
# National Diphtheria Surveillance and Outbreak Response Guideline

NCDC
NIGERIA CENTRE FOR DISEASE CONTROL AND PREVENTION

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This document was designed by Breakthrough **ACTION**-Nigeria

# About NCDC

The Nigeria Centre for Disease Control and Prevention (NCDC) is the national public health institute with the mandate to lead the preparedness, detection and response to infectious disease outbreaks and public health emergencies. The first formal step to establish the NCDC took place in 2011 when some departments in the Ministry of Health, including the Epidemiology Division, the Avian Influenza Project and its laboratories; and the Nigeria Field Epidemiology and Laboratory Training Programme (NFELTP) were moved to form the nucleus of the agency. The Bill for an Act to establish NCDC was signed into law in November 2018, by President Muhammadu Buhari.

### Vision

A healthier and safe Nigeria through the prevention and control of diseases of public health importance.

### Mission

To protect the health of Nigerians through evidence-based prevention, integrated disease surveillance and response activities, using a one health approach, guided by research and led by a skilled workforce.

### Core Functions

- Prevent, detect, and control diseases of public health importance.
- Coordinate surveillance systems to collect, analyze and interpret data on diseases of public health importance.
- Support states in responding to small outbreaks and lead the response to large disease outbreaks.
- Develop and maintain a network of reference and specialized laboratories.

- Conduct, collate, synthesize, and disseminate public health research to inform policy.
- Lead Nigeria's engagement with the international community on diseases of public health relevance
- Organization of the Nigeria Centre for Disease Control and Prevention

The NCDC under the leadership of the Director General has a staff size of about 500. At the national level, this comprises staff working across three sites - the Headquarters and National Reference Laboratory (NRL), located in Abuja as well as the Central Public Health Laboratory (CPHL) in Lagos State, a campus of the NRL. At the subnational level, there are State Surveillance Officers across the 36 States of the federation and the Federal Capital Territory (FCT).

The NCDC currently operates through eight departments. These include:

- Public Health Laboratory Services
- Health Emergency Preparedness and Response
- Planning, Research and Statistics
- Surveillance and Epidemiology
- Administration and Human Resources
- Finance and Accounts
- Subnational Support Department
- Disease Prevention and Health Promotion Department

# Foreword

The Nigeria Centre for Disease Control and Prevention (NCDC) is Nigeria's primary national public health institute entrusted with leading efforts to prevent, prepare for, detect, and respond to outbreaks of infectious diseases and public health emergencies.

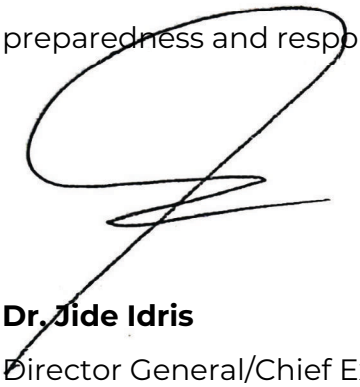
As a parastatal of the Federal Ministry of Health (FMoH), the NCDC is responsible for safeguarding the health of Nigerians through the prevention, detection, and control of communicable diseases. This document was developed in response to increasing stakeholder demand for streamlined coordination efforts in preventing and responding to diphtheria outbreaks in Nigeria.

It has been a privilege to oversee the development of the National Diphtheria Surveillance and Outbreak Response Guideline. In 2022, the NCDC responded to its first outbreak of diphtheria since its establishment, leading a multi-sectoral response. The availability of this technical document will bolster response operations in the current outbreak and in the future.

The purpose of this document is to offer guidance on preventing, detecting, and responding to diphtheria in Nigeria. It outlines specific measures such as preventing the disease, early detection of suspected cases, prompt reporting to higher authorities, activating coordinated responses at national and sub-national levels during outbreaks, enhancing surveillance and laboratory confirmation capabilities at all levels, and using this information for immediate public health responses.

The document encompasses all aspects of control including prevention strategies, surveillance methods, laboratory diagnostics, infection prevention and control (IPC), case management protocols, risk communication and community engagement (RCCE) strategies, vaccine logistics, Incident Management System (IMS), and practical annexes. Adhering to this guideline will enhance our ability to respond to any future outbreaks of diphtheria in Nigeria.

Therefore, I encourage all stakeholders involved in frontline outbreak control efforts to utilize this document as a comprehensive guide for diphtheria outbreak preparedness and response.



**Dr. Jide Idris**
Director General/Chief Executive Officer
Nigeria Centre for Disease Control and Prevention

# Acknowledgement

The Nigeria Centre for Disease Control wishes to express its immense gratitude to the leadership of the FMoH, especially the CMHSW, Prof. Muhammad Ali Pate for his guidance and leadership.
We also appreciate the joint leadership role with the NPHCDCA during the 2022 Diphtheria outbreak, an experience that supported the development of these guidelines.

We thank all members of the diphtheria EOC. Our since appreciation goes to our partners especially the MSF, U.S CDC, UKHSA, Africa CDC, WHO, UNICEF, NRCS/IFRC, ALIMA, AFENET, BA-Nigeria and CSOs that continue to support response activities at the national or sub-national levels. We remain grateful for all your support now and always.

# Acronyms

| | |
|---|---|
| AEFI | Adverse Event Following Immunization |
| Africa CDC | Africa Centre for Disease Control |
| AFENET | Africa Field Epidemiology Network |
| ALIMA | Alliance for Internation Medical Action |
| BA-N | Breakthrough Action Nigeria |
| CD | Corynebacterium Diphtheria |
| CHIP | Community Health Influencers and Promoters |
| DSNO | Disease Surveillance and Notification Officer |
| EOC | Emergency Operations Centre |
| EPR | Emergency Preparedness and Response |
| EPRC | Emergency Preparedness and Response Committee |
| FMoH | Federal Ministry of Health |
| HF | Healthcare Facility |
| IAP | Incident Action Plan |
| IDP | Internally Displaced Persons |
| IDSR | Integrated Disease Surveillance and Response |
| IFRC | International Federation of Red Cross and Red Crescent Societies |
| IHR | International Health Regulation |

| | |
|---|---|
| IMS | Incident Management System |
| IMT | Incident Management Team |
| IPC | Infection Prevention and Control |
| LGAs | Local Government Areas |
| MDAs | Ministries Department and Agencies |
| MSF | Medecins Sans Frontieres |
| NCDC | Nigeria Centre For Disease Control and Prevention |
| NEMA | National Emergency Management Agency |
| NiMET | Nigerian Meteorological Agency |
| NOA | National Orientation Agency |
| NPHCDA | National Primary Healthcare Development Agency |
| NRCS | Nigeria Red Cross Society |
| NYSC | National Youth Service Corp |
| PCR | Polymerase Chain Reaction |
| PHEOC | Public Health Emergency Operations Centre |
| RRT | Rapid Response Team |
| SEMA | State Emergency Management Agency |
| SMoH | State Ministry of Health |
| SOPs | Standard Operating Procedures |
| SPHCDA | State Primary Healthcare Development Agency |

| | |
|---|---|
| TP | Total Population |
| UKHSA | United Kingdom Health Security Agency |
| UNICEF | United Nations Children Fund |
| U.S CDC | United States Centre for Disease Control and Prevention |
| VCM | Voluntary Community Mobilizers |
| WHO | World Health Organization |

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# Introduction

Diphtheria is a vaccine-preventable disease caused by bacteria of the Corynebacterium species. It is mostly caused by toxin-producing Corynebacterium diphtheriae and rarely by toxin-producing strains of C. ulcerans and C. pseudotuberculosis. The most common type of diphtheria is classic respiratory diphtheria, whereby the exotoxin produced characteristically causes the formation of a pseudo-membrane in the upper respiratory tract and damages other organs, usually the myocardium and peripheral nerves. Acute respiratory obstruction, acute systemic toxicity, myocarditis, and neurologic complications are the usual causes of death.

In the 2022 diphtheria outbreak in Nigeria, common causes of death include respiratory distress, Acute kidney injury (AKI), heart disease (Myocarditis), and Bleeding disorders. The infection can also affect the skin (cutaneous diphtheria). More rarely, it can affect mucous membranes at other non-respiratory sites, such as genitalia and conjunctiva.

C. diphtheriae is transmitted from person to person by close and direct contact (respiratory secretions), in contrast, C. ulcerans and C. pseudotuberculosis are zoonotic infections, not transmitted from person to person. The incubation period of C. diphtheriae is two to five days (range 1– 10 days). A person is infectious when virulent bacteria are present in the respiratory secretions, usually two weeks without antibiotics, and seldom more than six weeks. In rare cases, chronic carriers may shed organisms and transmit the infection for six months or more. Skin lesions are often chronic and infectious for longer periods. Effective antibiotic therapy promptly terminates shedding in about one or two days.

Diphtheria has the potential for epidemics and recent outbreaks have highlighted the need for adequate surveillance and epidemic preparedness. Diphtheria surveillance would provide country/state-specific epidemiological data to be able to formulate appropriate control strategies. Surveillance data can be used to monitor levels of immunization coverage (target >90%) and disease as a measure of the impact of immunization programs.

In the past decade, there have been approximately 4,000–8,000 diphtheria cases reported annually worldwide. Global diphtheria cases reported to WHO are likely an underestimation of the real burden of the disease due to under-reporting, exclusion of non-respiratory diphtheria cases, and exclusion of cases caused by other potentially toxigenic species.

## Scope

This document is designed to guide national and sub-national response health authorities and key stakeholders involved in diphtheria preparedness and response, to prepare for, detect and respond to diphtheria outbreaks. This guideline covers the following technical areas: coordination, surveillance and epidemiology, infection prevention and control, case management, laboratory diagnosis, logistics, risk communication and community engagement.

## Aim

To provide guidance to public health officials at the national, state and local government levels on the prevention, detection and response to diphtheria outbreak in Nigeria.

## Objectives

- To guide the prevention, early detection and response to suspected diphtheria cases and prompt reporting of such cases from health facilities to higher levels for public health action.
- To guide the activation of response coordination structures at national and sub-national levels during outbreaks.
- To strengthen surveillance and laboratory confirmation at all levels and use of this information for immediate public health control measures.
- To guide preparedness and response plans for diphtheria outbreak.
- To improve case management outcomes and enhance adherence to IPC standards and protocols.


# 1.0

## Surveillance

# 1.0 Surveillance

### Focus of Surveillance on Respiratory Disease Caused by Toxigenic Corynebacterium Species

Classic respiratory diphtheria caused by toxigenic Corynebacteria species is the focus of the surveillance guidelines. This is because respiratory diphtheria constitutes most clinical diphtheria cases, is the most severe form of clinical diphtheria, and is easier to detect by surveillance systems. Clinically relevant mucosal and cutaneous conditions can spread the bacterium, especially in developing and tropical regions. Non-respiratory presentations, which account for around 2% of all diphtheria cases globally, are redundant and require screening for many patients using the clinical case definition to find them. However, Asymptomatic patients can be found by effective contact tracing.

When a state has a robust diphtheria surveillance system in place, it can pick other forms of diphtheria (cutaneous and mucosal).

### Rationale and Objectives of Diphtheria Surveillance

The objectives of diphtheria surveillance are to:

- Improve early detection of an outbreak to launch a prompt investigation using the 7-1-7 metrics.
- Enhance timely response to control the spread of the disease using the 7-1-7 metrics.
- Monitor disease burden and define transmission patterns.
- 
- Guide vaccination programs, including reactive vaccinations, booster doses or a different vaccine formulation where necessary.

### Audience and Purpose of This Guideline

The target audience of this guideline are health authorities, healthcare workers at all levels, and partners. The purpose is to provide guidance on diphtheria outbreak preparedness, early detection, response, and recovery.

## Public Health Importance

Diphtheria remains an important cause of morbidity and mortality especially in developing countries where diphtheria immunization coverage rates fall below the recommended 95% to achieve diphtheria elimination. The low immunization coverage leads to periodic diphtheria outbreaks with resultant complications. Preparedness and early detection are of great importance to reduce the deleterious effect of diphtheria outbreak.

## Preparedness

### Diphtheria outbreak preparedness

Preparedness is a crucial element of response against infectious disease threats under the International Health Regulations (IHR). It involves the development and maintenance of national, state, LGA and ward level public health emergency response plans. Other components of preparedness include risk mapping of potential threats, the identification and maintenance of available resources, including stockpiles and the capacity to support operations at all levels during diphtheria outbreaks.

While prevention of diphtheria is critical to health systems, there are instances when the health system must scale-up actions to be ready to respond to an imminent diphtheria outbreak and limit its potential spread.

Diphtheria response activities are coordinated at the Public Health Emergency Operations Centre led by an Incident Management System structure. A Public Health Emergency Operations Centre (PHEOC) is central for coordinating operational information and resources for the strategic management of public health emergencies. The EOC provides communication and information tools and services, and a management system during a response.

### Levels of preparedness and expected activities.

Diphtheria outbreaks response entails preparedness at all levels: National, States, LGAs, health facilities, and communities. The following activities are recommended to strengthen preparations for the outbreaks:

***Preparedness Level and Activities***

| LEVEL | ACTIVITIES |
|---|---|
| Community informants | • Create awareness to community members on community case definitions, identification, and reporting.<br>• Ensure his/her contact detail are available to the community members. |
| Health facility | • Knowledgeable of case definitions for diphtheria<br>• Awareness of reporting procedures<br>• Continued identification and laboratory confirmation of suspected cases<br>· **Training on:**<br>• Case definitions and identification<br>• Surveillance and reporting processes and procedures, including zero reporting.<br>• Use of standardized case-based forms<br>• Case management and referral mechanisms<br>• Designated reference laboratories where specimens should be sent to for confirmation and serotyping.<br>• Sample collection, handling, and transportation<br>• Infection prevention and control measures |
| LGA | • Convene and activate Emergency Preparedness and Response (EPR) Committee at the LGA level as indicated in the IDSR technical guideline.<br>• Provide relevant information to designated health facility surveillance focal persons.<br>• Train community informants on how to fill alert form, community case definition, identification and reporting.<br>• Analyse results of previous year's epidemics and vaccination campaigns to determine ward/community at risk. |

| | |
|---|---|
| | • Train healthcare workers on case definitions, reporting procedures, and collection of samples.<br>• Distribute consumables, sample collection kits, data collection tools etc., to health facilities |
| State | • Convene Emergency Preparedness and Response (EPR) Committee as indicated in the IDSR technical guideline.<br>• Complete the diphtheria Preparedness Checklist (Appendix 1).<br>• Analyse the results of each LGA level of preparedness assessment checklist.<br>• Analyse results of previous year's epidemics and vaccination campaigns to determine which LGAs at risk.<br>• EPR Committee should develop Preparedness and Response Plan based on risk assessments and specific resources available for response.<br>• Provide estimates of the population at risk.<br>• Evaluate for outbreak potential in neighboring States.<br>• Provides estimates of quantities of drugs, vaccines, and supplies for the outbreak.<br>• Train LGA DSNOs in use of case-based forms, line list compilation and reporting procedures.<br>• Ensure that training at LGA and health facility levels have been completed.<br>• Pre-position diagnostic reagents, test kits and surveillance materials (templates, reporting forms) within LGAs and health facilities based on NCDC guidance and recommendations.<br>• Ensure adequate supplies of vaccines and consumables.<br>• Print and distribute guidelines, surveillance data tools, and SOPs to LGAs. |

| | |
|---|---|
| National | • Analyse results of each State's level of preparedness assessment checklist.<br>• Ensure that training in the use of standard reporting forms and reporting procedures have been completed in all States.<br>• Analyse results of previous year's epidemics and vaccination campaigns to determine which States/LGAs are likely to be affected in the coming epidemic season.<br>• Provide feedback of the result of the analysis to States with recommendations for pre-positioning of diagnostic reagents, test kits and surveillance materials (templates, reporting forms) within LGAs and health facilities.<br>• Work with partners and relevant MDAs to preposition medicines and medical commodities such as vaccines (NPHCDA) and laboratory reagents (NCDC) in high-risk States.<br>• Support and supervise trainings at all levels.<br>• Support states to print and distribute guidelines, surveillance data tools, and SOPs. |
| **LEVEL** | **ACTIVITIES** |
| Community informants | • Awareness to community members on community case definitions, identification, and reporting<br>• Ensure his/her contact detail are available to the community members. |

| | |
|---|---|
| Health facility | • Awareness of case definitions for diphtheria<br>• Awareness of reporting procedures<br>• Continued identification and laboratory confirmation of suspected cases<br>· **Training on:**<br>• Case definitions and identification<br>• How and to whom to report cases, including zero reporting<br>• Use of standardized case-based forms<br>• Awareness of reference laboratory where specimens should be sent to for confirmation and serotyping.<br>• Sample collection, handling, and transportation |
| LGA | • Convene Emergency Preparedness and Response (EPR) Committee at the LGA level as indicated in the IDSR technical guideline.<br>• Provide information to designated health facility surveillance focal persons.<br>• Train community informants on how to fill alert form, community case definition, identification and reporting.<br>• Analyse results of previous year's epidemics and vaccination campaigns to determine ward/community at risk.<br>• Train healthcare workers on case definitions, reporting procedures, and collection of samples.<br>• Distribute consumables, sample collection kits, data collection tools etc., to health facilities |

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|---|---|
| State | • Convene Emergency Preparedness and Response (EPR) Committee as indicated in the IDSR technical guideline.<br>• Complete the diphtheria Preparedness Checklist (Appendix 1).<br>• Analyse the results of each LGA level of preparedness assessment checklist.<br>• Analyse results of previous year's epidemics and vaccination campaigns to determine which LGAs at risk.<br>• EPR Committee should develop Preparedness and Response Plan based on risk assessments and specific resources available for response.<br>• Provide estimates of the population at risk.<br>• Evaluate for outbreak potential in neighboring States.<br>• Provides estimates of quantities of drugs, vaccines, and supplies for the outbreak.<br>• Train LGA DSNOs in use of case-based forms, line list compilation and reporting procedures.<br>• Ensure that training at LGA and health facility levels have been completed.<br>• Pre-position diagnostic reagents, test kits and surveillance materials (templates, reporting forms) within LGAs and health facilities based on NCDC guidance and recommendations.<br>• Ensure adequate supplies of vaccines and consumables.<br>• Print and distribute guidelines, surveillance data tools, and SOPs to LGAs. |

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## Identify and Record Cases

### Case Definitions

#### Standard Case definition

- **A suspected case** of diphtheria is defined as:

A case of an upper respiratory tract infection characterized by:

- laryngitis or pharyngitis or tonsillitis.

AND

- adherent membranes of the tonsils, pharynx, and nose

A Diphtheria Case is said to be a confirmed case if it meets the following criteria:

- **A Laboratory-confirmed case** of diphtheria is defined as a person who has Corynebacterium spp. isolated by culture and is positive for toxin production, regardless of symptoms.
- **An Epidemiologically Linked case** of diphtheria is defined as a person who meets the definition of a suspected case and had close contact with a laboratory-confirmed within ten days of his/her symptom onset. This classification is done by a trained disease surveillance and notification officer. Note: This linkage can be to an epidemiologically linked case in a region where an outbreak is confirmed.
- **Clinically compatible case:** This refers to a case of diphtheria that meets the criteria for a suspected case but does not have a confirmatory laboratory test result or a known epidemiological link to a laboratory-confirmed case.

- **A discarded case of diphtheria** is a suspected case that meets either of these criteria:
    - Nontoxigenic Corynebacterium (negative Elek test)

  OR
    - Negative PCR for the diphtheria toxin (tox) gene.

**Community Case definition**

**What is the Community-case of diphtheria?**

**Suspected Case**

Any person who has sore throat with difficulty or pain while swallowing **OR** refusal to feed in children less than 5 years with or without neck swelling.

**Explanations on the case definition.**

**Pharyngitis and tonsillitis**: fever with pain and redness of the throat and/or tonsils.

**Laryngitis**: often presents as hoarseness of voice and cough.

**Pseudo-membrane**: initially isolated spots of grey or white patches appear in the

tonsillar and pharyngeal area. These spots often coalesce within a day to form a confluent sharply demarcated pseudo membrane that becomes progressively thicker, more tightly adherent to the underlying tissue, and darker grey in color. Dislodging the membrane is likely to cause bleeding. Unlike the exudate in streptococcal pharyngitis, the diphtheritic pseudo membrane often extends beyond the margin of the tonsils onto the tonsillar pillars, palate, or uvula.

**Date of Onset:** The date of onset for diphtheria should be considered as the date of onset of sore throat (laryngitis, pharyngitis, and tonsillitis).

**Report Suspected Cases**

**Case Detection and Reporting**

The detection and investigation of diphtheria outbreaks is a multidisciplinary task requiring training and skills in public health surveillance, epidemiology, and laboratory management. Early detection and investigation maximize the opportunity for early control of the outbreak and thus minimize the impact of the outbreak.

**Signal Detection and Verification**

Signals are any data or information that may represent an event of potential acute risk to human health and that require a rapid response. Signals of diphtheria-like illness may consist of individual reports or clusters of sore throat cases or deaths, notified through event- or community-based surveillance systems. Signal verification is an essential step in confirming that a signal has truly occurred. Signals from community-based surveillance will require an epidemiologic and laboratory investigation for verification.

**Case Reporting**

The reporting network for diphtheria surveillance should consist of reporting sites such as communities and health facilities (private and public) with the reporting channels as follows;

- Communities
- Health facilities
- Local Government
- State Government
- National

All reporting sites should immediately report a suspected case of diphtheria by the fastest mode of communication to the concerned health/surveillance authority. The minimum information required to report a case is:

- patient identification,
- contact details, and
- minimal medical history.

A standard Case Based Reporting form (IDSR 001) should be used to send this report from the surveillance reporting sites to the next reporting level. Sample should be taken (where feasible), and the Laboratory Form (IDSR 001B) should be used.

## ANALYSE

When more than one case of suspected diphtheria is reported from a reporting site, a line list of cases should be maintained at that site using the IDSR 001C line listing form (See Appendix 5).

A unique case identification number (Epid number) should be given to each suspected case. This case number should follow the standard pattern for Epid number in Nigeria which is a three-letter combination of the country code, state code, LGA code and a three digit case number.

### Data Analysis

Descriptive quantitative data analysis should be done continuously by the LGA and State to characterize the outbreak with respect to time, place, and person.

Minimum output from descriptive analysis should include:

a) **Time:** Epidemic curves during outbreaks (Epi curve – frequency of cases by date of sore throat onset)

b) **Person:**
   - Age/age group distribution (<1 year, 2-4yrs, 5-9yrs, 10-14yrs, etc.)
   - Sex distribution (male/female)
   - Vaccination status of cases (zero dose, 1 dose, 2 doses, >2 doses)
   - Outcome (alive/dead)

c) **Place:** Distribution of cases by settlement/ward/LGA/state

To evaluate the risk of further transmission, morbidity and mortality, the following factors should be taken into consideration:

- The magnitude of the outbreak at the time of the initial investigation
- Population characteristics such as size, density, movement, and setting
- Under-five mortality rates
- Vaccination coverage rates in the area
- Period of the year: seasonal outbreaks or holidays, festivals and social events that would increase opportunities for the spread.
- Cases reported and comparison with previous years and
- Access to health services.

## INVESTIGATE AND CONFIRM SUSPECTED CASES, AND OUTBREAKS

### Detailed Case Investigation

A trained disease surveillance officer should be responsible for case investigation within 48 hours of case reporting. A detailed case investigation should include:

- Completing a CIF form (see annex for sample of a CIF)
- Collecting a nasal and pharyngeal specimen, and
- Line listing of close contact. (see annex for sample of a line listing form)

For every suspected case, if any of the above are not conducted, then the investigation will be considered inadequate.

Note: Completing the old case-based reporting form (IDSR 001A) and collection of samples alone is not enough.

### Definition of Diphtheria Outbreak

**i. A suspected diphtheria outbreak** is when the threshold in the number of suspected cases in a defined geographical area (LGA and State) is exceeded (5 reported suspected cases within 2-incubation periods (20-days) within a community or LGA).

**ii. A confirmed diphtheria outbreak** is defined as the occurrence of at least 1 laboratory confirmed diphtheria case.

**Prioritization of testing for confirmation of diphtheria outbreaks**

The system should aim to test at least 80% of samples of all suspected cases. However, where resources are limited, further testing of samples for the purpose of confirmation of an outbreak for that location/LGA is no longer necessary while that outbreak is ongoing. Five (5) samples from a location where diphtheria outbreak has been confirmed should be tested every 20 days and should continue in each cycle until the end of the outbreak is declared. Priority should be given to transportation and testing of samples from a location where the outbreak has not been previously confirmed.

**Contact Tracing and Management**

**Who is a contact?**

A contact is defined as "a person who was within 3 feet (1 meter) of a diphtheria case for more than 15 minutes, or who had face-to-face contact, or who had contact with respiratory or other secretions, or who shared the same sleeping quarters, during the case's infectious period." The infectious period is defined as two days before the onset of symptoms or the date of the positive test, whichever comes first, until 20days after the onset of symptoms or until the person has been treated and tested negative for the bacteria.

**Contact Tracing Steps**

- Contact identification: This is done by engaging the patients or their caregivers.
- Contact listing refers to the systematic process of identifying and documenting individuals who have been in close contact with a confirmed case of a Diphtheria using contact line-list form (See appendix for contact listing form).
- Contact follow-up: This refers to the process of monitoring and assessing the contacts using a standardized checklist for a period of ten days through phone calls and physical visits.
- Contact discharge: A contact is discharged if:
    - Contact has been monitored for 10 days without symptoms.
    - Contact developed symptoms while being monitored and is classified as a suspected case.

- Contact is tested without symptoms (for whatever reason) and is found to be positive, in which case the contact is classified as a positive case.

NOTE: This guideline does not recommend testing of contacts until they develop symptoms.

**Types of Surveillance Recommended**

Active and passive surveillance for diphtheria need to be enhanced using a facility and community-based approach. Diphtheria is one of the diseases prioritized for case-based surveillance and should be mandatory for all providers who detect cases to promptly report them. All suspected cases should ideally undergo laboratory testing for confirmation. Case-based surveillance may not be feasible during large outbreaks since it would be logistically difficult to test every sample from every suspected case in the laboratory. Once a case is confirmed to be toxigenic diphtheria, subsequent suspected cases can be confirmed by epidemiologically linking all other cases within a geographical area where transmission is plausible. Reconfirming diphtheria among new cases should continue every two incubation periods.

When suspected cases of diphtheria are identified from referral and active case search, they should be reported based as prescribed by the IDSR guidelines.

**Detection and Investigation**

**Detection of Diphtheria Outbreaks**

Early detection and investigation maximize the opportunity for early control of the outbreak and thus minimize the impact of the outbreak. A single laboratory-confirmed case of diphtheria is considered an outbreak of diphtheria in Nigeria. An outbreak can be declared over when no new confirmed cases are detected after the two incubation periods of the last case.

**Routine surveillance data review and analysis**

Suspected outbreaks can also be detected through the routine review and analysis of diphtheria surveillance data. In this case, the standard case definition for

diphtheria outbreaks will be used to confirm whether or not a suspected outbreak exists or not.

**Notification of Suspected Diphtheria Outbreak**

When an outbreak is suspected, the LGA DSNO should notify all community volunteers, community informants, facility surveillance focal persons and facility-in-charges in the LGA to intensify surveillance. The state (SMOH and SPHCDA) should also be informed.

Once an outbreak of diphtheria is confirmed, an official communication should be sent by the state to the affected LGA, National and partners.

**Confirm Occurrence of an Outbreak**

For all suspected cases that meets the case definition, an Immediate case-based reporting form(001A) is filled, sample (nasal and pharyngeal specimens) is collected, and the laboratory form(001B) is filled. A Case Investigation Form (CIF) is filled and reported on SORMAS.

Laboratory testing (both culture and ELEK test) is necessary to confirm an outbreak, but the inability to get laboratory confirmation should not delay the implementation of the initial outbreak response, including case management and isolation.

Filling of case investigation form and collection of specimens for all suspected cases continues until a diphtheria outbreak is confirmed (occurrence of at least 1 ELEK positive test for diphtheria case). Once the diphtheria outbreak is confirmed, subsequent confirmation of suspected cases from the same geographical location can be based on epidemiological linkage.

**Surveillance Outbreak Response**

Detection of an outbreak relies on the ability of the responsible authority to recognize an increase in diphtheria cases significantly above the number normally expected. This recognition is simpler if a routine surveillance system collects either

summary or case-based information on clinical and confirmed cases of diphtheria. As soon as an outbreak is suspected, the risk of the outbreak extending into a large one, with high morbidity and mortality, must be assessed. This evaluation is needed to determine susceptibility and potential spread in both affected and neighboring communities as well as the appropriate vaccination response to control the outbreak. To evaluate the risk of further transmission, morbidity and mortality, the following factors should be taken into consideration:

- Population characteristics such as size, density, movement, and setting.
- Under five mortality rates.
- Routine vaccination coverage in the area
- Period of the year: seasonal outbreaks or holidays, festivals and social events that would increase opportunities for spread.
- Cases reported and comparison with previous years; and
- Access to health services.

**Surveillance Performance Indicators**

Surveillance should be evaluated at least yearly to ensure that the country is able to meet the objectives of surveillance accurately. Below are suggested surveillance performance indicators.

| SURVEILLANCE ATTRIBUTE | INDICATOR | TARGET | HOW TO CALCULATE (NUMERATOR / DENOMINATOR) | COMMENTS |
|---|---|---|---|---|
| ADEQUACY OF INVESTIGATION | Percentage of all suspected diphtheria cases that have had an adequate investigation | >= 80% | # of suspected cases of diphtheria for which an adequate investigation was done / # of suspected diphtheria cases x 100 | Note 1: Adequate investigations include completing a case investigation form, collecting a nasal and pharyngeal specimen, line listing of close contacts. Note 2: For any case, if any of the above are not conducted, the investigation will be considered inadequate. |
| TIMELINESS OF INVESTIGATION | Percentage of all suspected diphtheria cases that have had an investigation initiated within 48 hours of notification | >= 80% | # of suspected cases of diphtheria for which an investigation initiated within 48 hours of notification / # of suspected diphtheria cases x 100 | |
| SPECIMEN COLLECTION | Percentage of suspected diphtheria cases with two specimens collected (pharyngeal swab and a nasal swab) | >= 80% | # of suspected cases of diphtheria with 2 specimens collected / # of suspected diphtheria cases x 100 | During outbreak investigations where epidemiological linkage increases, epidemiologically linked cases should be removed from the denominator. |
| TIMELINESS OF SPECIMEN COLLECTION | Percentage of suspected diphtheria cases with specimens taken before antibiotic administration | >= 80% | # of suspected cases of diphtheria with a specimen collected before antibiotics / # of suspected diphtheria cases with a specimen collected x 100 | Indicator only applies to public laboratories |
| TOXIGENICITY TESTING RATE | Percentage of specimens tested for toxigenicity by Elek testing | >= 80% | # specimens tested for toxigenicity by Elek testing / # of isolates received x 100 | |
| TIMELINESS OF SPECIMEN TRANSPORT | Percentage of specimens received at the laboratory within 2 days of collection | >= 80% | # of specimens received within 2 days of collection by laboratory / # of specimens x 100 | Indicator only applies to public laboratories |
| TIMELINESS OF REPORTING LABORATORY RESULTS | Percentage of specimens tested by culture with results reported within 5 days of receipt of specimen **and/or** isolates tested by ELEK with results reported within 10days | >= 80% | # of specimens tested by culture with results reported within 5 days of specimen receipt **OR** # of isolates tested by ELEK with results reported within 10 days of specimen receipt / # of specimens tested by culture x 100 | |

## Surveillance, Investigation, and Response in Outbreak Settings

### Changes to Surveillance During an Outbreak

During outbreaks, you can identify additional cases using clinical diagnosis based on typical pseudomembranous pharyngitis without laboratory confirmation. However, laboratory investigation of suspected cases is strongly recommended. Do not delay treatment pending laboratory confirmation.

