
**PERSISTENT CHALLENGES IN DIPHTHERIA CONTROL:
ANALYZING IMMUNIZATION BARRIERS AND OUTBREAK
DYNAMICS IN INDIA**

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ABSTRACT

Background: Diphtheria is a vaccine-preventable disease caused by *Corynebacterium diphtheriae* and continues to be a public health problem in India, despite the availability of effective immunization programmes. Periodic outbreaks and sporadic cases indicate persistent gaps in vaccination coverage and disease surveillance. **Objective:** This review aims to identify and analyze barriers to diphtheria prevention in India by examining immunization strategies, outbreak patterns, and programmatic challenges during 2015-2023. **Methods:** The literature review was conducted using PubMed, WHO databases, and Indian government health reports. Studies, outbreak reports, and immunization data from 2015 through 2023 were reviewed. Inclusion was based on all peer-reviewed articles, epidemiology reports, and official health statistics on the prevention of diphtheria and its outbreaks in India. **Results:** Immunization gaps in various major states varied from 62% to 91%, with marked disparities in urban and rural areas. Significant barriers included insufficient cold chain infrastructure; vaccine hesitancy; missed opportunities for vaccination related to migration; and weak surveillance systems. From 2015 to 2023, India reported several outbreaks with case fatality rates ranging from 5% to 16%. **Conclusion:** Despite the availability of effective vaccines, diphtheria prevention in India faces systemic barriers. Strengthening of immunization infrastructure, improvement in surveillance, and addressing socio-behavioral factors are crucial components for disease elimination.

KEYWORDS: Diphtheria, immunization barriers, vaccination coverage, disease outbreak, India, public health.

INTRODUCTION

Diphtheria is an acute infectious disease caused by toxigenic strains of *Corynebacterium diphtheriae* that affects, primarily, the upper respiratory tract and occasionally the skin. Despite the availability of safe and effective vaccines for more than seven decades, the disease remains a significant public health challenge in many countries with suboptimal immunization coverage.

The EPI introduced a diphtheria-tetanus-pertussis vaccine globally, and this has dramatically reduced disease incidence worldwide.

India initiated the Universal Immunization Programme in 1985, with diphtheria vaccination as a cornerstone of childhood immunization. The primary vaccination series consists of three doses of pentavalent vaccine containing DTP, Hepatitis B, and *Haemophilus influenzae* type b at 6, 10, and 14 weeks of age. Booster doses are given at 16-24 months and 5-6 years. In spite of this, diphtheria cases continue to be reported from within the country, with periodic outbreaks in certain parts, indicating persisting fragilities in the prevention architecture.

According to the World Health Organization, globally, diphtheria cases have declined significantly from 100,000 cases annually in 1980 to less than 20,000 by 2016, although several countries like India, Indonesia, Yemen, and Venezuela have reported resurgences. In India, the epidemiological pattern indicates that cases tend to cluster in states with low vaccination coverage, urban slums, and migrant populations. Outbreaks of variable intensity were reported between 2015 and 2023 across different Indian states, indicating geographical and programmatic variability.

The fact that diphtheria persists in India despite the widespread availability of vaccines suggests that there are several barriers operating at the individual, community, health system, and policy levels. These barriers must be understood so that appropriate targeted interventions can be developed in pursuit of the goal of diphtheria elimination. Previous studies have highlighted factors such as vaccine hesitancy, poor maintenance of the cold chain, weak surveillance mechanisms, and socioeconomic determinants as probable causes for ineffective immunization.

However, there is a considerable lack of comprehensive analyses that explore how immunization strategies interact with outbreak characteristics and specific barriers in the

Indian context during recent years (2015-2023). This knowledge gap limits the development of evidence-based strategies tailored to India's diverse geographical, cultural, and health system landscape.

This review is warranted by the impending need to synthesize the available evidence regarding the challenges of diphtheria prevention in India, identify actionable gaps, and provide recommendations to strengthen the immunization program. Due to the large population, diverse socio-cultural context, and structure of the federal health system, addressing the identified barriers requires an understanding of local and national factors.

The objectives are to systematically review barriers to diphtheria prevention in India through immunization coverage data, outbreak reports, and programmatic challenges during 2015-2023, and to identify strategies for improving disease prevention and control.

Methods

This study used a narrative literature review to identify barriers to diphtheria prevention in India from 2015 to 2023, studying immunization strategies and outbreak patterns. The data were gathered from various sources: PubMed/MEDLINE, WHO immunization databases, Ministry of Health and Family Welfare reports, National Health Mission documents, state health department outbreak reports, and survey data, including the Coverage Evaluation Survey, NFHS-4, and NFHS-5. The search terms used were related to diphtheria, vaccination coverage, and immunization barriers, using Boolean operators for efficient combinations of these terms.

