

## Diphtheria in India: Trends, Antitoxin Availability, and Challenges in Early Diagnosis

Mamatkulova Nazgul<sup>1\*</sup>, Sivasankaran Sripriya<sup>2</sup>, Christudhas Astridline<sup>2</sup>, Mohd Massom Ansari<sup>2</sup>, Mohammad Adil<sup>2</sup>, MD Salman<sup>2</sup>

<sup>1</sup>Teacher of «Infectious Disease» Department, International Medical Faculty of Osh State University

<sup>2</sup>Students of International Medical Faculty of Osh State University

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\*Corresponding author: Mamatkulova Nazgul

Teacher of «Infectious Disease» Department, International Medical Faculty of Osh State University

### Abstract

### Original Research Article

Diphtheria remains a persistent public-health concern in India, with a worrying resurgence and shifting epidemiology over the last several years. After steady declines in the late 20th century, recent surveillance and outbreak reports document increases in reported cases and an age-shift from young children toward older children, adolescents and adults — driven by incomplete immunization, gaps in booster coverage, and pockets of susceptible populations. India contributed a substantial share of globally reported diphtheria cases in recent surveillance data. Therapy for toxin-mediated disease depends critically on timely administration of diphtheria antitoxin (DAT) in addition to antibiotics and supportive care. However, the global supply chain for DAT is fragile: manufacturers are few, production is limited, and shortages have been reported constraints that complicate outbreak response and raise case-fatality risk in resource-limited settings. India has been both a producer and a country facing distribution challenges in coordinating antitoxin access during outbreaks. Early diagnosis is frequently delayed for several reasons. Clinically, diphtheria can mimic other causes of pharyngitis and lower-respiratory infections, producing diagnostic uncertainty at initial presentation. Laboratory confirmation requires culture and demonstration of toxigenicity (historically by the Elek test) or molecular detection of tox gene — methods that are unevenly available across peripheral laboratories. Shortages of diagnostic reagents (including diphtheria antitoxin used in some toxigenicity assays), limited molecular capacity, and delays in specimen transport further hinder rapid confirmation and public-health action. These diagnostic gaps, together with suboptimal booster vaccine uptake, lead to delayed treatment, missed contact tracing, and sustained transmission. To reduce morbidity and mortality, India's response must combine strengthened routine and booster immunization (catch-up campaigns where needed), secure and centrally coordinated DAT stockpiles with transparent distribution protocols, expanded laboratory capacity for rapid toxigenicity testing (including validated PCR workflows), clinician awareness to lower thresholds for empirical DAT in severe suspected cases, and improved surveillance to detect and contain outbreaks early. Continued monitoring of vaccine coverage and targeted public-health interventions in under-immunized communities will be essential to reverse current trends.

**Keywords:** Diphtheria, India, Epidemiological Trends, Diphtheria Antitoxin, Immunization Gaps, Early Diagnosis.

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## INTRODUCTION

Diphtheria is caused by gram-positive bacillus known as *Corynebacterium diphtheriae* and was considered a significant public health problem before the advent of universal immunization.

However, reports of a possible resurgence are slowly coming to light and primary care physicians along with microbiology laboratories must be able to assist in diagnostics in such cases.

The present case suggests that immunization coverage and awareness with appropriate intervention along with laboratory confirmation is lacking. Case study was conducted after obtaining approval from Institutional Ethical Committee and hospital Medical Superintendent.