In this situation, the definition of an epidemiologically linked case can be extended to include linkage to another epidemiologically linked case, rather than to a laboratory-confirmed case. This chain should only continue for approximately two to three incubation periods (about 20 to 30 days), at which point any new cases identified should be tested to confirm the outbreak continues to be toxigenic diphtheria. Once five cases are confirmed to be toxigenic diphtheria, epidemiological linking to other epidemiologically linked cases can continue.

The process of reconfirming diphtheria among new cohort of cases should continue every two to three incubation periods. Cases should be line listed and their contacts identified. Modifications may need to be made to the case investigation form to capture new risk factors.

Of note, whilst PCR is usually considered complementary to culture and Elek testing; in a very large outbreak, PCR could be used as the standalone confirmatory test as long as toxigenic diphtheria has been confirmed by culture and Elek testing in at least five cases. However, culture and Elek testing are still critical in large outbreaks; culture and Elek testing should be undertaken if new suspected cases are identified in a new area with no epidemiologic link to the current outbreak.

Additionally, for outbreaks lasting for an extended period, at least 5 samples should be tested by culture and Elek test every month among suspected cases with no epidemiologic link to a PCR-confirmed case. This helps to balance the limited resources and field challenges existing in low-resource settings that are most likely to experience a diphtheria outbreak while also ensuring that a toxigenic diphtheria outbreak is still ongoing.

Investigations of contacts might reveal asymptomatic cases, mild respiratory cases without pseudo-membranes, or non-respiratory manifestations of the disease. These should be identified and counted as laboratory-confirmed or epidemiologically linked cases. They should be treated as outlined in the Clinical case management section above.

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# 2.0

# Laboratory Diagnosis Of Diphtheria

# 2.0 Laboratory diagnosis of diphtheria

**Sample Management**

**Sample Type**

Nasopharyngeal and Oropharyngeal swab samples should be collected from a respiratory diphtheria suspected case (one of each per patient). Cutaneous swabs should be collected from suspected cutaneous diphtheria cases. Swabs from other localized body sites should be collected where applicable.

**Sample Collection**

The isolation of *C. diphtheriae* strains depends on the correct collection of swabs and their immediate transfer to the laboratory. As diphtheria is most commonly an upper respiratory tract infection, specimens from the oropharynx, nasopharynx should be collected appropriately If a pseudo-membrane is present, a swab from beneath the membrane should be collected (See Appendix for Diphtheria sample collection). If cutaneous diphtheria is suspected, swabs should be collected from any wounds or cutaneous lesions. Ideally, specimens should be collected at the onset of symptoms and before antimicrobial or antitoxin therapy.

From suspected cases of respiratory diphtheria and contacts, specimen collection procedures usually induce coughing, spluttering, sneezing, and watering eyes; health workers collecting specimens should be appropriately protected. Droplet precautions are necessary, including a surgical mask and eye protection (See Appendix for Standard Operating Procedures for Diphtheria sample collection).

**Sample Handling, Storage and Transportation**

All samples must be transported in Amies or Cary Blair transport media. Other transport mediums including Stuart /Silica Gel Sachets can be used. Ship at 2-8°C using a triple packaging system. Samples should be transported to the laboratory immediately after collection and ensure they arrive at the testing laboratory within 2 days. State Lab. focal person/DSNO should notify the sample courier services for

pick up and the testing laboratory as soon as the specimen is handed over to the courier service. (See Appendix-Template of email to request for movement of Samples/isolates).

**Procedure For Delay in Sample Transport**

If transport delays are expected, samples should be kept at 2-8°C in the refrigerator (See appendix for Packaging and Transportation of Diphtheria Samples/ Isolates).

**Laboratory Investigation of Diphtheria**

The laboratory diagnostic methods for Diphtheria in Nigeria are the conventional culture method, the PCR, Modified ELEK Toxin production test, and Genomic sequencing. Due to the difficulty in obtaining the specialized media and reagents required for the ELEK test, PCR for tox gene is a rapid diagnostic alternative but must be used in conjunction with a phenotypic test for toxin expression. (see WHO surveillance standard). Definitive Laboratory diagnosis of Diphtheria in Nigeria is undertaken by the National Reference Laboratory.

Conventional culture methods (gold standard of confirming diphtheria) for pharyngeal swab, nasal swab and other swab specimens are done at the secondary facilities.

Antibiotic Susceptibility testing is done at the reference laboratory to select the antibiotic for the management of the patient and as the guide to set policy on the right antibiotic to be adopted nationally.

The use of standardized molecular epidemiological tools is essential in monitoring the spread of epidemic *C. diphtheriae* strains and to differentiate between epidemic, endemic and imported cases.

Molecular testing for Diphtheria is performed at the designated molecular laboratories.

See appendix for Standard Operating Procedure of Laboratory diagnosis of diphtheria.

**Interpretation of Results**

Interpretation of laboratory results should be done with care at the various levels of testing. A culture test with a corresponding conventional biochemical result

**alone** is inadequate to report as laboratory confirmed (positive). A diphtheria laboratory result is only interpreted as Positive if a PCR/ API CORYNE/Maldi-tof test is carried out for identification of Corynebacterium diphtheriae **and** ELEK toxin production test is positive.

**Storage and transportation of Isolates**

Isolates should be stored and transported as highlighted in Table 1.0 below.

Table 1.0: Minimum Acceptable Standard for Storage and Transportation of Isolates

| **Transport Medium** | **Storage Temperature** | **Number of Days** |
|---|---|---|
| **Samples in Amies/ Cary Blair medium** | **4$^0$c** | **2 days** |
| **Silica Gel Sachet** | **4$^0$c** | **5 days** |
| **Chocolate slant(isolates)** | **4$^0$c** | **2days** |
| **Microbank beads in Glycerol / Skimmed Milk with Glycerol (Long Term Storage)** | **-80$^0$c** | Years. According to facility's storage policy |

Note- Duration of long-term storage in years is according to facility's storage policy (See appendix for Packaging and Transportation of Diphtheria Samples/ Isolates)

**State Level Testing**

**Negative Culture Result:**

Any culture test that yields no growth on primary culture plates after 24-48 hours of incubation from a suspected diphtheria sample **or**

Any 24-48 hours growth on primary culture plate that shows no gram reaction of gram-positive rods (pleomorphic, club shaped, Chinese letters) from a suspected diphtheria sample **or**

Any culture test that does not correspond with the biochemical reactions specified for *Corynebacterium species* as stated in the biochemical chart (see appendix on Procedure for Identification of *C. diphtheriae* using Culture Method).

**Presumptive Positive Culture Result**:

Any culture test that shows a gram reaction of gram-positive rods (pleomorphic, club shaped, Chinese letters) after 24-48 hours of incubation from a suspected diphtheria sample **AND**

Any culture test that corresponds with the biochemical reactions specified for *Corynebacterium species* as stated in the biochemical chart in the appendix.

**In a situation where the biochemical reagents are unavailable in a facility, a culture test that shows a gram-positive rod (pleomorphic, club shaped, Chinese letters) reaction should be reported as presumptive positive and isolates referred to the National Reference Laboratory for further confirmation.**

**National Level Testing**

**Negative Result:**

Any culture test that yields no growth on primary culture plates after 24-48 hours of incubation from a suspected diphtheria sample **or**

Any 24-48 hours growth on primary culture plate that shows no gram reaction of gram-positive rods (pleomorphic, club shaped, Chinese letters) from a suspected diphtheria sample **or**

Any test that is negative for PCR/ API CORYNE/Maldi-tof assays, used for identification of Corynebacterium spp and ELEK Toxin production.

**Note:**

In a situation where a positive reaction of Corynebacterium diphtheriae for PCR/API CORYNE/Maldi-tof is gotten, but negative for ELEK Toxin production, interpret as 'non-toxigenic Corynebacterium diphtheria' isolated.

**Positive Result (Laboratory Confirmed):**

Probable Laboratory Confirmed Result

In the context of outbreak investigation, a Corynebacterium diphtheria strain with tox gene detected by PCR without an ELEK test result, is considered to be a Probable Laboratory confirmed result

**Reporting of Results**

There are two levels of reporting results. Presumptive positive culture results generated at the state laboratory should be reported to the State Surveillance unit and NCDC. Then the State Surveillance unit shares presumptive positive culture results with the LGAs and Health Facilities. The presumptive Corynebacterium species are then shipped to the National Reference Laboratory for further testing and confirmation.

Secondly, the laboratory confirmed (Positive) result generated at the NRL is shared with the State Surveillance unit, National surveillance unit, Incident Manager, Technical Working Group, Emergency Operation Centre, FMoH and partners. The State Surveillance unit then shares the laboratory confirmed result with the LGAs and Health Facilities. See appendix for reporting template.

**Laboratory Data Management**

The process of data management involves converting the data collected using data collection tools, most commonly Case Investigation Forms (CIFs), into electronic data that can then be statistically analyzed.

### Archiving of CIFs

CIFs should be kept in locked filing cabinets in locked rooms only accessible by authorized personnel. Protected against environmental damage such as damp or fire, without water sprinklers.

If CIFs must be transferred to a coordinating laboratory for data entry, a copy of the CIF forms should be retained by the health facility and another copy given to courier or registered post who is conveying the sample / isolates to the receiving Laboratory to minimize the risk of losing data. A log should always be maintained of documents sent and received at each laboratory. involved. If electronic data transfer is used, this should be via a secure system, password protected and encrypted where possible.

### Diphtheria Laboratory Network

The national surveillance for Diphtheria in Nigeria currently operates within a network of twelve (12) laboratories, NRLs inclusive. Ten (10) laboratories across the country have capacity for preliminary isolation/identification for Diphtheria.

The national Diphtheria laboratory surveillance should operate within a national diphtheria laboratory network consisting of national, zonal, and state laboratories. In an ideal situation, there should be two National Reference Laboratories (NRL), six Zonal Reference Laboratories (ZRL) and thirty-six state laboratories, having at least one state laboratory in each state.

### Roles and Responsibilities of the Laboratories

**National Reference Laboratory (NRL):** The NRL carries out culture, isolate identification, ELEK Toxin producing test, Antimicrobial Susceptibility test to guide case management nationally and implementing Quality Assurance across the Diphtheria laboratory network in-country, including distribution of External Quality Assurance panels. The NRL coordinates laboratory surveillance activities nationally and facilitates capacity building in the laboratory network. Isolates are shipped from the Zonal Reference Laboratories. The reference laboratories are equally responsible for teaching and training scientists on the laboratory diagnosis of diphtheria, both within their own laboratories as well as those from other hospitals.

**Zonal Reference Laboratory (ZRL)**: The ZRL plays the role of an intermediary between the state laboratories and the NRLs. The ZRL carries out culture, isolate

identification using PCR/API CORYNE, biobanking of isolates and basic implementation of Quality Assurance including inter laboratory comparison and capacity building at the peripheral level. The presence of the ZRLs contributes to shortening time of sample transport and turnaround time of laboratory results. Isolates / samples are shipped from the state laboratories to the ZRLs.

**State Laboratory:** The State laboratory conducts culture and conventional biochemical tests on clinical samples. It is the first point for laboratory testing from sample collection. The state laboratory ships presumptively isolate to the ZRL.

**Laboratories at any of the three levels of testing that have the complete laboratory reagents and consumables for confirmatory tests are encouraged to carry out such tests, perform AST and ship isolates to the NRL for parallel testing.** See appendix for National Testing Algorithm for Diphtheria.

**Table 2.0: Minimum Expectations for Different Levels of Testing**

| TESTS | NATIONAL | ZONAL | STATE | LGA |
|---|---|---|---|---|
| **Sample Collection** | Not Performed | Not Performed | Performed | Performed |
| **Culture** | Performed | Performed | Performed | Not Performed |
| **Biochemical/API** | Performed | Performed | Performed | Not performed |
| **PCR** | Performed | Performed | Not Performed | Not Performed |
| **ELEK** | Performed | Not Performed | Not Performed | Not Performed |
| **Genomic Sequencing** | Performed | Not Performed | Not Performed | Not Performed |

**Laboratory Monitoring and Evaluation**

This will enable periodic visit to all the laboratory network that have received training and optimized for Diphtheria laboratory diagnosis. This will put in place

system for improving quality based on plan, do, act and check cycles. Tools will be used to support this process and documentation of progress would be a motivating factor for maintaining quality. Enrolment in international proficiency would be explored. For network of laboratories, site visits will be done as part of the monitoring systems to check testing quality with measurable indicators. Adherence to standard operating procedures, safety guidelines, quality assessment activities, laboratory performance and workload will be considered in this process.

**Laboratory Performance Indicators**

Performance indicators (PIs) are important tools for monitoring and evaluation of laboratory performance at pre-analytical, analytical, and post-analytical phases. The laboratory plays a vital role in management and control of diseases by providing timely and accurate test results which help in patient management. Almost 80% of all diagnosis is made based on laboratory test results. So, the qualities of laboratory results have a huge impact on the patient outcome.

Table 3.0: Showing the laboratory KPIs, their definitions and targets.

| Indicators | Definitions | Targets |
|---|---|---|
| Turn Around Time | Number of results released within the stipulated Time as Numerator (5days for preliminary culture test and 10 days for confirmatory tests) by Total number of specimens received in a month as Denominator | >80% |
| Period of Service Interruption due to Reagent/Consumables/Equipment | Number of days service was interrupted due to lack of reagent/ consumables/ Equipment as Numerator by Total number of working days in a month as denominator | ≤5 days |
| Sample Rejection | Number of specimens rejected as numerator by Total number of specimens received in a month as denominator. | ≤100% |

| | | |
|---|---|---|
| Presumptive Culture Positivity Rate | Number of presumptive positive isolates as numerator by Total number of cultures performed as denominator in a month | ≥10% |
| Isolate Positivity Rate | Number of confirmed **C. diphtheriae** isolates as numerator by Total number of isolates received as Denominator in a month | ≥70% |
| Diphtheria Laboratory Optimized | Minimum of 1 laboratory optimized for Diphtheria testing per state | 1 per state |
| Total Positivity Rate | Total number of laboratories confirmed samples as numerator by Total number of samples tested | |
| Antimicrobial susceptibility test | Number of AST done as numerator by total number of confirmed isolates | |

## Appendices

### Table 4.0: Minimum Requirement for a Diphtheria Culture Laboratory

| S/N | Equipment |
|---|---|
| 1 | Biosafety Cabinet Class 2 (Certified) |
| 2 | Autoclave |
| 3 | Incubator |
| 4 | Microscope |
| 5 | Bunsen Burner connected to gas cylinder |
| 6 | Drying oven |
| 7 | UPS for critical equipment |
| 8 | Weigh balance |
| 9 | Refrigerator (2 – 8 degrees) |
| 10 | Freezer (-20 degrees) |
| | Reagent |
| 11 | Sheep Blood |
| 12 | Nutrient Agar |
| 13 | Gram Stain Kit |
| 14 | Hydrogen Peroxide |
| 15 | Nitrate Reagent |
| 16 | Urease Reagent |
| 17 | Urea Agar Base |
| 18 | Tellurite Agar Base |
| 19 | Potassium Tellurite Solution |
| 20 | Immersion oil |
| 21 | Columbia Agar Base |
| 22 | Normal Saline |
| | Consumables |
| 23 | Microscope Glass Slide |
| 24 | Glass cover slip |
| 25 | Sterile Petri Dish (90-100mm) |
| 26 | Wire loop (10ul) |
| 27 | Autoclavable conical flask (minimum of 2) |
| 28 | Test tubes (for biochemical test) |
| 29 | Disposable Pasteur pipette |
| 30 | Permanent Marker |

| | |
|---|---|
| 31 | Autoclave tape |
| 32 | Hand Gloves |
| 33 | Laboratory Coat |
| 34 | Sterile Cotton Gauze |
| 35 | Absolute Ethanol |
| 36 | Bleach |
| | Infrastructure |
| 37 | Clean sink with running tap water |
| 38 | Dedicated Gram staining sink |
| 39 | Power supply with back up system |
| 40 | Adequate waste segregation |
| 41 | Dedicated room/ workspace for media preparation |
| 42 | Adequate lighting and ventilation |
| 43 | Dedicated work benches for lab procedures including installation of equipment |

**Table 5.0: BASIC EQUIPMENT LIST FOR DIPHTHERIA PCR TESTING:**

| S/N | EQUIPMENTS |
|---|---|
| 1 | Biosafety Cabinet<br>Class 2 |
| 2 | Real-Time PCR machine (Open or closed system) |
| 3 | Computer for Data |
| 4 | Backup UPS |
| 5 | Dead- air/ PCR workstation |
| 6 | Automated Nucleic Acid Extractor (optional) |
| 7 | Pipettes 0.5-10ul |
| 8 | Pipettes 10- 100ul |
| 9 | Pipettes 20-200ul |
| 10 | Pipettes 100-1000ul |
| 11 | Pipettes tips |
| 12 | Tubes and cryovials |
| 13 | Fridge |
| 14 | Freezer |
| 15 | Vortex mixers |
| 16 | Thermo-Mixers/heating block |
| 17 | Refrigerated micro centrifuge (1.5-2 ml) |
| 18 | Micro centrifuge (1.5-2 ml) |
| 18 | Racks for 1.5 mL micro centrifuge tubes |

| | |
|---|---|
| 19 | 2 x 96-well -20°C cold blocks |
| 20 | PPE |
| 21 | Autoclave for waste management |
| 22 | Incinerator |
| 23 | Backup Generator |
| 24 | Long term storage ultra-low freezers |

**Table 6.0: Reagents & Consumables required for Diphtheria testing (PCR Laboratory)**

| S/N | REAGENT AND CONSUMABLES |
|---|---|
| 1 | Nucleic Acid Extraction kit |
| 2 | PCR Assay kit |
| 3 | Gauze and wipes |
| 4 | 10% bleach |
| 5 | Absolute Ethanol (99-100% molecular grade ethanol) |
| 6 | BSA |
| 7 | Tris (10 Mm) |
| 8. | 1.5/2ml micro-centrifuge tubes |
| 9. | 2 ml cryovials tubes with screw cap |
| 10 | PCR tubes/ plates |
| 11 | Sample storage boxes |
| 12 | cry boxes |
| 13 | Biohazard bags |

**STANDARD OPERATING PROCEDURE FOR DIPHTHERIA SAMPLE COLLECTION**

1. **Materials required for sample collection.**

- Strong light source for illuminating the pharynx.
- Dacron cotton-tipped or flocked swab.
- Amies transport medium or CaryBlair medium or silica gel pack or Chocolate agar slant for isolates.
- Sterile tongue depressor.
- Gloves.
- Surgical mask.
- Goggles/ Face shield.

## 0. Safety Measures

- Perform hand hygiene before and after procedure.
- Wear protective clothing, surgical mask, face shield and gloves during sample collection.
- Dispose gloves after collection from each patient.

In addition, health workers collecting the swabs should ensure that they are vaccinated according to the recommended schedule published by WHO, and that their booster vaccines against diphtheria are up to date.

## 0. Procedure

### 4.1 Oropharyngeal swabs

- Position head slightly back
- Ensure pharynx is clearly visible using a good light source.
- Depress the tongue with a sterile tongue depressor so that the back of the throat can be seen.
- Swab the throat without touching the tongue, uvula or inside of the cheeks.
- Rub vigorously over any membrane, white spots, or inflamed areas; slight pressure with a rotating movement must be applied to the swab.
- Place swab in Amies or Cary Blair transport medium or into a silica gel sachet.

### 4.2 Nasopharyngeal swabs

- Insert the swab into one nostril, beyond the anterior nares.
- Gently introduce the swab along the floor of the nasal cavity, under the middle turbinate until the pharyngeal wall is reached.
- Rotate swab 2-3 times and ensure force is not used to overcome any obstruction.
- Place a swab in Amies or Cary Blair transport medium or into a silica gel sachet.

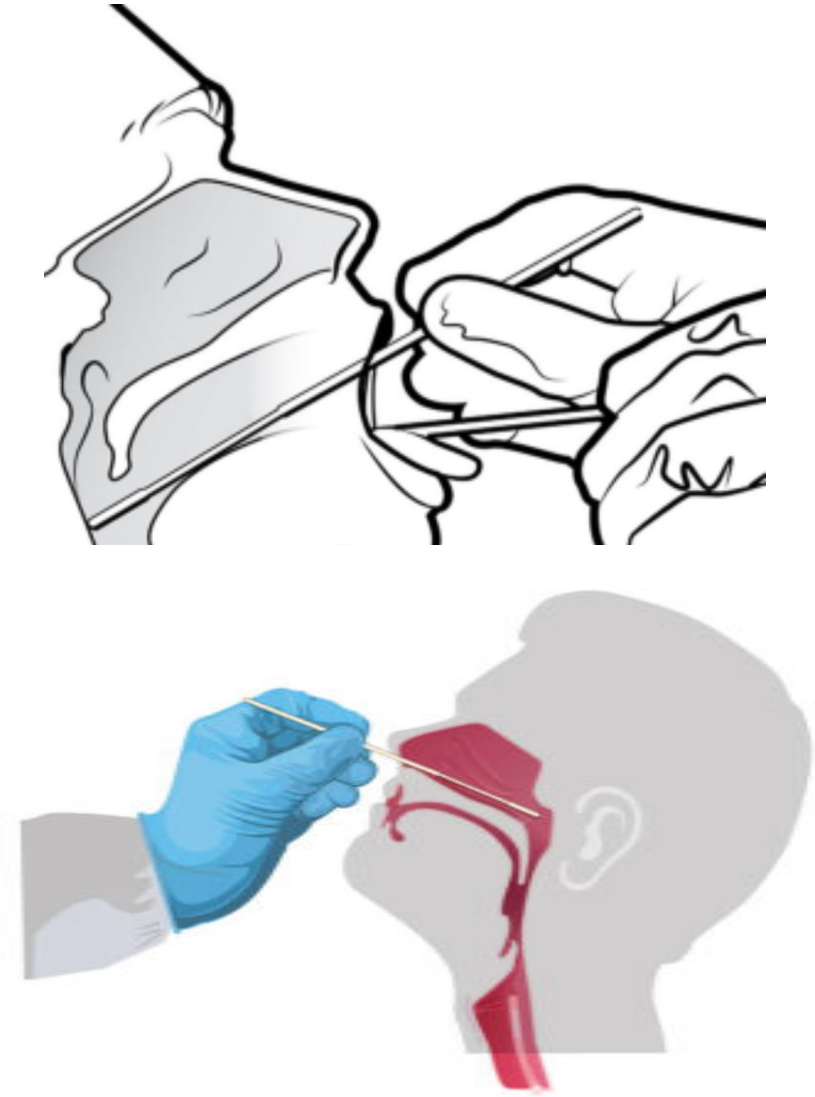


**Figure 1.0: L-R Image of Oropharyngeal Swab, Nasopharyngeal Swab collection**

### 4.3 Nasal swabs

- Insert the swab into the nose through one nostril beyond the anterior nares.
- Gently introduce the swab along the floor of the nasal cavity.
- Place in Amies or CaryBlair transport medium or into a silica gel sachet.

### 4.4 Cutaneous lesions

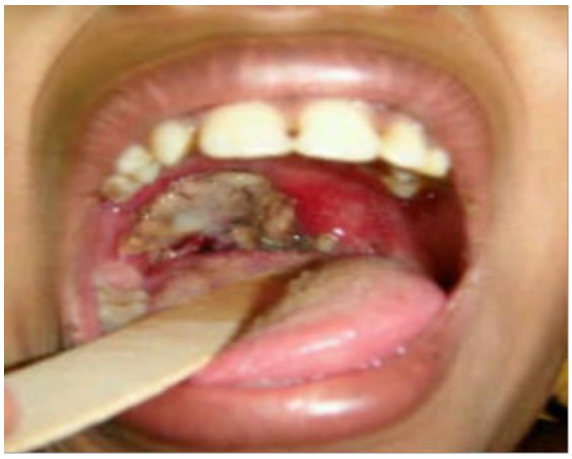
- Lesions should be moistened with sterile normal saline and crusted material removed.
- Press the swab firmly into the lesion.
- Place into a routine semi-solid transport medium or into a silica gel sachet.

### 4.5 Pseudo-membrane

**Note: To be undertaken preferably by a trained Health Care Worker as there is a considerable risk of severe bleeding.**

i. Swab the surface and around the membrane, ensuring firm contact between the swab and the membrane (take caution to avoid the membrane form being dislodged).

ii. Place the swab into either Amies / Cary Blair transport medium.



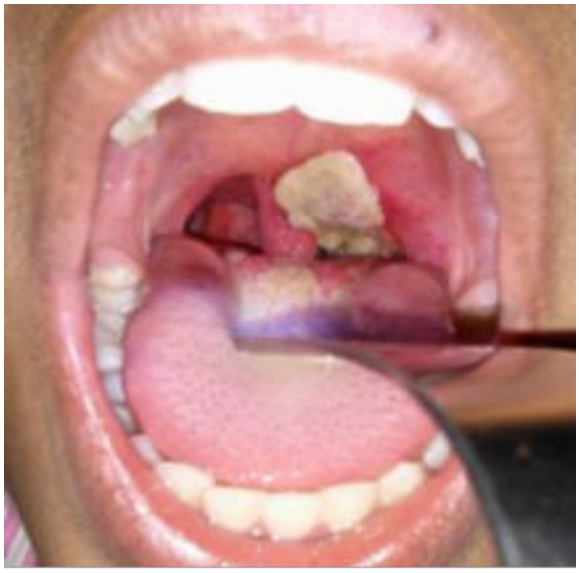


**Figure 2.0: Image of sample collection from Pseudo-membrane**

### 4.6 Other Localized Body Sites

- Using a sterile swab stick, swab the affected area.
- Place swab in Amies or Cary Blair transport medium or into a silica gel sachet.

## STANDARD OPERATING PROCEDURE FOR PACKAGING AND TRANSPORTATION OF DIPHTHERIA SAMPLES / ISOLATES

Samples should be packed in triple packaging container and transported under appropriate temperature to the testing laboratory as described below:

1. **Materials required for sample packaging and transport.**

- Amies Transport Medium/ Cary Blair medium or Silica gel pack or Chocolate Agar Slant (Bacterial Isolates)
- Ziploc bag
- Biohazard label
- Secondary container
- Hard frozen gel packs
- Case investigation form
- Sample transport form
- Marker
- Gio-style carrier
- Transport box/hard card box

## 0. Procedure

Wrap the transport medium, silica gel pack (for samples and isolates) and chocolate agar slant for isolates in an absorbent material that can absorb the content of the medium in the event of breakage or spillage.

**Note:**

Cotton balls, tissue paper, paper towel, stryo-foam may be used as adsorbent material.

1. Paraffin or masking tape should be used to hold the absorbent material in place if the material sits loosely.
2. Place the medium wrapped in adsorbent material in a leak-proof secondary container.
    I. A falcon tube can be used for bijou bottles as a secondary container and cryobox for cryovial tubes. Ziploc bags can be used for swabs and sachets.
    II. Where cryotubes and cryoboxes are used, place the absorbent paper on the cryotubes before covering with the lid of the cryobox and seal the cryobox with a masking tape or paraffin to ensure it is firmly sealed.
3. Place the secondary container in a zip-loc bag and attach a biohazard sign on the zip-loc bag.
4. Place the zip-loc bag into another airtight, sturdy container (e.g Bio-bottle)
5. Place the sturdy container into gio-styles ensuring the specimen is surrounded (bottom and sides) by hard frozen gel packs or ice packs to make certain the sample is preserved during transport.
6. Transport sample at 4°C within a period of 5 days.
7. Disinfect the gio-style (cool box)
8. Place the gio-style into hard card box container and disinfect again.
9. Notify the sample courier services for pick up.

10. Notify the testing laboratory as soon as the specimen is handed over to the courier service.

**Note: Unused silica packages should be kept away from any moisture in well-sealed zip bags.**

**Procedure for use of silica gel packs**

I. Sterilize scissors with 70% ethanol.
II. Cut the top of the silica package with the sterilized scissors.
III. Check the content of the silica gel pack. A good silica gel should contain blue and white silica gel. The blue silica should constitute 25% of the silica gel content inside the silica package:

- If some blue indicator silica is still visible (**Figure 3.0**), proceed with steps iv-vi.
- If no visible blue silica is found inside the package (only transparent or pinkish/violet), moisture is present, then the package must be discarded and not used to transport bacterial isolates or clinical swabs.

A. Visible blue silica indicates the package is good to use. B. Illustration of how to fold the aluminum package with a cotton swab inside. Modified and courtesy of Centers for Diseases Control and Prevention, Atlanta, Georgia, USA.

**A** **B**

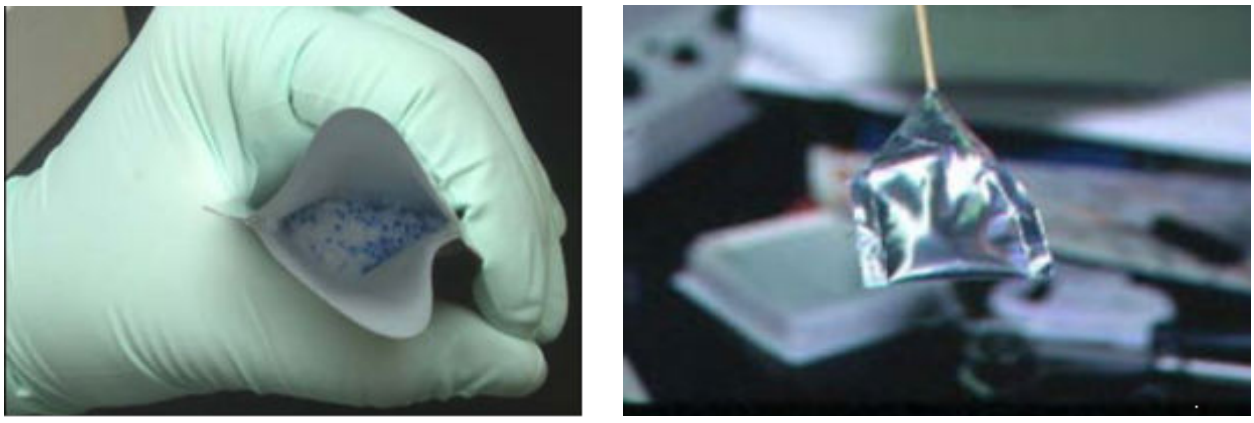


**Figure 3.0. Silica gel packs for temporary storage and transportation.**

iv. Using a sterile cotton swab, roll it over the sample site or all culture growth areas (use care to touch only the end of the swab shaft to avoid contamination) and place the swab containing the culture growth or the clinical swab sample directly into the silica gel pack.

v. Fold the two upper sides of the aluminum package overlapping each other firmly on the swab stick to ensure it is airtight giving an image of the apex of a triangle similar to the way a lollipop is packaged as seen in figure 3.0 above.

vi. Use a masking tape to seal round the point of contact of the shaft of the swab and folded corners to secure the swab and seal the package.

vii. Carefully sterilize the package with 0.5% hypochlorite solution.

viii. Clearly label the package with patient details.

ix. Place the pack in a secondary container (Ziploc bag with biohazard label)

Continue with steps iv to xi on procedure for sample packaging mentioned above.