Studies and reports were considered to have met the inclusion criteria if they were published during 2015-2023 and specifically addressed diphtheria in India, having quantitative data on vaccination rates or outbreak patterns. The ones excluded are studies that were carried out outside India, those that have been published prior to 2015, or which do not specifically provide data on diphtheria. Systematic data extraction was done by focusing on immunization coverage, outbreak characteristics, and barriers to immunization categorized under health system, socio-behavioral, and programmatic factors. Quantitative data were tabulated, and qualitative data were thematically analyzed. Ethical approval was not required since it utilized existing literature and data from public sources, and all are correctly cited in the paper.

RESULTS

Trend of National Immunization Coverage: 2015-2023

Analysis of the national immunization data showed fluctuating coverage rates for the three-dose DTP series.

Full national DTP3 coverage stood at 78.4% as per NFHS-4 (2015-16), which increased marginally to 76.4% in NFHS-5 (2019-21). However, the routine immunization data as reported through the HMIS presented administrative coverage of 88-93% for the period 2015-2023, reflecting gaps between survey-based estimates and reported data.

Table 1: DTP3 immunization coverage in India, 2015-2023.

Year	National Coverage (%)	Urban (%)	Rural (%)	Dropout Rate (DTP1-DTP3) (%)
2015-16	78.4	83.2	76.8	6.3
2017	85.1	87.9	84.2	5.8
2018	87.2	89.4	86.3	5.4
2019	88.7	90.8	87.9	4.9
2019-21	76.4	82.6	74.2	7.1
2021	89.3	91.2	88.5	4.6
2022	91.1	92.7	90.3	3.9
2023	90.8	92.1	90.1	4.2

Sources: NFHS-4, NFHS-5, HMIS reports, WHO-UNICEF estimates

State-wise Inequalities in Vaccination Coverage

There were significant geographical variations across states in India. The high-performing states, such as Kerala, Tamil Nadu, and Punjab, consistently maintained coverage above 90%, whereas states such as Nagaland (62.3%), Arunachal Pradesh (67.8%), and Uttar Pradesh (68.5%) had reported substantially lower coverage in 2019-21.

Table 2: Variation in State-wise DTP3 Coverage (2019-21)

State Category	States	Coverage Range (%)	Population Affected (million)
High Coverage	Kerala, Tamil Nadu, Punjab, Goa	92-96	98
Moderate Coverage	Maharashtra, Karnataka, West Bengal	82-88	287
Low Coverage	Uttar Pradesh, Bihar, Madhya Pradesh	68-75	356
Very Low Coverage	Nagaland, Arunachal Pradesh, Manipur	62-70	8.2

Source: NFHS-5 (2019-21)

Diphtheria Outbreak Pattern Analysis (2015-2023)

During the review period, a number of outbreaks of diphtheria were reported from several states. The major outbreaks occurred in Karnataka during 2015-2018, Kerala in 2015, Telangana in 2017, Andhra Pradesh during 2018-2019, and Assam during 2017-2018. Several states reported a resurgence during 2021-2023, which could be linked to COVID-19 pandemic-related disruptions in the routine immunization services.

Table 3: Major Diphtheria Outbreaks in India (2015-2023)

Year	State/UT	Total Cases	Deaths	CFR (%)	Age Group Most Affected	Primary Risk Factor
2015	Kerala	89	6	6.7	5-14 years	Low booster coverage
2015-18	Karnataka	324	19	5.9	5-15 years	Inadequate immunization
2017	Telangana	142	8	5.6	1-14 years	Urban slum populations
2017-18	Assam	267	43	16.1	5-14 years	Low coverage, tribal areas
2018-19	Andhra Pradesh	198	12	6.1	5-15 years	Migration, missed doses
2021-22	Multiple states	187	11	5.9	Mixed age groups	COVID-19 disruption
2022-23	Delhi NCR	56	4	7.1	5-12 years	Migrant populations

Sources: State health department reports, Integrated Disease Surveillance Programme (IDSP)

Age Distribution of Diphtheria Cases

The analysis of outbreak data showed that the age group 5-14 years accounted for the majority of reported cases (62-68%), indicating low booster dose coverage and waning immunity. Some 18-22% of the cases were seen among children less than 5 years of age, indicating incomplete primary vaccination. An emerging trend was that cases also started appearing among adolescents and adults, 12-18% of the total cases, due to the absence of a systematic booster immunization beyond childhood.

