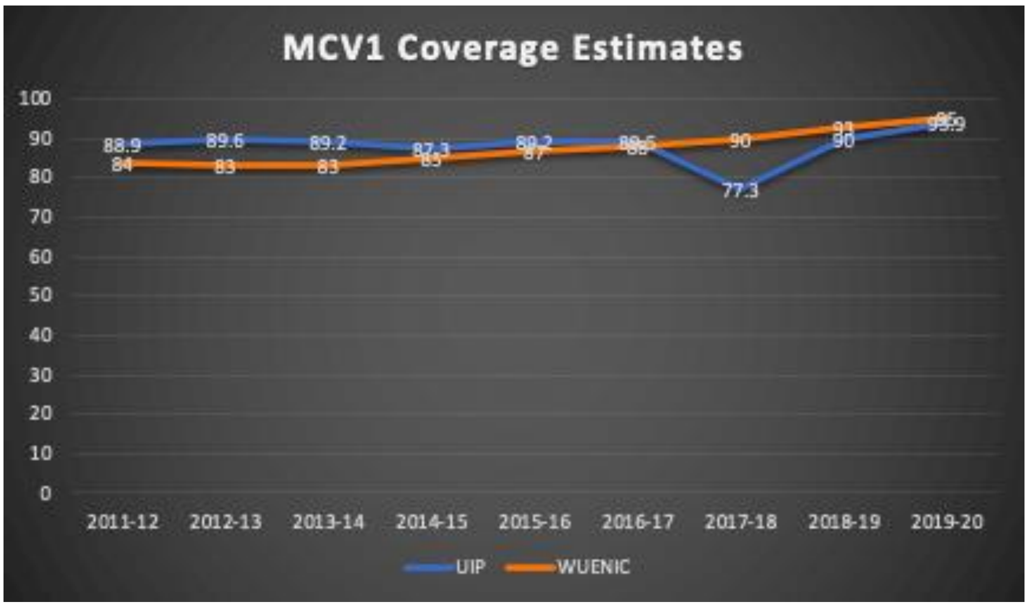


Figure 14: Depiction of administrative MCV1 Coverage estimates from UIP & WUENIC data sets

C) **External Consistency at National level *(Coverage comparison with UIP with NFHS-4 survey data estimates),***

The coverage estimates from the UIP, and NFHS-4 were compared. The coverage for BCG and MCV1 were in a similar range between the two sources. However, the DPT3 coverage showed a stark difference. As mentioned above, this can be explained due to the introduction of the pentavalent vaccine in the UIP. The coverage estimates for OPV3 showed a variation of more than 10 % between the two sources.

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[2] *Under the UIP, at nine months of age Measles vaccine was routinely given till 2017. The rubella vaccine was introduced for the first time in India as a measles-rubella vaccine during the MR campaign in 2017. Currently, it is a part of the UIP.

Table 6: Comparison of immunization coverage between routine administrative data (UIP) and population based survey (NFHS-4,2015-16)   (1year baseline v/s 2015-16)

Antigen	**UIP Data (2015-16)**			**NFHS-4 (2015-16**
	Numerator	**Denominator**	**Administrative Coverage (%)**	**Coverage (%)**
BCG	2,58,70,000	2,42,40,390	93.7	91.9
DPT3	2,58,70,000	82,81,173	32.0	78.4
OPV3	2,58,70,000	2,27,68,699	88.0	72.8
MCV1	2,58,70,000	2,30,68,189	89.2	81.1

Impact Data

Table 7: Burden of vaccine preventable diseases and the immunization coverage at national level.

	2019	**2018**	**2017**	**2016**	**2015**
DPT3 Coverage* (%)	91	90	89	88	87
No of reported cases of Diphtheria	9622	8788	5293	3380	2365
Incidence rate of Diphtheria (per 1000,000 of total population)	7	6.5	4	2.6	1.8
No of reported cases of Pertussis	11875	13208	23766	37274	25206
Incidence rate of Pertussis (per 1000,000 of total population)	8.7	9.8	17.8	28.1	19.2
MCV1 Coverage*	95	93	90	88	87
No of reported cases of Measles	10430	19474	12032	17250	30168
Incidence rate of Measles (per 1000,000 of total population)	7.6	14.4	9	13	23

**WUENIC estimates of immunization coverage*   *Source: WHO Immunization Data portal* [56]

These coverage comparisons cannot be compared with the incidence rate of the diseases. As the incidence rate is calculated for the total population. Also, the impact of campaigns as well as delayed/booster doses could reflect higher coverage rates. The other aspects include the vaccination status of the affected population. There is a possibility for the clustering of cases in unvaccinated groups of children. In contrast, the cases in vaccinated children could also be attributed to vaccine failure instead of data quality issues. These aspects need to be closely scrutinized to draw cautious and meaningful interpretation.