**Preservation of Pure Cultures**

Once an isolate has been confirmed and identified as positive for C. diphtheriae, C. ulcerans or C. pseudotuberculosis, it is important to preserve the sample as a pure culture. This isolate may be sent to a reference laboratory or preserved in the original laboratory for future testing. Traditional ways to store isolates include:

1. Short-term (up to 7 days): placed on an agar slant, incubated at 35-37°C overnight and stored in a refrigerator at 4°C
2. Long-term: Freezing at –80°C in skimmed milk glycerol broth or in tubes containing cryobeads, such as Microbank beads.

Isolates for storage should be grown in pure culture for no more than 24 hours on blood agar medium. Media containing tellurite or antibiotics must not be used for this purpose. The storage vial should be labeled with the isolate reference number and date to link it with the patient information in the future. For strain revival from frozen Microband beads it is necessary to work in a biosafety cabinet according to the laboratory safety protocol. Vials of strains should not be completely thawed and should be returned to the freezer as soon after subculture as possible.

**TEMPLATE FOR EMAIL TO REQUEST FOR MOVEMENT OF SAMPLES/ISOLATES**

TITLE OF EMAIL: REQUEST MOVEMENT OF SAMPLES FROM XXX STATE

Dear (To whom it may concern),

I trust this email finds you well.

There are xxx (number and type of samples) samples in XXX (name of state) state that needs to be pick-up for testing.

The details are as follows:

Location of Pick-up: XXX (the address where the sample is located)
The contact person: XXX (name of contact person in the state)
Phone number: XXX (phone number of contact person in the state)

Destination for testing: NCDC National Reference Laboratory, Abuja.

Kind Regards,

(Name of the requester)
(Designation)
(Location)

PLEASE NOTE:

In your email, kindly send to:

Chiamaka.ifenwanta@ncdc.gov.ng

copy the following:
james.onwuka@ncdc.gov.ng
Adesuyi.omoare@ncdc.gov.ng
israel.ogunmakinde@ncdc.gov.ng
marcel.dibang@ncdc.gov.ng

For states in SOUTH-WEST and NORTH-CENTRAL.

Please copy carter Biggs logistics company with the following email:
esther@carterbiggs.com.ng
dipo.williams@carterbiggs.com.ng
martins.olajide@carterbiggs.com.ng

For states in the SOUTH-EAST AND SOUTH-SOUTH. Please copy zenith Carex limited with the following email:

omolayo.lukas@zenithcarex.com
anyogopeter1@gmail.com

For states in the NORTH -EAST AND NORTH- WEST. Please copy Zamel Integrated services with the following email:

zamelintegratedservices@gmail.com
melisobaro@gmail.com
utomifavour18@gmail.com

**SAMPLE REJECTION CRITERIA**

- An incorrectly labeled or unlabeled sample
- Sample information on sample container is not clear.
- A sample with duplicate Laboratory Identification number
- Samples not properly placed into the transport medium.
- Long term isolates of diphtheria pathogens (in Skimmed milk, Sheep blood etc.) not transported on cold chain (-20°C)
- A sample without case investigation form (CIF) /request form or line list
- Sample was collected in improper container/additive.
- Patient name/date of collection on CIF/request form did not match the same details on the sample label.

Any sample that meets the above rejection criteria is logged in the sample rejection logbook, inform the Unit Supervisor/Laboratory manager to contact the requesting State, then proceed with the sample processing.

**Procedure for the Identification of Corynebacterium Diphtheriae using Culture Method**

**Abbreviations**

CBA- Columbia Blood Agar

PPE- Personal Protective Equipment

BSC- Biosafety Cabinet

API- Analytical Profile Index

PYZ - Pyrazinamidase

**Culture**: Culture media provides a balanced mixture of the required nutrients such as Glucose or glycerol (often used as carbon sources) and ammonium salts or nitrates (as inorganic nitrogen sources), at concentrations that will permit good growth of microorganism which can be basal, selective, enriched, enrichment or differential.

**Recommended Equipment**

- Incubator
- Microscope
- Biosafety cabinet
- Autoclave
- Refrigerator
- Hot air oven

**Reagents**

- Gram Stain Reagent
- Tellurite Agar
- Blood Agar
- Normal Saline
- Tinsdale Agar

- Elek Basal Medium
- API
- PYZ
- Nitrate
- Urease
- Hydrogen Peroxide
- Oxidase

**Consumables**

0.5% and 0.05% hypochlorite

70% alcohol

PPE

Pasteur pipette

Glass Slides

Gloves

Gauze/Cotton Wool

Wire loop

Marker

**Safety and Environmental controls**

- Wear personal protective equipment (PPE) such as gloves, lab coats when handling specimen and treat all isolates as potential biological hazards.
- Perform all test activities in the Class II Biosafety Cabinet
- Dispose all used materials such as gloves; contaminated materials should be put into a biohazard bin prior to decontamination and incineration.
- Avoid generation of aerosols.
- Use a micro-incinerator or pre-sterilized plastic loops rather than flaming a loop in an open flame where possible. Use a cooled loop for insertion into a culture suspension. Streak plates where the surface of the medium is smooth (i.e. avoid

bubbles). Drain pipettes gently with the tip against the inner wall of the receiving vessel. Work over an absorbent, plastic-backed pad to avoid aerosol dispersion from drops falling on hard surfaces.

- Do not mix materials by alternate suction and expulsion through a pipette (use vortex mixer). For centrifugation, always use sealed safety cups and sealed rotors. Open cups and tubes inside a biosafety cabinet, allow items to sit prior to opening to allow aerosols to settle. When withdrawing a needle from a stoppered bottle, wrap the needle and bottle cap in a disinfectant-soaked absorbent. Use a vortex mixer instead of inverting tubes and wait 30 seconds after shaking a tube before opening.

**Procedural Steps**

**Specimen Reception**

- Log the specimen in the Sample logbook.
- Inside the BSC II, virtually check the sample for adequacy following the rejection criteria below.
- An incorrectly labeled or unlabeled sample
- Sample information on sample container is not clear.
- A sample with duplicate Laboratory Identification number
- Long term isolates of diphtheria pathogens (in Skimmed milk, Sheep blood etc.) not transported on cold chain (-20°C)
- A sample without case investigation form (CIF) /request form or line list
- Sample was collected in an improper container/additive.
- Patient name/date of collection on CIF/request form did not match the same details on the sample label.
- Any sample that meets the above rejection criteria is logged in the sample rejection logbook, inform the Unit Supervisor/Laboratory manager to contact the requesting State, then proceed with the sample processing.

**Culture and Identification**

**Minimal laboratory criteria for reporting a specimen as culture positive**

The minimal laboratory criteria required to presumptively confirm an isolate as C. diphtheriae, C. ulcerans or C. pseudotuberculosis are as follows:

• **Catalase positive**

· **Urea negative for C. diphtheriae, positive for C. ulcerans and C. pseudotuberculosis**

· **Nitrate positive (except biovar belfanti, C. ulcerans and C. pseudotuberculosis)**

· **Pyrazinamidase negative**

• **Cystinase positive (Tinsdale agar)**

**Day 1**

- Inoculate suspected sample onto Blood agar, Hoyle's tellurite and Tindale agar.
- Incubate aerobically at 37°C for 18 - 24 hrs

**Day 2**

- Examine colony morphology of the overnight cultured plates (Blood agar, Hoyle's tellurite and Tinsdale). See Table 7.0 for description of colonial morphology.

If no growth, reincubate for another 24 hours. If no growth after 48 hours discard

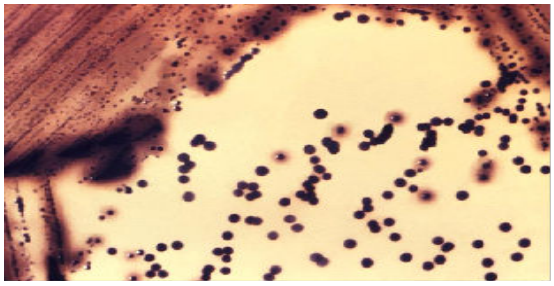
- Pick the suspected black/grey colonies from Hoyle's tellurite and gram stain.
- Check out for gram-positive bacillus (pleomorphic, club-end)
- Subculture all suspected/identified discrete colonies from Tinsdale or Hoyles Tellurite agar onto Blood agar. If not available, subculture from Blood agar to Blood agar
- Incubate aerobically at 37°C for 18 - 24 hrs.

Table 7.0: **Colonial Morphology of *Corynebacterium Diphtheriae, C. ulcerans and C. pseudotuberculosis***

| **Medium** | ***Corynebacterium diphtheriae*** | ***C. ulcerans*** | ***C. pseudotuberculosis*** |
|---|---|---|---|
| **Blood Agar** | Appears greyish | May exhibit a small zone of β-hemolysis | Exhibit a small zone of β-hemolysis |
| **Tellurite Agar** | Gives black colony with greyish periphery. | Appears grey/black, very dry opaque colonies. | Appears grey/black, very dry opaque colonies. |
| **Tinsdale Agar** | A **brown halo around the black colony** is considered presumptive evidence of C. diphtheriae. This can sometimes be seen after 10–12 hours of incubation, although 48 hours may be required for the appearance of typical dark-brown halos. | Produce the characteristic black colonies surrounded by a brown halo after overnight incubation | Produce the characteristic black colonies surrounded by a brown halo after overnight incubation |

A

B



C

**Figure 4.0. Appearance of Corynebacterium Diphtheria in different culture media as shown in the keys below (A, B and C)**

**KEY:**

A- Corynebacterium diphtheriae on sheep Blood Agar

B- Corynebacterium diphtheria on Hoyles Tellurite Agar

C- Corynebacterium diphtheriae on Tinsdale Agar

**Day 3**

i. Examine colonial morphology of the growth on blood agar.

ii..Gram Stain suspected colonies from the Blood Agar

iii. Observe for gram Positive bacilli (Pleomorphic, club shaped or chinese letters)

iv. Proceed to carryout biochemical tests on suspected colonies.

## Procedure for Gram Stain

### Gram Staining using isolates.

1. Using a pipette, add one drop of sterile water or saline to the circle.
2. Use an inoculating loop to pick up a single colony from the 18-24hr pure culture plate.
3. Gently swirl the loop in the sterile water or saline to create a slightly turbid suspension and allow it to air dry.
4. Repeat steps i to iii for each isolate.
5. The slide MUST be completely dry before proceeding to the next step.
6. Completely cover the dried cell spot (or flood the slide) with 95% methanol and incubate for two minutes.
7. If methanol fixation (preferred method) is not possible, fixation can be also completed by heating. Smear can be heat fixed by quickly passing the slide through a flame three times.
8. Do not over-heat the slide as overheating will cause significant distortion or destruction of the cells.

### Staining slides

1. Apply the reagents listed in the next few steps directly onto smear. Avoid touching the slide with the tip of the reagent bottle.
2. Flood the slide with crystal violet for one minute. Rinse with distilled water. Shake off excess water.
3. Flood the slide with Gram's iodine for one minute. Rinse with distilled water. Shake off excess water.
4. Rinse with decolorizer for 2-5 seconds (depending on manufacturer's instructions) until the solution becomes clear. Rinse with distilled water. Shake off excess water.
5. Flood the slide with safranin for approximately one minute to counterstain. Rinse with distilled water. Shake off excess water.
6. You may replace safranin with fuchsin, which is found to be more appropriate for long-term storage of stained slides.
7. Gently blot/dab slides on bibulous paper/paper towel to remove excess water and let air dry.

8. Once dried, examine the stained smear under a microscope with 100X oil immersion objective.

**Quality Control**

Both positive and negative controls must be tested alongside the test organism**.**

**Result interpretation**

The common microscopic characteristics of pathogenic Corynebacteria are gram-positive bacillus (pleomorphic, club-end)

**Bacterial Isolates**

This procedure is for culture isolates to be transported to the National Reference Laboratory for confirmation.

**Note: Amies Transport or CaryBliar medium or Silca Gel pack can be used for transport of isolates**

Inoculate isolate on chocolate agar slant or regan lowe agar slant (for pertussis) and incubate over night at 37°C aerobically.

**Store all samples at 4°C for not more than 5 days in the fridge.**

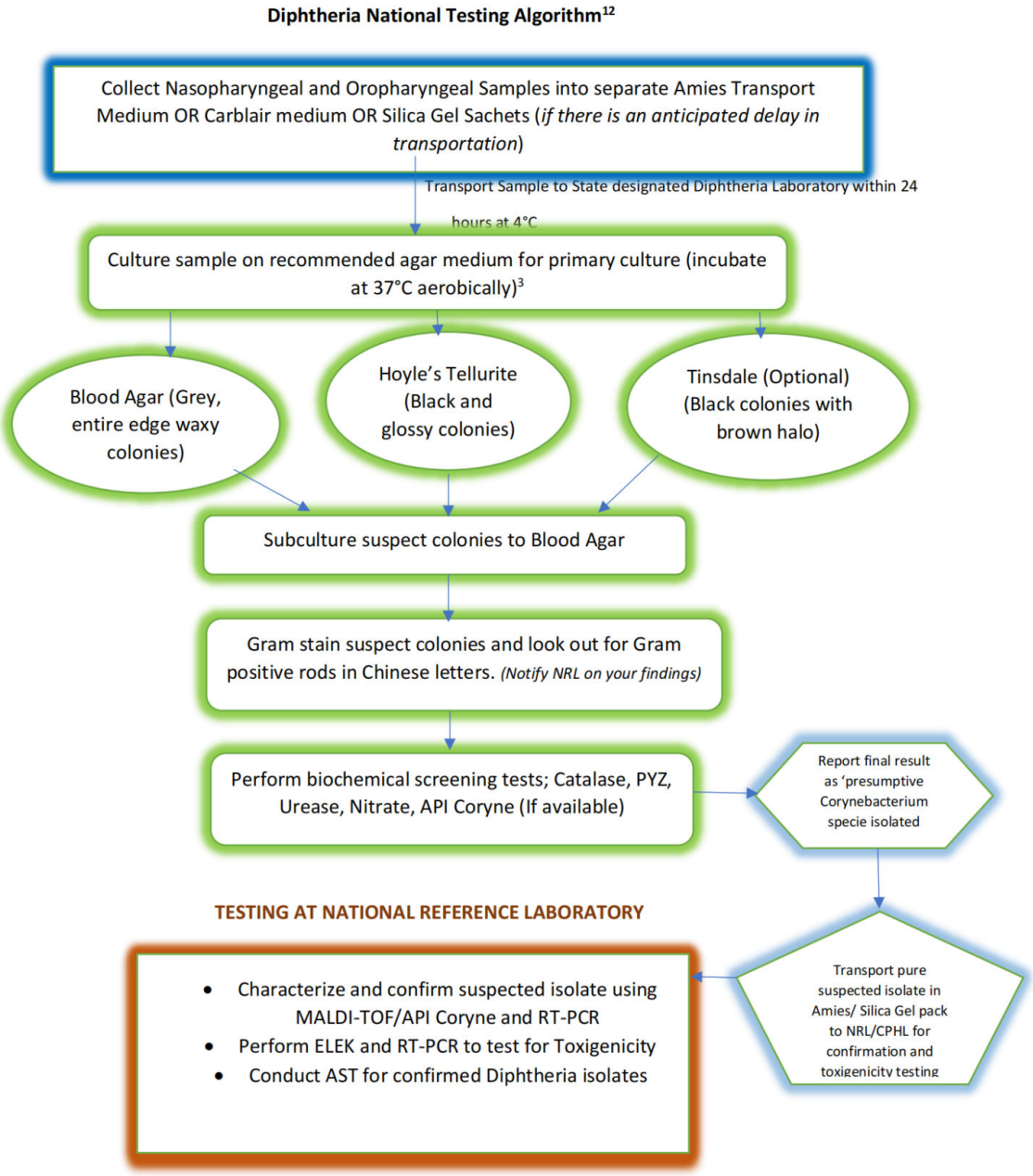
Notify testing laboratory and State Surveillance unit for sample pick up and send email to **Augusta.zuokemefa@ncdc.gov.ng** for sample referral to NRL.

**Responsibilities**

Laboratory Scientist: Performs the test as described in this SOP.

Unit Supervisor: ensure the SOP is adhered to from day to day. Reviews the results, logs and worksheets.

Laboratory Manager: reviews and sends the result to the requesting facility.




[1] Adapted from WHO Laboratory Manual for the Diagnosis of Diphtheria and other Infections

[2] Follow same algorithm for samples from wounds and other affected sites

**3 PCR can also be performed for rapid response alongside culture in state labs that have the capacity**

**Figure 5.0. Diphtheria National Testing Algorithm**


# 3.0

# Case Management

# 3.0 Case Management

**Recommendations**

Ideally, all suspected diphtheria cases should be managed in dedicated isolation units or centers.

Avoid using fans or air conditioning for these patients.

For suspected or confirmed diphtheria cases, the NCDC recommends using macrolide antibiotics (Azithromycin, Erythromycin) over penicillin antibiotics and suggests administering diphtheria antitoxin (DAT) without performing a sensitivity test beforehand.

If the severity or duration of the disease increases, NCDC advises escalating the dose of DAT.

**Table 8.0. Dosage of DAT based on severity and time since onset of symptoms.**

| Characteristic of diphtheria disease | Dose of diphtheria antitoxin (IU) |
|---|---|
| • Laryngitis **or** pharyngitis<br>**and**<br>• Duration < 48 hours | 20 000 |
| • Nasopharyngeal disease (extensive pseudomembrane)<br>**and**<br>• duration < 48 hours | 40 000 |
| One or more of:<br>• Diffuse swelling of the neck<br>• Any disease ≥ 48 hours<br>• Severe disease (respiratory distress, shock) | 80 000 |

*A nurse, and if possible, a medical doctor, should stay at the patient's bedside for the first 15 minutes of the infusion, followed by monitoring every 15 minutes.*

**Microbiology and pathogenesis**

Corynebacterium diphtheriae is a gram-positive rod, non-spore forming, non-encapsulated and non-motile. It also produces exotoxin encoded by tox gene (not present in all strains of *C. diphtheriae*. some strains of *C. ulcerans* also produce the toxin). Not all C. Diphtheriae which have the tox gene produce the toxin.

**Pathogenesis**

- C. diphtheriae itself produces only a mild inflammatory disease in the upper respiratory tract, and ulceration when the infection is localized to the skin.
- The serious pathology in diphtheria is a result of the exotoxin and its effect on the respiratory tract (membrane and oedema), hematologic (DIC and bleeding), the heart (myocarditis), nerves (demyelination and polyneuropathy), and kidneys (AKI and tubular necrosis)
- The characteristic lesion, caused by liberation of a specific cytotoxin, is marked by a patch or patches of an adherent greyish-white membrane with surrounding inflammation. The infection most often manifests as membranous naso-pharyngitis or obstructive laryngotracheitis. The toxin produced by some strains can cause severe damage to the throat or other tissues. Occasionally, *C. diphtheriae* disseminates from the skin or respiratory tract and causes invasive systemic infections including bacteremia, endocarditis, and arthritis.

**Natural immunity:**

- Immunity to disease depends mainly on the presence of diphtheria toxin antibodies (IgG). Cell-mediated immunity may also play a role.
- Natural infection gives moderate serogroup-specific protection for at least three years.
- Occasionally, protective immunity does not develop after recovery from the disease. Individuals recovering from diphtheria should therefore receive a complete course of age-appropriate diphtheria antigen containing vaccine during convalescence.

## Epidemiology

Humans are the only reservoir of C. diphtheriae. Transmission is by respiratory droplets, or direct contact with either respiratory secretions or exudates from infected skin lesions. Asymptomatic respiratory carriage is important in both endemic and epidemic transmission, and chronic carriers may be infectious for more than six months.

The incubation period is between two and five days. The infectivity period is usually between two and six weeks in the absence of treatment, but timely antibiotics reduce this to as low as 48 hours. Diphtheria is a highly infective disease, with a basic reproductive number (R0) of 6 to 7, i.e., one index case can generate 6 to 7 secondary cases. That explains the need for improvement in herd immunity to halt transmission through high vaccination coverage, and good vaccine policy and efficacy.

## Clinical presentation

Diphtheria is an acute bacterial disease that can affect any mucous membrane. The onset of the disease is typically gradual, and symptoms initially are general and nonspecific, often resembling a typical viral upper respiratory infection (URI). The most common presenting features are: sore throat, malaise, cervical lymphadenopathy/bull neck, coryza-like symptoms and low-grade fever. These can then progress to bloody nasal discharge, hoarse voice, cough, and/or pain while swallowing with drooling and pooling of secretions. In severe cases, patients may develop noisy breathing (inspiratory stridor, wheezing and shortness of breath), bleeding and decreased urine output. Fever may or may not be present. Skin lesions can become infected with the bacteria (cutaneous diphtheria), presenting with whitish-gray membrane covering.

Any primary contact of an index case (suspected or confirmed) presenting with upper respiratory tract symptoms without throat pseudo-membrane should be considered as an early case of diphtheria and should be managed as such.

## Case Definition

Suspected cases are any persons with an illness of upper respiratory tract with adherent pseudo-membrane of the pharynx, tonsils, larynx or nose.

Final Case classification is as follows:

- **Laboratory confirmed cases** are persons with Corynebacterium spp. Isolated by culture and positive for toxin production, regardless of symptoms. In a very large outbreak, PCR (detecting the A and B units of the diphtheria toxin gene (tox)) could be used as the standalone confirmatory test if toxigenic diphtheria have been confirmed by culture and Elek testing

  in at least five cases. However, culture and Elek testing is still critical in large outbreaks; culture and Elek testing should be undertaken if new suspected cases are identified in a new area with no epidemiologic link to the current outbreak. Additionally, for outbreaks lasting for an extended period, at least 5 samples should be tested by culture and Elek every month among suspected cases with no epidemiologic link to a PCR-confirmed case. This helps to balance the limited resources and field challenges existing in low resource settings which are most likely to experience a diphtheria outbreak while also ensuring that a toxigenic diphtheria outbreak is still ongoing.

- **Epidemiologically linked cases** are persons that meet the definition of a suspected case and is linked epidemiologically to a laboratory confirmed case. Depending on the size of the outbreak, it may be decided NOT to test all suspected cases, to avoid overwhelming the laboratory. In this situation, the definition of an epidemiologically linked case can be extended to include linkage to another epidemiologically linked case, rather than exclusively to another laboratory-confirmed case. This chain should only continue for approximately two to three incubation periods (about three weeks), at which point any new cases identified should be tested to confirm that the outbreak continues to be caused by toxigenic strains of diphtheria. Once five cases are confirmed to be toxigenic diphtheria, epidemiological linking to other epidemiologically linked cases can continue. The process of reconfirming diphtheria among new cases should continue every two to three incubation periods.

- **Clinically compatible case** are persons that meet the definition of a suspected case and lacks both a confirmatory test and epidemiological linkage to a laboratory confirmed case. Treatment should be commenced in clinically compatible cases in the setting.

- **Discarded cases** are suspected case that meets either of these criteria: Corynebacterium spp. but negative Elek test (non-toxigenic Corynebacterium) OR negative PCR for the diphtheria toxin (tox) gene.

**Throat and nares examination**

Conduct a careful examination. Be careful not to cause distress in children as this may worsen the clinical situation. On inspection, child may also have an obviously swollen neck, referred to as “bull neck” due to swollen cervical lymph nodes, soft tissue oedema and mucosal oedema. Look at the nares and throat to visualize the typical grey-white adherent membrane overlying the inflamed, oedematous mucosa. The grey membrane may be localized asymmetrically (i.e., affecting nares, tonsils, pharynx) or may extend to affect the larynx and trachea. Care should be taken during throat examination and swab-taking, as any traction on the adherent membrane may dislodge it, leading to bleeding and/or aspiration.

**Watch out for the presence danger signs (impending airway or circulatory failure), If any present, call for immediate specialist consultation. Where such expertise is unavailable, REFER immediately.**

- Any sign of respiratory distress such as inspiratory stridor, fast breathing, chest indrawing, accessory muscle use, or restlessness are warning signs of impending airway obstruction and the need to secure the airway.
- The presence of lethargy, cyanosis or SpO2 < 92% is ominous in child with upper airway obstruction (implies overt airway obstruction) and emergent need to secure airway.
- Any sign of shock such as capillary refill > 3 seconds, presence of cold extremities, fast pulse rate, or low blood pressure, is also an emergency that needs urgent attention.
- Presence of laboratory/clinical evidence of thrombocytopenia
- In case of Acute Kidney Injury (AKI)
- Cardiac complications e.g., sinus bradycardia, tachyarrhythmias and heart failure

**Classification**

Classification can be by clinical severity and anatomical classification**:**

**Clinical Classification**

This can be broadly classified into 2:

A. Mild: A patient presenting with a throat pseudo-membrane, and upper respiratory tract symptoms without respiratory obstruction or systemic manifestations.
B. Severe: A patient presenting with a throat pseudo-membrane and upper respiratory tract symptoms with respiratory obstruction and/or systemic manifestations (see 6.0). (reference)

**Anatomical Classification**

This can be broadly classified into 2:

A. Respiratory
B. Non-respiratory

Respiratory diphtheria can be classified based on site of the infection:

**Pharyngeal/tonsillar:**

This is the most common site of infection and is associated with the absorption of toxin. The onset is insidious. Early symptoms include malaise, sore throat, anorexia, and low-grade fever. Two to three days later the membrane appears in the pharyngeal/tonsillar area. The membrane initially appears white and glossy but evolves into a dirty grey colour with patches of green or black necrosis. The extent of the membrane correlates with the severity of symptoms (i.e., with posterior pharynx, soft palate and peri-glottal area involvement, profound malaise and obstructed breathing may occur). In cases of severe disease, the individual may also develop oedema of the submandibular areas and the anterior neck, along with lymphadenopathy, giving the characteristic “bull neck” appearance. The individual may recover or, depending on the amount of toxin absorbed, develop severe

illness, pallor, shock, renal impairment, stupor, and coma with death occurring in 6 to 10 days.

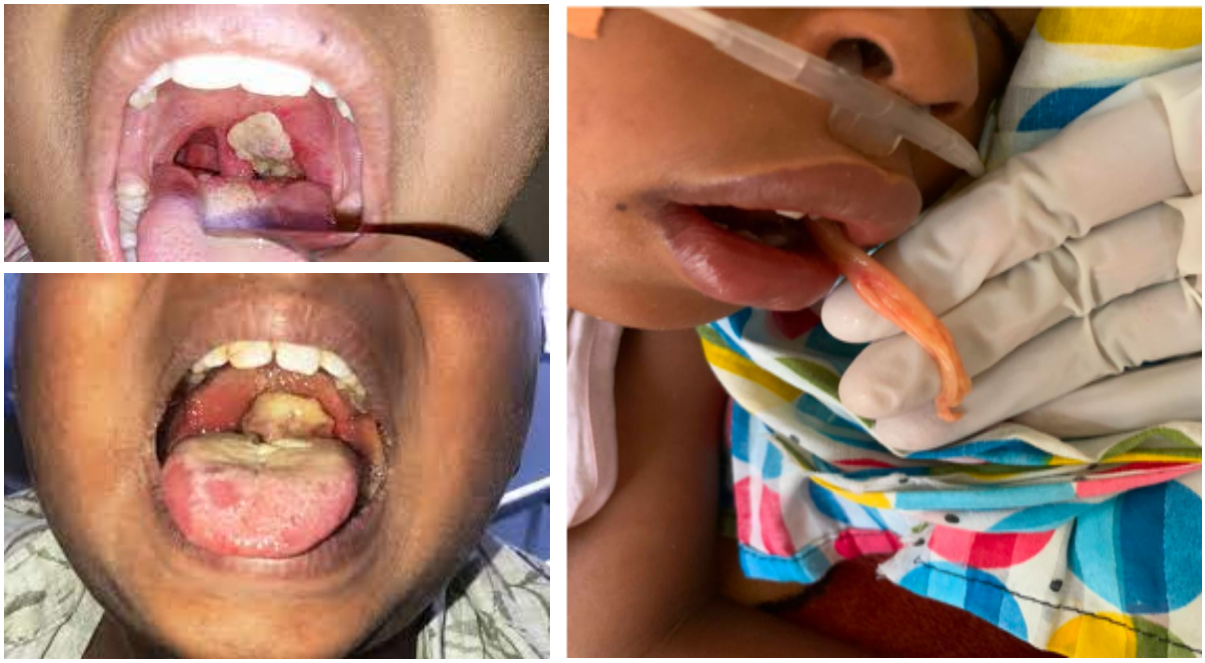


**Figure 6.0: Showing typical picture (left and middle) of pharyngo-tonsilar diphtheria with pseudo membrane (white-greyish patch), while the right shows an extensive pseudo membrane sloughing off following hydrogen peroxide gaggle.**
(photo credits: Dr. Salma Ali Suwaid, MMSH, Kano State)

**Nasal:**

This is the mildest form of presentation. Infection limited to the anterior nares presents with a serosanguinous or seropurulent nasal discharge often associated with a subtle whitish mucosal membrane, particularly on the septum. Signs indicating toxin effects are rare.

**Laryngeal:**

This may be either an extension of the pharyngeal form or the only site involved. Symptoms include fever, hoarseness, barking cough and progression of the membrane may lead to airway obstruction, coma, and death.

**Non-respiratory**

Under this classification, it can be:

Cutaneous: C. diphtheriae can also cause clinical skin infections characterized by a scaling rash or by chronic non-healing ulcers with a dirty grey membrane and often co-exist with Staphylococcus aureus and Streptococcus pyogenes (Group A Streptococcus). **Cutaneous diphtheria** may present as a scaling rash or ulcers with clearly demarcated edges and membrane, but any chronic skin lesion may harbor C. diphtheriae along with other organisms. This type of diphtheria is often associated with overcrowding, low socio-economic status, and poor environmental sanitation. Cutaneous sites of C. diphtheriae have been shown both to contaminate the inanimate environment and to induce throat infections in others. Bacterial shedding from cutaneous infections continues longer than from the respiratory tract. Cutaneous diphtheria can also manifest on the genitals, and it can also occur as a form of purpura fulminans (presenting as haemorrhagic diphtheria with or without throat pseudo-membrane).

Rarely, the patients can present arthritis as the sole presentation.

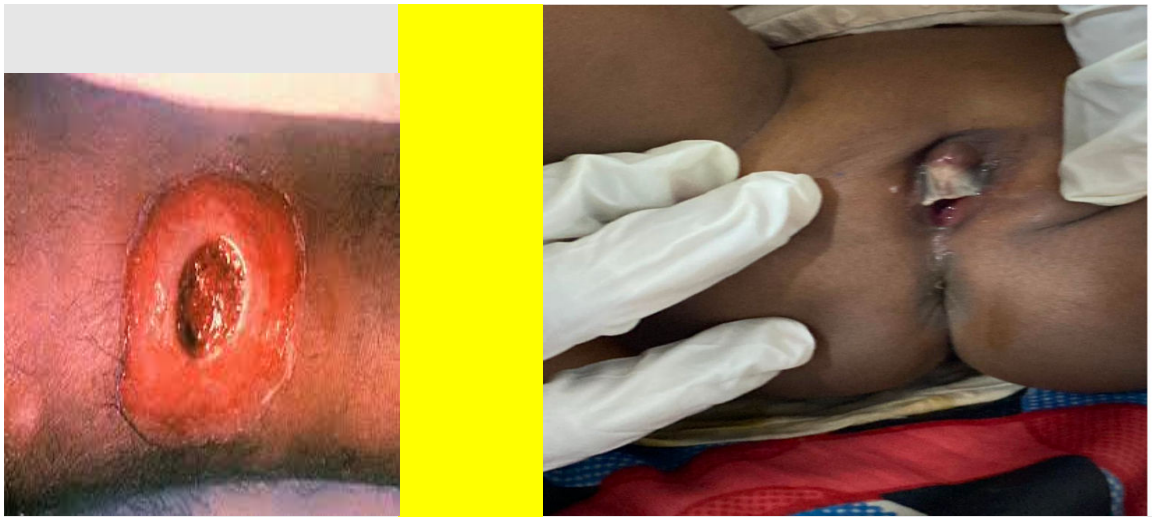


**Figure 7.0: Showing a picture of cutaneous diphtheria presentation** – From left an ulcer on the leg and right an infant with diphtheria presenting with vaginal pseudo membrane. (Photo credits: Dr. Salma Ali Suwaid, MMSH, Kano State)

**Complications**

- Bull neck appearance occurs from combination of cervical adenopathy, swollen soft tissue and mucosa that imparts a “bull neck” appearance to

many of the infected patients.

