Infection prevention and control and water, sanitation and hygiene measures for diphtheria in health-care settings

*Operational guide*

February 2024

**Key Messages**

- All health and care workers’ vaccines should be up to date with an age-appropriate diphtheria toxoid-containing vaccine, including booster doses.
- Immediately isolate any suspect or confirmed diphtheria patients in single, well-ventilated patient rooms; if single patient rooms are limited, do not cohort suspect patients.
- Use droplet precautions (medical mask) when at least 1 metre of distance cannot be maintained with additional personal protective equipment (PPE) (eye protection, gown, gloves) based on a risk assessment.
- Visitors (or caregivers) should wear PPE for droplet precautions when at least 1 metre distance cannot be maintained and be instructed on any additional PPE needs and procedures for hand hygiene and putting on and taking off PPE.

**Intended audience**

This document is for health-care facility/treatment centre administrators and managers, Infection prevention and control (IPC) personnel, occupational health and water, sanitation and hygiene (WASH) focal points, health and care workers in health-care facilities and diphtheria treatment centres.

This document primarily addresses respiratory *Corynebacterium diphtheriae* (*C. diphtheriae*).

**Background**

**What is diphtheria?**

Diphtheria is an infection caused by the bacterium *Corynebacterium diphtheriae*. It can cause respiratory (pharyngeal, tonsillar, laryngeal, nasal) or non-respiratory (cutaneous and other mucus membranes) diseases. Signs and symptoms usually start 2 – 5 days after exposure and range from mild to severe. Symptoms of respiratory diphtheria often come on gradually, beginning with a sore throat and fever. Patches of exudate appear in the pharynx and may form a greyish-white membrane (pseudomembrane) that covers the entire pharynx, including the tonsillar area, soft palate and uvula. Efforts to remove it often result in bleeding. Lymph nodes become enlarged and, in severe disease, can result in airway obstruction. Details on clinical signs and symptoms of diphtheria are in the Field guide for preparedness and response to diphtheria outbreaks in the Western Pacific Region (*1, 2, 3*).

Toxigenic strains of *C. diphtheriae* present a public health concern. These bacteria produce a toxin that may also get into the bloodstream, causing complications that may include inflammation and damage to the heart muscle, inflammation of nerves, kidney problems and bleeding problems due to low blood platelets. The damaged heart muscles may result in an abnormal heart rate and the inflammation of the nerves may result in paralysis. *C. diphtheriae* can also cause skin and wound infections (cutaneous diphtheria) and, more rarely, affect non-respiratory mucosal sites (genitalia and conjunctivae) (*1, 2, 3*).

**Modes of Transmission**

*C. diphtheriae* is spread from person to person through respiratory droplets, such as from coughing or sneezing, as well as by direct contact with respiratory secretions, infected skin lesions or articles of clothing or other items soiled with discharges from lesions from an infected person (*1, 2*).
Incubation period
Respiratory diphtheria usually occurs after an incubation period of 2 – 5 days but the onset of symptoms can be longer (range 1 – 10 days) (1, 2, 4).

Period of communicability
A person is infectious if virulent bacteria are present in respiratory secretions or, in the case of cutaneous diphtheria, in wounds or lesions. People with untreated diphtheria can be infectious for 2 weeks and up to 4 weeks. The period of communicability can be reduced with appropriate antibiotic use (1, 4, 5).

IPC measures for a patient with suspected or confirmed diphtheria
IPC measures are based on the principles of standard and transmission-based precautions. When implemented effectively, IPC measures can prevent or control transmission, keeping patients, health and care workers and visitors/caregivers safe.