4.4.3 Internal Consistency between related indicators: National Level

For checking the internal consistency between related indicators, the comparison of vaccination doses given at the same age was analyzed. The ratio of the number of children vaccinated for DPT3 and OPV3 was calculated.

The consistency ratio of DPT3/OPV3 at the national level with a wide range of variation from 0.01 to 1.05. There is poor consistency between the number of vaccinated children reported for DPT3 and OPV3 beginning from the year 2013. The number of children vaccinated with DPT3 shows a downward trend from the year 2013 till 2017. This could however be due to the introduction of Pentavalent vaccine (DPT included) in a phased manner in the country which was completed by the year 2017. Other than the transition period for DPT to Pentavalent, the consistency ratios were comparable.

Table 8: Ratio of the number of children vaccinated for DPT3 and OPV3 at 14 weeks of age

Year	**No of children vaccinated with DTP3 at 14 weeks**	**No of children vaccinated with OPV3 at 14 weeks**	**Ratio of DTP3/OPV3**
(2011-12)	2,26,67,705	2,16,19,445	1.05
(2012-13)	2,14,15,783	2,23,18,853	0.96
(2013-14)	1,92,04,437	2,30,68,837	0.83
(2014-15)	1,78,32,261	2,25,91,680	0.79
(2015-16)	82,81,173	2,27,68,699	0.36
(2016-17)	6,68,580	2,31,06,579	0.03
(2017-18)	1,22,469	2,30,19,822	0.01
(2018-19)	2,29,61,939	2,25,47,547	1.02
(2019-20)	2,41,05,038	2,39,67,159	1.01

4.4.4 Sum of Subnational equals national level: UIP estimates

The national numbers of births with sums of numbers of births over all subnational areas was calculated. It was found that the national births were equal to the sum of subnational births for any year. At this point, it is important to understand that the data aggregated at national level often fails to

4.4.5 External Consistency at Subnational level *(Denominator comparison with UIP and CRS data sources)*

A high inconsistency among the denominators from the two sources was observed during the 2011-19 assessment period at subnational level.

Table 9: State wise birth cohort ratio from UIP and CRS Data source

	2011	2012	2013	2014	2015	2016	2017	2018	2019
All India	0.86	0.86	0.88	0.89	0.89	0.85	0.84	0.89	0.94
Arunachal Pradesh	1.20	1.60	1.63	1.60	2.30	1.78	3.54	2.93	1.76
Assam	0.89	0.91	1.01	1.03	1.43	1.03	1.00	1.11	1.09
Manipur	0.78	0.79	1.11	1.34	1.36	m	1.69	1.53	0.67
Meghalaya	1.37	1.48	1.09	1.04	1.21	m	1.03	1.23	1.83
Mizoram	1.50	1.53	1.45	1.36	1.38	1.25	1.17	1.19	1.34
Nagaland	1.47	1.52	1.53	1.84	2.49	2.28	2.16	1.64	2.67
Sikkim	0.78	0.78	0.78	0.73	0.72	0.65	0.65	0.66	0.61
Tripura	0.87	0.91	0.91	0.80	0.91	0.76	1.39	1.46	1.42
Bihar	0.59	0.73	0.56	0.62	0.64	0.61	0.72	0.77	0.96
Chhattisgarh	0.55	0.74	0.87	1.39	1.08	1.24	1.12	0.93	0.90
Himachal Pradesh	1.18	1.17	1.12	0.95	1.02	0.85	0.88	0.86	0.83
Jammu & Kashmir	0.68	m	0.70	0.72	0.71	0.71	0.72	0.75	0.75
Jharkhand	0.60	0.61	0.77	0.80	0.86	0.86	0.86	0.83	0.88
Madhya Pradesh	0.91	0.92	0.88	0.85	0.80	0.77	0.76	0.78	0.82
Odisha	0.98	0.99	0.96	0.99	0.97	0.95	0.85	0.86	0.86
Rajasthan	1.01	1.02	1.02	1.00	1.01	1.02	0.95	0.99	1.00