The most frequent cause of death is airway obstruction or suffocation following aspiration of the pseudo-membrane.

- The toxin produced by the bacteria disseminates and causes the systemic disease. Within 1-12 weeks, after the initial pharyngeal phase, some patients may develop myocarditis (congestive heart failure, conduction abnormalities, and arrhythmias), debilitating neurologic dysfunction (neuropathy of cranial and peripheral nerves, and/or motor weakness/paralysis), or renal failure. Details as below:

    - Cardiac complications can occur a few days after the onset of the acute illness and might be a predictor of high mortality:
        - AV- Heart blocks and other conduction disturbances
        - Ventricular and supra-ventricular tachyarrhythmias
        - Cardiomyopathies
    - Myocarditis (may occur within 1–7 weeks after the onset of illness) can present with a weak, irregular pulse and evidence of heart failure. Treat with supportive therapies according to national standards.
    - Neurological complications: This may arise because of the disease and or serum sickness from DAT administration. Up to 10-20% of patients might develop neurological problems, which are partially reversible, or result in long term sequelae. Neurologic paralysis may occur 1 to 3 months after the onset of the disease and can lead to difficulty in swallowing (paralysis of the soft palate), change in voice (paralysis of the vocal cords), vision (ocular motor paralysis), breathing (paralysis of respiratory muscles) and gait abnormalities (limb paralysis).
        - Signs are usually bilateral. Motor dysfunction is more common than sensory deficits.
        - Cranial nerve palsies can manifest as ocular and bulbar involvement.
        - Peripheral polyneuropathy can develop.
    - Acute kidney injury (AKI):
        - AKI might be caused by the effects of exotoxin linked to the primary infection.

    - AKI might also be associated with other organ- dysfunctions: respiratory failure, shock/sepsis.
- Hematological complications: This arises due to the toxin effect on the bone marrow leading to thrombocytopenia (symptomatic or asymptomatic) and disseminated intravascular coagulopathy. Thrombocytopenia usually occurs within the first week of the disease and is associated with high mortality.
- Hepatic complications: this usually manifests with deranged liver function test which presents with jaundice that can ultimately lead to acute liver failure. This can also occur within the first week of the disease.

**Clinical management**

Management of diphtheria is a multi-disciplinary care involving various specialties such as, pediatrician, Infectious disease specialist, ENT specialist, cardiologist, pulmonologist, nephrologist, neurologist, hematologist, dietician, intensivist, nurses etc. Ideally all suspected cases should be managed in dedicated isolation unit or centre which should comprise of a triage, inpatient ward, contacts clinic, follow up and immunization unit.

The following steps should be followed:

- Triage and resuscitation
- Isolation
- Definitive therapy
- Supportive therapy
- Management of complications
- Management of contact

**Triage and resuscitation**

All health workers should adhere to proper hand hygiene and apply standard, droplet and contact precautions at all times including the use of appropriate PPE (gloves, long-sleeved gown, surgical mask and goggle/ face shield for eye

protection) which entails prevention of contact with nasopharyngeal and cutaneous secretions from diphtheria patients. Ensure patients are separated from one another by at least 1m distance, with medical masks given to patients while they wait in a well-ventilated area. **The use of fans and air conditions are highly discouraged.** Categorize patients according to their clinical presentation and severity. Ensure patient's vital signs are recorded upon presentation and are closely monitored during the patients' admission.

Resuscitation involves quickly assessing the patency of airway, breathing, and circulation, extent of pseudo-membrane in respiratory tract and instituting corrective measures. Those with emergent signs and symptoms such as acute respiratory distress are resuscitated immediately on clinical presentation. Ensure patients with severe signs are attended to first.

**Collection of nasal and pharyngeal swabs for culture**: multiple swabs should be taken according to the NCDC guidelines in section 2, as soon as possible after diphtheria is suspected, ideally before any antibiotic treatment has started. However, treatment should not be delayed while waiting for laboratory results.

SPO2 monitoring should be instituted, critical samples such as full blood count, electrolytes, urea and creatinine, blood culture (for those with sepsis), random blood sugar, and malaria parasites for all patients. Other investigations relevant to the patient's presentation may be required. Brief history should be taken as soon as possible and contact tracing should commence immediately.

**N.B**

For patients with extensive pseudo- membrane (pharyngo-tonsillar) who can gargle usually >5 years), 1% hydrogen peroxide should be instituted immediately to remove the membrane and ameliorate acute respiratory distress and the need for tracheostomy (concentrations may differ – for dilution guide, see appendix).

**Isolation**

Maintain isolation until elimination of the organism is demonstrated by negative cultures of two samples obtained at least 24 hours apart after completion of antimicrobial therapy. If facilities are not available for droplet isolation, screens should be placed between patients to limit potential transmission and limit contact between the case and other patients in the health facility.

Waste materials generated should be properly disposed of and medical equipment adequately sterilized. Strict infection prevention and control measures **MUST** be instituted at every stage of patient care. Proper handling of dead bodies should be strictly adhered to.

**Definitive therapy**

**Neutralization of circulating toxins:**

DAT is the mainstay of treatment and should be administered (ideally within 1 hour of admission) as soon as possible in a hospital setting. Disease course and outcome depends on how early antitoxin treatment is started; after about three days from onset, the risk of complications and fatal outcome increases with each passing day DAT administration is delayed. DAT is administered only once following sensitivity screening. If diphtheria is strongly suspected, treatment with DAT should be given immediately without waiting for laboratory results, preferably intravenously in serious cases and intramuscularly otherwise (see appendix on the modalities of IM administration). The dose of DAT given varies depending on site and extent of pseudo membrane, time of onset and severity of infection.

If there is a reaction to the Besredka test, then give preventively, as a single dose before administering the DAT intravenously:

- Anti-histaminic treatment: Chlorpheniramine oral (oral solution 2mg/5mL or 4 mg tablets): Adult or children above 12 years (>39 kg): 4 mg po
  6-12 years (21-39 kg): 2 mg/Kg to avoid anaphylaxis
  1-6 years: 1 mg p/Kg

- Alternative for adults or children above 15: Promethazine, 25 mg orally.
  Hydrocortisone (sodium succinate):
  Adult: 200 mg intravenously
  Children: 2 mg/kg in one injection. Dilute 100 mg in 2 ml water for injection and administer by IM injection or slow IV push.

If the risk of allergy is thought to be high (patient with a previous history of severe allergic reactions to antivenoms, serums, vaccines, etc.), it is possible to skip the Besredka test and to give a half-dose of epinephrine, subcutaneously.

**Administration of DAT**

DAT are from equine origin, there is a risk of rare but severe anaphylaxis reaction and a frequent risk of mild reaction. Therefore, several measures need to be taken to mitigate the risks. The first one is that DAT must be given in a hospital setting.

- <u>To whom?</u>

All patients that have met the diphtheria case definitions should be referred to diphtheria treatment units urgently. There they will be re-assessed by a medical doctor who will confirm the clinical suspicion for diphtheria. If confirmed, the patient should receive DAT, as quickly as possible.

In the absence of shortage, every case of diphtheria should receive DAT, whatever the severity. In case of shortage, criteria may have to be implemented to prioritize the patients at greater risk of complications and death (see annex Priority criteria).

- Set-up

A space with all relevant biomedical equipment should be set up Nurses and medical doctors involved must be specifically trained in DAT administration and management of reactions. Ensure the following:

- Check availability: Bag and mask (ambubag) appropriate for age oxygen, if possible, hydrocortisone, anti-histamine, epinephrine, salbutamol, normal

saline or ringer lactate, and relevant medical materials (syringes, needles, gloves, face mask etc.). Vials of DAT from the cold chain are to be warmed up between the palms and doses for the patient calculated in advance before the infusion starts. All items must be readily available.

- Monitoring and documentation: Pulse rate, respiratory rates, blood pressure, conscious level, rash, itching, malaise, abdominal pain, diarrhea, vomiting, respiratory distress, cough, or wheezing should be closely monitored and documented.
- Monitoring: A nurse and if possible, the medical doctor remains at the patient's bedside for the first 15 minutes of the infusion, then monitor every 15 minutes. Permanent presence of someone in the room during the infusion is required, and as much as possible the nurse should stay. If this is not possible, the patient and the person staying must be aware of what to look out for and should have a very low threshold to call for help. Both the nurse and medical doctor should be always around in the ward/facility.

**DAT dosage**

- The amount of antitoxin required depends on the site and size of the pseudo-membranes, the duration of illness, and the overall clinical condition of the patient. It does not depend on the weight/age of the patient, as the dose aims at neutralizing the circulating toxin.
- Larger amounts are recommended for people with extensive local lesions because the size of the membrane reflects the amount of toxin produced that increases with delayed DAT administration.
- The entire dose should be administered IV once, slowly, over 2 to 4 hours. Start at a very slow rate for the first twenty minutes, then increase progressively to the final rate if no allergic reactions are observed.
- DAT administration diluted in normal saline must have its separate IV access. If there is a need for maintenance IV fluid, another IV access should be secured.
- Keep patient fasting during the infusion as a precaution in case a severe reaction occurs.

- For children under five, check glycemia before starting, and then every 60 minutes. In case of hypoglycemia (Glycemia ≤ 60 mg/dL or 3.3 mmol/L), give Dextrose 10% 2mL/kg IV, and control after 30 minutes.
- In case of DAT shortage, use the lower proposed dose.

**Table 9.0: Half-doses of preventive epinephrine SC or IM NOT IV**

| **Dosage for epinephrine intramuscular or subcutaneous injection PREVENTIVE - (1 mg/ml)** with **1mL syringe** | | |
|---|---|---|
| | ½ Epinephrine dosage | |
| Adults or > 12 years or > 40kg | 250 µg | 0.25 mL |
| Children 6-12 years | 150 µg | 0.15 mL |
| Children < 6 years or < 25kg | 75 µg | 0.08 mL |
| | | |
| In case 1 mL syringe is not available, dilute the 1mL ampule with 9 mL of NaCl 0,9%, **0,1 mg/mL (10 mL** | | |
| **syringe)**, and give: | | |
| Adults or > 12 years or > 40kg | 250 µg | 2.5 mL |
| Children 6-12 years | 150 µg | 1.5 mL |
| Children < 6 years or < 25kg | 75 µg | 0.75 mL |

**Caution**

The absence of reaction during the Besredka method does NOT guarantee that there will be no allergic reaction to DAT infusion. It only indicates that no preventive medication is required. REMAIN CAUTIOUS!

In case of exceptional and high workload, it can be considered to skip the Besredka test, and give systematic premedication before the DAT administration, as was done in Bangladesh. However, this is only a second option, and the test should otherwise be the regular procedure.

Caution: 250 mL is quite a large volume of fluid for children below 10 kg. Give the infusion over four hours and decrease the overall maintenance to make sure you do not overload the patient (standard maintenance volume for children below 10 kg is 100 mL/kg/24 hours if no cardiac failure)
*Some sources recommend going as high as 120 000 iu in case of severe forms, bull neck or evolution > 3 days (SANFORD, updated edition 09-2018).

**Reactions**

Three types of reaction could happen following DAT administration, namely: Anaphylaxis, Pyrogenic reaction, and Serum sickness. Three types of reactions can be observed, during or after the administration of equine immunoglobulins like the diphtheria anti-toxin. Anaphylaxis and pyrogenic reactions happen early during or just after the administration, while serum sickness is delayed by several days.

- **Pyrogenic reactions** typically occur during the first hour. They usually present as fever, but may include chills, rigor, myalgia, headache, tachycardia or at the maximum hypotension due to vasodilatation. They are due to contamination during the manufacturing process by pyrogenic substances and can usually be managed by simple antipyretics.
- **Anaphylaxis reactions** are often mild (urticaria, nausea, vomiting, headache, fever) and must be recognized. More severe reactions include facial oedema, abdominal signs with diarrhea, pain and vomiting, or cough and bronchospasm. Ultimately anaphylactic shock can happen. For more details, please see Appendix 3 about anaphylaxis in children.
- **Serum sickness usually occurs 7 to 21 days after the DAT administration**. The symptoms are fever, maculopapular skin rashes, or urticaria in milder forms. Arthritis, arthralgia, and lymphadenopathy also possible in more severe forms. Rarely, angioedema, glomerulonephritis, Guillain-Barré syndrome, peripheral neuritis, or myocarditis can occur. People who have previously received equine serums (like antivenoms) are more at risk to develop it, and it can occur earlier than the typical delay. Treatment of the most severe cases includes combine antihistamines, non-steroid anti-inflammatory drugs, and corticosteroids. Mild cases will resolve spontaneously.

### V.I Reaction to DAT administration

| |
|---|
| If you suspect a reaction:<br><br>STOP THE INFUSION<br>Call for help<br>PREPARE EPINEPHRINE AND START APPROPRIATE RESUSCITATION ABCD |

**Management of anaphylactic reaction in adults following DAT administration.**

A. For severe anaphylaxis (shock or respiratory distress, asthma or a combination of incoercible cough, violent abdominal pain, rash, etc.):

- Give epinephrine (adrenaline) 0.5 ml Epinephrine 1:1000 solution intramuscular or subcutaneous if conscious (table 4) + Bolus of Ringer-lactate 1 litre as fast as possible (5-10 min) in case of confirmed shock with hypotension or delayed CRT (>2 sec) or loss of consciousness.

**Table 10.0 Epinephrine for anaphylaxis reactions during the DAT infusion**

| Dosage for epinephrine IM or SC injection for anaphylactic shock - 1: 1000 **(1 mg/ml)** | | |
|---|---|---|
| Age | Dose | Volume of epinephrine |
| Adult and child 12 – 18 yrs | 500 µg | 0.5 ml |
| Dosages might be repeated several times with 5 minutes interval according to blood pressure, pulse, and respiratory function. If circulatory collapse or deterioration after IM, give diluted epinephrine intravenously as per instructions in Essential Drugs Guidelines. | | |

Epinephrine must always be **given SC or IM** in anaphylaxis (except refractory anaphylaxis, and big resuscitation)

B. Adjunctive treatment and initial treatment for mild-moderate reactions:

- **Anti-histaminic treatment: Chlorpheniramine** (oral solution 2mg/5mL or 4 mg tablets): Adult or children above 12 years (>39 kg): 4 mg po 6-12 years (21-39 kg): 2 mg PO: 1-6 years: 1 mg PO

Alternative for adults or children above 15: Promethazine, 25 mg orally **Hydrocortisone** (sodium succinate):

- Adult: 200 mg intravenously
- Children: 2 mg/kg, in one injection. Dilute 100 mg in 2 ml water for injection and administer by IM injection or slow IV push.

C. In case of mild persistent bronchospasm:

- **Salbutamol 100mcg** / metered inhalation – **2-4 puffs** (1-2 puffs for young children) **every 10 – 30 minutes** depending on severity. Consider use of spacer device.
- The treatment for any significant bronchospasm in the context of anaphylaxis is Epinephrine SC or IM (see table 3.0).

**Eradication of the organism**

Antibiotics appropriately administered can help to eliminate.

the bacteria and its subsequent toxin production, preventing further transmission and limiting carriage that can persist even after clinical recovery. Treatment should be continued for two weeks. For patients who cannot swallow or are critically ill, use IV or IM preparations. For severely ill patients unable to take oral therapy, use IV/IM formulation at the onset. Once patient improves clinically, stepdown to oral antimicrobials. For less sick patients, oral therapy can be used at the onset.

N. B – choice of empirical antibiotics should be guided by the antibiogram (sensitivity testing) in the area. However, parenteral, and oral erythromycin have

been found to be effective globally and in Nigeria. In addition to Azithromycin and erythromycin, I.V ceftriaxone may also be added for severely ill patients to target other bacterial pathogens.

**All the below antibiotics, injectable or oral, can be administrated to pregnant and lactating women.** Antibiotics are less effective than DAT in reducing mortality (DAT is the priority treatment). Antibiotics are very useful to reduce risk of transmission (after 2 days in contacts /approx. 4 days in cases).

**Table 11.0: Diphtheria antibiotic management (subject to antibiotics sensitivity testing)**

| **Patient category** | **Antibiotic** |
|---|---|
| Severe / Not able to swallow | **IV Azithromycin**<br>All persons: 10mg/kg/dose in 250ml of normal saline over 2-3 hours, daily (Be cautious with the fluid administration in infants and the malnourished), maximum of 500mg per dose. Treat for 3 days.<br>**IV Erythromycin**<br>All persons: 40 mg/kg/day (maximum, 2 G/day): 10 mg/kg every 6 hours, maximum 500 mg per dose. Treat for total 14 days. |
| Mild/Able to swallow. | **Oral Azithromycin x 14 days**<br>Once daily 10-12 mg/kg/day (maximum 500mg), orally for 14 days (duration under evaluation by WHO panel)<br>The first day give a loading dose of 1g for adults, or 20 mg/kg in children.<br>OR |
| | **Oral erythromycin x 14 days**<br>All persons: 40 mg/kg/day (maximum, 2 gm/day) dose, 10 mg/kg every 6 hours, maximum 500 mg per dose. Treat for total 14 days.<br>Do not give < 2 months of age.<br>OR |

| | |
|---|---|
| In case of shortage of the above only, as a last resort | **IV/Oral Amoxicillin (IV for severe, oral for others)** 100mg/kg/day (max 3g) in 3 divided doses, 7 days for contacts, 14 days for cases. |

**Supportive therapy**

7.4.1 Airway management: which will involve adequate care to maintain airway patency, regular suctioning in patients with tracheostomy and in children with drooling, oxygen therapy in hypoxemic patients and regular examination of patients to determine those that may need intermittent hydrogen peroxide gurgle.

7.4.2 Fluid: In patients that can take orally, liberal fluid intake should be encouraged, I.V fluid maintenance to ensure adequate hydration and glycemic control.

7.4.3 Steroids: Given in cases of respiratory distress and bullneck. Dexamethasone is rapidly absorbed in the tissues and has less side effects.

**7.4.4 Nutrition**

Diphtheria can be a long-lasting disease. Additionally, it can cause respiratory distress and swallowing disorders, hindering proper intakes for the duration of the acute phase of the disease. Consequently, nutritional status must be carefully followed throughout the treatment, and a nutritional support provided.

**Some points to emphasize include:**

- **Nutritional status must be assessed:** at admission and at discharge and managed as per facility protocol. For patient who has a prolonged admission, assess again the nutrition status when minimum appetite and feeding capacity are restored. Assess also if you have suspicion of decreasing weight.

- **Nasogastric tube:** the insertion of a nasogastric tube can tear the membranes present in the upper airways and cause a hemorrhage, which can worsen the patient's condition. It can therefore be extremely dangerous and must be avoided in patients with membranes. The use of nasogastric tube could be considered in patients with other complications such as malnutrition or whose membranes have decreased or are minimal, but if so, the decision must be made by an ENT surgeon, after a careful assessment of the risk/benefits for the patients, and well documented in the medical chart. High protein calorie diet (e.g., F100) can be considered, where available, total parenteral nutrition (TPN) can be given.

The patient's ability to take food will guide the nutritional management: There are 3 patient categories in relation to nutrition:

- **Critical patient:** very poor appetite, and /or eating-swallow difficulties (bull neck, major membranes, or severe other complications).
- **Intermediate situation:** patient with some appetite and able to eat-swallow some food.
- Patient capable of eating normally.

**Table 12.0 Food commodities to be considered for diphtheria patients.**

| | |
|---|---|
| **Critical patient**<br><br>Sip feeds according to the capacity of the patient. | Prefer liquid, fortified, high density energy food as:<br>2 Ready-to-use drink[1]<br>2 And/or Therapeutic milk F100[1]<br><br>If the patient cannot (or not enough) drink/eat and NGT cannot be considered, give IV maintenance to ensure at least adequate hydration and glycemia (refer to your facility pediatric protocol for fluid volumes in children). As soon as possible, introduce food/drink commodities. |

| | |
|---|---|
| **Intermediate**<br><br>If difficulties eating prefer soft/mashed or semi-liquid foods<br><br>Do not limit the quantity of food the patient demands[2] | Fortified and high-density energy food should be given in priority:<br>2 RUTF/RUSF, High Energy Biscuit (HEB given by WFP), Emergency Food Ration biscuit, (can be diluted to obtain a porridge[1]);<br>2 And/or Ready to use drink and/or Therapeutic milk.<br>2 And/or 1-2 CSB meals made into a porridge or added into other foods (Supercereal for adults or Supercereal+ for children < 5 years);<br><br>* Family meal[3] and anything the patient likes and can eat can be added; |
| **Capable of eating**<br><br>Do not limit the quantity of food the patient demands[2] | 2 Family meal[3];<br>2 And snacks with fortified high-density energy food (as RUTF/RUSF (paste or biscuit form) and/or High Energy Biscuit (HEB given by WFP), Emergency Food Ration biscuit and/or fortified-CSB meals (Supercereal for adults or Supercereal+ for children < 5 years);<br><br>*Anything the patient likes can be added |

[1] If Ready-to-use-drink and Therapeutic milk are not available and the patient is able to swallow enough: RUTF biscuits (BP100) or RUTF/RUSF paste can be diluted with water to obtain a semi-liquid porridge. The RUTF/RUSF should be diluted with 1ml water/kcal (1 sachet + 500 ml or 1 biscuit + 300 ml)

[2] Convalescent patients, for example, usually need and want higher quantities of food.

[3] If the patient does not take RUTF or RUSF, the family meal should be enriched by Micronutrient paste e.g.QBmix®.

### 7.4.5 Other measures

- Oxygen therapy should be instituted in hypoxemic patients and there is need for continuous monitoring for all patients to determine desaturation and managed as appropriate.
- Pain and fever control using analgesics e.g., paracetamol. NSAIDs should be avoided because of the risk of bleeding from thrombocytopenia.
- Oral toileting: entails gargling with hydrogen peroxide 6 hourly until membrane sloughs-off.

**Management of complications**

This can be broadly divided into 2:

**Early and late complications.**

I. **Early and life-threatening complications:** usually occur within 1 week from the 1st onset of symptoms and consist of: acute respiratory distress, respiratory failure, acute renal failure, AKI, thrombocytopenia, cardiac complications in the form of pan-carditis, rhythm disorders, cardiogenic shock, and heart failure. Management of the above complications should be done as per facility protocols in conjunction with a specialist. Where a specialist is not available, the patient should be referred to the appropriate facility.

II. **Late complications:** Occur in the form of polyneuropathy presenting as ataxic gait, proximal myopathy, change of voice, difficulty in swallowing, cardiac abnormalities, and renal pathology e.g., nephrotic syndrome, Chronic Kidney Disease Rarely, it can also lead to reactivation of latent tuberculosis. Management of the late complications should be done by specialist, where a specialist is not available, the patient should be referred to the appropriate facility.

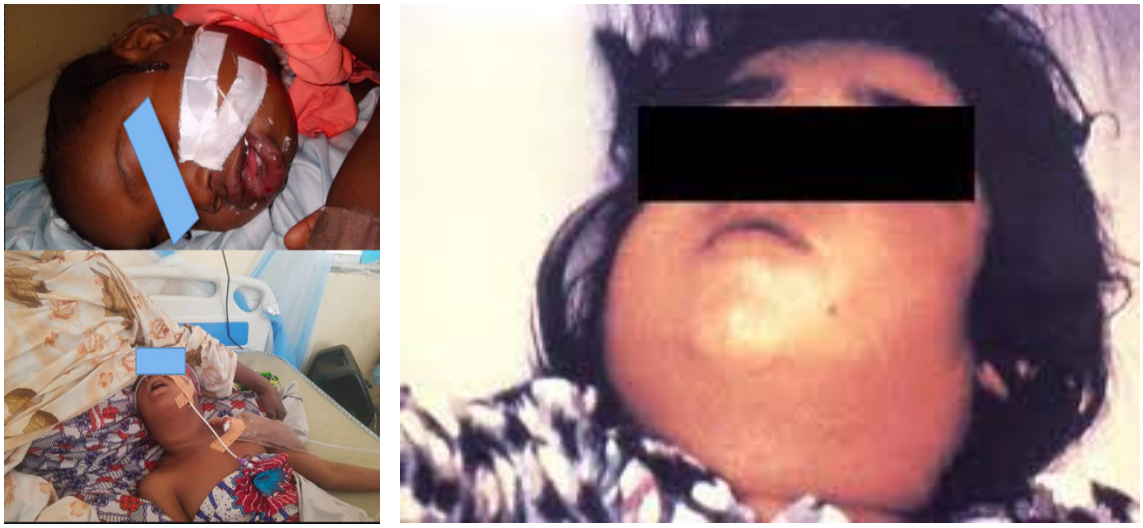


**Figure 8.0: The above shows bullneck appearance in diphtheria cases** (Photo credits: Top left by Dr. Hanga (AKTH, Kano State), bottom left by Dr. Salma Ali Suwaid (MMSH, Kano State), right: Medscape)

**Severe acute respiratory distress**

Ideally, a patient with severe respiratory distress should receive advanced or surgical airway management i.e intubated by a trained physician or have a tracheostomy performed in the operating theatre, with a well-trained, highly skilled and multidisciplinary team providing high-level intensive care

I. **Severe sign**

The table 13 below is extracted from an MSF OCBA guidance document for basic and advanced/ surgical airway management of diphtheria patients (March 2018). It provides a suggested list of warning signs, which should trigger the discussion for referral to high level facility.

**Table 13.0 respiratory warning signs**

| Respiratory warning signs | |
|---|---|
| • Laryngeal membrane<br>• Bull neck<br>• Inspiratory stridor<br>• Accessory muscle use<br>• Oxygen saturation <95% on room air<br>• Feeding difficulties | • Tachypnea :<br>o <2 months ≥60<br>o 2-12 months ≥50<br>o 1-5 years ≥ 40<br>o 6-12 years ≥ 30<br>o >12 years ≥ 20<br>• |

**Table 01 - Respiratory warning signs for diphtheria patients.**

**Important!**
**In the presence of respiratory signs, early referral to a higher level of care with experience in the management of advanced airway and ventilation should always be considered if time and situation allows.**

**Table 14.0 Indications/contraindications for advanced airway management**

| Indications (severity signs) | Contraindications (relative) |
|---|---|
| • Persistence or progression of warning signs<br>• $SpO_2$ < 92%<br>• Lethargy<br>• Cyanosis<br>• Restlessness,<br>• Bradypnea<br>o <2 months ≤ 30<br>o 2-12 months ≤ 30<br>o 1-5 years ≤ 25<br>o 6-12 years ≤ 20<br>o >12 years ≤ 14<br>• Signs of shock (Delayed capillary refill, tachycardia and cold extremities) | • Lack of requisite skills among team<br>• Prolonged transfer anticipated<br>• Poor outcome expected<br>• Logistical constraints (ventilator, oxygen ) |

**Table 02 – Indications/contraindications for advanced airway**

The choice of appropriate technique depends on the clinical skills and experience of the medical team. This includes the skills required to provide safe sedation or anaesthesia, as well as the skills to perform laryngoscopy and intubation, surgical tracheostomy or cricoidotomy.

**(OCBA, 2018)**

## II. Medical treatment:

In addition to the regular good practices (positioning to open airways, oxygen, humidification, etc), some medical measures may help to manage acute respiratory distress situations such as :

Stridor and/or respiratory distress and/or bull neck: Use high dose IV steroids (Dexamethasone or Hydrocortisone)

**Dosage:**

Dexamethasone IV 0.6mg/kg stat dose then 0.4mg/kg/day in 4 divided doses every 6 hours (maximum 10mg per dose) for 48-72 hours. Or

Hydrocortisone IV 3-5mg/kg per dose (1month to <12years old), or 100-200mg per dose in adults every 6-8 hours for 48-72 hours.

**Tracheostomy/cricothyroidotomy**

An anatomical opening created at the front of the neck so a tube can be inserted into the trachea to aid breathing. The procedure is done by a trained ENT surgeon, intensivist or an experienced medical officer trained on the procedure. Before doing the above procedure, a few key elements can be considered to weigh the benefit/risk:

- **Access to DAT:** patients show a clear improvement within a few hours after the administration of DAT, whereas if DAT is not available, improvement will come only after several days, and the patient can even worsen before improving.
- **Cause of severe respiratory distress:** if it is purely obstructive respiratory distress in a patient otherwise, stable, opening the airways can have a huge impact on survival and should be considered depending on the available resources and skills, whereas if the patients is overall unstable, with severe shock or myocarditis and cardiac failure… the expected results may differ.
- **Available resources:** items available, skills of the clinicians and their experience with the procedures, basic set up or high level of care with OT, ICU, ventilation, and nursing care possibilities.
- **Possibility of referring the patient to a better resourced health facility:** level of emergency, security/geographical constraints. Try and anticipate deterioration as much as you can!

## Case Management and contact tracing flowchart.

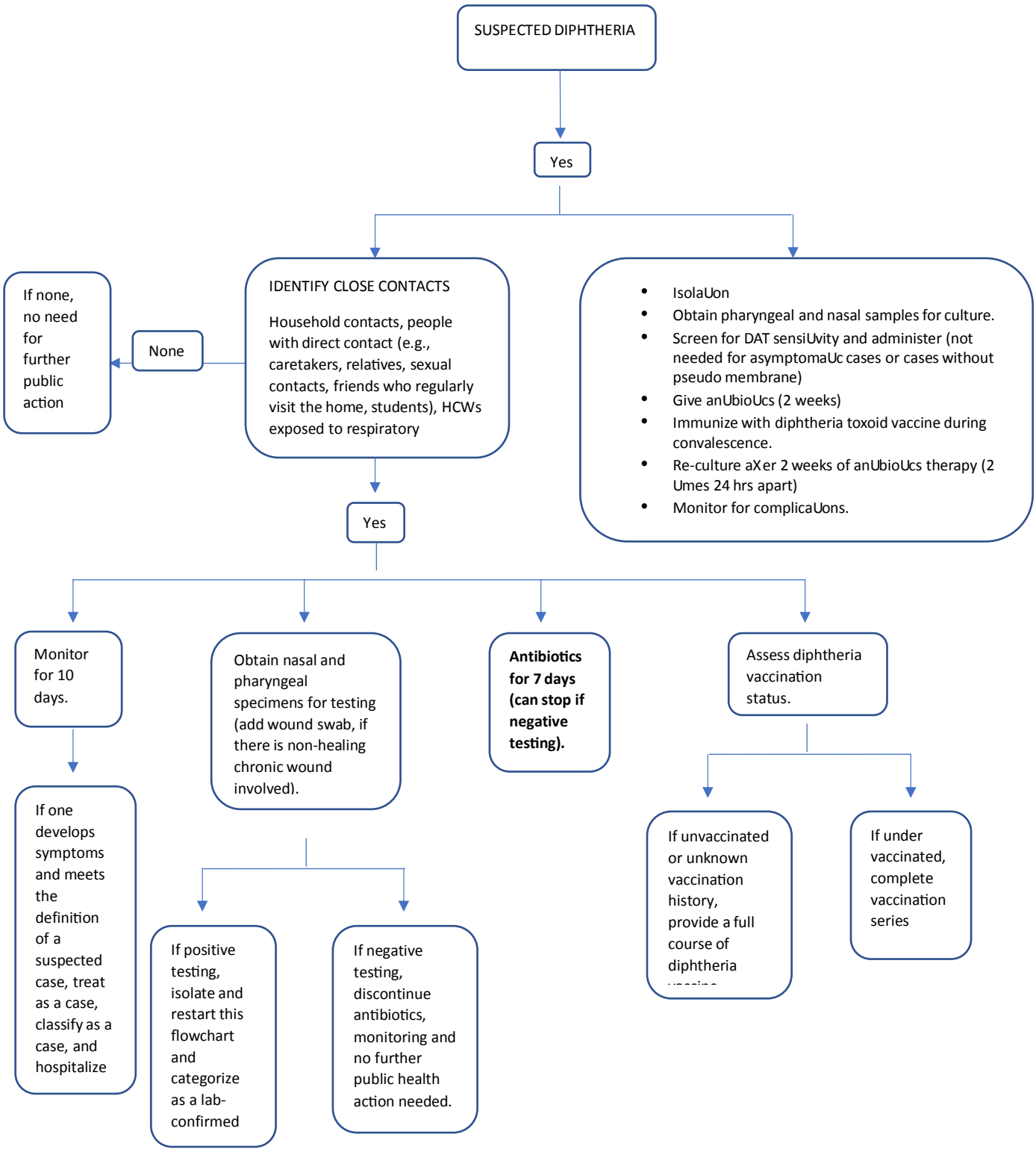



**Figure 9.0: Showing the adopted algorithm by the WHO, U.S. CDC, and Public Health England**

**Outpatient care**

**THIS SHOULD BE CONSIDERED ONLY WHEN THERE IS A MASSIVE OUTBREAK LEADING TO OVERWHELMING OF THE HEALTHCARE FACILITIES.** Only patients clinically diagnosed with mild diphtheria are eligible for home-based care.