1. Identify and isolate individuals with suspected or confirmed diphtheria.

Screening and triage
In areas where diphtheria is known to be circulating, cases should be screened for rapid identification, assessment (triage) and isolation. Health and care workers should have a heightened awareness of the disease and use a standard set of screening criteria or a case definition (national or the WHO case definition as in Annex 1 of this document).
   i. Screening can be performed in areas such as the emergency unit, outpatient department/primary care clinic, in the community by a community health worker or by telemedicine using a simple algorithm (to be developed based upon the case definition in use in the country and the defined referral pathway).
   ii. Screening for diphtheria should be performed at a distance of at least 1 metre between the patient and the health and care worker.
   iii. Personal protective equipment (PPE) is not required provided the physical distance of at least 1 metre can be maintained.
      a. If at least 1 metre cannot be maintained, put on PPE for droplet precautions and, based upon risk assessment, consider putting on additional PPE such as eye protection, gown and gloves;
      b. Provide the patient and companions with a medical mask and instruct them to follow proper hand hygiene practices and respiratory hygiene/cough etiquette.
   iv. Ideally, the dedicated space for screening and triage of cases should be located at the entrance to the facility and be well-equipped and well-ventilated, including:
      a. Hand hygiene stations and access to alcohol-based hand rub;
      b. Barriers to promote 1 metre distance and avoid overcrowding;
      c. PPE for health and care worker use (e.g. medical mask, eye protection, gowns, gloves);
      d. Medical mask for patient use;
      e. Signage (hand hygiene, cough etiquette);
      f. Waste bins.

Patient placement
Immediately isolate any suspect or confirmed patient:
   i. Place in single, well-ventilated (mechanical or natural ventilation) patient rooms (6,7);
      a. 60 L/s/patient or 6 air changes per hour
      b. If fans are used, they should be placed close to and facing an open window to pull the air and exhaust to the outside.
ii. If single patient rooms are not available, cohorting can be implemented with the following considerations:
   a. Ideally, cohorting should be used only for confirmed cases (see case definition Annex 1).
      i. Cohort patients with respiratory diphtheria separate from patients with cutaneous diphtheria;
      ii. Maintain at least 1 metre distance between patients and draw the curtain between patient beds.
   iii. Suspect cases should remain in single-patient rooms separate from confirmed cases. Prioritize single-patient rooms for patients with respiratory symptoms.
   iv. If the facility does not have the capacity to isolate suspect or confirmed (including cohorted) cases of diphtheria, a referral system should be in place to transport patients to designated treatment facilities that have transmission-based precautions in place. A patient should wear a medical mask or cover any lesion(s) until a single room is available and during transport.

2. **Standard and transmission-based precautions**
   i. Prior to any interaction with a patient, health and care workers should assess the likelihood of potential exposure to infectious agents for themselves and others and should take precautions accordingly. These include, for example, patient placement and the selection and use of PPE (8).
   
   ii. Apply standard precautions for all patients at all times. In addition to applying standard precautions, apply transmission-based precautions for patients with known or suspected infection or colonization with transmissible and/or epidemiologically significant pathogens. For more information, see Standard precautions for the prevention and control of infections: aide-memoire and Transmission-based precautions for the prevention and control of infections: aide-memoire.
   
   iii. **For diphtheria, the following transmission-based precautions are advised (9):**
      a. For respiratory diphtheria - implement droplet precautions with additional PPE if the risk assessment identifies a risk of splashes or sprays and soiling of uniform.
      b. For cutaneous diphtheria - implement contact precautions.

**Prior to entering the patient’s room**

Post signage at the doorway to the patient room or on the curtain surrounding the bed space that clearly alerts health and care workers and visitors to precautions they need to take before entering the patient’s room (e.g. droplet and/or contact precautions).

   i. **For respiratory diphtheria:**
      a. Perform hand hygiene;
      b. Wear a well-fitted medical mask;
      c. If there is a risk of exposure to splashes or sprays when within 1 metre of patient, wear eye protection, gown and gloves.

   ii. **For cutaneous diphtheria:**
      a. Perform hand hygiene;
      b. Wear a gown and gloves;
      c. If there is a risk of exposure to splashes or sprays when within 1 metre of patient, wear a well-fitted medical mask\(^1\) and eye protection to protect mucous membranes in addition to the gloves and gown.