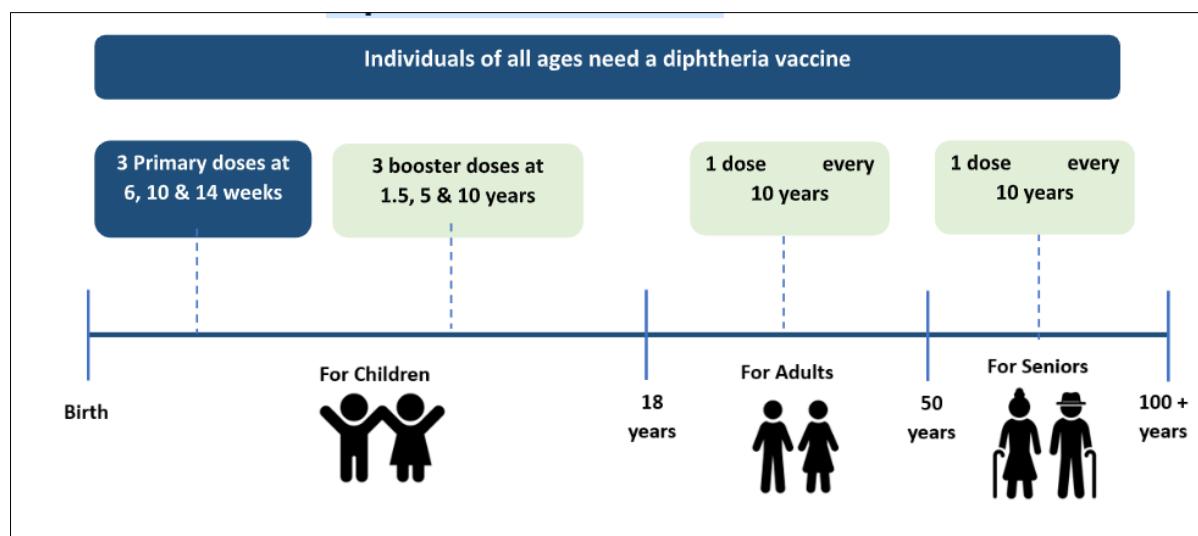
The cornerstone of diphtheria treatment is early administration of diphtheria antitoxin, which neutralizes circulating toxin but does not reverse tissue damage already caused. Therefore, delayed diagnosis and lack of antitoxin can lead to poor outcomes even with

appropriate antibiotic therapy. Understanding trends, treatment gaps, and diagnostic challenges is critical for effective disease control.

## METHODS

Diphtheria is an acute disease caused by exotoxin-producing *Corynebacterium diphtheriae*. Globally, diphtheria has been showing a declining trend due to effective childhood vaccination programs. A substantial proportion of global burden of diphtheria is contributed by India. Hospital-based surveillance studies as well as diphtheria outbreaks published in last 20 years (1996-2016) indicate that diphtheria cases are frequent

among school-going children and adolescents. In some Indian states, Muslim children are affected more. As per the national level health surveys, coverage of three doses of diphtheria vaccine was 80% during 2015-2016. Information about coverage of diphtheria boosters is not routinely collected through these surveys, but is expected to be low. Few studies also indicate low diphtheria immunity among school-going children and adults. The strategies for prevention of diphtheria need to focus on improving coverage of primary and booster doses of diphtheria vaccines administered as a part of Universal Immunization Program as well as introducing diphtheria vaccine for school-going children [Picture :1]



Diphtheria is a potentially fatal, vaccine-preventable bacterial disease caused by toxigenic strains of *Corynebacterium diphtheriae*. Despite long-standing inclusion of diphtheria-containing vaccines in India's Universal Immunization Programme (UIP), the disease continues to persist and re-emerge in various parts of the country. India contributes a substantial proportion of global diphtheria cases, reflecting gaps in immunization coverage, waning immunity due to missed booster doses, and weaknesses in disease surveillance. Effective management of diphtheria depends on early clinical diagnosis and prompt administration of diphtheria antitoxin (DAT); however, limited availability of DAT and diagnostic delays remain major challenges. This review examines epidemiological trends of diphtheria in India, evaluates the status and constraints of antitoxin availability, and discusses barriers to early diagnosis. Strengthening immunization strategies, improving clinician awareness, and ensuring timely access to antitoxin are essential to reducing diphtheria-related morbidity and mortality.