**Inclusion criteria for outpatient care**

- Patients four years and above and clinically diagnosed with **MILD** diphtheria.
- Proximity to a fixed or mobile diphtheria clinic.

Difficulty accessing a health facility.

**Exclusion Criteria**

- Children less than 4 years.
- Malnourished children
- Pregnant and lactating mothers
- Frail elderly people
- Far distance from a health facility

**Outpatient care guide:**

**Day Zero:** All patients that meet the criteria above should be given DAT and the recommended antibiotics and observed for 24 hours (to monitor for adverse reaction and worsening of the diseases) before discharge for outpatient care.

- Proper health promotion is key: education on signs and symptoms, mode of transmission, importance of self-isolation at home, reduction of contact with others, importance of antibiotic and adherence, etc.
- Nurses & doctors to re-assure the patient/caretaker (to avoid panic).
- Restrict contact with others until completion of antibiotic therapy (14 days)
- Stay at home, do not use public transports, or go to school or work,
- Do not share a bed; sleep separately (in a separate ventilated room if possible)
- To counsel patients and family to reinforce hand hygiene practices with water and soap.

- To counsel patients to apply respiratory hygiene (Cover your mouth and nose with a tissue when you cough or sneeze. Put your used tissue in a dedicated waste basket at home and burn waste afterward. Wash hands with soap and water after coughing or sneezing).
- Provide antibiotics according to protocol (14 days) and importance of adherence.
- The patient should return immediately to the health facility when danger signs begin to emerge (shortness of breath, bull neck, bleeding from the nose, difficulty in swallowing, high fever, etc.)
- Stress the importance of close contact to visit the contact clinic.
- Ensure follow-up visit.

**Outpatient documentation/report**:

- Contact form for outpatient care should be filled out by the nurse before sending the patient home.
- Give follow-up slip and inform patient/caretaker about the place of mobile contact clinic near to geographical location of the patient.
- Importance of close contact to access the mobile contact clinic.

The health promotion team will communicate with the close contacts of outpatient care patients to access mobile contact clinic according to schedule.

**Outpatient Follow-up:**

1. **Day two of outpatient Care:** A phone call is made. If not reachable, the outreach team visits their home. The main purpose of the phone call is to check for any complications and adherence to antibiotics. If there is any arising complication or non-adherence, the patient should return to the facility for hospitalized care.
2. The outpatient will be informed by health promotion team to visit the mobile contact clinic: on a weekly basis for 4 weeks.

- First week: Check for diphtheria symptoms, early complications & progress of recovery. Adherence to oral macrolide.

- Second week: Detect early complications and to ensure the oral macrolide full course (14 days).
- Third week: Progress of recovery, check for complications and provide vaccine according to NPI.

Fourth week: last visit, check for complication, information regarding late complications and discharge. During any follow-up visit nurse to check for complication and symptoms of diphtheria. During this time, the not infectious and clear of the organism. Complications arising should be sorted at the facility a referred to the appropriate specialist clinic.

**Management of contacts**

A proper identification and management of close contacts is key, both to prevent them from developing the disease, and to stop transmission.

**Close contact definition**

Persons living under the same roof, caretakers from infants, persons in close contact on a regular basis (same class and close friends for children, confined workplace, etc. But NOT the whole school).

**8.1 Management**

**8.1.1 Antibiotics: (Guided by Antibiotics sensitivity testing)**

**Table 14.0 Antibiotics for contacts of a diphtheria case**

| | |
|---|---|
| **Contacts** | **Oral erythromycin x 7 days (challenging for observance)**<br>For children: 40 mg/kg/day, in 4 divided doses, 10 mg per dose, every 6 hours<br>For adults: 1 g/day for adults, administered in divided dose, 250 mg per dose every 6 hours.<br>**OR** |
| | **Oral Azithromycin, once daily x 7 days (2nd choice)**<br>10-12 mg/kg/day (max. 500 mg/day) orally 7 days (no loading dose) |

**Immunization**

Being a vaccine preventable disease, effective vaccination remains the cornerstone for improving herd immunity and outbreak prevention. Currently, the vaccine schedule in Nigeria is summarized below.

**Table 15.0 Summary of immunization strategy per age groups**

| Age | Routine | Outbreak | Interval | Dose | Route | Site |
|---|---|---|---|---|---|---|
| 6 weeks-23 months | 3doses of Penta at 6,10 and 14weeks | Identify children with incomplete doses of penta for completion of doses | 4weeks apart | 0.5mls | Intramuscular | Anterolateral part of left thigh |
| 24-59 months | - | Identify children with incomplete doses of penta for completion of doses | 4 weeks apart | 0.5 mls | Intramuscular | Anterolateral part of left thigh |
| 5-14 years | - | 3 doses of Td as | Tdap/Td1 at contact, | 0.5mls | Intramuscular | Left upper arm |
| | | booster doses. | Tdap/Td2 after 4 weeks, Tdap/Td3 after 6months | | | |

**Annexure:**

1. In outbreak situation, priority should be given to Health Workers directly treating cases of diphtheria to receive Tdap/Td vaccine booster doses.

2. In outbreak situation, target age can be extended for Tdap/Td (especially for all health workers and other vulnerable) depending on availability of vaccines and other logistics.

***Remember that for the diphtheria cases who have receive the DAT, it is important to try and delay the beginning of the vaccination up to three weeks after the time of the DAT administration.***

**8.2 Protection following vaccination**:

For information, children can be protected two weeks after the third dose of pentavalent (≤ 1year) or the second dose (1-5 years).
Adults who had no prior vaccination are protected two weeks after the second dose of Td.
People who meet requirements for a booster dose are protected almost immediately after receiving the booster.

**8.3 Follow up of contacts:**

To be determined based on feasibility. Incubation period is 2 to 5 days. Any close contact of a probable case developing pharyngitis or sore throat becomes a probable case, requires urgent assessment and if relevant urgent DAT administration.

## 9.0 Special cases

### 9.1 Pregnant women

Obstetric respiratory diphtheria has high fatality rates and fetal loss, or premature delivery is frequent in survivors, as high as a third of the cases.

**Antibiotic:**

All antibiotics cited in case or contacts management are compatible with a pregnancy usage, irrespective of the gestational age.

**Diphtheria antitoxin:**

Pregnancy is not a contra-indication to DAT administration.

Moderate or severe diphtheria pregnant patients have a benefit/risk balance in favor of DAT administration, especially as DAT administration is more efficacious if administered earlier. Carefully monitor. In case of reaction, there is no contra-indication for the use of hydrocortisone or adrenaline, nor antihistamines.

For mild cases of diphtheria disease in pregnant women, DAT can be administered if there is no doubt on the diagnosis. The decision is with to the clinician, and the mother/family head must be informed.

### 9.2 Lactating women

**Antibiotic:**

All antibiotics cited in case or contacts management are compatible with breastfeeding.

**Diphtheria antitoxin:**

DAT can be administered in lactating women, and breastfeeding can be continued. Prevention of transmission to the breastfeeding baby While the mother or her child is sick, everything must be done to protect the milk

production +++, especially in children under 6months, exclusively breastfeeding. Keep the mother well hydrated. Express the breastmilk several times a day if the child cannot breastfeed (irrespective of the reason).

If the mother's condition allows it and if the baby is young, the baby can stay with the mother in the isolation area, to protect the bond and the lactation, but with adherence to standard and isolation precautions.

**Elements to mitigate transmission risks.**

- If the mother has received more than four days of antibiotics, chances that she still carries the C. diphtheriae are very low. Before this delay, or if the mother is still very "productive" (cough, secretions), she must wear a mask when holding the baby tight, for instance when breastfeeding. Also ensure good hand hygiene practices.
- As a contact, the baby must receive antibiotics as a prophylaxis. Ensure dosage and number of daily intakes are adequate with the age.
- Check and correct the vaccination status: diphtheria vaccination is part of the pentavalent vaccine and should be administrated at 6, 10, 14 weeks of age (4 weeks apart).

**N. B**

Some patients do present with other comorbidities such as SCA, TB, DM , in such cases, a wholistic approach in management should be instituted.

**Table 16.0: TT Immunization schedule for women of childbearing age (15-49yrs)**

| Vaccine Doses | **WHEN TO GIVE** | **EXPECTED DURATION OF PROTECTION** |
|---|---|---|
| Td1 | At first contact or as early as possible in pregnancy | None |
| **Td2** | At least 4 weeks after Td1 | 1-3 years |
| **Td3** | At least 6 months after Td2 or during subsequent pregnancy within 3 years. | 5 years |

| | | |
|---|---|---|
| **Td4** | At least 1 year after Td3 or during subsequent pregnancy | 10 years |
| **Td5** | At least 1 year after Td4 or during subsequent pregnancy | All the childbearing years |

## 10.0 Discharge and follow-up

1. Immunization: Ensure the patient is vaccinated or refer them to the relevant place, but in any case, explain!

   Diphtheria does not necessarily confer immunity. It is therefore key that the patients receive immunization against diphtheria during the convalescence phase. Vaccines and schedule are specified as per NPI schedule.

2. Please note that the antitoxin may interfere with the vaccine (by destroying the anatoxin contained in the vaccine), and therefore the first dose should be administrated at best from three weeks after the DAT administration. If there is no other possibility, and you fear the patient will not get the vaccine later, do it whenever you can.
3. Patients need to know what to monitor in the coming weeks: Pre-condition: they need to know what they had, how to recognize it, what to do if somebody develops diphtheria. Check that this information has been provided.
   Late complications of diphtheria: mostly myocarditis, from the second week (tachycardia, signs of heart failure, sudden death), and polyneuropathy, usually between week 3 and 8.
4. Polyneuropathy can present as a nasal voice and regurgitations (soft palate paralysis), sight/oculomotricity disorders, or limb paralysis, for instance. Overall, patients must be aware that some things may occur, and that any atypical experience can be related to diphtheria and must result in a quick consultation.

5. Serum sickness: can happen up to the third week after DAT administration. Inform the patient of possible signs, and for the need to come back for assessment and management.
6. Nutrition support during convalescence:
   A final nutritional screening must be done at discharge (especially for children), and malnourished patients referred as per national protocol. See appendix for malnutrition criteria and how to proceed. Non-malnourished patients could receive a convalescence ration of 5 bars of BP5 or 3 sachets of RUSF per day, for two weeks.

**10.1 Protection following vaccination:**

For information, children can be protected two weeks after the third dose of DTPHib-HepB (≤ 1year) or the second dose (1-5 years).
Adults who had no prior vaccination are protected two weeks after the second dose of Td.
People who meet requirements for a booster dose are protected almost immediately after receiving the booster.

**10.2 Follow up of contacts:**

To be determined based on feasibility. Incubation period is 2 to 5 days.
Any close contact of a probable case developing pharyngitis or sore throat becomes a probable case, requires urgent assessment and if relevant urgent DAT administration.

## 11.0 Basic facility requirements for diphtheria case management

1. Identify a designated area for triage, isolation with a functional Infection Prevention and Control programme, and case management capacity.
2. Human resource: Infectious disease specialists, pediatrician, ENT surgeon, medical officers, nurses, and hygienists trained in diphtheria management.
3. Equipment: Resuscitative equipment such as: AMBU bag (bag and mask), ET tubes, NG tubes, laryngoscope, tracheostomy kits, glucometers and pulse oximeters, suction machine, oropharyngeal airway, bed screens etc.

4. Provision of oxygen: preferably 100% with other accessories e.g., nasal prongs, nasal catheters, masks
5. Medical consumables: DAT, antibiotics, IV fluids, drugs such as hydrocortisone, adrenaline, dexamethasone, analgesics (NSAIDs should be avoided because of the risk of bleeding from thrombocytopenia), IV fluids and antipyretics (paracetamol), hydrogen peroxide, ACT, Kwashipap or RUTF.
6. Referral services: Functional ambulance with resuscitative equipment and oxygen, driver, telecommunication
7. Specialist services:
8. PPE: Medical mask, googles/face shield, gloves, single use disposable gown.
9. WASH Facility: running water, single use towel, liquid soap, ABHR, colour coded waste bin and liner.

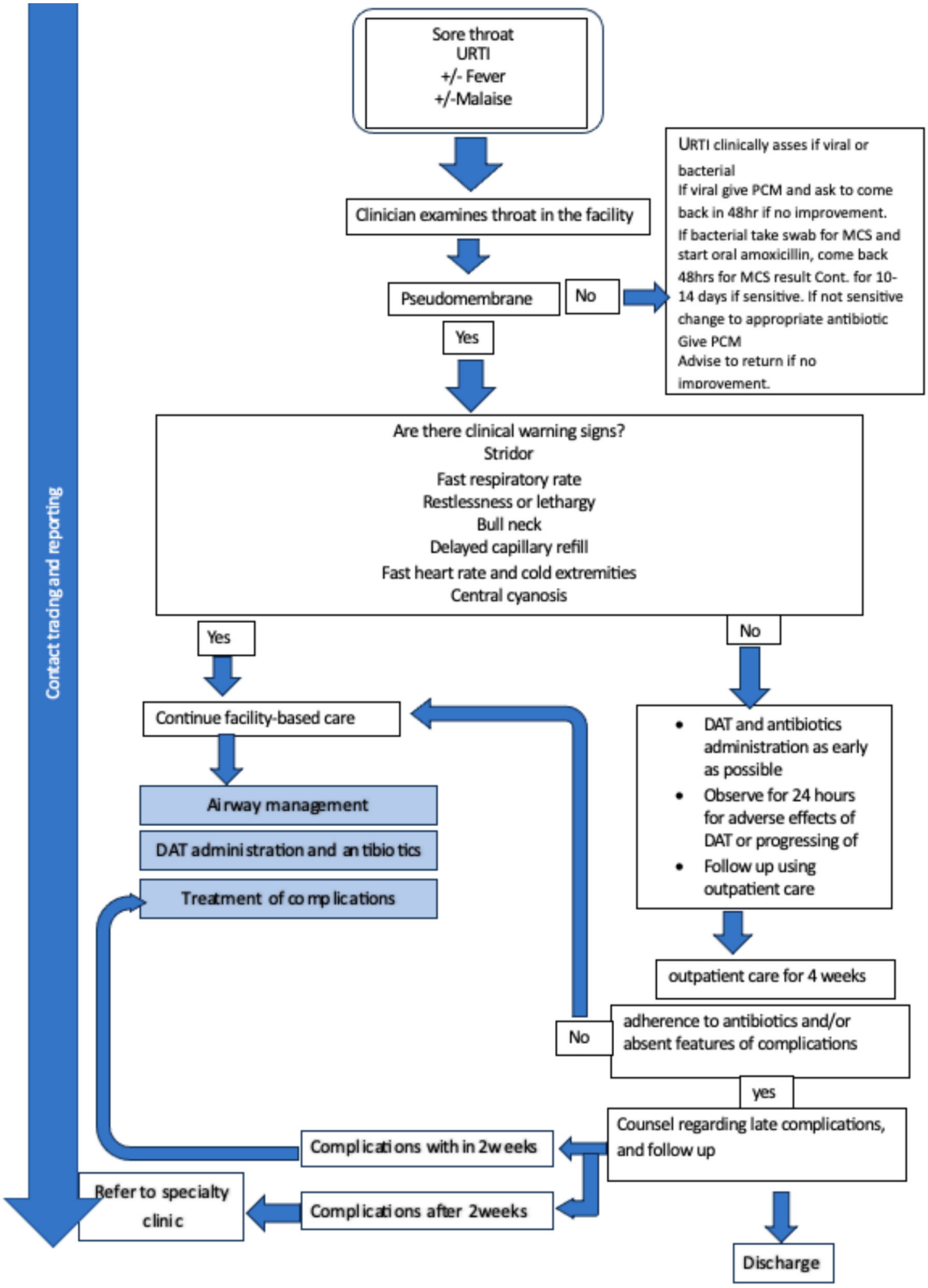
## 17.0 Case management and infection prevention and control pillar indicators for diphtheria response

These are useful variables that provide insight on diphtheria case management and infection prevention and control at the national and sub-national levels. The indicators used for the response include:

| Indicator | Definition | Target | Remarks |
|---|---|---|---|
| Bed occupancy | Number of cases admitted/Total number of beds available *100 | Not to exceed the expected ratio of HCW per bed | Assess workload and staffing needs, congestion/overcrowding which could facilitate disease transmission |
| HCW infection rate | Number of healthcare workers that contract diphtheria in the healthcare environment/Total number of | 0% | |

| | | | |
|---|---|---|---|
| | healthcare workers in the state * 100 (disaggregated by cadre) | | |
| CFR% | Number of deaths from diphtheria/Total number of confirmed diphtheria cases * 100 | <5% | Depends on other variables e.g. early presentation |
| Proportion discharged patients linked to the immunization | Number of diphtheria cases managed and linked to the immunization and child welfare clinic at a particular time /Total number of diphtheria cases at a particular time * 100 | 100% | Quality of care including immunization services |
| % of cases given DAT | Number of diphtheria cases admitted and given DAT at a particular time/Total number of diphtheria cases at a particular time * 100 | 100% | Measures access to/and availability of DAT |
| % of cases with adverse events from DAT | Number of diphtheria cases given DAT and | 0% | Ideally should be given immediately to improve |

| | | | |
|---|---|---|---|
| | manifest adverse effects at a particular time/Total number of diphtheria cases at a particular * 100 | | clearance of unbound circulating toxins |
| % of cases given appropriate macrolides for 48 hours | Number of diphtheria cases given appropriate macrolides at a particular time/Total number of diphtheria cases at a particular time * 100 | 100% | Measures access to/and availability of appropriate (oral/parenteral) macrolides |




Footnote: refer to the text for case management.

**Figure 10.0. Case Management Algorithm**

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# 4.0

# Infection Prevention and Control Guidelines for Diphtheria

# 4.0 Infection Prevention and Control Guidelines for Diphtheria

**Host Susceptibility**

Prior vaccination protects against the disease and reduces the frequency and severity of disease. At the population level, it is believed that vaccine coverage of 80–85% must be maintained to maintain herd protection/ community protection and reduce the threat of an outbreak. Vaccination provides prolonged but not lifelong immunity. Lifelong immunity is generally (but not always) acquired following disease or inapparent infection. [6] The protection is antibody related and immunity is primarily against the toxin rather than the bacteria; therefore, vaccinated persons can still harbor the organism. There is no clearly defined level of antitoxin demonstrated to provide complete protection. Levels between 0.01 IU/mL and 0.09 IU/mL are regarded as providing basic immunity, while levels of > 0.1 IU/mL may be needed for full protection.[7]

Additional factors that may increase an individual's susceptibility include the dose and virulence of the bacteria, as well as the person's general immune status.

**Prevention of Transmission in Healthcare Settings:**

Involves early detection and identification of cases, implementation of standard and transmission-based precautions (droplet and contact precautions), vaccination of HCW, PEP, exclusion of HCW suspected to have diphtheria from clinical work.

**Early Detection and Identification of Cases:**

Triaging of cases: People that fit the case definitions for diphtheria, are rapidly reviewed and isolated to reduce contact with other patients.

At triage immediately place patients with symptoms of URTI in a separate ventilated area until reviewed, provide patient with a medical mask, maintain 1meter distance between patients and ensure adherence to respiratory hygiene.

**IPC Requirements for Triage:**

- A well-defined triaging station at entry or exit points in the facility.
- Trained staff supporting these stations
- Ensure that appropriate PPE are available
- A high index of suspicion by staff
- Use of screening questionnaires with updated case definitions for Diphtheria
- Posters and reminders for symptomatic patients to urgently alert HCWs or relevant authorities
- Waste bins
- Flow charts and protocols
- Algorithm for triage
- Hand Hygiene materials
- Clear signages

**Standard Precautions:**

The core components of standard precautions are:

- Hand hygiene
- Respiratory hygiene/Cough Etiquette
- Patient placement and physical distancing
- Appropriate use of Personal Protective Equipment (PPE)
- Environmental cleaning and disinfection of patients' equipment
- Safe handling of linen
- Waste management
- Safe injection practices

**Table 18.0: Standard Precautions for the Care of Patients in Healthcare Settings**

| **Component** | **Recommendations** |
|---|---|
| **Hand hygiene:** should be observed at the 5- moments and requirements made available at points of care. 5-Moments for Hand Hygiene (described in more detail below in this guideline). | |
| **Moments** | **Actions** |
| Moment:1 | Before touching a patient |
| Moment:2 | Before performing clean/aseptic procedures |
| | After body fluid exposure risk (e.g., after handling any potentially |
| Moment:3 | contaminated equipment or material such as laundry, wastes, |
| | dishes, vomit and stool buckets, etc.) |
| Moment:4 | After touching a patient |
| Moment:5 | After touching patients' surroundings |
| **Respiratory hygiene/cough etiquette** | |
| Instruct symptomatic persons to cover mouth/nose when sneezing/coughing (especiallyimportant in waiting areas or crowded rooms)<br>Use tissues and dispose in no-touch receptacle.<br>Encourage patients to cough into elbow if disposable tissue is not available.<br>Observe hand hygiene after sneezing/coughing/soiling of hands with respiratory secretions.<br>Wear medical mask if tolerated.<br>Maintain spatial separation, >1 meter if possible.<br>Symptomatic patients should be prioritized. | |
| **Patient Placement** | |

| | |
|---|---|
| Isolate patients who require additional precautions in a private room<br><br>Where single patient rooms are not available, suspected cases can be cohorted in the same room with a minimum of 1 meter in between patient beds. Maximize natural ventilation<br><br>Similarly, confirmed cases can be cohorted in the same room with a minimum of 1 meter in between patient beds.<br><br>Ventilation: natural ventilation in patient care areas reduces the risk of droplet transmission. | |
| **Personal protective equipment (PPE)** | |
| **Gloves** | Used when there is risk of contact with skin lesions, respiratory secretions, mucous membranes and contaminated items. Gloves should be changed between patients. |
| **Gown/Apron** | Used during procedures and patient-care activities when contact of clothing/exposed skin with secretions are anticipated. Gown should be changed, if soiled. |
| **Mask, Eye-protection (goggles), Face shield** | Used during procedures and patient-care activities likely to generate splashes. |
| **Environmental Cleaning and Disinfection** | |
| **Cleaning of surfaces** | There should be routine cleaning of patient care areas followed by disinfection of frequently touched surfaces at least twice daily. Terminal cleaning should be done upon patient discharge. Cleaning of the room should be done with the appropriate detergent and followed by disinfection with an appropriate disinfectant e.g., 70% ethyl alcohol (if available). Hypochlorite dilution should be 0.1 % and allowed a contact time of 15 minutes. Focus on frequently touched surfaces and equipment near the patient (patient zone). |

| Patient care equipment-Linen Management | |
|---|---|
| **Soiled patient-careequipment** | These should be handled to prevent microorganisms transferring to others and the environment. Gloves should be worn while handling soiled patient-care equipment and hand hygiene should be performed before and after. |
| **Linen and laundry** | Linen should be handled in a manner that prevents transfer of microorganisms to others and the environment. Appropriate PPEshould be used when handling dirty and/or soiled linen and hand<br>hygiene should be done after. |
| **Waste Management** | |
| Proper waste segregation at the point of generation and final disposal should be ensured. Color coded waste bins and bin liners as well as sharp boxes should be positioned at entrances of care areas and sharp boxes at arm's length of the point of care. Waste handlers should wear appropriate PPE (gloves, apron/gown and medical mask) when handling wastes. Hand hygiene should be performed before and after handling wastes | |

**Transmission Based Precautions (TBP):**

These are used in addition to standard precautions for suspected or confirmed cases of Diphtheria. TBP for preventing further spread Diphtheria in a hospital includes droplets and contact precautions.

2.3.1 Contact precautions for Diphtheria (Skin presentation): These include:

1. Patient Placement

- Have in place signages on entrances to patient areas

2. PPE

- Put on a clean, non-sterile gown and gloves before entering the patient-care area
- Remove and discard PPE before exiting the patient area
- Perform hand hygiene immediately after removing PPE

3. Patient equipment and environmental cleaning

- Use disposable or when unavailable dedicated patient-care equipment (for example, thermometer). For shared re-usable equipment, clean and disinfect equipment after each use.
- Cleaning should be with increased frequency (for example, more than once a day), with a focus on frequently touched surfaces and equipment, such as bed rails, doorknobs and toilets.

4. Patient transport outside of a room

- When transport is necessary, ensure any wounds or lesions on the patient's body are covered.
- Remove and dispose of PPE, then perform hand hygiene, prior to transporting patients on contact precautions
- Do not wear used PPE outside of a patient's room.

2.3.2 Droplet Precautions for Diphtheria

Patients are placed on droplet precautions when they have known, or suspected infections transmitted by respiratory droplets. Droplets are small amounts of liquid from the lungs, mouth, or nose that are expelled into the air when people cough,

talk or sneeze. Droplets can also spread via hands when people sneeze or cough into their hands and then touch mucous membranes of another person

1. Patient placement

- Single-patient rooms are preferred for patients who require droplet precautions
- Special air handling and ventilation are not needed for droplet infections

2. PPE:

- Put on a medical mask (not a respirator) before entering the patient care area. Additional PPE might be indicated based on a risk assessment.
- Remove and properly discard PPE before exiting the patient room
- Perform hand hygiene immediately after removing PPE
- PPE used include Medical Mask, Apron and Gloves

3. Patient Transport Outside of a room: Avoids movement or transport out of isolation area.

If movement is necessary, use a medical-surgical mask if he/she must move outside of isolation area and instruct the patient to wear a mask and follow respiratory hygiene and cough etiquette.

**Healthcare Worker Protection:**

Vaccination: Healthcare workers involved in patient care and outbreak response should be vaccinated with dT (in accordance with NPHCDA guidelines). Other HCW at high risk of infection eg previously unvaccinated HCWs should also be considered for vaccination with dT.

Post Exposure Prophylaxis (PEP): For HCWs who have had occupational exposure, viz:

- Unprotected exposure: HCWs who attended to cases of diphtheria without droplet precautions (face mask).
- Close face to face contact: HCWs who performed clinical procedures like intubation, nebulization and bronchoscopy without airborne precautions (Respirator).

Exclusion of HCWs from work: HCWs who are clinically compatible or confirmed to have diphtheria should be excluded from work until discharged in accordance with case management (Refer case management module)

HCWs surveillance: HCWs with diphtheria should be identified, documented and reported. Facility IPC personnel should monitor HCWs for symptoms suggestive of diphtheria using the HCW monitoring form (Appendix I)

IPC precautions for sample collection: HCWs collecting samples from patients for testing should adhere to droplet (medical mask, googles/face shield) and contact precautions (Gloves, gowns/aprons) in addition to other precautions required based on risk assessment.

**Advise for caretaker/visitors:**

- One (1) caretaker/patient (especially if child) maximum
    - Caretaker should be educated about the precautions to use, the duration of precautions, as well as the prevention of transmission of disease to others with a particular focus on use of mask, hand hygiene with water and soap or alcohol-based hand rub, environmental cleaning, and disinfection.
    - Caretaker should be instructed about the indications for and appropriate use of personal protective equipment (PPE).

The number of visitors should be limited/minimized to essential visitors (e.g., parent, guardian, or primary caretaker) only.

Handling of dead bodies after suspected/confirmed Diphtheria:

Transmission risk: While there is currently no evidence of increased risk of transmission due to handling of dead bodies, it is important to implement standard and droplet precautions to prevent transmission during handling of dead bodies.

**Community Based IPC**

1. Where patients are not hospitalized or if patients return home before the end of the recommended period of isolation or people who are symptomatic, the following precautions should be taken at home:

    a. Restrict contact with others until completion of effective antibiotic therapy.

        I. Patient should stay at home, do not use public transports, avoid public places like schools and religious gatherings.
        II. Do not share a bed, sleep separately (in a separated ventilated room if possible)

Patient and family: regular use of medical mask and adherence to standard precautions e.g., hand hygiene, use of single-use disposable gloves, environmental cleaning and disinfection are necessary and apply respiratory hygiene (Cover your mouth and nose with a tissue when you cough or sneeze. Dispose-off used tissue in a dedicated waste bin at home and dispose appropriately. Wash hands with soap and water after coughing or sneezing).

**Immunization Schedule**

**Vaccination:**

1. Complete 3 injections of DTC-Hib-HepB (Pentavalent) for children under 5 years or Td vaccine for adults and children over 5 years
2. If 3 injections were already given with the last one more that 1 year ago give a booster dose (DTC-Hib-HepB < 5 years and Td > 5 years)
3. Please note that if Td vaccine is not available and the authorities agree, it is possible to give the Pentavalent up to 7 years of age.

**Schedule:**

4. Below 1 year: 3 doses 4 weeks apart
5. After 1 year: 2 doses 4 weeks apart + 1 dose 6 months later

**Table 19.0: Summary of immunization strategy per age groups**

| | **0-1 year** | **1-5 year** | **5-7 year** | **>7 or adult** |
|---|---|---|---|---|
| **Vaccine** | DTPHib-HepB | DTPHib-HepB | Td but DTPHib-HepB is possible | Only Td |
| **Schedule (if not vaccinated before)** | M0-M1-M2 | M0-M1-M7 | M0-M1-M7 | M0-M1-M7 |
| If another situation, refer to WHO table 3 for routine immunization catch up*<br>M0: time of first dose. M1: a month later. M7: seven months after the first dose (Minimum. No maximum) | | | | |

*https://www.who.int/immunization/policy/Immunization_routine_table2.pdf?ua=1
https://www.who.int/immunization/policy/Immunization_routine_table3.pdf?ua=1

***Remember that for the <u>diphtheria cases who have receive the DAT</u>, it is important to try and <u>delay</u> the beginning of the vaccination up to three weeks after the time of the DAT administration.***

**Protection following vaccination:**

- Children can be protected two weeks after the third dose of DTPHib-HepB (≤ 1year) or the second dose (1-5 years).
- Adults who had no prior vaccination are protected two weeks after the second dose of Td.
- People who meet requirements for a booster dose are protected almost immediately after receiving the booster.