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\(^1\) The medical mask should have an adjustable nose piece and an elastic band or ties that are secured behind the head. If using a mask with ear loops, attach the ear loops with a connector behind the head to improve the fit and minimize gaps in the sides, top and bottom of the mask (19).
iii. For visitors:
   a. Visitors (or caregivers) should wear PPE for droplet precautions when at least 1 metre distance cannot be maintained and be instructed on any additional PPE needs and procedures for putting on and taking off PPE, including hand hygiene;
   b. Identify a designated family member or caregiver for children to limit the number of caregivers/visitors;
   c. If the patient has cutaneous diphtheria, visitors should be instructed to follow contact precautions.

IPC precautions during patient care
i. While wearing PPE:
   a. Refrain from touching eyes, nose or mouth with contaminated gloves or ungloved hands;
   b. Avoid contaminating surfaces not involved with direct patient care (i.e. doorknobs, light switches, mobile phones).

ii. Use disposable or dedicated patient-care equipment:
   a. If this is not possible, clean and disinfect equipment with an approved disinfectant (e.g. with 70% alcohol) before use on other patients.

iii. Avoid unnecessary movement of suspected/confirmed patients:
   a. If the patient must be moved, ensure transmission-based precautions are maintained and place a medical mask on the patient (provided the patient is able to tolerate it);
   b. If the patient has cutaneous diphtheria and must leave the room, cover the patient’s wounds.

After exiting the patient’s room
i. Remove PPE in a designated area (or if a designated area is not available, remove PPE just before exiting the patient room or immediately outside the room) according to the required steps for safely removing PPE.
ii. Perform hand hygiene.

Environmental cleaning and disinfection
i. Clean and disinfect the patient environment at least once per day (refer to Environmental cleaning and infection prevention and control in health care facilities in low- and middle-income countries) (10).
   a. Use an approved disinfectant for health-care settings (e.g.70% alcohol or standard concentrations of 1000 ppm hypochlorite solution (bleach) (11, 12).
   b. Follow the instructions for preparation and use, including contact time.

ii. Ensure appropriate waste management and disposal of PPE according to local regulations:
   a. Properly sort waste and place it in appropriate bins at the point of use.

Duration of precautions for patient with confirmed diphtheria2
i. Maintain transmission-based precautions until elimination of the organism is demonstrated by negative cultures of two samples obtained at least 24 hours apart after completion of effective antimicrobial therapy (1, 3).
ii. During an outbreak where there is limited/no laboratory testing and isolation capacity:
   a. Patients should remain on transmission-based precautions for the duration of their hospitalization;

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2 Criteria for discontinuation of transmission-based precautions are currently under review.
b. Discharged patients should remain in isolation at home (see section 5.1) until they have completed their prescribed antimicrobial therapy (1) and have been symptom-free for at least 24 hours;

c. Discontinuation of home isolation may be considered after 5 days of treatment, according to some data (13).

iii. Maintain use of standard precautions.

Water, sanitation and hygiene (WASH) in the health-care facility

Patient-care activities should be undertaken in a clean and hygienic environment that facilitates practices related to the prevention and control of health-care-associated infections (HAIs), including all elements around WASH infrastructure and services and the availability of appropriate IPC materials and equipment.

For details on recommendations for water, sanitation and hygiene (WASH) and waste-management services for health-care facilities, review WASH FIT: A practical guide for improving quality of care through water, sanitation and hygiene in health care facilities. Second edition.

Health and care worker training, monitoring and exposure management

1. Health and care worker training

Health and care workers are trained on standard and transmission-based precautions (targeted to diphtheria), including the use of standardized screening and triage algorithms to identify and isolate suspected and confirmed cases (see Annex 1 for WHO case definition).