Uttar Pradesh	0.69	0.61	0.72	0.71	0.70	0.62	0.63	0.83	0.90
Uttarakhand	0.79	0.80	0.78	0.86	1.11	1.18	0.87	1.09	1.26
Andhra Pradesh Old	0.83	0.78	0.50	1.01	1.01	0.96	0.97	0.92	0.91
Goa	1.10	1.12	1.08	1.02	1.03	0.98	0.97	0.95	0.90
Gujarat	1.03	1.02	1.01	0.95	0.99	0.92	0.90	0.91	0.91
Haryana	1.06	1.05	1.08	1.05	1.02	1.03	0.95	0.96	0.93
Karnataka	1.00	1.01	0.96	0.97	0.94	0.96	0.97	0.93	0.94
Kerala	1.11	1.10	1.09	1.06	1.03	0.96	0.99	0.99	0.97
Maharashtra	1.05	1.05	1.07	1.02	1.01	0.91	0.93	0.91	0.91
Punjab	1.17	1.10	1.03	1.05	0.99	1.04	0.95	0.93	0.89
Tamil Nadu	1.03	1.08	1.06	1.08	1.04	0.95	0.85	0.83	0.85
Telangana	N/A	N/A	N/A	0.90	0.96	0.97	0.97	1.05	1.34
West Bengal	1.03	1.06	0.94	0.92	0.93	0.97	0.90	1.02	1.03
A & N Islands	0.94	0.91	0.90	0.95	0.87	0.82	0.94	1.29	0.87
Chandigarh	1.61	1.59	1.68	1.62	1.66	1.66	1.70	1.35	1.54
Dadra & Nagar Haveli	0.76	0.74	0.70	0.68	0.79	0.82	1.06	1.00	0.90
Daman & Diu	0.83	0.85	0.86	0.82	0.87	0.80	0.82	1.08	0.61
Delhi	1.22	1.22	1.22	1.19	1.19	1.29	1.13	1.07	1.14
Lakshadweep	0.73	0.73	0.69	0.66	0.82	0.84	0.82	1.21	0.89
Puducherry	2.10	1.91	1.81	1.83	1.79	1.82	1.86	1.16	1.96

m= missing data, NA- not applicable. Note: The state of Telangana gained its independence in 2014. Earlier it was a part of Andhra Pradesh. Provisional figures were reported for the state of Maharashtra and Tamil Nadu.

Table 10: State wise Surviving Infants (SI) ratio from UIP and CRS Data source

	2011	2012	2013	2014	2015	2016	2017	2018	2019
All India	0.86	0.86	0.87	0.88	0.89	0.84	0.83	0.89	0.94
Arunachal Pradesh	1.20	1.60	1.63	1.60	2.30	1.78	3.54	2.93	1.76
Assam	0.88	0.91	0.99	1.04	1.43	1.03	1.00	1.11	1.09
Manipur	0.77	0.78	1.10	1.33	1.35	m	1.69	1.53	0.66
Meghalaya	1.33	1.45	1.06	1.03	1.17	m	1.00	1.20	1.79
Mizoram	1.44	1.48	1.39	1.39	1.35	1.23	1.15	1.17	1.32
Nagaland	1.47	1.52	1.52	1.90	2.49	2.28	2.16	1.64	2.67
Sikkim	0.77	0.77	0.77	0.72	0.70	0.64	0.64	0.64	0.60
Tripura	m	0.89	0.90	0.88	0.89	0.75	1.38	1.45	1.40
Bihar	m	m	0.56	0.59	0.64	0.61	0.72	0.77	0.96
Chhattisgarh	0.54	m	m	1.34	1.06	1.23	1.11	0.92	0.89
Himachal Pradesh	1.17	1.16	1.11	0.97	1.01	0.85	0.87	0.85	0.83
Jammu & Kashmir	0.67	m	0.69	0.69	0.70	0.70	0.71	0.74	0.74
Jharkhand	m	m	m	m	m	m	m	m	m
Madhya Pradesh	0.90	0.91	0.87	0.84	0.80	0.76	0.75	0.77	0.82
Odisha	0.96	0.96	0.94	0.98	0.95	0.94	0.84	0.85	0.84
Rajasthan	1.00	1.01	1.01	0.99	1.00	1.01	0.94	0.98	1.00
Uttar Pradesh	0.68	m	0.72	0.71	0.70	0.62	0.62	0.82	0.90
Uttarakhand	0.79	0.80	0.78	0.87	1.11	1.18	m	1.08	1.25
Andhra Pradesh Old	0.83	0.78	0.50	1.00	1.01	0.96	0.96	0.91	0.90
Goa	1.09	1.11	1.08	1.01	1.02	0.97	0.96	0.94	0.89
Gujarat	1.02	1.01	1.00	0.94	0.98	m	0.89	0.90	0.90
Haryana	1.05	1.04	1.07	1.06	1.01	1.02	0.94	0.95	0.92
Karnataka	0.99	1.00	0.95	0.95	0.92	0.95	0.96	0.92	0.93
Kerala	1.10	1.09	1.08	1.07	1.02	0.96	0.98	0.99	0.97
Maharashtra	1.03	1.04	1.06	1.02	1.00	0.91	0.92	0.90	0.90
Punjab	1.16	1.09	1.02	1.05	0.98	1.04	0.94	0.92	0.89