**Acknowledgement**

WHO, U.S. CDC, MSF, Public Health England, and Alberta Health Canada.

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# 5.0

# Diphtheria Risk Communication and Community Engagement Guideline

# 5.0 Diphtheria Risk Communication and Community Engagement Guideline

**Background**

Risk communication and community engagement is one of the key priorities in mitigating and controlling diseases before, during and after outbreaks. Risk communication capacity at the national and state level should be characterized by timely and efficient two-way communication among concerned stakeholders and the population at risk.

Effective risk communication and community engagement entails the conduct of a rapid needs assessment on the knowledge, attitudes and practices that aid or mitigate the spread of the disease; the analysis of the findings to guide the development of key messages in collaboration with community representatives which meets the needs of the population at risk; identifying the appropriate channels for the dissemination of key messages to improve healthy behaviours; and the establishment of community listening structures including complainst and reactions mechanisms to ensure feedback on community concerns are addressed in a manner that builds trust in government.

The exchange of information and opinions should be through channels that are socially and culturally acceptable to the population at risk such as social media engagement and other health promotion and social mobilization activities. Effective risk communication enables the comprehension and adoption of preventive behaviours by people at risk. It provides an avenue or platform for stakeholders to collate, analyse and address the concerns and needs of the population at risk. Broader response strategies are developed in collaboration community members to increase the likelihood of ownership by community members.

Diphtheria is a vaccine preventable bacterial infection that can cause respiratory symptoms and can be fatal if left untreated. The recent re-emergence and increase in cases of diphtheria in Nigeria has been attributed to factors such as sub-optimal vaccination coverage in certain parts of the country, weak healthcare system, poor

health-seeking behavior linked to low risk perception. and poor hygiene and sanitation practices. Thus, risk communication is critical to diphtheria outbreak response as it facilitates inclusiveness and the flow of accurate and up-to-date information about diphtheria in affected communities, and ensures that individuals, organizations and communities are empowered to protect themselves and prevent the spread of diphtheria. Implementation of risk communication and community engagement activities is effective when the One Health approach is adopted, which ensures that all relevant stakeholders communicate clearly on the strategies, coordinate, collaborate, and strengthen local capacity through partnerships.

In addition, monitoring and evaluation mechanisms should be established and implemented during risk communication activities at the national level, and especially at the subnational level, where outbreaks occur. The WHO Benchmark for strengthening subnational health security in Nigeria recommends the following considerations in monitoring and evaluating risk communication at the subnational level:

1. Government risk communications plans, arrangements, systems and structures are in place.
2. Existence of risk communication coordination mechanisms for internal and stakeholdern.
3. Evidence that the public communication unit or team operates efficiently and effectively.
4. Evidence that risk communication units systematically engage populations at the community level before, during and after emergencies.
5. Existence of a system to gather information on perceptions, risky behaviours, ethics and behaviors, misinformation and disinformation to analyse public concerns and fears.

This document provides guidelines and recommendations on risk communication and community engagement components for the diphtheria outbreak response, using the Multihazard Risk Communication Guideline, the WHO International Health Regulations (IHR) Benchmark and the Joint External Evaluation (JEE) 3.0 tool/framework as reference documents.

**Specific Objectives**

- To develop a system for risk communication for diphtheria outbreak response.
- Strengthening coordination of risk communication for diphtheria.
- Strengthen communication and engagement with communities on diphtheria.

**Risk Communication and Community Engagement (RCCE) Systems for Emergencies**

1. Establish a system that will strengthen synergy and coordination among all MDA personnel in charge of all technical areas for disease risk assessment, and risk communication needs assessment (See Annex for RCCE needs assessment template).
2. Establish mechanisms for collaboration and coordination between risk communication and surveillance pillars on Infodemic Management system/Community Based Surveillance (CBS) and Event-Based Surveillance (EBS).
3. Develop or adopt risk communication and community engagement plans at the national and subnational level, using findings/insights from the risk communication needs assessment.
4. Assess the capacity needs of stakeholders and develop training modules that will address identified gaps.
5. Train frontline healthcare staff and RCCE focal points on effective risk communication.
6. Develop a mechanism for conducting audience analysis and surveys on knowledge, attitude, and practices that will be utilized to direct RCCE response strategies, including targeted content creation.
7. Regularly assess the performance of risk communication and community engagement for emergencies through monitoring and evaluation and

**Risk Communication**

1. Identify and map RCCE stakeholders across all levels.
2. Establish a regular risk communication coordination mechanism between relevant key stakeholders at national and subnational level, with established objectives, communication flow charts, SOPs and ways of working between

units, agencies/organizations, for risk communication and community engagement.

3. Establish and expand information-sharing and implementation mechanisms with other pillars and across sectors including media, influencers, civil society organisations (CSOs), and other private sector entities, using a whole-of-government approach.
4. Develop appropriate action plans that identify priority interventions, languages, and communication preference to key populations at risk.
5. Regularly assess the performance of risk communication coordination at the national and subnational level and share findings with relevant stakeholders.

**Community Engagement**

1. Conduct information needs analysis for effectively engaging with traditional/religious leaders, women and youth organizations, affinity groups, vulnerable groups, CSOs (including female-oriented organizations) and non-governmental organizations. Community engagement starts with listening to community members to understand their concerns, to help adapt our interventions to be more acceptable to the population.
2. Identify trusted community leaders and champions, i.e. focal points, at the subnational level to support community engagement such as religious leaders, traditional leaders, and community networks, e.g., Ward Development Committees (WDC).
3. Identify focal points from the relevant ministries and partners for community engagement at the subnational level.
4. Develop guidelines, procedures, ToRs, SOPs or tools for systematic community engagements with linkage to emergency response.
5. Leverage existing community mechanisms/establish mechanisms for systematically receiving community feedback through multiple channels including social media and direct community dialogue, and that communities are involved in emergency response and the co-design of emergency response initiatives.
6. Regularly assess the performance of community engagement efforts and share results with stakeholders.

## Annex

### 1.1 RCCE needs assessment template

### 1.1 Risk Communication and Community Engagement Template

**Guide to RRT for Risk Communication activities**

**Objective:** To guide the RRT in conducting risk communication activities in a systematic manner.

**Steps include**;

A. Rapid risk communication needs assessment

B. Setting objectives

C. Stakeholders mapping

D. Stakeholders engagement

E. Audience segmentation and analysis

F. Message development and dissemination

G. Feedback management

**Table 20.0: Rapid Needs Assessment Form on Risk Communication Preparedness and Response Capacity**

| **A. Rapid Risk Communication Needs Assessment** | | | | |
|---|---|---|---|---|
| Objectives | Actions | Questions | Responses | Comments |
| Conduct risk appraisal | Obtain information from the surveillance team/unit (EBS) | 1. How many cases do you have?<br>2. Where are they located?<br>3. How did they get infected?<br>4. What household practices increase the risk?<br>5. Who is most affected? What proportion?<br>6. Who is most vulnerable? What proportion?<br>7. Is there denial?<br>8. Is there stigmatization?<br>9. Is there amplification?<br>10. Vaccination Coverage | | |
| Conduct risk perception | | | | |

| | | | | |
|---|---|---|---|---|
| | Obtain information from clinicians in health facilities, CBOs, Community leaders, and partner organizations. | Apply the KAP questionnaire here. (See annex in the Nigeria Multihazard Risk Communication Guideline for the tool) | | |
| | Conduct community dialogue meeting/FGD to obtain conflicting messages and understand needs and concerns of the people | Apply FGD Guide or guide for meeting. (See annex in the Nigeria Multihazard Risk Communication Guideline for the tool)<br><br>Note if there are circulating misinformation and myths | | |
| Conduct capacity assessment | | | | |

| | | | | |
|---|---|---|---|---|
| | Asses risk communication structure/system | 1. Is there a guideline/SOP?<br>2. Is there a structure in place for communication?<br>3. What s trategy is being adopted? Is it clear?<br>4. Is there a plan for implementing the strategy?<br>5. Is there a resource mobilization plan?<br>6. Is there an M&E process for the plan?<br>7. Are there trained manpower? | | |

| | | | | |
|---|---|---|---|---|
| | Assess stakeholders' coordination and communication | 1. Is there a list of stakeholders?<br>2. Is stakeholder analysis performed?<br>3. Are roles shared among the stakeholders?<br>4. Are the stakeholders meeting? Any minutes?<br>5. Is there a platform for communication among stakeholders?<br>6. Is risk information shared with stakeholders?<br>7. Is there feedback from stakeholders on the information shared?<br>8. Are stakeholders accountable for their roles? | | |

| | | | | |
|---|---|---|---|---|
| | Asses the public communication process | 1. Do data, science and context drive the messages?<br>2. Is the audience segmented?<br>3. What means are used in getting the messages to the audience?<br>4. Are there IEC materials displayed?<br>5. Are Jingles aired?<br>6. Are the messages translated into local languages?<br>7. Is there a trained spokesperson?<br>8. Is there engagement with the media?<br>a. Are there media appearances?<br>b. Any press conferences?<br>c. Any press releases?<br>9. Is there a hotline? | | |

| | | | | |
|---|---|---|---|---|
| | | 10. Are there other means of interacting with the public?<br>11. Any use of social media platforms? | | |
| | Assess the community engagement process | 1. Is there a community needs assessment tool in use?<br>2. Is there a meeting for the buy-in of community leaders?<br>3. Is there a meeting to understand the needs and concerns of the community?<br>4. Is there a list of community influencers?<br>5. Are community influencers involved in communicating the messages?<br>6. Any plan for community dialogue to address emerging issues like rumor, stigma and panic?<br>7. Are SBC materials displayed in public places in the community?<br>8. Is there a list of (trained) community volunteers?<br>9. Is there a bottom -up approach to community engagement? | | |

| | | | | |
|---|---|---|---|---|
| | Assess misinformation and perception | 1. Is there a hotline?<br>2. Are there meetings or arrangements to understand conflicting messages in the community?<br>3. Is a media scan conducted? (Traditional & Social Media)<br>4. Are rumours documented and analyzed?<br>5. Is there a mechanism for addressing rumours? | | |
| **B. Setting Objectives** | | | | |
| | Aim/Objectives | Key messages | | |

| | | | | |
|---|---|---|---|---|
| Set behaviour objectives | 1. To avoid getting the disease at all<br>2. To reduce the risk of spread.<br>3. To avoid complications of the disease<br>4. To get people vaccinated<br>5. HCWs need to protect themselves | 1. Routine vaccination is the most effective way to prevent diphtheria.<br>2. Children must complete the three doses of vaccination at 6, 10 and 14 weeks of life.<br>3. Get your children fully vaccinated.<br>4. Children who have missed getting vaccinated for diphtheria, can also get vaccinated through catch-up vaccination, reactive or outbreak response vaccination campaigns<br>1. If your child is experiencing any symptoms of diphtheria, please visit the nearest health facility. Wash hands frequently | | |

| | | | | |
|---|---|---|---|---|
| Set Communication objectives | 1. What they need to understand<br><br>2. What do they need to do to protect others and themselves | 1. Ensure consistent messaging to the public.<br><br>2. Distribute SBC materials.<br><br>3. Broadcast audio jingles<br><br>4. Conduct sensitization meetings.<br><br>5. Engage community influencers to support the message dissemination.<br><br>6. Conduct community dialogues to address the concerns of the people.<br><br>7. Debunk rumors<br><br>8. Support people in attaining behavioral objectives.<br><br>9. Respond to the emotional needs of the people. | | |
| **C. Stakeholders Engagement** | | | | |

| | | | | |
|---|---|---|---|---|
| Stakeholders engagement | Map and analyze stakeholders | 1. Identify stakeholders in the state<br>2. Define their interests<br>3. Assess their potential effect on the event | | |
| | Meet with stakeholders and agree on roles | 1. Invite the stakeholders to a meeting<br>2. Discuss the findings of the risk communication need assessment<br>3. Communicate the objectives above<br>4. Agree on roles with the stakeholders<br>5. Define coordination mechanism<br>6. Establish communication platforms<br>7. Establish feedback mechanism | | |

| D. Audience Segmentation and Analysis | | | | |
|---|---|---|---|---|
| | | | | |
| Audience segmentation and analysis | Segment the audience based on association with risk /event | 1. Those that are affected<br>2. Those that are vulnerable<br>3. Those at high risk<br>4. Those at low risk<br>5. Those at no risk | | |
| | Analyze the audience for the concerns, needs and expectations | 1. Level of understanding<br>2. Demography: Age, Sex<br>3. Needs<br>4. Concerns/ barriers to adopting desired behaviour<br>5. Expectations | | |

| | | | | |
|---|---|---|---|---|
| | Identify how to reach the audience | 1. Identify the best channels of reaching each group of audience<br>2. Use more than one channel for reaching each audience<br>3. Consider the most effective formats of reaching the audience: Graphics, audio, video<br>4. Determine the most reliable source to the audience | | |
| **E. Message Development and Dissemination** | | | | |
| Message development/adoption and dissemination/ translation | Key messages and considerations in developing them: what why and how | 1. Are you crafting, adapting or adopting existing messages?<br>2. What is driving the message? (science, data, context)<br>3. What is the focus of the messaging? (Facts, feelings, issues/ barriers, context)<br>4. Why do you want to pass it across?<br>5. Translate into local language and dialects? | | |

| | | | | |
|---|---|---|---|---|
| | Pretest the message | 1. Review the materials<br>2. Pretest the materials<br>3. Incorporate findings of review and pretest | | |
| | Disseminate widely in different channels and appropriate formats | 1. How do you want to pass it across?<br>2. Who should pass it across?<br>3. When should it be passed across? | | |
| **F. Feedback management** | | | | |
| Feedback | Collect feedback | 1. Observe change in behaviour and norms<br>2. Collate data from field officers (Activities, outputs, outcome)<br>3. Conduct meetings/polls/survey to obtain feedback from the community<br>4. Engage the leaders, CBOs, FBO for feedback | | |

| | | | | |
|---|---|---|---|---|
| | Collate and analyze feedback | 1. Analyze feedback | | |
| | Share findings with response team (EOC), stakeholders and source of information | 1. Share findings with EOC, other relevant pillars, health care professionals community and policy makers | | |
| | Adjust messaging and approach accordingly | 1. Ensure findings are incorporated into response planning and operation | | |

**Tools and Resources**

1. **Risk communication and community engagement strategy (COVID-19)** https://covid19.ncdc.gov.ng/media/files/04122020_RCCE_Strategy_Review_copy2.pdf
2. **THE WHO IHR Benchmark 2005** https://apps.who.int/iris/rest/bitstreams/1210452/retrieve
3. Nigeria Multihazard Risk Communication Guideline https://ncdc.gov.ng/themes/common/docs/protocols/326_1702538423.pdf

# 6.0

# Vaccination

# 6.0 Vaccination

**Introduction**

Diphtheria is a vaccine preventable disease, and the vaccines are administered during routine immunization and during reactive vaccinations for outbreaks. These vaccines enable the development of immunity against this disease in children that have received them.

The vaccine administered during routine immunization is the Pentavalent vaccine comprising Diphtheria, Pertussis, tetanus, Hemophilus Influenza type B and Hepatitis B for age 6 weeks to 23 months at 6$^{th}$, 10$^{th,}$ and 14$^{th}$ weeks and Td vaccine for pregnant women compromising diphtheria and tetanus. It is also administered during outbreaks for children less than 4 years yet to complete their doses of Penta and for those who have not taken at all so they can start and complete.

During outbreaks, the vaccine administered for children >4-14 years is Td which is a booster vaccine against Tetanus and Adult Diphtheria while children less than 4 years will get a booster of Penta vaccine in three doses.

Non-pharmacological interventions include avoiding over-crowding, ensuring cross ventilation in gatherings and isolation of suspected and confirmed cases.

### 6.1 Outbreak Response

#### 2.1 Target age group:

The target age group for vaccination response will be determined by the surveillance data/ report i.e., ages most affected either by disease burden or fatality. However, all heath workers and vaccination team members should be dully vaccinated.

#### 2.2 Approach to campaign:

The outbreak response will be in three (3) phases viz.

a. Primary response (immediate) Ro: response of the State to the outbreak limited to settlements and Wards using available resources.
b. Secondary response, R1: an expanded response covering the entire LGA affected.
c. Tertiary response, R3: response covering the entire State with outbreak and other States with contiguous LGAs.

### 2.3 Vaccination strategy:

The strategy for vaccination will be by fixed posts and temporary fixed post (Mobile post).
Each team should have Gio'style® to hold the bulk of the vaccines and 2 vaccine carriers (Rush) to vaccinate from

The team should have adequate means to handle waste (safety boxes for needles and syringes and waste bins (buckets) for other waste.

Every individual vaccinated should be given a vaccination card and asked to wait for at least 15 minutes for Adverse Events Following Immunization (AEFI) observation before they leave. The vaccinator should be ready to handle AEFI. Each vaccinator should be trained on the possible side effects and how to handle them and there should be an emergency kit within reach.

### 2.4 Vaccination post lay out.

Each Vaccination post must be spacious enough to provide for waiting areas prior to and after vaccination and there must be crowd control. Waiting and vaccination queues should be separate for male and female. The outline below should be used as a guide.

### 2.5 Vaccination Team Composition:

The team will comprise 6 members both at fixed and temporary fixed post (Mobile):

1. 2 vaccinators (qualified health workers who are certified to give injection) the most senior vaccinator to act as post supervisor.
2. 2 recorders who can read and write.
3. 1 crowd controller
4. 1 mobiliser

### *2.5.1 Role of vaccination Post supervisor:*

The Vaccination Post Team Supervisor must be:

a) Health worker with minimum qualifications of Nurses, Midwives, CHO, CHEW, who can supervise administration of injectables.

b) Preferably working or residing in the respective Ward /settlement

Table 21.0

**Roles and responsibility of Vaccination Post Supervisor**

1. Develop catchment area map together with community leader.
2. Ensure the community leaders are mature and respected persons selected within the catchment area who can influence change in the community.
3. Ensure plans are in place and understood by the community.
4. Ensure the town announcers and social mobilization volunteers and the community leaders conduct house-to-house mobilization daily.
5. Ensure the availability of cold chain & logistics materials based on the daily implementation work plan.
6. Ensure the availability of vaccines & injectable devices based on the daily implementation work plan.
7. Ensure screening is done accordingly.
8. Ensure the vaccination post is functioning according to the vaccination post daily work plan.
9. Monitor, manage and audit all AEFI cases and report to the Ward Focal Person daily.
10. Conduct daily data collection, collation, and submission to the Ward level.
11. Collect the safety boxes from the fixed post to the ward-designated areas every day.
12. Monitor the waste management issues in the outpost.
13. Attend daily ward review meetings.

### *2.5.2 Role of the Vaccinators:*

- Must be qualified health worker who are allowed by the laws of Nigeria to give injections.
- Must give vaccine appropriately (IM route in the left deltoid muscle for Td in children >4-14 years and anterolateral aspect of the mid-thigh for children 0-4 years)
- Maintain injection safety.
- Tally clients after vaccination
- Give messages on diphtheria to the clients and expected side effects (interpersonal communication)

### *2.5.3 Role of Recorders:*

- Fill in the vaccination card for each client after vaccination.
- Issue the filled card to the vaccinated clients.
- Record information for each vaccine in the Diphtheria register

### *2.5.4 Role of Mobiliser:*

- Make announcement within the settlements to be covered the night before.
- Inform the community what disease is being responded to
- Confirm eligibility of clients by age
- Inform the community where the post is situated.
- Inform the community on who is to receive the vaccine- target age group.
- Inform the community on the dates of the campaign.
- Inform the community that the vaccine is free.

### 2.6 Vaccination dates:

The exercise will be conducted **over a 6-day period.** Mop-up will be determined where necessary.

### 2.7 Requirements for each post:

- 2 Giostyles
- bundle vaccines
- Cotton wool swabs
- Waste bin
- Vaccination record cards
- Safety boxes

- AEFI kit
- Data tools
- Pen marker

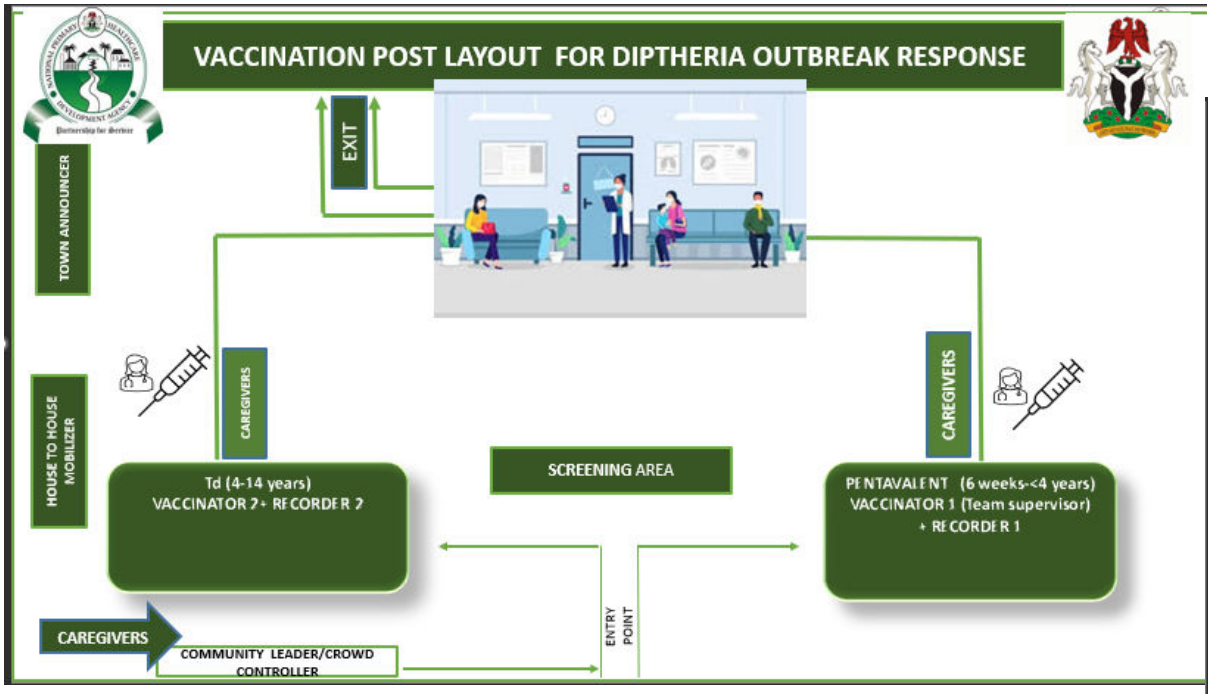


**Figure 11. Vaccination Post Layout**

## 2.8 Training:

Cascaded training will be planned for and conducted at National, State and Ward levels. Effective collaboration with the Training sub- committee across all levels is key to a successful campaign. This sub-committee is expected to function based on previous best practices for training and in line with global standards and country context. The training will be for 1 day at all levels

- At the LGA level, to minimize bias selection of vaccination team members, the LGA team including partners and traditional leaders will supervise and validate team member selection.
- All training must have a planning meeting and a plan developed that has the following: venue, number of facilitators, number of participants, dates, Agenda, Budgets (Feeding, training materials, transport, etc.)

- Training planning meetings should include a visit to the training venue and assembling training materials; facilitators should be made to rehearse their topics or presentation for colleagues to comment on and critique to provide final inputs.
- Various training methodologies will be adapted (role play, demonstrations, and return demonstration, lecture, and use of teaching aids) according to the target group and topic to be covered. At the ward level, role-plays and practical demonstrations will be used to ensure a clear understanding of the subject matter.

### *2.8.1 Micro plan review and daily implementation (DIP) plan development*

Orientation of team supervisors and ward focal persons at the ward level for desk review of the micro plan should be carried out. This is to estimate all resources including personnel required to implement a quality reactive vaccination campaign.

### *2.8.2 Implementation Training*

The implementation training will build the capacity of the State, LGA and Ward to effectively implement the reactive vaccination campaign. The training will cover the following topics:

- Overview of disease
- Scope of campaign
- Cold chain & logistics
- Vaccine management
- Vaccine administration
- Waste management
- Management and reporting of AEFI.
- Monitoring and supervision
- Data management and tools
- Advocacy, Communication and Social mobilization

### *2.8.3 Training Materials*

A conducive training venue must be identified, taking into consideration the number of persons to be trained. Below are lists of materials to be used. These

materials are not exhaustible and can be adapted to match the needs of the target audience. They include:

- Reference materials: Field Guide
- Agenda
- White or blackboard, marker pens and chalk
- Flipcharts
- In focus and screen
- Laptop
- Folders containing writing pads, pens, pencils, and rulers.
- Injection equipment: vaccine vials, syringes, safety boxes, AEFI kit, waste disposal equipment, rubbish bin and plastic bags, cotton swabs
- Cold chain equipment: vaccine carriers, ice packs, and cold boxes
- Data tools: vaccination cards, tally sheets, checklists, daily summary, GIS maps and settlements, AEFI data tools.
- Training evaluation form, pre and posttest forms.

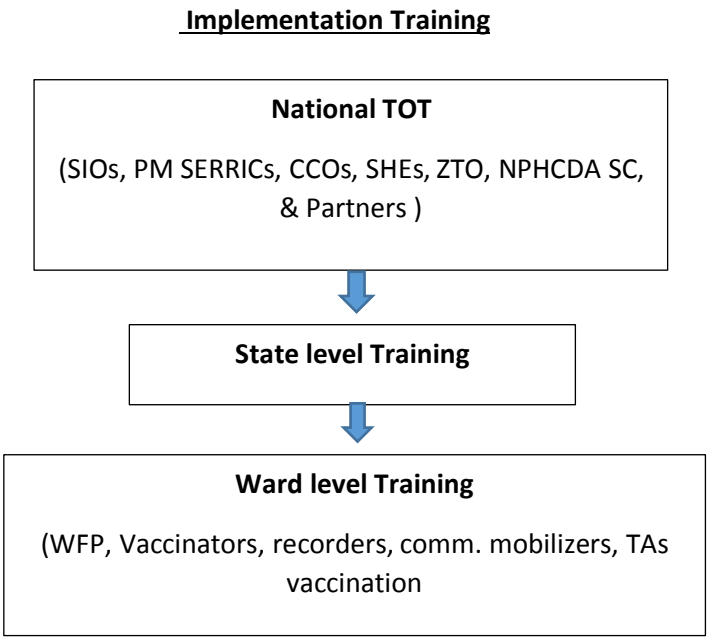


FIG 12. Training flow chart

### 6.2 Data Management

Data management is the process of collecting, collating, analyzing and interpreting data for action. Data helps to estimate coverage, identify needs for supplies, and identify implementation problems and take corrective action.

### 3.1 Data tools

1. Pre-campaign monitoring tools (pre campaign checklist, raining monitoring using ODK)
2. Tally sheets and registers: To capture data by settlement, Age, Sex, (1-2yrs, 2-4yrs, >4 - 9yrs and >9-14yrs)
3. Daily Call-in data template
4. Vaccination Cards
5. AEFI reporting form.
6. AEFI Investigation form
7. Household monitoring
8. Outside of household monitoring
   a. Independent monitoring data will be summed and reported separately for in-process and end-process.
   b. For missed people on monitoring indicate sex and reason
9. Implementation checklist using ODK.
10. Vaccination card: to be issued to clients after Penta or Td vaccination.
11. Vaccine accountability form
12. Summary sheets (Ward and LGA)

### 3.2 Data collection

***Implementation***

a) At the beginning of the day the vaccination post supervisor should record the number of vials of vaccine (Penta and Td vaccines), AD syringes, safety boxes and vaccination cards received and record in the lower half of the Vaccinators Tally Sheet.
b) The vaccinators should on confirming the age of the client, make a tally in the appropriate part of the Tally Sheet after administering of the vaccines.
c) The Recorders complete the vaccination card for all the clients after vaccination.

d) The Team Supervisor is to review and verify all the tally sheets used by the vaccination teams.

e) At the end of the day, the cold chain officer should collate the total number of vials given, empty /opened vials returned, usable/usable vial returned.

### 3.3 The flow of data

a) The Team Supervisor submits the summarized tally sheets at the end of the day to the Ward Focal Person and all AEFI reporting forms.

b) The Ward Focal Person cross checks and summarizes the daily report on the Ward Daily Summary Sheet, enters all AEFI cases on the line-list for submission to the LGA team at the daily LGA review meeting.

c) At the end of each meeting the LGA Technical Facilitator with LIO compiles the information on the Ward Daily Summary Sheet and completes the LGA Daily Summary Sheet and collates all ward line-list into one LGA list then relays this information to the State, and the State makes a state summary of tally sheet and one line-list of all reported AEFIs and submit daily to the national level for analysis.

### 6.3 Advocacy Communication and Social Mobilization (ACSM)

ACSM remains an important public health response strategy during disease outbreaks. One aspect of ACSM in outbreak response is creating a real-time communication management system to effectively monitor and understand concerns and perception of the target communities and addressing their needs through multiple communication channels like mass media, social media, and community engagement.

Disease Surveillance Report will to be used for Needs assessment to guide outbreak response ACSM strategies.

The ACSM component of the outbreak response will adopt an integrated approach based on 5 thematic areas:

1. Coordination and accountability
2. Targeted Advocacy
3. Risk Management
4. Media Engagement
5. Community Engagement/Mobilization

This focuses on strengthening ACSM and partner coordination platforms to facilitate information sharing and management of resources throughout the response activities. Formation/Reactivation of ACSM TWG at the National, State and LGA levels to coordinate response activities. These includes but not limited to:

- Development of term of reference for National, State and LGA ACSM WG
- Identify partners and stakeholders at all levels to mobilize resources.
- Assign roles and responsibilities to partners and other stakeholders to avoid duplication of efforts.
- Develop ACSM accountability framework to monitor state performance.

The Advocacy Communication and Social Mobilization Working Group (ACSM WG) will facilitate the implementation of key activities at National, State and LGA levels.

### *4.1.1 National Level*

The National Advocacy Communication and Social Mobilization Working Group will facilitate implementation of the following activities:

- Develop guidelines and tools for communication at all levels and distribute to the states for implementation.
- Develop a robust communication plan including crisis management plan.
- Conduct high-level advocacy visits/ meetings to relevant key stakeholders including Religious and Traditional leaders, MDAs, CSOs etc for buy-in and resource mobilization.
- Conduct sensitization meeting for Traditional/Religious leaders, CSOs, CBOs, etc.
- Conduct media orientation for media managers and Health reporters.
- Conduct information/crisis management meeting with key stakeholders to gain support.
- Plan and conduct media and press releases/briefs to enhance coverage.
- Track and monitor communication activities at the state and LGA levels.

### *4.1.2 State Level*

The State Advocacy Communication and Social Mobilization Working Group will facilitate implementation of the following:

- Develop state specific communication plans adapted from the National plan, including a crisis communication plan.
- Advocacy visit to stakeholders, including MDAs, Traditional/religious leaders, CSOs.
- Production of local media messages suited to local context.
- Development/Translation of information education and communication (IEC) materials into local languages
- Establish, sustain, and monitor social media groups to promote immunization messages and mitigate rumors.
- Develop and disseminate consent letters to various stakeholders.
- Engagement / Sensitization of key stakeholders, including the media.
- Plan and conduct campaign flag-off ceremonies
- Engagement of influential personalities as champions/ambassadors
- Establishment of Crisis Rapid Response Team to tackle non-compliance issues.
- Conduct routine monitoring and supervision of communication activities at LGA and Ward levels.