2. Monitoring and management of health and care worker exposure

i. All health and care workers are adequately vaccinated with an age-appropriate diphtheria toxoid-containing vaccine, including booster doses (14, 15).

ii. A protocol for assessing and managing health and care worker occupational exposures should be in place. An occupational exposure is defined as any unprotected contact, including with non-intact skin, percutaneous or muco-cutaneous exposure to blood, body fluids, secretions or excretions, from a suspect or confirmed patient with diphtheria, or unprotected exposure to contaminated equipment or surfaces that may result from or be related to the performance of an employee’s duties (15).

iii. A health and care worker with an exposure should be:

a. provided with information on the signs and symptoms of diphtheria;

b. instructed to self-monitor for signs and symptoms for 10-days after the last date on which they may have been exposed to diphtheria;

c. instructed to seek early medical care if signs and symptoms of diphtheria develop;

iv. Health and care workers who:

a. develop signs or symptoms of infection should be excluded from work duties and clinically assessed for diagnosis and management;

b. have confirmed diphtheria infections should remain isolated until elimination of the organism is demonstrated by negative cultures of two samples obtained at least 24 hours apart after completion of antimicrobial therapy or, in areas where laboratory capacity is limited, after the health and care worker has completed the prescribed therapy (1,3) and has been symptom-free for at least 24 hours.

Criteria for discontinuation of transmission-based precautions are currently under review.
HAI surveillance

1. Surveillance for health-care-associated diphtheria infections
   i. Health and care workers should monitor in-patients for signs and symptoms of diphtheria and, upon suspicion that a patient is infected, immediately isolate and implement transmission-based precautions.
      a. Determine if the patient meets the case definition for suspected or confirmed diphtheria according to the standard (community) case definition (used by local health authorities or the WHO case definition - see Annex 1) OR the health care-associated infection for diphtheria case definition described below.

2. HAI diphtheria case definition
   i. A case of suspected or confirmed diphtheria with recent exposure (within 10 days from symptom onset) to a patient (within at least 1 metre) with suspected or confirmed diphtheria is currently being treated OR cared for by a health and care worker with suspected or confirmed diphtheria in the last 10 days AND after a review that finds no evidence of potential exposure in a community or household setting to a person with symptoms of diphtheria within 10 days from symptom onset (1,3,16).
   ii. Below are suggested criteria to include in a line list for cases identified at least 48 hours after admission to hospital who meet both the standard diphtheria case definition and the HAI diphtheria case definition:
      a. Unique case ID/patient identifier
      b. Date of admission or visit to health-care facility
      c. Demographics: age, patient, visitor/caregiver
      d. Date of onset of symptom(s)
      e. Admission diagnosis or reason for visit
      f. Date of discharge
      g. Vaccination status
      h. Room bed # or ward/unit
   iii. Monitor for onset of symptoms known contacts of patients who develop symptoms of diphtheria after admission to health-care facility or where identification of a case of suspected or confirmed case was delayed.
      a. Roommates of patients with diphtheria and health and care workers who have worked in close proximity (less than 1 metre) to patients who develop symptoms of diphtheria after admission to a health-care facility and prior to initiating transmission-based precautions should be monitored for onset of symptoms.

Setting specific considerations/populations at risk

1. IPC measures for patients discharged with confirmed diphtheria
   i. In the exceptional event that a patient with diphtheria is discharged home prior to completion of the recommended antibiotic therapy, they should be advised to:
      a. Remain at home and refrain from interacting with others outside the household until completion of antibiotic therapy (i.e. do not attend school, childcare, work or go to other public places until the treatment course is complete). If possible, stay in a separate room away from other people and use a separate bathroom if there is one.
      b. Avoid sleeping in the same bed with anyone else.
      c. Avoid sharing personal items. Items such as bedding, eating utensils, linens, towels and electronic devices should be used exclusively by the person with diphtheria.
d. Cover coughs and sneezes with a tissue or cough/sneeze into the elbow or upper sleeve. Always clean hands after coughing or sneezing or after using a tissue.

e. Designate a household member to facilitate care of the patient with diphtheria. The designated person should be in good health; have no underlying chronic conditions; and have had previous diphtheria vaccination.

f. Household members and patients with diphtheria should clean their hands frequently with soap and water and dry them with a paper towel or a cloth towel that no one else is using. An alcohol-based hand sanitizer may also be used.

g. Household members should be provided prophylaxis according to the eligibility definitions for close contacts.

h. Vaccination status of household contacts should be reviewed to ensure they are up to date; even though this might not prevent diphtheria if an exposure has already occurred, it can be protective for any possible future exposures.