Tamil Nadu	1.02	1.07	1.05	1.06	1.03	0.94	0.84	0.82	0.84
Telangana	NA	NA	NA	0.94	0.96	0.97	0.96	1.04	1.33
West Bengal	1.02	1.05	0.93	0.90	0.92	0.97	0.89	1.01	1.03
A & N Islands	0.92	0.89	0.88	0.93	0.85	0.80	0.92	1.27	0.86
Chandigarh	1.49	1.46	1.56	1.51	1.58	1.62	1.59	1.21	1.43
Dadra & Nagar Haveli	0.76	0.74	0.70	0.68	0.78	0.81	1.04	0.99	0.88
Daman & Diu	0.82	0.84	0.85	0.81	0.86	0.79	0.81	1.08	0.61
Delhi	1.19	1.19	1.19	1.18	1.16	1.26	1.10	1.04	1.11
Lakshadweep	0.73	0.73	0.69	0.65	0.80	0.84	0.81	1.20	0.89
Puducherry	2.04	1.86	1.78	1.72	1.76	1.80	1.84	1.14	1.94

m= missing data, NA- not applicable. Note: The state of Telangana gained its independence in 2014. Earlier it was a part of Andhra Pradesh. Provisional figures were reported for the state of Maharashtra and Tamil Nadu.

4.4.6 Internal Consistency between related indicators: Subnational Level *(UIP State wise data)*

For checking the internal consistency between related indicators, the comparison of vaccination doses given at the same age was analyzed. The ratio of the number of children vaccinated for DPT3 and OPV3 was calculated. The state wise datasets from the UIP showed missing data from 2011-14 for the state of Puducherry which was reflected in the ratios. Poor reporting of data was observed from the state of West Bengal and Delhi from 2011-13 which resulted in erratic ratios.

The consistency ratio of DPT3/OPV3 at the subnational level showed a wide range of variation. The variation decreases with time and the last two years show normal ratios. There is poor consistency between the number of vaccinated children reported for DPT3 and OPV3 from the year 2013 onwards. This was due to the introduction of the Pentavalent vaccine in a phased manner in the country which was completed by the year 2017.

Table 11: Ratio of the number of children vaccinated for DPT3 and OPV3 at 14 weeks of age