### *4.1.3 LGA Level*

- Develop LGA specific communication plans adapted from the State plan, including a crisis communication plan.
- Facilitate advocacy visit to the LGA chairman and council, community leaders, RTLs, CBOs, Youth Groups, Line Ministries among others:
- Facilitate dialogue with community leaders especially RTLs and Youth Groups to gain support for community acceptance.
- Sensitization meetings with various religious bodies such as JNI, CAN, FOMWAN, Youth Groups, CBOs etc. to inform and mobilize communities.
- Use of relevant local media like town announcers, community health workers, radio jingles, road shows, rallies, edutainment activities etc. to create public awareness and understanding of the campaign.

## 4.2 Targeted Advocacy

– This will focus on engagement of stakeholders at all levels to get buy in and garner multi-sectoral support for effective implementation of ACSM activities during outbreak response. The target for advocacy should include but not limited to:

- Development of advocacy brief and work plan to guide implementation of advocacy activities at all levels.
- Identify and engage key stakeholders such as MDAs, State Governors, Traditional/Religious leaders, Media, CSOs, CBOs, Professional bodies, and other influencers.
- Conduct media orientation for Program Managers and Health reporters.
- Sensitization meeting with Traditional/religious leaders, CSOs and other professional bodies
- Assign roles and responsibilities to stakeholders based on the following key functions:

  **Model** – Advocate and champion community response activities through practice of priority behaviours.

  **Map** - Leverage existing systems including audience and reach.

  **Mobilize** - Share and promote key messages on outbreak using existing community structures and channels.

  **Mitigate** – Support community sensitization to minimize the impact of the disease.

  **Monitor** - Collaborate and provide regular community feedback to all other stakeholders/partners.

### 4.2 Risk Communication

Risk Communication, in the immunization context, can be defined as a planned, evidence-based approach that uses communication tools and processes to prepare for and respond to a vaccine-related crisis such as rumour, misinformation, and AEFI or any other crisis which arises from immunization. Vaccine- and vaccination-related crises require a communication response that is different from the communication strategies used to promote the benefits and importance of vaccines in general. A distinct guideline is needed to develop a communication plan that is appropriate for managing crises related to vaccine and vaccination safety. These guidelines will be useful for managers in the areas of immunization and vaccine and vaccination safety. They will also be useful for safety crises preparedness and response teams to optimize the development of communication plans that help regain, maintain, or strengthen trust in vaccines, vaccination, and immunization programs in general.

### *4.2.1 Risk Communication Plan (State/ LGA/ Ward Level)*

- Conduct a situation appraisal.
- Produce and use communication materials/tools.
- Develop /finalize and distribute a press release.
- Organize a press conference (If needed).
- Engage religious/traditional leaders, community leaders/ group professional groups, and line ministries.
- Activate the communication tree.
- Support spokespersons.
- Keep media updated and respond to queries.
- Monitor media.
- Ensure close coordination among stakeholders (who does what? Where? When.
- DO NOT REPEAT THE RUMOUR WHEN ADDRESSING IT.

### *4.2.2 Key Principles*

- Be First
- Be Right
- Be Credible
- Express Empathy
- Promote Action
- Show Respect

### *4.2.3 What We Should Avoid*

- Mixed messages from multiple experts
- Late release of Information
- Paternalistic attitudes
- Delay in countering rumors and myths in real-time
- Public power struggles and confusion

### 4.3 Media Engagement

The media is a strategic partner in emergency response and their engagement should be early and sustained throughout the preparedness and response activities to create visibility. The media campaign will be implemented on multiple, mutually reinforcing communication channels, including:

Mass Media – Create of content such as PSA, Jingles, Print Media, Audio-visual clips to be broadcasted on Radio and TV to create public awareness.

Media Appearance – Feature Subject Matter Expert, Community Leaders and trusted voices on live Radio and TV programs to sensitize the public on the disease and possible preventive measures.

Social Media – Develop social media content like e-flyers, FAQs, short animation videos and leverage NPHCDA and SPHCDAs handles to disseminate messages using all available Social media platforms. Engage social media influencers to support promotional activities online to build public confidence and trust on the campaign.

Press Briefing – Periodically conduct press releases/briefs at the national and state level to provide situation report on the outbreak and the response efforts to boost public confidence and trust.

Toll Free Line – Leverage NPHCDA and SPHCDA's call centres to disseminate key messages on preventive and control measures to the public.

## 4.3 Community Engagement

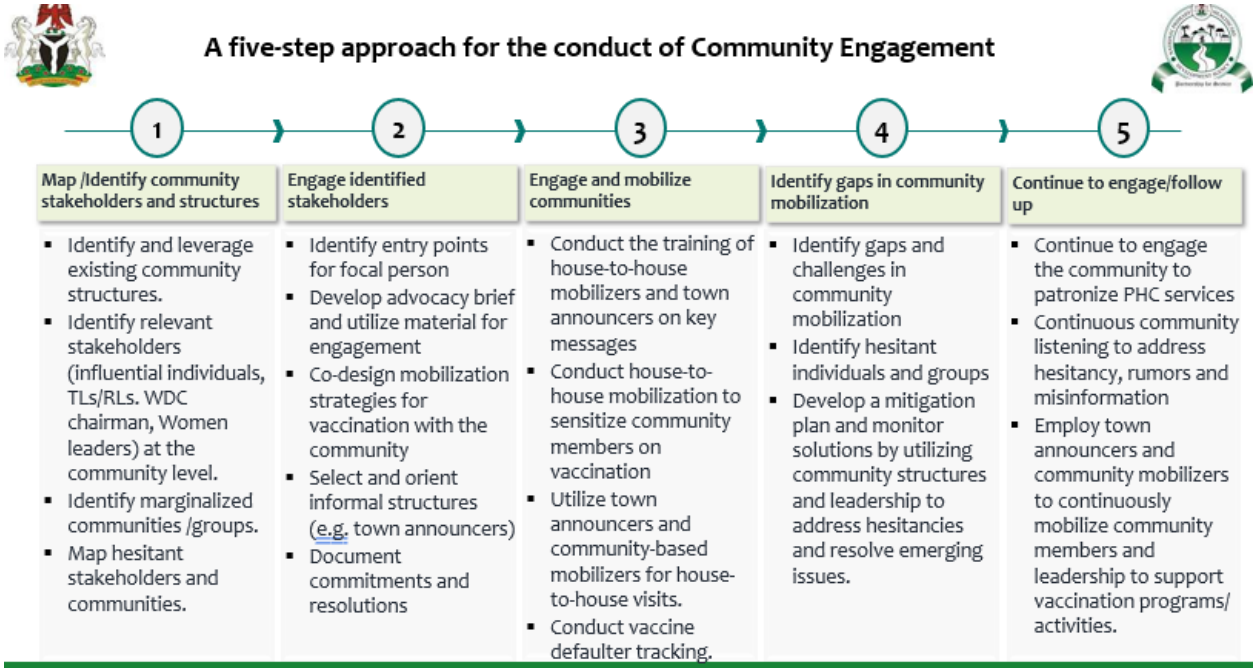


*Fig. 13. Approach to Community Engagement*

### Table 22.0: Community Structures and Channels of Engagement

| Structure | Channels |
|---|---|
| Community leaders | Community dialogue |
| Religious and traditional leaders | House to House visit |
| Town announcers | Town announcement |
| Village Development Committee members | Social media platforms e.g., WhatsApp, Facebook, etc |
| Ward Development Committee members | Motorize campaign |
| Community volunteers | Town Hall Meeting |
| Community based organizations | Compound Meeting |
| Traditional Birth Attendants | PSAs, Jingles |
| CBOs, youth-groups/associations, etc. | Edutainment Activities – Road shows, Rallies |

### 6.4 Vaccine and Cold Chain Logistics

There are only two vaccine that contain Diphtheria antigens which are Pentavalent vaccine and Tetanus diphtheria vaccine.

### 5.1 The Vaccines

#### Table 23.0: The Vaccines

| **Pentavalent vaccine** (6 weeks - 4 years) | **Td vaccine** (>4 – 14 years) |
|---|---|
| • Comes in a liquid form, as 10 doses per vial.<br>▪ It is freeze-sensitive vaccine and should be stored and transported at +2 to +8 degree.<br>▪ Discard if the vaccine is frozen or VVM reaches discard point (stage 3 or 4).<br>▪ Vaccine administration: The vaccine is given:<br>o Route: intra-muscular (IM)<br>o Site: antero-lateral aspect of left thigh (6 weeks to 23 months)<br>o Site: upper left arm (2 to 4 year)<br>o Dosage: 0.5ml | • Comes in a liquid form, as 10 doses per vial.<br>▪ It is freeze-sensitive vaccine and should be stored and transported at +2 to +8 degree.<br>▪ Discard if the vaccine is frozen or VVM reaches discard point (stage 3 or 4).<br>▪ Vaccine administration: The vaccine is given:<br>o Route: intra-muscular (IM)<br>o Site: upper left arm (>4 to 14 years)<br>o Dosage: 0.5ml |

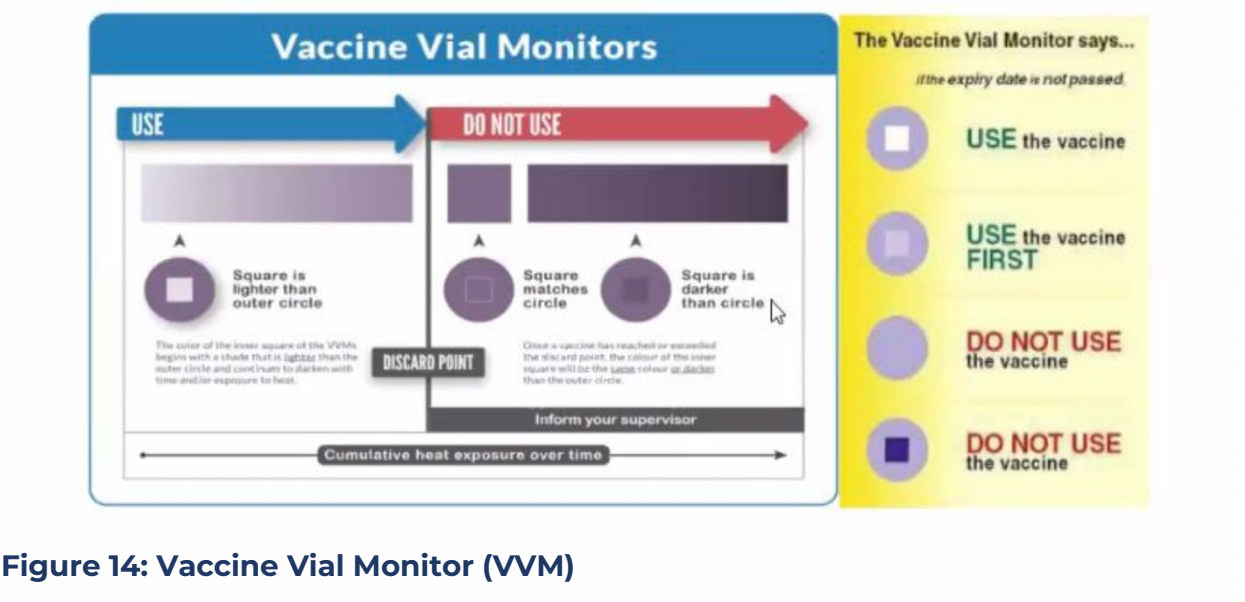


**Figure 14: Vaccine Vial Monitor (VVM)**

### 5.2 Vaccine handling:

Table 24.0: Vaccine handling

| Pentavalent vaccine | Td vaccine |
|---|---|
| • Stored between 2 °C and 8 °C.<br>• Do not freeze.<br>• When freezing is suspected, conduct "Shake" test (Refer to RI basic guide manual) | |

### 5.3 Contraindications and precautions

Table 25.0: Contraindications and precautions

| Pentavalent vaccine | Td vaccine |
|---|---|
| • Severe allergic reactions: a child who has had a severe reaction to pentavalent vaccine earlier should not be given another dose.<br>• Defer vaccination of children with severe acute illness. | • Do not administer in the event of allergic reactions after a previous dose of tetanus or diphtheria vaccine.<br>• Defer vaccination of children with severe acute febrile illness.<br>• minor illnesses are not contra-indicated.<br>• **Pregnancy and breast-feeding**: no contra-indication |

| | |
|---|---|
| • Minor illnesses such as upper respiratory infections (URI) are NOT a contraindication to vaccination. | |

### 5.4 Estimating requirements:

**Vaccines, syringes & needles, and other immunization supplies.**

#### *5.4.1 Vaccines: The formula for estimating vaccine needs*.

| |
|---|
| No. of doses of Pentavalent vaccine/Td = Target Population (TP) x coverage x wastage factor x no of doses per person. |

**Note: Target population = % of the total population under focus**

**Coverage = Expected Coverage for the outbreak response**

**Wastage Factor = 100/(100-wastage rate)**

The wastage rate for vaccines during campaign is 5%. The wastage factor is therefore 1.05.

#### *5.4.2 AD syringes: Calculating AD Syringes needed.*

Number of AD syringes equals number of doses of vaccines.

| |
|---|
| No. of AD syringes (0.5mls) = Number of doses of vaccines (Target Population (TP) x coverage x wastage factor x no of doses per person.) |

#### *5.4.3 Safety boxes: Estimation of Safety boxes required.*

To estimate safety boxes requirement, a wastage rate of 5% is applied to get a wastage factor of 1.05. The formula for estimating safety boxes.

| |
|---|
| No. of Safety boxes = (No. of AD syringes)/100 x **wastage** factor |

### *5.4.4 Cotton wool: Estimation of cotton wool required.*

To estimate the cotton wool requirements the number of posts is multiplied by the number of cotton wool rolls required per post for the duration of the campaign. The formula is.

| No. of cotton wool = No. of posts x 2 rolls |
|---|

### 5.5 Data Tools:

For data tools, the estimation is based on the number of posts, number of vaccinators per post, number of days of implementation and a wastage factor of 1.1. The formula is

| No. of tally sheets = No. of posts x No of vaccinators per post x No. of days of implementation x 1.1 |
|---|

### 5.6 Vaccination Posts:

To estimate the number of posts required the parameters needed are the daily vaccinations, the number of days of implementation and the target population. The formula is

| No. of posts = TP / (daily vaccinations per post x number of days) |
|---|

### 5.7 Cold chain equipment:

The cold chain equipment required for this campaign depends on the level of storage and implementation. At the national level, cold chain equipment requires cold rooms. At the state levels, a mix of cold rooms and refrigerators will be required while LGAs will require refrigerators. At the state and LGA levels also, freezers will be required to produce icepacks which will be "**conditioned"** for both transport and for immunization posts during implementation. Storage capacities need to be estimated for both vaccines storage and icepacks production.

At the ward and facility levels, including at temporary posts, fast cold chain equipment is required. This is for storage at the Ward level and implementation at vaccination posts.

Each Ward will need 2 large cold boxes for vaccine and icepack storage and each vaccination post will require 2 Gio'style® vaccine carriers. However, where Gio'style® vaccine carriers are not available, a combination of Gio'style® and "Rush" vaccine carriers could be used.

Icepacks will be required to maintain the temperature of the vaccines within range when using fast cold chain equipment. For the ward level, 24 units of 0.6L icepacks are required for each cold box for vaccine storage and depending on the number of posts, the requisite number of 0.3L icepacks for the posts at 4 units per Gio'style® and where Rush vaccine carriers are used each will require 2 units of 0.3L icepacks.

### *5.7.1 Passive cold chain equipment:*

To estimate requirements for passive cold chain equipment (cold boxes, vaccine carriers and icepacks) the variables required are the number of wards and number of posts.

| |
|---|
| **For cold boxes:** The formula is = No. of wards x 2<br>**For vaccine carriers:** The formula is = No. of posts x 2 |

### *5.7.2 Icepacks:*

The formula is.

| |
|---|
| **Icepacks for cold boxes** = (No. of wards x 2) x 24 x 2 x 1.05 (for 2 cycles of storage).<br>**Icepacks for vaccine carriers** = (No. of posts x 2) x 4<br>x 3 x 1.05 (planning for 3 days) |

### *5.7.3 Storage space:*

Each dose of Pentavalent and Td vaccines requires 2.6cc of storage space respectively. To calculate the volume of storage required for a given target population, the formula is:

| |
|---|
| Storage volume required = TP x coverage (100%) x wastage Factor (1.05)x 2.6/1,000 |

For estimation of icepack producing space: Each icepack 0.3/0.4lts occupies 0.5lts storage space. The volume required is calculated as follows.

| |
|---|
| Freezing space required = No. of icepacks required x 0.5Lts |

### 5.8 Planning for waste management:

In planning waste management, it is imperative to look at the available facilities for disposal of sharps and other wastes as well as training in segregation. The facilities need to be equipped with safety boxes for sharps and waste baskets or bins to collect other wastes. To estimate the number of safety boxes and waste bins required, the formular is as follows:

| |
|---|
| No. of Safety boxes = (No. of AD syringes)/100 x 1.05 |
| No. of waste bins required = No. of posts |

The waste management for this campaign will leverage available incinerators in the state or contiguous states. LGAs will plan the use of these incinerators beginning with the movement of the waste products from the posts to the wards and finally to the LGA headquarters from where they are transported to the incinerating sites for disposal. Where a ward has an incinerator installed, the waste from the ward is collected and disposed immediately. Where the number of incinerators is few, plans should be made by the state on how best to collect the waste from each LGA and dispose of appropriately. This will involve adequate transport logistics and facilities to ensure acceptable means of packing, transporting, and cleaning vehicles used for the waste movement.

In places where there are incinerators with secondary burning facilities, e.g., Teaching hospitals, efforts will be made to use them by paying for the services as mutually agreed to by HFs, Wards, LGAs and State.

Each LGA must ensure a central collection point for waste generated and transported to the LGA by the teams and wards. This facility must be secure and only authorized personnel should have access to the waste storage site.

A process for documentation of the quantity of waste delivered and received at each level must be maintained. The teams must record number of safety boxes

generated and returned to the ward level while the wards must also record receiving the safety boxes including the quantities received and from which team it was received. The wards then deliver to the LGA, and the same documentation process is replicated.

At the waste disposal points also, the quantity of safety boxes received and disposed of must be recorded daily. This means that the number of safety boxes received are documented, the number destroyed also documented and the balance for that day recorded. This is to ensure accountability for all safety boxes generated and destroyed and to prevent misuse and hazard to the community and environment.

Other inputs for the posts are hand towels, washing bowls or wash hand basins (one per post) and disposable gloves. In addition, each post **must** be equipped with an AEFI kit.

### 5.9 Injection Safety.

It is important to understand the dangers of unsafe injection practices so that we do not:

- Harm the recipient,
- Expose the Health Worker to any avoidable risk.
- Result in waste that is dangerous to the community.

#### *5.9.1 Poor Injection Practices that harm the HEALTH WORKERS*

- Re-using needles and syringes.
- Carrying needles or placing them on a surface prior to disposal
- Recapping needles
- Reaching into a container of used syringes or needles

#### *5.9.2 Poor Injection Practices that harm the GENERAL PUBLIC*

- Indiscriminate disposal of syringes and needles
- Giving or selling needles and syringes to vendors who will resell them
- Leaving needles and syringes in areas accessible to the public

#### *5.9.3 Poor Injection Practices that harm the RECIPIENT.*

- **Inability to use auto disable syringes and needles.**
- **Lack of aseptic techniques in vaccine administration**

- **Lack of correct dose and route of administration**

## 6.5 Adverse Events Following Immunization (AEFI)

### 6.1 Basic Concept of AEFI

#### *6.1.1 DEFINITION*

An Adverse Event Following Immunization (AEFI) is any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any ***unfavorable, unintended sign, abnormal laboratory finding, or symptom or disease.*** The causality of AEFIs is determined using scientific processes by an independent team of experts. In Nigeria, the National Expert Committee on AEFI is responsible for guiding and conducting a causality analysis on AEFI.

#### *6.1.2. Classifications of AEFI:*

I. The regulatory classification
   - **Non serious**
   - **Serious**

II. The cause specific classification includes five categories:
   - Vaccine Product related reaction
   - Vaccine quality defect related reaction
   - Immunization error related.
   - Anxiety related reaction &
   - Coincidental

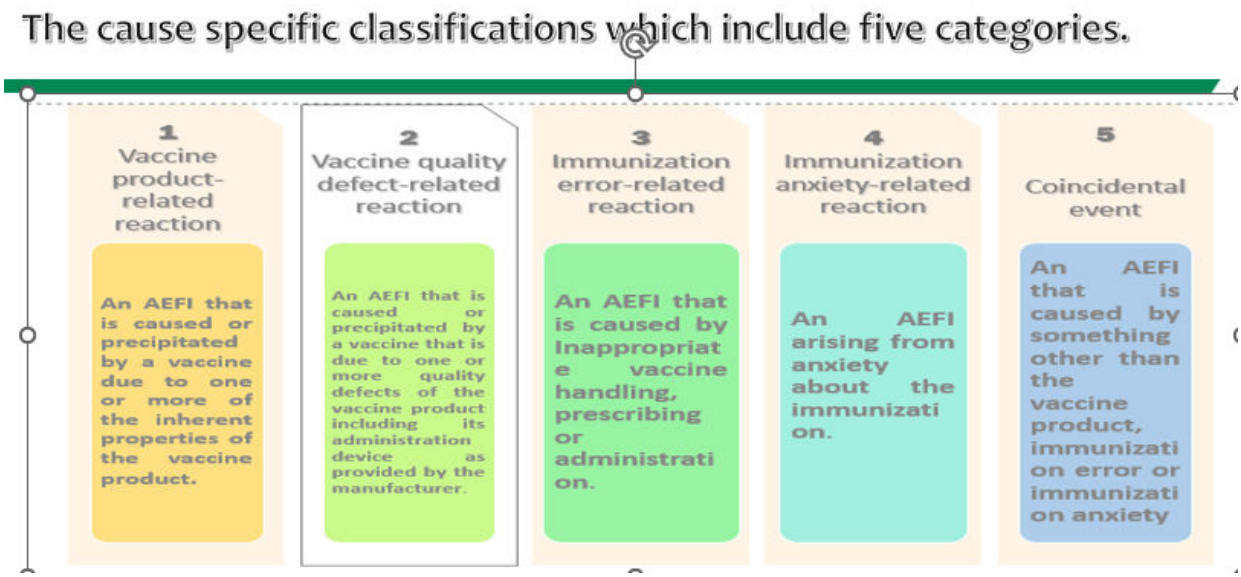


**Figure 15: Categories of cause specific classification.**

### *6.1.3 Types of AEFI:*

**Non-Serious AEFIs:** An event that is not 'serious' and does not pose a potential risk to the health of the recipient (occurs within 2hrs of injection, resolves after a short period, poses little danger).

**Note: Non-serious AEFI such as pain, erythema, swelling at site of injection, low grade fever, fatigue and headache can occur within 3 days of injection, and they resolve within 3 days of appearance of symptoms.**

**Serious AEFIs:** An event causing a potential risk to the health/life of a recipient leading to:

- Hospitalization or prolongation of existing hospitalization (e.g., encephalopathy, seizures, aseptic meningitis)
- Persistent or significant disability or incapacity (e.g., paralysis)
- Life-threatening
- Death

  Both pentavalent and Td vaccines are safe. However, there are some common AEFI associated with them.

  - Local Reaction: (pain, swelling, redness, and warmth at the injection site)
  - Chills, Soreness, or fever

- Tiredness, Fatigue, headache, muscle or Joint pain, nausea, or diarrhea
- Allergic reactions (hives, difficulty in breathing, fast heartbeat, dizziness, and weakness
- Brachial neuritis for TD Vaccine

## 6.2 Component of AEFI

### *6.2.1 Detection of AEFI*

Before vaccination, client should be oriented on the likely AEFIs that may occur, and how to report it. After vaccination, a client should be observed by health worker for minimum of 15 minute to detect any AEFI that may occur.

### *6.2.2 Reporting of AEFI*

- Reporting adverse events following immunization (AEFI) from Diphtheria vaccine is an essential component of vaccine safety surveillance.
- Reporting AEFI will be done using the AEFI data tools by manual filling on the tools and uploading on electronic platforms, the following methods will apply:
- Health workers should complete the hard copy forms, using Line Listing form, reporting form and DSNO Fill the investigation forms in case of serious AEFIs.
- Reporting should also be done via the E-platform, using DHIS2.
- All filled forms should be submitted to the LGA DSNOs then to the State DSNOs

### *6.2.3 Investigation of AEFI*

- Non serious AEFIs MUST be line listed, and reported while Serious AEFI MUST be Line listed, reported, and investigated.
- The report of a serious AEFI or a cluster of AEFIs should be investigated as early as possible, ideally within 24 hours of notification. This is done to determine the potential cause and take corrective measures to prevent future occurrences.
- The LGA DSNO with the support of the LGA team should carry out investigation immediately.
- The State AEFI committee should support the LGA Team.

- All line listing forms, reporting forms and investigation forms should be properly filled and submitted to state Epidemiologist /SDSNO and then to National.

### *6.2.4 Monitoring of AEFI*

- AEFI monitoring is very important to track the quality-of-service delivery during immunization sessions.
- To detect, Report, investigate and treat all AEFI cases and prevent loss of life.
- To communicate and correct any immunization errors and report all AEFIs within 30 days of RI and within 42 days after a mass campaign.
- To preserve public confidence in the immunization programs and to increase immunization acceptance and improve quality of service.
- To obtain more information on rare events as part of post licensure surveillance.

### *6.2.5 Management of AEFI*

It is important that all health facilities and vaccination sites are equipped with AEFI kits and health workers can detect, manage, and refer serious AEFI cases to the designated Health facilities as may be required.

They should be provided with clinician contacts for management of serious AEFI.

### *6.2.6 Content of AEFI Kit*

At vaccination posts during campaign

- Hydrocortisone (100mg) –
- Analgesics e.g., Paracetamol.
- Injection water for reconstitution
- 2ml syringes and needles.
- 5ml syringe and needle for reconstitution
- Cotton wool.

At Referral HF for treating serious AEFI cases

- Adrenaline (1:1000) solution – 2 ampoules

- Hydrocortisone (100mg) – 1 vial.
- Disposable syringes (insulin type) have 0.01 ml graduations.
- Analgesics, Cotton wool
- Normal saline and 5% dextrose saline.
- IV cannula, examination gloves, Thermometer, plaster
- IV fluid giving set, Scalp vein set.
- 5ml syringes and needles. 2ml syringes and needles
- Oxygen support and airways intubation equipment

### *6.3 Data tools for documentation of AEFI Cases that occur during outbreak response*.

- During vaccination activities such as SIAs, AEFI is likely to occur which may be Non serious or serious.
- Every Non serious AEFI case should be line listed and reported using Line listing form.
- Every serious case of AEFI should be line listed, reported, and investigated using line listing form, reporting form, and investigating form.

#### *6.3.1 The key AEFI data tools to be used during the outbreak response.*

- AEFI Line listing form
- AEFI Reporting form.
- AEFI Investigating form.
- AEFI Monthly summary form.

### 6.4 Line of reporting

Health workers are to report all cases of AEFI to the LGA DSNO (disease surveillance and notification) officers who in turn notifies the State DSNO. The State DSNO in collaboration with the State Epidemiologist is expected to submit all reports to the AEFI National Technical working group of the NPHCDA.

#### *6.4.1 Reporting process for HWs and Clients*

Reporting tools for HWs

- Paper form (line listing form, reporting form, investigation form)

- DHIS2, Med Safety App

  Reporting Process for Clients
- Visit the nearby HF and report a case.
- Call the number of LIO/DSNO in the immunization card or
- Call the NPHCDA toll free number 7722.
- Report using Med Safety (Self reporting)

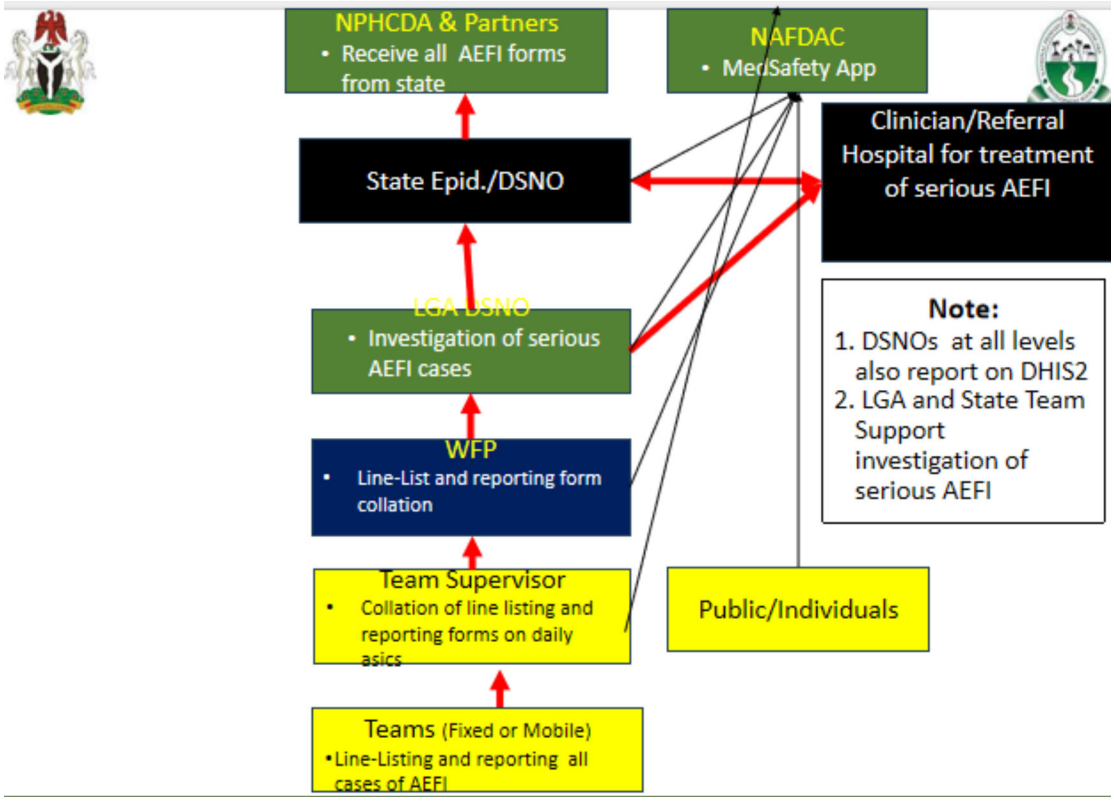


**Figure 16 AEFI Reporting Flow chart during supplementary immunization campaign.**

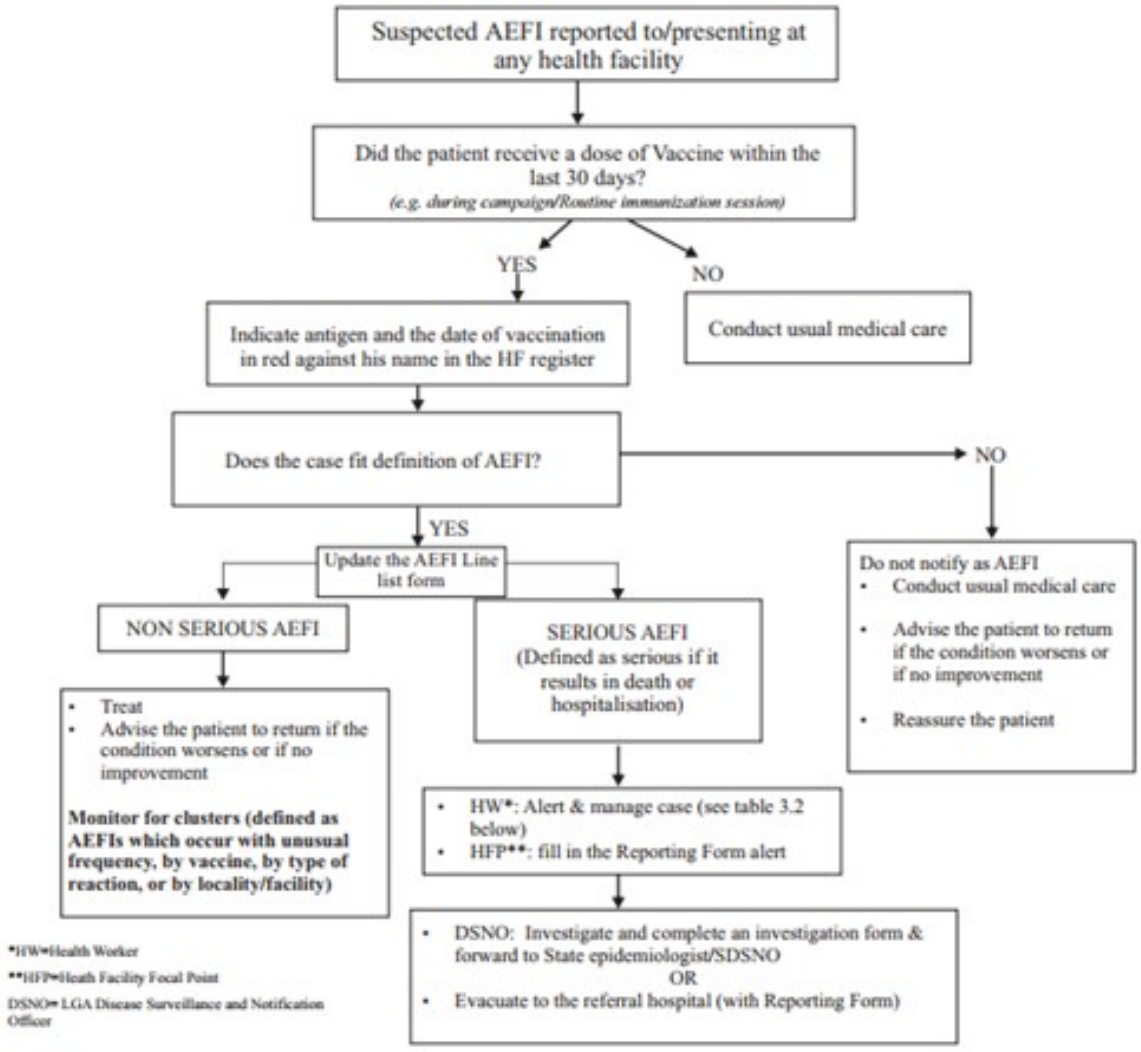


**Figure 17 AEFI Decision Implementation Flowchart**

## Monitoring and Evaluation

Monitoring and Supervision are necessary to ensure quality of planning and implementation and both processes involve observing, collecting data, and making decisions to guide and support personnel for quality implementation of the campaign. Supervision entails looking and seeing, supporting, and motivating staff, and identifying and solving problems.