2. IPC measures during vaccination campaigns

i. Standard precautions should be followed at all times.

ii. Health and care workers who are working in vaccination campaigns should be adequately vaccinated with an age-appropriate diphtheria toxoid-containing vaccine, including booster doses (15).

Setting up the vaccination area

i. A clean, hygienic area should be identified for administering vaccines.

ii. Persons arriving for vaccination should be screened for signs and symptoms prior to entering the area. If symptoms are identified, these persons should be referred to an appropriate health-care facility for assessment (see section 1a screening).

iii. Ensure hand hygiene stations (alcohol-based hand rub is preferable) are available at points of contact for vaccination procedures.

Administering the vaccinations

i. Health and care workers should follow the WHO 5 moments for hand hygiene for Vaccination campaigns.

ii. PPE is not required when delivering vaccinations, as those being immunized should not have symptoms.

iii. Follow safe injection practices that reflect the 7 steps for safe injections.

iv. Ensure approved sharps containers are available at each vaccination area for immediate disposal of sharps.

v. The use of safety-engineered devices is preferred when administering vaccines (17).

vi. Appropriate waste bins should be available for waste according to standard precautions for waste management (8).

vii. At least twice daily, perform regular cleaning and disinfection of surfaces where vaccines are prepared and administered, with special attention to high-touch areas (10, 18).
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**WHO IPC Public Health Emergencies Working Group**

Mohammad Abd El Fattah Abd El Aziz, Ministry of Health, Egypt; Colin Brown, WHO Collaborating Centre for Reference and Research on Antimicrobial Resistance and Healthcare Associated Infections, United Kingdom; Omar El Hattab, UNICEF, United States of America; Dale Fisher, Yong Loo Lin School of Medicine, National University of Singapore, Singapore; Carole Fry, UK Health Security Agency, United Kingdom; Muzammil Gadanya, Nigeria CDC, Nigeria; Zahir Hirji, Infection Prevention and Control (IPAC) Canada, Canada; Emilio Hornsey, UK Public Health Rapid Support Team, United Kingdom; Mushtaq Husain, Institute of Epidemiology, Disease Control & Research, Bangladesh; Devin Jopp, Association for Professionals in Infection Control and Epidemiology (APIC), United States of America; Elizabeth Katwesigye, Ministry of Health, Uganda; Fernanda Lessa, International Infection Control Program, US Centers for Disease Control and Prevention (CDC), United States of America; Ling Moi Lin, Asia Pacific Society of Infection Control (APSIC) Singapore; Paul Malpicked, US Centers for Disease Control and Prevention (CDC), United States of America; Kalisvar Marimuthu, National Centre for Infectious Diseases, Tan Tock Seng Hospital, Singapore; Nico Mutters, European Committee on Infection Control (EUCIC), Germany; Pierre-Yves Oger, UNICEF, France; Ben Park, The Global Fund, Switzerland; Mahbubur Rahman, Institute of Epidemiology Disease Control and Research, Bangladesh; Kemal Rasa, World Surgical Infection Society (WSIS), Türkiye; Jennifer Rickard, Surgical Infection Society, United States of America; Muna Abu Sin, Robert Koch Institute, Belgium; Sara Tomczyk, Robert Koch Institute, Germany; Katie Wilson, International Infection Control Programme, US Centers for Disease Control and Prevention (CDC), United States of America; Deborah Yokoe, The Society for Healthcare Epidemiology of America (SHEA), United States of America.

**WHO Regional Offices**

Lucia Alonso, Regional Office for the Americas; Deborah Barassa, Regional Office for Africa; Landry Cihambanya, Regional Office for Africa; Ana Paula Coutinho Rehse, Regional Office for Europe; Iman Heweidy, Regional Office for the Eastern Mediterranean; Pilar Ramon-Pardo Regional Office for the Americas; Aparna Shah, Regional Office for South-East Asia; Li Zhao, Regional Office for the Western Pacific

**WHO Headquarters**

From the Infection Prevention and Control Unit, Country Readiness Strengthening, WHO Health Emergencies Programme (WHE):

Devika Dixit; Kathleen Dunn; Hannah Hamilton; Hibak Mahamed; Madison Moon; Maria Clara Padoveze; Nosheen Usman.