	2011	2012	2013	2014	2015	2016	2017	2018	2019
All India	1.05	0.96	0.83	0.79	0.36	0.03	0.01	1.02	1.01
Arunachal Pradesh	1.01	1.00	1.01	1.00	0.92	0.08	0.01	1.03	1.00
Assam	1.13	1.01	1.01	1.08	0.16	0.00	0.00	1.06	1.00
Manipur	1.00	1.00	1.00	1.01	0.91	0.13	0.01	1.01	1.01
Meghalaya	1.00	1.00	1.00	1.00	0.89	0.07	0.01	1.03	1.00
Mizoram	1.01	1.00	1.00	1.00	0.77	0.01	0.04	1.05	1.06
Nagaland	1.00	1.01	1.00	1.02	0.94	0.25	0.04	1.04	1.01
Sikkim	0.99	0.98	0.96	0.95	0.65	0.00	0.00	1.00	1.01
Tripura	1.04	1.00	1.00	1.00	0.88	0.07	0.01	1.00	1.00
Bihar	1.27	1.17	1.00	1.03	0.10	0.02	0.00	1.01	1.00
Chhattisgarh	1.02	1.01	1.00	1.01	0.21	0.00	0.00	1.00	1.00
Himachal Pradesh	1.00	1.00	1.00	1.00	0.63	0.00	0.00	1.00	1.00
Jammu & Kashmir	1.00	1.00	0.44	0.02	0.01	0.00	0.00	1.00	1.00
Jharkhand	1.27	1.13	1.01	1.06	0.22	0.01	0.00	1.08	1.00
Madhya Pradesh	1.10	1.03	1.00	0.84	0.02	0.00	0.00	1.01	1.00
Odisha	1.10	1.02	1.00	1.00	0.68	0.00	0.00	1.02	1.00
Rajasthan	1.00	1.00	1.00	0.79	0.01	0.01	0.00	1.01	1.00
Uttar Pradesh	1.01	1.02	1.01	1.02	0.97	0.10	0.01	1.04	1.01
Uttarakhand	1.01	1.00	1.01	0.97	0.05	0.00	0.00	1.02	1.01
Andhra Pradesh Old	1.00	1.00	1.00	1.00	0.37	0.03	0.01	1.01	1.01
Goa	1.03	0.97	0.04	0.02	0.02	0.02	0.01	1.01	1.00
Gujarat	1.04	0.99	0.13	0.03	0.02	0.02	0.01	1.02	1.00
Haryana	1.02	0.98	0.08	0.01	0.01	0.00	0.00	1.02	1.01
Karnataka	1.01	1.01	0.28	0.01	0.01	0.01	0.00	1.01	1.01
Kerala	0.91	0.05	0.01	0.00	0.00	0.00	0.00	1.01	1.01
Maharashtra	1.00	1.00	1.00	1.00	0.88	0.01	0.00	1.00	1.00
Punjab	1.01	1.00	1.00	0.99	0.09	0.00	0.00	1.00	1.00

Tamil Nadu	0.91	0.02	0.00	0.00	0.00	0.00	0.00	1.00	1.00
Telangana	NA	NA	NA	1.00	0.43	0.02	0.03	1.03	1.01
West Bengal	294.55	328.5	287	1.01	0.09	0.00	0.00	1.02	1.00
A & N Islands	0.31	0.28	0.30	0.99	0.91	0.81	0.04	1.04	1.02
Chandigarh	2.28	2.25	2.19	0.91	0.49	0.02	0.00	1.00	1.00
Dadra & Nagar Haveli	2.46	2.27	2.27	1.00	0.53	0.00	0.00	1.00	1.00
Daman & Diu	0.01	0.01	0.01	1.00	0.52	0.01	0.00	1.01	1.01
Delhi	238.0	262.8	145.3	0.18	0.09	0.04	0.03	1.02	1.02
Lakshadweep	0.06	0.06	0.09	1.00	0.88	0.09	0.03	1.04	1.00
Puducherry	m	m	m	m	0.01	0.00	0.00	1.00	1.00

m= missing data, NA- not applicable. Note: The state of Telangana gained its independence in 2014. Earlier it was a part of Andhra Pradesh.. Provisional figures were reported for the state of Maharashtra and Tamil Nadu.

4.5 Semi structured Interviews

This assessment tried to gain insights to validate the study results from the key informants involved in the immunization programme. A total of four key informants involved in the immunization programme at state level from the states of Maharashtra, Uttar Pradesh, Rajasthan, and Delhi were interviewed. The work experience of these officials in the immunization programme ranged from 5-7 years on an average. The findings obtained from the interview were in line with the results obtained in the study.

It was mentioned that the source of data for population denominator estimation was the birth rate projection obtained from the yearly SRS estimates. Some interviewees specifically added that the national immunization program had limited authority to influence the denominators as these adjustments were directly influenced by the predictions from the Census and SRS, handled by the national statistics division. It was also mentioned that some states had started utilizing the microplanning data along with the SRS data while estimating the target population. It was also clarified that the UIP used the HMIS data portal for reporting data. Based on the data available, some of the key issues in terms of forecasting the vaccine needs at state level were the quality of data reported with chunks of missing data. It was also mentioned that the shortage of healthcare staff at lower administrative levels as an important cause for poor quality of reporting. It was also mentioned that at higher administrative levels, there were less chances of reporting errors in coverage data as the data gets compiled or adjusted using provisional figures in the absence of actual data.