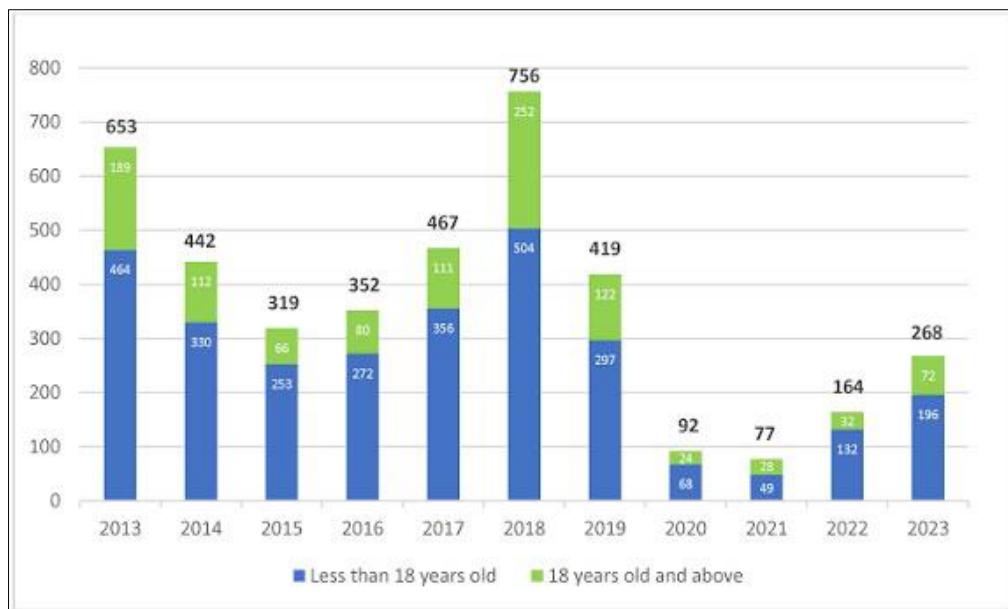
### Objectives

1. To analyze epidemiological trends of diphtheria in India
2. To assess the availability, distribution, and challenges related to diphtheria antitoxin
3. To identify clinical and laboratory challenges in early diagnosis of diphtheria
4. To discuss public health strategies for improved prevention and control

### Methods

This study is a narrative review of existing literature on diphtheria in India. Data were collected from:

- Peer-reviewed medical and public health journals
- National surveillance data and reports
- Guidelines and publications from the World Health Organization (WHO) and Government of India [Picture :2]

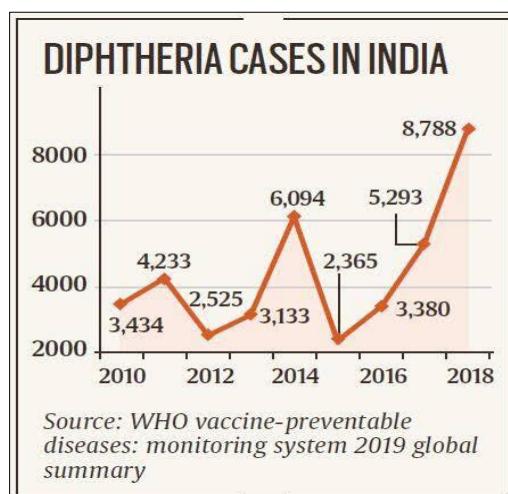


The review focused on disease burden, age and geographic distribution, antitoxin supply chains, diagnostic practices, and health system challenges. Both observational studies and outbreak reports were analyzed to provide a comprehensive overview.

## RESULTS

Epidemiological Trends of Diphtheria in India  
India remains a major contributor to the global diphtheria burden. Key epidemiological observations include:

- Persistent endemic transmission with periodic outbreaks
- Shift in age distribution, with increasing cases among older children, adolescents, and adults
- Higher incidence in states with lower routine immunization and booster coverage [Picture :3]



Association with socioeconomically disadvantaged populations, overcrowding, and poor access to healthcare. Incomplete primary immunization and failure to receive booster doses at school age and adolescence have been identified as critical risk factors.