From the Infection Prevention and Control (IPC) Unit, IPC Taskforce and the Global IPC Network:

Benedetta Allegranzi; Miranda Deeves.

From the Clinical Management Unit, Country Readiness Strengthening, WHO Health Emergencies Programme (WHE):

Steven McGloughlin.

**External Peer Review**

Eimear Brannigan, AMRIC Division, Health Service Executive, Ireland; Nizam Dimani, Southern Health & Social Care Trust, United Kingdom; Shaheen Mehtar, Stellenbosch University, South Africa; Paul Ananth Tambyah, National University Hospital Singapore, Singapore; Joseph Tannous, Emirates Health Services, United Arab Emirates.
References

1. Field guide for preparedness and response to diphtheria outbreaks in the Western Pacific Region. World Health Organization, Regional Office for the Western Pacific; 2023. (https://www.who.int/publications/i/item/9789290619925, accessed 29 November 2023)


Annex 1. WHO case definition for diphtheria

Suspected case
Any person with an illness of the upper respiratory tract with: pharyngitis, nasopharyngitis, tonsillitis or laryngitis; **AND** adherent pseudomembrane of the pharynx, tonsils, larynx and/or nose.

Final case classification

Laboratory-confirmed case
Laboratory-confirmed case: a person with Corynebacterium spp. isolated by culture and positive for toxin production, regardless of symptoms.

i. Laboratory-confirmed classic respiratory diphtheria cases meet the suspected case definition and are laboratory-confirmed as defined above.

ii. Laboratory-confirmed, mild respiratory/asymptomatic diphtheria cases have some respiratory symptoms such as pharyngitis and tonsillitis, but no pseudomembrane, or no symptoms (usually identified via contact tracing).

iii. Non-respiratory, laboratory-confirmed diphtheria cases have a skin lesion or non-respiratory mucosal infection (for example, eye, ear or genitalia) from which Corynebacterium spp. is isolated by culture and tests positive for toxin production.

Epidemiologically linked case: a person who meets the definition of a suspected case and is linked epidemiologically to a laboratory-confirmed case.

Clinically compatible case: a person who meets the definition of a suspected case and lacks both a confirmatory laboratory test result and epidemiologic linkage to a laboratory-confirmed case.

Discarded case/non-case: a suspected case who meets either of these criteria: Corynebacterium spp. but negative Elek test (non-toxigenic Corynebacterium) OR negative PCR for the diphtheria toxin (tox) gene (3).

This operational guide is tailored to address essential IPC measures required within the context of a diphtheria outbreak. This document serves as a single reference resource for implementing IPC measures by consolidating existing WHO documents, such as guidelines, guidance documents, fact sheets and training modules. Such documents were selected from the WHO database based on their applicability and information relevant to IPC practice.

For some topics, an additional rapid search for literature was conducted as well as a review of existing guidelines from reputable agencies such as the US Centers for Disease Control and Prevention and the European Centre for Disease Prevention and Control and information was included where appropriate. Further reviews are planned for specific areas, such as discontinuation of isolation requirements, in which any additional evidence will be evaluated according to GRADE and advice adjusted accordingly. These areas have been footnoted in the document.

The standing IPC for Public Health Emergencies working group of external experts reviewed this document as did various other units within WHO, including focal points within the six WHO regions; their feedback was integrated into the final document. Further external peer review members were identified for specific technical areas and provided additional review of the guide. Conflict of interest declaration forms for external reviewers were collected and reviewed according to WHO policy. No conflicts of interest were identified. For more information on authorship and contributions, please refer to the acknowledgement section.
Annex 3. Resources

Diphtheria IPC and WASH resources


General IPC and WASH resources

IPC


WASH


For further information, please contact:

WHO Health Emergencies (WHE) IPC & WASH
https://www.who.int/teams/health-care-readiness/infection-prevention-and-control
Email: wheipc@who.int

World Health Organization
Avenue Appia 20, CH-1211 Geneva 27, Switzerland