The interviewees mentioned that with microplanning being introduced in a phased manner along with strengthening of ‘supportive supervision’ in the country, the estimation of population denominators was improving. In the end, all the interviewees unanimously agreed that newer technologies like eVIN and digital methods of capturing data and its linkage with the national identity card (Aadhar card) could result in the improvement of the immunization programme in the long run.

A.5 Discussion

In this study, the application of data triangulation for target population estimation for India was illustrated using a case study. The initial part of the study involved a literature review to provide an overview of the evolution of the Universal Immunization programme in India. This was done to provide background information for the better understanding of the immunization system in the country. This was followed by a review of the sources and methods of data for denominator estimation. The last part of the study involved semi structured interviews of key informants working in the immunization programme for the validation of the study findings. The following sections provide an in-depth discussion of these linked topics.

Universal Immunization Programme

It is important to understand the progress and development of the immunization programme of any country prior to formulating and devising strategies for the delivery of its services. The immunization programme in India has constantly evolved with time. The programme was completely revamped in the year 2014 with the introduction of Mission Indradhanush to improve the coverage in hard to access areas. The microplanning strategy currently being implemented in routine immunization evolved during this campaign mode. The newer initiatives like eVIN and ANMOL could be digital solutions for better data capture.

A well-functioning VPD surveillance system is necessary to monitor the trends in diseases. The existence of numerous sources of data for VPD surveillance has certain limitations. There is an urgent need for the collation of data from similar sources to avoid duplication as well as to report the trends in an effective manner. This should also be linked to a research and development unit for conducting rapid reviews and ongoing studies. Such reports generated can be a part of evidence-based research necessary to make informed decisions in immunization planning.

The other aspects of the programme like shortage of health care staff also requires urgent attention at lower administrative levels for better data handling and execution of tasks.

Sources and methods of denominator estimation

With the rapid transition into the digital era, the sources of data have also transitioned with time. The sources of data are moving towards digitalization. This transition period for the different data sources reflects some of the limitations which could be improved with time. The results section provides an overview of the various sources and methods used in denominator estimation. The advantages as well as the disadvantages of the data sources were highlighted.

Currently, the UIP uses the estimates for estimating the target population from the SRS predictions. The SRS predictions are in turn based on the baseline values obtained from the most recent census. Even though the adequacy of the sample size and the fixed sample units used in the SRS have been debated by researchers, this is the most reliable estimate currently available for denominator estimation in the country. The SRS also provides updated estimates on a yearly basis.

The coverage estimates can largely vary based on the source of data. The estimates obtained from administrative coverage may not be comparable to survey coverage. Apart from the sampling method difference, the other difference is the inclusion of different age groups during coverage estimation. A routine administrative data report would include children up to 1 year of age for the estimation of coverage whereas a survey data would be inclusive of children in the 12-23 months during the survey period. This would lead to the inclusion of children older than 12 months leading to higher coverage estimates. In addition, surveys would also be inclusive of the doses received during a campaign mode and reflect higher coverage patterns.

Microplanning is one of the most important strategies and forms the base for the planning and management of immunization services. It can be a powerful tool for the estimation of denominators for immunization sessions. Currently, this strategy is being advocated at the lower administrative levels. This in turn, could promote improved planning of immunization services and better utilization of resources. This method is currently being implemented in a phased manner in the country. However, the limitations associated with this method also need attention and should be tackled for better results.

Data Triangulation

The criteria mentioned in the WHO Denominator guide was used to triangulate data from alternate sources and assess the quality, immunization trends and consistency patterns of the datasets at national and subnational level. It is a simple and cost-effective tool and can be easily incorporated in routine use for the better understanding of the trends in reported target population. The datasets were assessed for completeness and data quality including internal and external consistency. The critical synthesis of data from multiple sources ensures the comprehensive understanding of the immunization data.[13] The findings obtained from the key informant interviews were in line with the literature review findings and case study results.

At the national level, it was observed that the target population included in the UIP did not take into consideration the infant mortality rates. The birth cohort was used as the target population for all the vaccines up to one year of age. This discrepancy observed in UIP data was flagged. For the comparison at subnational level, other than the UIP data only CRS estimates were available for estimating target population. The limitations associated with the use of CRS estimates due to underreporting seen in the last nine years could undermine the findings. However, with improvement in the data reporting of births and infant deaths in the last 3 years have shown promising results. The strengthening of the CRS reporting system in the country could provide the most accurate estimates for the estimation of target population in immunization as well as serve as a valuable tool for planning and management. Other sources of data such as the vaccine logistics system (eVIN) could be a good source of data and could be used for triangulation for planning immunization services including estimation of denominators. The surveillance data should be strengthened and included under the UIP. This would help in understanding diseases trends. It could also provide coverage information from an epidemiological perspective. This robust surveillance system would not only provide data on disease trends but could also aid in formulation of vaccination strategies.