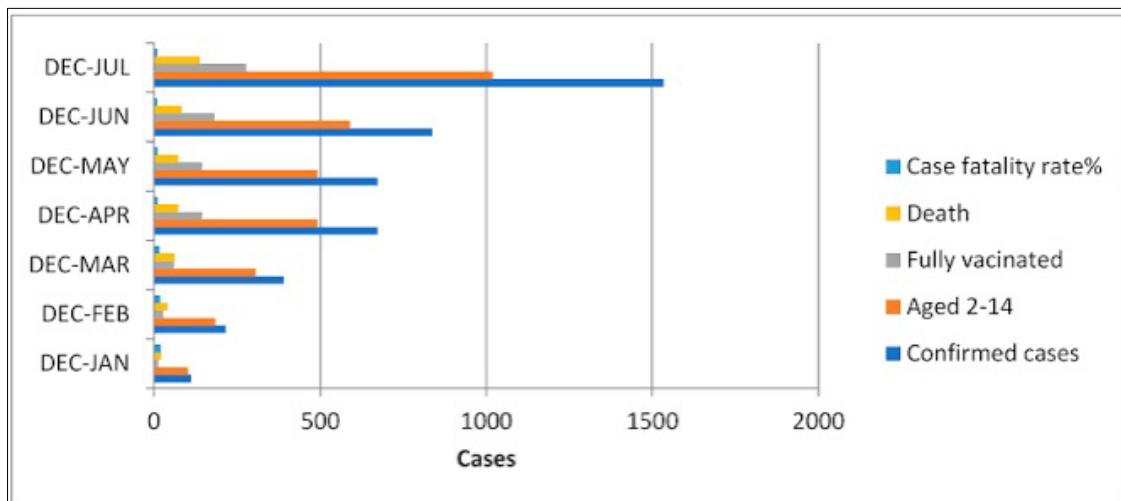
### Antitoxin Availability and Accessibility

Diphtheria antitoxin (DAT) is derived from equine serum and remains the only specific therapy

capable of neutralizing diphtheria toxin. Major issues related to DAT in India include:

- Limited domestic production and reliance on a few manufacturers
- Centralized storage at select tertiary care centers
- Delays in procurement and transportation to peripheral hospitals

- Concerns about hypersensitivity reactions and lack of clinician familiarity with DAT administration [Picture :4]



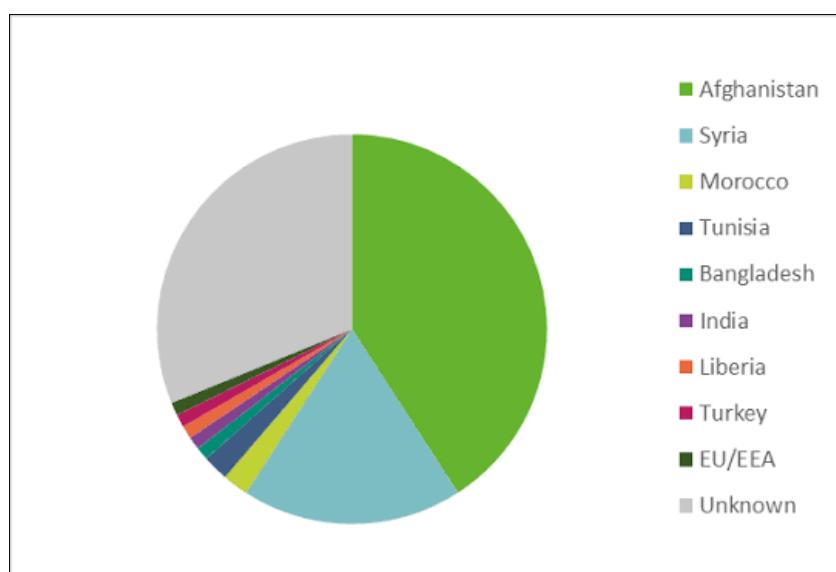
These challenges often result in delayed or non-availability of DAT at the time of patient presentation, significantly increasing case fatality rates.