Identified Barriers to Prevention of Diphtheria

The review identified several barriers operating at various levels of the health system:

Health System Barriers

- Poor cold chain infrastructure in 28-35% of rural health facilities
- Stock-out of vaccines reported in 15-22% of primary health centers annually
- Inadequate number of health workers who are specifically trained for immunization activities
- Weak disease surveillance systems with estimated under-reporting at 30-40%
- Limited laboratory capacity for confirmation of *C. diphtheriae*, with only 45 laboratories nationwide

Programmatic Challenges:

- High dropout rates across DTP1 to DTP3 range from 3.9 to 7.1%.
- Poor booster dose coverage at 16-24 months, estimated at 65-72%
- Poor second booster at 5-6 years' coverage estimated at 55-68%
- Many have limited catch-up immunization strategies for children who missed doses.
- Poor integration of routine immunization into the outbreak response

Socio-behavioural barriers

- Vaccine hesitancy and refusal were reported in 8-12% of target populations in some areas.
- Religious and cultural misunderstandings about vaccines
- Parental ignorance regarding the importance of the booster dose
- Migration-related challenges to continuity of immunization
- Low level of health literacy in marginalized communities

Socioeconomic Factors:

- Poverty and opportunity costs inhibit access to healthcare.
- Urban slum populations whose outreach services are minimal
- Tribal and remotely located populations with geographical access barriers
- Vaccination completion rates consistent with maternal educational levels

Table 4: Categorized Barriers to the Prevention of Diphtheria

Barrier Category	Specific Challenges	Prevalence/Impact (%)	Primary Affected Population
Cold Chain	Infrastructure inadequacy	28-35	Rural areas
Vaccine Supply	Stock-outs	15-22	All areas
Dropout	DTP1 to DTP3	3.9-7.1	All areas

	incomplete		
Booster Coverage	First booster inadequate	28-35	All age groups
Vaccine Hesitancy	Refusal/delay	8-12	Urban and certain religious groups
Surveillance	Under-reporting	30-40	All areas
Laboratory	Limited confirmation capacity	55 (% inadequate)	National level
Migration	Missed opportunities	15-20	Urban migrants

Impact of COVID-19 Pandemic on Immunization Services

The COVID-19 pandemic (2020-2021) significantly disrupted routine immunization services in India. Lockdown measures, resource diversion, and public fear of healthcare facility visits led to substantial declines in vaccination coverage. Data indicated that DTP3 coverage dropped from 89.3% in 2019 to approximately 82-84% during 2020, with gradual recovery observed in 2021-2023. This disruption contributed to increased susceptibility and potential for outbreaks in the post-pandemic period.

Interventions and Their Results

Several interventions were implemented during outbreak responses:

- Intensified Mission Indradhanush campaigns in areas with low immunization coverage
- Supplementary immunization activities in outbreak-affected districts
- School-based catch-up campaigns for older children
- Improved mechanisms for surveillance and laboratory confirmation
- Community mobilization through ASHA workers

States that implemented comprehensive outbreak response measures, including mass immunization campaigns and enhanced surveillance, reported reduced case numbers within 3-6 months. However, long-term sustainability remained challenging without addressing underlying systemic barriers.

DISCUSSION

The review has underlined barriers in India's UIP, despite the availability of efficacious vaccines against diphtheria. It has outlined complexities that challenge high immunization coverage due to geographic and socio-economic, along with systemic variations, within the country.

Substantial differences between reported coverage by routine immunization (88-93% HMIS) and estimates from household surveys (76-90%) indicate concern regarding the integrity of these data, indicating either over-reporting from administrative data or a difference in survey sampling. The findings are supportive of the WHO recommendation to assess multiple data sources for coverage assessment to ensure their accuracy.

There are significant geographical inequalities, with states such as Nagaland, Arunachal Pradesh, and Uttar Pradesh showing low immunization rates—a reflection of the fact that reaching marginalized people remains a big challenge. Low-coverage states house an estimated 356 million people, which presents a substantial population at risk from outbreaks—a finding that echoes results from global studies, which have associated immunization inequities with poverty and a lack of health infrastructure.

The analysis of outbreak patterns shows important trends, especially in the age group of 5-14 years, indicating inadequate booster vaccinations and waning of immunity from initial vaccination series. The appearance of diphtheria cases even among older age groups indicates a systemic failure of booster immunizations beyond early childhood has persisted despite recognition by WHO. A high fatality rate of 16.1% in Assam compared to variable rates observed in other outbreaks highlights the importance of timely diagnosis and availability of diphtheria antitoxin (DAT), particularly in tribal and remote areas with poor access to timely medical care.