It was also observed that DPT3 coverage reported by the UIP during three consecutive years showed a major dip in coverage. This was due to the introduction of the pentavalent vaccine in a phased manner in the country.[57] As pentavalent vaccine includes the DPT antigens along with HepB and H. influenzae, this variation could be explained. It is important to understand the country's existing factors to draw valid conclusions from data.

It is also vital to recognize the limitations associated with population estimates at lower administrative units, for planning, monitoring and evaluation. The UIP estimates showed poor internal consistency at subnational level. This provides an indirect indication of the possibility of masking these observed errors when aggregated at national level. Studies show that poor reporting of data occurs from lower administrative levels. [6,10] It is important to strengthen the quality of data reporting at all levels for the improvement in the system. The discordance in data at subnational level warrants further investigation which in turn could result in improved data quality. It may not always be feasible to predict target populations with a high degree of precision. However, assessment of the consistency in data over time can be an important cost-effective tool to guide the improvement in immunization data over time.[45]

Limitations and Strengths of the study

At subnational level, the data was compared between the UIP and CRS as no other dataset was available. The coverage estimates from routine immunization sessions were used for comparison in the study. The data from supplementary immunization activities (SIAs) like the Intensified Mission Indradhanush (IMI) and Measles Rubella (MR) Campaign and other campaigns were not included in the study. There was paucity of peer reviewed literature on data triangulation in immunization programmes.

Despite these limitations, the study is a novel attempt to illustrate the use of data triangulation for the estimation of population denominators and in turn planning of immunization services.

The use of recent data sets along with time trend analysis can be regarded as an additional strength of the study.

A.6 Conclusions and recommendations

As advances in public health are dependent on accurate data and robust data systems, methods like data triangulation can be used to improve the accuracy of existing data sources. This approach of critical synthesis of existing data could serve as a valuable tool to track the progress made in the programme and guide further planning and decision-making. The simultaneous improvement of the existing data sources at all levels can further help in triangulating data.

The following are some of the recommendations:

At National level - Ministries/ policymakers

- The strengthening of the Civil registration system and incorporation of this data in the immunization programmes for target population estimation. Since, there has been a major improvement in the reporting pattern among states in the past few years, this data could serve as a promising and reliable source of information.
- Data quality improvements should be incorporated in the UIP at lower administrative levels. Efforts should be taken to correct the target population estimates used for surviving infants by incorporating the factor of infant mortality.
- The collation of surveillance data for vaccine preventable disease into a single unit under the immunization programme should be incorporated. This could enable the use of surveillance data for decision-making and monitoring progress.

Research recommendations

- Studies on the use of data triangulation in immunization programmes for population denominators can be explored for different countries due to the paucity of data on this topic.
- Further studies involving data triangulation at lower administrative levels (district or block level) can be researched in-depth. The microplanning data (available in selected regions) along with health facility data can also be used for comparison.
- Research studies assessing the surveillance and coverage pattern using comparable data at national level.
- Research studies involving the use of GIS enabled datasets along with routine data can be further researched as this field remains unexplored and needs strong evidence prior to being used in the system.

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Appendix 1: Search strategy used for Literature review

Table 1: Search strategy used for Literature review

Literature	Source	Objective 1	Objective 2	Objective 3
Peer-reviewed published articles	MEDLINE (PubMed) & EMBASE	"Immunization", "coverage", "vaccination coverage", "EPI", "UIP", "India" ,"states of India" "Infants", "children", "under5"	"Sources of Health data", "health information system", "immunization, coverage", "methods", "Denominator" "Target Population"	"Denominator" "Target Population" "Data Triangulation" "Triangulation" "Data quality" , "consistency'
Grey literatures	WHO, UNICEF, MoHFW, NFHS, Census, CRS, HMIS	Annual reports, Programme reports, Guidelines, Survey Reports.	Annual reports, Programme reports, Guidelines, Survey Reports.	Annual reports, Programme reports, Guidelines, Survey Reports.