#### Challenges in Early Diagnosis

Early diagnosis of diphtheria is primarily clinical, as laboratory confirmation may take several days. Diagnostic challenges include:

- Declining clinical experience due to reduced disease prevalence

- Atypical or mild presentations in partially immunized individuals
- Misdiagnosis as viral pharyngitis, streptococcal tonsillitis, or infectious mononucleosis
- Delayed laboratory confirmation due to limited availability of specialized culture media and toxin testing [Picture:5]



Low clinical suspicion leads to delayed isolation, treatment, and antitoxin administration, contributing to disease transmission and poor outcomes.

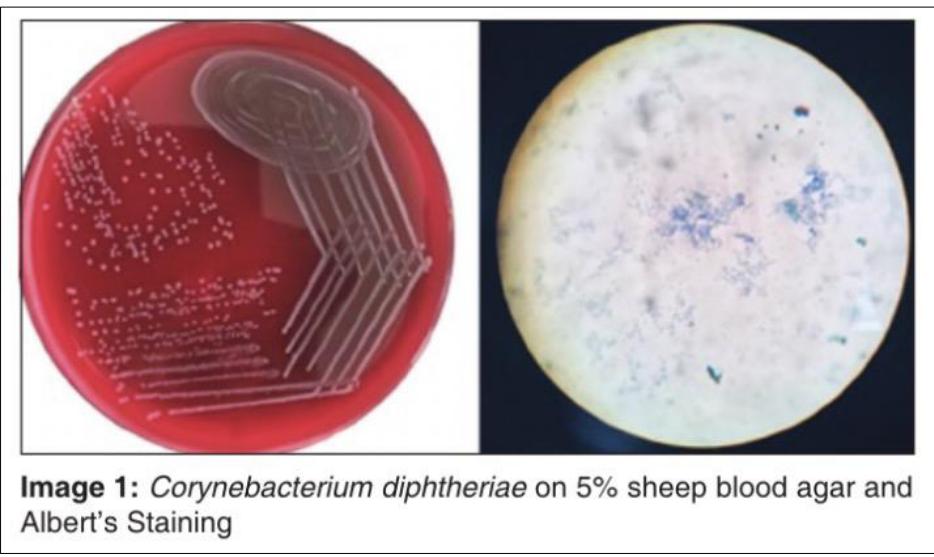
## DISCUSSION

Case reports noting the possible resurgence of diphtheria in India are on the rise, despite multiple

national immunization programs in place like “Mission Indradhanush” (MI) and “Intensified Mission Indradhanush” (IMI), which are significant steps toward the hope of diphtheria free nation. India follows the universal immunization program (UIP) recommending 3 doses, 4 weeks apart followed by 2 booster dose schedule; However, average diphtheria-tetanus-pertussis (DPT) vaccine coverage remains at only 84% [4]. Lack

of awareness among primary care physicians, delay in clinical suspicion and requests for appropriate investigations are also key factors in mortality associated with such vaccine-preventable diseases. The present case study highlights the possible delays in administration along with limited availability of diphtheria antitoxin (DAT) and the importance of identifying toxigenic *C. diphtheriae* in the laboratory. DAT is not readily available in all health facilities and its manufacture is

also at a minimum. It has been suggested that this unavailability may be due to lack of awareness of the reemerging status of the disease and a sense of false security on the immunization coverage as community-based screening of antibody titers against diphtheria has not been evaluated [5]. It is important to understand DAT only neutralizes the circulating toxin and not that bound to tissues; thus, [Picture :6].



Late presentations are closely linked to case fatalities [6]. Furthermore, early diagnosis is paramount in preventing the rapid decline of diphtheria patients, as seen in the present case. Front line physicians and primary care providers are the key players in identifying early manifestations of faecal diphtheria, bacteremia, and toxemia, as initial penicillin therapy can halt disease progression.

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