The review identifies several health system and programmatic barriers. Inadequacies in the cold chain affecting 28-35% of rural health facilities constitute a critical obstacle to vaccine efficacy, given that exposure to improper temperatures compromises vaccine potency. Geographic diversity and erratic electricity supply make cold chain maintenance difficult, as has also been documented by studies from a variety of low- and middle-income countries.

Despite the reductions in dropout rates from 7.1% to 3.9%, millions of children remain incompletely vaccinated due to reasons such as lack of information about the need for further doses, inconvenient service delivery times, or parents forgetting to complete the course. The particularly low coverage of booster doses signals an important concern, given that booster doses are highly important for long-lasting protection against diphtheria.

Surveillance system weaknesses compromise timely detection of outbreaks and response, as

only an estimated 30-40% of cases are reported, and many suspected cases remain untested due to limited laboratory capacities. The country's laboratory network with respect to diphtheria diagnosis is incomplete compared to countries that have well-developed systems, blocking evidence-informed policy decisions.

Cultural factors also contribute to the variance in immunization rates, and vaccine hesitancy has been estimated at 8-12% in some populations, further exacerbated by misinformation, historical distrust, and religious beliefs that challenge vaccination efforts. The mobility within populations due to internal migration complicates continuity in immunization, leading to gaps in coverage, especially within urban slum areas. More broadly, vaccination rates are correlated with maternal education; less-educated mothers often lack the basic health literacy and capacity to navigate health systems.

The COVID-19 pandemic significantly disrupted routine immunization services, with declining DTP3 coverage in 2020; WHO estimates for the loss of routine vaccinations stand at 23 million children globally. Gradual recovery by India from this setback was indicative of resilience but also of vulnerability, given the unvaccinated cohorts that remain susceptible to diphtheria.

India's challenges are shared with other large, federated countries like Nigeria and Pakistan, while some countries, like Bangladesh, have been able to achieve better coverage through political commitment and innovative service delivery mechanisms. The WHO Global Vaccine Action Plan emphasizes the need for $\geq 90\%$ national coverage, which India has achieved only intermittently at localized levels. Systematic booster strategies are non-existent in India but crucial to maintaining high immunity, as modeled in successful programs in Europe. It also leverages an in-depth look at various data sources but is limited by potential biases in the reliance on literature, data quality concerns, and the nature of the methodology for the narrative review. In general, it shows a detailed analysis of the challenges with immunization and the multi-dimensional effort required to meet them.

Recommendations based on the analysis include strengthening health system infrastructure by modernizing cold chain systems, especially in rural areas, using solar-powered equipment and temperature monitoring. Improving booster dose coverage can be achieved by implementing school-based immunization at age 5-6 years and in adolescence. Vaccine hesitancy needs to be addressed through culturally sensitive approaches and the involvement

of trusted community members. Strengthening surveillance systems with improved lab capacity and real-time tracking will contribute to the detection of outbreaks. Special strategies should focus on vulnerable populations, including mobile vaccination units. Integrating immunization with other health services will improve vaccination opportunities. Finally, improving data quality through electronic registries and audits is essential for more accurate coverage assessment.

Suggestions for Future Research

Future research should focus on:

- Longitudinal studies examining immunity duration after primary and booster doses in Indian populations
- Cost-effectiveness analyses of various booster dose strategies (school-based vs. health facility-based)
- Implementation research on innovative service delivery models for reaching migrant and marginalized populations
- Studies on optimal communication strategies to address vaccine hesitancy in specific cultural contexts
- Research on integrating diphtheria surveillance with other vaccine-preventable disease surveillance systems
- Economic analyses of outbreak costs vs. prevention investments to inform policy decisions.

CONCLUSION

Diphtheria prevention in India suffers from complex barriers, including health system inadequacies, programmatic gaps, socio-behavioral difficulties, and socioeconomic determinants. Despite effective vaccines and a national immunization program, high uniform coverage and the prevention of outbreaks have yet to be realized. The persistence of geographical disparities, inadequate booster dose coverage, and vulnerable populations creates ongoing risk for disease transmission.

Overcoming these barriers requires comprehensive, multi-pronged strategies that strengthen health infrastructure, enhance service delivery, address social determinants, and ensure sustainable financing. The disruption caused by the COVID-19 pandemic has underlined the fragility of the immunization systems and the need for resilient, adaptable programs. Lessons

from India's best-performing states and international best practices can help inform contextually appropriate interventions.

The goal of eliminating diphtheria in India is achievable but requires ongoing political commitment, adequate resource allocation, innovative strategies to reach the underserved populations, and continuous monitoring and improvement of immunization systems. This review synthesizes the evidence that forms a basis for informed, evidence-based policy and programmatic decisions toward this goal.

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