Supervision must be supportive, systematic, aiming at correcting problems at the vaccination posts, screening the community and referring unvaccinated people to vaccination posts.

### 7.1 Qualities of an effective supervisor

1. Must be familiar with the area being supervised.
2. Is systematic, thorough, and a reliable problem solver.
3. Motivates and encourages local staff.
4. Understands and is involved in the planning of the campaign.
5. Is fully knowledgeable of the tasks, logistics, and all other campaign forms.
6. Has experience in training others.

Supervision and monitoring are in three phases as follows:

1. **Pre-implementation**: to ensure plans are complete, all logistics are in place and all estimates are correct, ensure all teams have daily implementation plans, and the community is aware of the program.
2. **Implementation**: to ensure good quality vaccines are safely being given to children during the vaccination exercise and relevant information is collected appropriately and reported accordingly. Supervisors will use GTS ODK
3. **Post- implementation**: to ensure all children in the target group have been reached and all campaign waste has been disposed of safely according to the guidelines. The supervisor should ensure accurate data/report is submitted to national level 7 days after implementation and continue to monitor and report occurrence of AEFIs 42 days' post campaign.

### 7.2 Pre- implementation

#### *7.2.1 Steps of pre-implementation supervision*

a) 3 days prior to implementation, preparedness will be assessed at all levels (State, LGA, Vaccination Posts) using the ODK pre-implementation checklist.
b) Pre-implementation checklist data will be analyzed and based on the findings, if the State or LGA is not prepared, the implementation will be postponed till the LGA is prepared.

### 7.3 Implementation Phase

During implementation the supervisor should complete the Implementation Checklist (ODK embedded in the GTS). High risk and hard-to-reach populations,

particularly in urban areas, should receive more intense supervision with the best supervisors.

The supervisor should carry extra materials, like tally sheets, summary sheets, vaccines, icepacks, pen markers, and plastic bags. Supervisor should have the daily implementation plan (DIP) to ensure that the reactive vaccination campaign is being implemented as planned.

### 7.4 Independent monitoring

The monitors should have a working understanding of local language. The monitor should be trained and assigned the area of work daily by the LGAF/STF. The Monitor is expected to start work on day two of the implementation. Monitoring should be conducted in the area that was covered before. The monitor should be assigned two settlements a day and should visit 15 households in each settlement. Monitoring will be conducted inside, and outside households and the indicator will be the finger marks and vaccination card. Complete the monitoring ODK checklists for each settlement. Random selection of houses should be done with an interval of 5 houses in urban/densely populated and 3 houses in rural areas. It is very important for monitors to give accurate information since this information is used to guide the implementation. The data should be discussed with the community leader and WFP before leaving the settlement. All monitors are expected to give report of findings during evening review meetings daily.

### 7.5 Analysis of rapid monitoring data

1. List the unvaccinated people by age and gender and give the reasons why they were not vaccinated.
2. For the social mobilization questions, find the percentage of households where the family knew the disease against which the vaccination is for and whether the team asked if all people in the family were vaccinated.
3. For question "How did the family hear about the campaign", calculate the percentage of households listing each response.

The results of the rapid monitoring tool should be discussed at the LGA daily review meeting for immediate actions and should be included in the final report of the monitor.

## Annexure

### 2023 DIPHTHERIA OUTBREAK RESPONSE

### Pre-Implementation Check List

Instructions:

To be filled by Supervisors from National, State team, LGA, Ward Team and conducted at the a) LGA, b) ward, and c) health facility levels. Verification must be conducted 3 weeks, 2 weeks, 1 week, and 3 days prior to implementation. The report of the verification exercise must be submitted accordingly Checklists should be completed and shared at LGA and State levels. Checklist should be scored by section **(Yes = 1, No =0).**

| **Scoring should be done by section** | | |
|---|---|---|
| **Section** | **Minimum Score** | **Score Achieved (Total Score per Section)** |
| A: Planning (11 points) | 7 | |
| B: Social Mobilization (7 points) | 5 | |
| C: Logistics (20 points) | 15 | |

**Indicate Level of supervision: ▫ LGA ▫ Ward ▫ Health Facility Start Date of Campaign: _____**

Supervisor Name: _____ Agency: _____ Date: _____

| State: | LGA: | Ward: |
|---|---|---|
| Settlement: | Health Facility: | |

| | **YES (1 point)** | **NO (0 points)** |
|---|---|---|
| | | |
| | | |
| | | |
| | | |

| | | |
|---|---|---|
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | **YES**<br>**(1 point)** | **NO**<br>**(0 points)** |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| **C.COLD CHAIN AND LOGISTICS**<br>**Vaccines and devices are expected to be at the State at least 2 weeks before the campaign, LGA 3 days before the campaign. Freezing of ice packs (IPs) should commence at least 1 week at all levels** | **YES**<br>**(1 point)** | **NO**<br>**(0 points)** |
| **1.Have vaccines, AD syringes and safety boxes been distributed as bundled (i.e. all together), to the lower level?** Tick "YES" if you observe records | | |

| | | | |
|---|---|---|---|
| of distribution of vaccines and devices to the lower levels and are satisfied that lower levels were supplied an equal number of vials of vaccines. | | | |
| **2.** Has this level developed vaccine and devices distribution plan? **Tick YES after sighting the distribution plan** | | | |
| **3.** Has this level commenced freezing of icepacks for the campaign? Tick YES after verifying availability of sufficient frozen icepacks for the Campaign 4 (0.3L/0.4L) Ice Packs per Gio'style® and 24 Ice Packs (0.6L)/48(0.3L/0.4L) per cold box | | | |
| **4. Has this level made adequate arrangements to meet the transport requirements of the campaign operation?** Tick "YES" if you are satisfied with the arrangements made | | | |
| **Based on the Target Population, Number of Vaccination Teams, and Target Population, fill out the table below:** | | | |
| Target Population: _____ | Number of Vaccination Teams: _____ | **Adequate Number?** | |

| **Supply (requirement)** | **Number Required** | **Number Available** | **YES (1 point)** | **NO (0 points)** |
|---|---|---|---|---|
| **5. Gio'style® Vaccine Carriers** (2/team) | | | | |
| **6. Ice Packs** (16/team) | | | | |

| | | | | |
|---|---|---|---|---|
| **7. Cold Box** | | | | |
| **8. Pentavalent/Td vaccines vials** (Target population * 1.05 / 10, rounded up) | | | | |
| **9. Auto-disable Syringes/Needles** (Target population * 1.05) | | | | |
| **10. Safety boxes** (AD syringes*1.05 / 100) | | | | |
| **11. Tally sheets** (Number of vaccination teams * 10 * 2 * 1.11) | | | | |
| **12. Summary sheets** (10 per ward * 1.11) | | | | |
| **13. Cotton wool** (500g roll) (# teams * 2) | | | | |
| **14. Vaccination cards** (Target population * 1.05) | | | | |
| **15. AEFI kits** (# vaccination teams) | | | | |
| **16. AEFI forms** (# teams * 1.11) | | | | |
| **17. Plastic bags** (# vaccination teams * 6 * 2 * 1.11) | | | | |
| **18. Pen Markers** (# teams * 4 * 1.11) | | | | |
| **19. Has this level made adequate arrangements for the disposal of used needles/syringes and other wastes?** Each level is expected to have a waste management plan. Request for this plan and confirm that the site for disposal has been prepared and waste management staff assigned and trained | | | | |

**REMARKS**

_____

_____

**Supervisor Signature:** _____ **Date:** _____

**2023 DIPHTHERIA OUTBREAK RESPONSE**

**Implementation Check List**

This is an implementation process checklist to supervise the quality of implementation of YF PMVC at the vaccination post and the immunization catchment area. Every supervisor at LGA and Ward levels must use the checklist at the vaccination post. As much as possible, application of this checklist should not interrupt services at the post.

Supervisor Name: _____ Agency: _____

| | | |
|---|---|---|
| State: | LGA: | Ward: |
| Settlement: | Health Facility: | Target Population: |
| Vaccination Team Code: | Vaccination Post Code/Location: | |

| **A. COLD CHAIN** | **YES** | **NO** |
|---|---|---|
| 1. Does each vaccination team have two Gio'style® vaccine | | |
| 2. Is there a vaccine carrier solely dedicated for storing | | |
| 3. Are ice packs conditioned? | | |
| 4. Are vaccines vials being used placed on a foam pad inside a | | |
| 5. Are vaccines not in use stored in the second vaccine carrier | | |
| **B. REQUIRED and AVAILABLE COMMODITIES AND SUPPLIES** Complete the table below **before answering** questions 6–20 | | |

| | **Req** | **Avail.** | | | **Req.** | **Avail** |
|---|---|---|---|---|---|---|
| # Vials of Penta vaccine | | | | # Pen Markers | | |
| # Vials of Td vaccine | | | | # AEFI Case Investigation Forms | | |
| # Auto-disable Syringes | | | | # AEFI Line Listing Forms | | |
| # Safety Boxes | | | | # AEFI Kits | | |
| # Rolls Cotton Wool | | | | # Plastic Bags | | |
| # Tally Sheets | | | | # Waste bins | | |

| C. ADEQUATE QUANTITIES OF COMMODITIES AND SUPPLIES | YES | NO |
|---|---|---|
| 6. Is there at least a day supply of vaccines? | | |
| 7. Is the number of AD syringes equal to the number of doses of injectable vaccines? | | |
| 8. Is the number of safety boxes to be used today sufficient? (A total of Auto-disable Syringes for one safety box) | | |
| | | |
| | YES | NO |
| | | |
| | | |
| | | |
| | | |
| | YES | NO |
| | | |
| | | |
| | YES | NO |
| | | |
| | | |
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| | | |
| | | |
| | | |
| | YES | NO |
| | | |
| | | |
| | | |
| | | |
| | | |
| | | |
| I. WASTE MANAGEMENT | YES | NO |
| 28. Are safety boxes appropriately assembled with no exposed flaps? | | |
| 29. Are the disposed syringes exposed out of the safety box? | | |

| | | |
|---|---|---|
| 30. Are only syringes placed in the safety box? | | |
| 31. Are the safety boxes filled more than three quarters (3/4)? | | |
| 32. Are filled up safety box kept in a secure location away from the public? | | |
| 33. Are the safety boxes closed and marked as used? | | |
| 34. Do the vaccinators know the plan for disposal of filled up safety boxes? | | |
| | **YES** | **NO** |
| | | |
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| | | |
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| | | |
| | **YES** | **NO** |
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**REMARKS**

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**Supervisor Signature:** _____ **Date:** _____

**DIPHTHERIA OUTBREAK RESPONSE**

**TALLY SHEET FOR VACCINATION TEAMS**

**Instruction: To be filled by the Vaccinator. Use a separate tally sheet each day**

**State:** **LGA:** **Ward::**_____

**Health Facility Name:**_____ **Facility Type (Private/Public) :**_____ **Date:** _____

**Session Type (Fixed/Outreach/Mobile):** _____ **If Outreach/Mobile , Write Site Name** _____

| | | | | | | | | | | | | Sub-Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MALE | Age 2- 4 years | Penta 1 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | Penta 2 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | Penta 3 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| FEMALE | Age 2 - 4 years | Penta 1 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | Penta 2 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | Penta 3 | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | | | | |
| | | | | | | | | | | | Total | |

| | Serious | | | Non serious | | | TOTAL AEFI |
|---|---|---|---|---|---|---|---|
| AEFI REPORTED | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | |
| | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | |
| | 00000 | 00000 | 00000 | 00000 | 00000 | 00000 | |

| | MATERIALS RECEIVED,USED AND RETURNED | | |
|---|---|---|---|
| | Penta Vials | Syringes | |
| | Vaccines | Auto Disable | Safety Boxes |
| 1. Received | | | |
| 2. Total opened/used | | | |
| 3. Returned | | | |
| 4. Batch Number | | | |

| Quantity of Td vials discarded due to: | | | | | |
|---|---|---|---|---|---|
| Expiry | Breakage | VVM Change | Frozen | Label Removed | Others |
| | | | | | |

**Has AEFI form been completed for each adverse event following immunization?** _____

**Vaccination Supervisor's Name and phone number :** _____ **Signature:** _____

**DIPHTHERIA OUTBREAK RESPONSE**

**TALLY SHEET FOR VACCINATION TEAMS**

**Instruction: To be filled by the Vaccinator. Use a separate tally sheet each day**

State: LGA: Ward::

Health Facility Name: Facility Type (Private/Public) : Date:

Session Type (Fixed/Outreach/Mobile): If Outreach/Mobile , Write Site Name

| | | | | | | | | | | | | Sub-Total |
|---|---|---|---|---|---|---|---|---|---|---|---|---|
| MALE | Age 10-14 years | Td 1 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | | | | |
| | | Td 2 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | | | | |
| | | Td 3 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | | | | |
| | Age > 4-9 years | Td 1 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | | | | |
| | | Td 2 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | | | | |
| | | Td 3 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | | | | |
| FEMALE | Age 10-14 years | Td 1 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | | | | |
| | | Td 2 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | | | | |
| | | Td 3 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | | | | |
| | Age > 4 -9 years | Td 1 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | | | | |
| | | Td 2 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | | | | |
| | | Td 3 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | 00000 00000 00000 00000 | | | | |
| | | | | | | | | | | | | Total |
| | | | Serious | | | Non serious | | | | | | TOTAL AEFI |
| AEFI REPORTED | | | 00000 00000 00000 | 00000 00000 00000 | 00000 00000 00000 | 00000 00000 00000 | 00000 00000 00000 | 00000 00000 00000 | | | | |

| | MATERIALS RECEIVED,USED AND RETURNED | | |
|---|---|---|---|
| | Td Vials Vaccines | Syringes Auto Disable | Safety Boxes |
| 1. Received | | | |
| 2. Total opened/used | | | |
| 3. Returned | | | |
| 4. Batch Number | | | |

| Quantity of Td vials discarded due to: | | | | | |
|---|---|---|---|---|---|
| Expiry | Breakage | VVM Change | Frozen | Label Removed | Others |
| | | | | | |

Has AEFI form been completed for each adverse event following immunization? _____

Vaccination Supervisor's Name and phone number : _____ Signature: _____

**DIPHTHERIA OUTBREAK RESPONSE**

**WARD SUMMARY**

Instruction: To be filled by Ward Focal Person. Use one sheet for each day

Ward_____ LGA_____ Total HFs in Ward_____ Number of Public HFs_____ Number of Private HFs_____

Number of Reporting HFs in Ward_____

| Type of Vaccination team (Fixed or Outreach) | Total number of persons vaccinated | | | | | | TOTAL | Penta vials | | | | AD Syringes | | | Safety Boxes | | | Vaccination Cards | | | No. of AEFI Cases Reported | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MALE | | | FEMALE | | | | Vaccine | | Returned | | | | | | | | | | | | |
| | 2 - 4 YEARS | | | 2 - 4 YEARS | | | | Received | Opened | Returned ( VVM1 & VVM2)) | Returned ( VVM3 & VVM4)) | Received | Used | Returned | Received | Used | Returned | Received | Used | Returned | Serious | Non serious |
| | Penta 1 | Penta 2 | Penta 3 | Penta 1 | Penta 2 | Penta 3 | | | | | | | | | | | | | | | | |
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| Total | | | | | | | | | | | | | | | | | | | | | | |

| Quantity of Td vials discarded due to: | | | |
|---|---|---|---|
| Expiry | Breakage | VVM Change | Frozen |
| | | | |

Remarks:

Note: Copy of this form should be sent to the LGA team. The WARD should file a copy centrally for future reference. *All sections must be completed*

Ward Focal Person Name and phone number _____ Signature_____

**DIPHTHERIA OUTBREAK RESPONSE**

**WARD SUMMARY**

Instruction: To be filled by Ward Focal Person. Use one sheet for each day

Ward_____ LGA_____ Total HFs in Ward_____ Number of Public HFs_____ Number of Private HFs_____

Number of Reporting HFs in Ward_____

| Type of Vaccination team (Fixed or Outreach) | Total number of persons vaccinated | | | | | | | | | | | | TOTAL | Td vials | | | | AD Syringes | | | Safety Boxes | | | Vaccination Cards | | | No. of AEFI Cases Reported | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MALE | | | | | | FEMALE | | | | | | | Vaccine | | Returned | | | | | | | | | | | | |
| | >4-9 YEARS | | | 10-14 YEARS | | | >4-9 YEARS | | | 10-14 YEARS | | | | Received | Opened | Returned ( VVM1 & VVM2)) | Returned ( VVM3 & VVM4)) | Received | Used | Returned | Received | Used | Returned | Received | Used | Returned | Serious | Non serious |
| | Td1 | Td2 | Td 3 | Td1 | Td2 | Td 3 | Td1 | Td2 | Td 3 | Td1 | Td2 | Td 3 | | | | | | | | | | | | | | | | |
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| Total | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Quantity of Td vials discarded due to: | | | | | |
|---|---|---|---|---|---|
| Expiry | Breakage | VVM Change | Frozen | Label Removed | Others |
| | | | | | |

Remarks:

Note: Copy of this form should be sent to the LGA team. The WARD should file a copy centrally for future reference. *All sections must be completed*

Ward Focal Person Name and phone number _____ Signature_____

**DIPHTHERIA OUTBREAK RESPONSE**
**LGA SUMMARY**
**Instruction: To be filled by State Technical Facilitator. Use one sheet for each day**

LGA_____ State_____ Total HFs in LGA_____ Number of Public HFs_____ Number of Private HFs_____

Number of Reporting HFs in LGA_____

| Ward name | Total number of persons vaccinated | | | | | | TOTAL | Penta vials | | | | AD Syringes | | | Safety Boxes | | | Vaccination Cards | | | No. of AEFI Cases Reported | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MALE | | | FEMALE | | | | Vaccine | | | | | | | | | | | | | | |
| | 2 - 4YEARS | | | 2 - 4 YEARS | | | | Received | Opened | Returned | | Received | Used | Returned | Received | Used | Returned | Received | Used | Returned | Serious | Non serious |
| | Penta1 | Penta 2 | Penta 3 | Penta 1 | Penta 2 | Penta3 | | | | Returned ( VVM1 & VVM2)) | Returned ( VVM3 & VVM4)) | | | | | | | | | | | |
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| Total | | | | | | | | | | | | | | | | | | | | | | |

| Quantity of Td doses discarded due to: | | | |
|---|---|---|---|
| Expiry | Breakage | VVM Cha | Frozen |
| | | | |

Note: Copy of this form should be sent to the state team. The LGA should file a copy centrally for future reference.

*All sections must be completed*

STF Name and phone number _____ Signature_____

**DIPHTHERIA OUTBREAK RESPONSE**
**LGA SUMMARY**
**Instruction: To be filled by State Technical Facilitator. Use one sheet for each day**

LGA_____ State_____ Total HFs in LGA_____ Number of Public HFs_____ Number of Private HFs_____

Number of Reporting HFs in LGA_____

| Ward name | Total number of persons vaccinated | | | | | | | | | | | | TOTAL | Td vials | | | | AD Syringes | | | Safety Boxes | | | Vaccination Cards | | | No. of AEFI Cases Reported | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | MALE | | | | | | FEMALE | | | | | | | Vaccine | | | | | | | | | | | | | | |
| | > 4-9YEARS | | | 10-14 YEARS | | | > 4-9YEARS | | | 4-14 YEARS | | | | Received | Opened | Returned | | Received | Used | Returned | Received | Used | Returned | Received | Used | Returned | Serious | Non serious |
| | Td1 | Td2 | Td 3 | Td1 | Td2 | Td 3 | Td1 | Td2 | Td 3 | Td1 | Td2 | Td 3 | | | | Returned ( VVM1 & VVM2)) | Returned ( VVM3 & VVM4)) | | | | | | | | | | | |
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| Total | | | | | | | | | | | | | | | | | | | | | | | | | | | | |

| Quantity of Td doses discarded due to: | | | | | |
|---|---|---|---|---|---|
| Expiry | Breakage | VVM Cha | Frozen | Label Removed | Others |
| | | | | | |

Note: Copy of this form should be sent to the state team. The LGA should file a copy centrally for future reference.

*All sections must be completed*

STF Name and phone number _____ Signature_____


# 7.0

## Standardizing Diphtheria Outbreak Response & Reporting using the 7-1-7 Timeliness Metric and Performance Improvement Framework

# 7.0 Standardizing Diphtheria Outbreak Response & Reporting using the 7-1-7 Timeliness Metric and Performance Improvement Framework

Recent global events have shown that rapid detection, notification, and response are critical to containing public health threats before they become epidemics or pandemics.

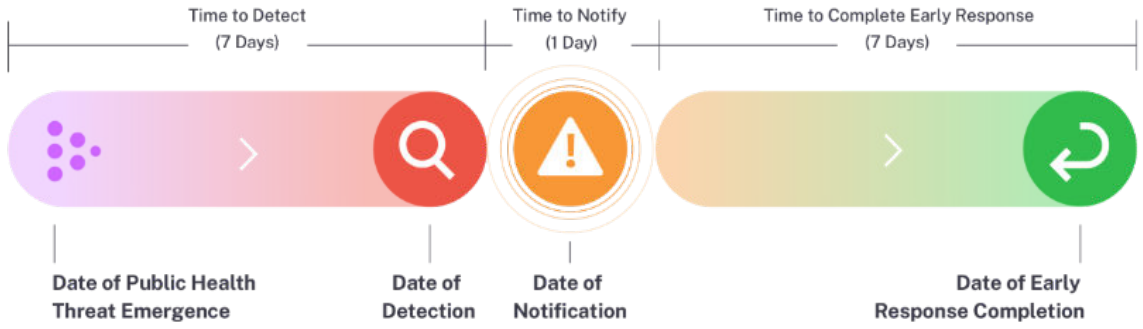
Quickly detecting and effectively responding to infectious disease outbreaks such as diphtheria is critical in evaluating a country's current and future outbreak response capacity and capabilities when outbreaks do occur. A timeliness framework that routinely measures the time it takes for a country to attain notable milestones in outbreak management such as detection, notification, and response in conjunction with clear targets, allows governments to determine strengths while identifying challenges that can drive performance improvements.

The 7-1-7 framework is a globally accepted timeliness metric that sets specific time intervals between key surveillance and response actions (outbreak milestones). The 7-1-7 target proposes a simple set of three timeliness metrics with corresponding targets of 7 days to detect an outbreak ,1 day to inform the appropriate national public health authority to initiate an investigation and 7 days to complete the initial early response activities. 7-1-7 is aligned with targets for detection and notification of outbreaks and describes key actions to be taken during the early days of a response to contain a new threat.7-1-7 tool can be used to assess how the IDSR system is performing in achieving its goal: to detect, notify and respond to threats early, reduce morbidity and mortality and identify those steps that can be taken to strengthen IDSRs.

The application of the 7-1-7 timeliness metric and performance improvement framework will ensure the collection of data relevant to detection and response milestones, evaluation of the timeliness of recent event responses using the 7-1-7 target tool and subsequently use these data to conduct real-time performance improvement by identifying bottlenecks to timely detection, notification, and

response, and proposing as well as implementing remediation plans. Adherence to this framework will also improve the timeliness and quality of event responses by providing a pathway for the National and subnational to communicate to the public, political leadership, and donors about where improvements have been made and where additional evidence-based funding and support are needed for outbreak management. The 7-1-7 approach is an accountability framework that provides real-time improvement recommendations for prioritization into the national and subnational operational plans which focuses on strengthening the existing health Systems.

## 7-1-7: Timeliness metrics and milestones






**During an outbreak of Diphtheria :**

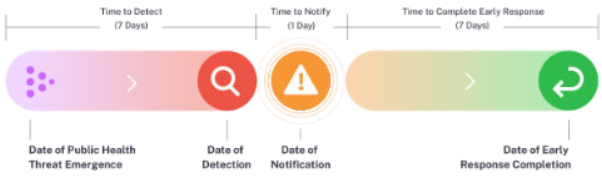
Date of emergence is the date when the index case or first epidemiologically linked case in a new population first experienced symptoms

Date of detection is the date the first case of diphtheria is recorded by any source or in any system

Date of notification: for diphtheria cases detected at health care facility notification will be to a higher level authority responsible for coordinating initial investigation i.e LGA level

Date of response : Dates when each componentof the early effective response actions as indicated in the response checklist are completed

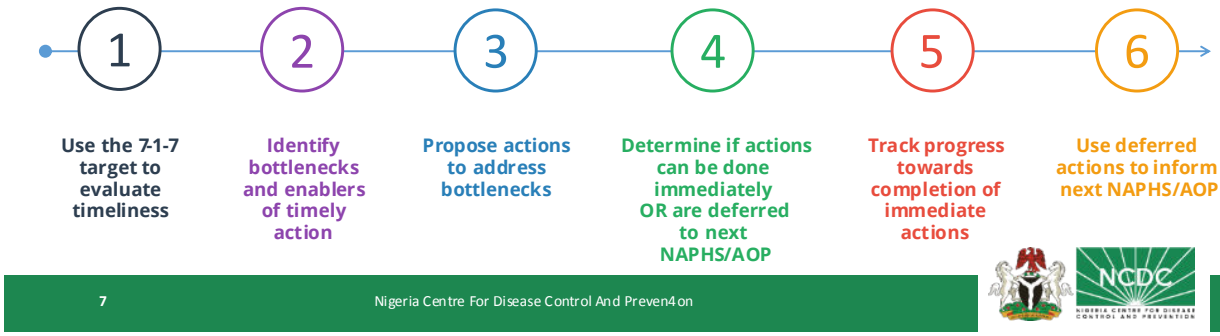
## 7 early response ac-ons




- The date when all early effec/ ve response ac/ ons, as defined by the Response Checklist, were completed:
  - ❑Component #1: Ini. ated inves. ga. on or deploy inves. ga. on/response team
  - ❑Component #2: Conducted epidemiological analysis of burden, severity and risk factors
  - ❑Component #3: Obtained laboratory confirma. on of the outbreak e. ology
  - ❑Component #4: Ini. ated appropriate case management and IPC measures
  - ❑Component #5: Ini. ates appropriate public health countermeasures
  - ❑Component #6: Began risk communica. on and community engagement
  - ❑Component #7: Established a response coordina. on mechanism

7 Nigeria Centre For Disease Control And Preven4on

# 7-1-7 Performance Improvement Approach




**Outbreak investigation and response reporting: expectations for performance improvement**

All relevant stakeholders should be appropriately informed of findings during and after outbreak investigation and response. During investigation, team members, relevant health professionals, public health officials, policy makers and the public at large should be adequately informed about the origin and evolution of the outbreak, transmission pattern of diphtheria, established coordination mechanisms, resource mapping etc.

Once the investigation is completed, the findings can be shared through an oral de-briefing or a written report.

A written report serves multiple purposes including serving as a record of performance, identifying best practices, highlighting challenges & bottlenecks, proposing remedial actions that need to be taken to ensure performance improvement, sharing new insights, supporting research and evaluation activities. The report provides valuable information that can guide decision-making and facilitate future investigations or studies. Additionally, the report can serve as an official record of the investigation and can be referred to as necessary.

Standardized reporting templates with indicators incorporating the 7-1-7 timeliness metric and performance improvement framework are readily available to guide diphtheria outbreak response and reporting (See Attached reporting and debrief templates in annex)

Upon return of PHERRTs from field deployments, and having satisfied the conduct of a debriefing session at the national (during the National Surveillance and Outbreak Review Meeting – NaSORM) and at state level and subsequent submission of a final report, To improve performance and drive sustainability it is incumbent upon the teams to continue to follow up with the responsible institutions and identified focal persons for the implementation of immediate and short term remedial actions and improvement plans while long term remedial actions can be deferred for operational planning purposes

**Details of Health Care Workers positive for Diphtheria**

| S/N | Initials | Age | Gender | Date of onset of symptoms | Date confirmed | Diphtheria Vaccination status | Specialty/Department | Category of health worker (nurse, doctor, pharmacist, lab scientist, attendant, Cleaners, Admin Staff) | Exposure (Unprotected (without medical mask) /close face-face contact) | Current symptoms |
|---|---|---|---|---|---|---|---|---|---|---|
| | | | | | | | | | | |
| | | | | | | | | | | |
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NB:

I. No established link between any of the healthcare workers and contact with a patient, in the line of duty.

II.

**DIPHTHERIA HCAI SURVEILLANCE FORM FOR HCWS**

**FORM NO:_____**

**Purpose:** The purpose of this form is to assist hospital staff investigate Diphtheria infections in Healthcare Workers (HCW). It is standardized and uses a set of predefined questions that assesses exposure risks and aims to identify areas of improvement and to reduce the risk of further HCW infections.

**Instructions:** Circle where appropriate (e.g. yes, no, different options). Unknown = HCW can't remember or unknown. ***Please complete all questions including if the answer is 'No'***. This form should be completed as soon as the HCW is confirmed positive for Diphtheria. This form should be administered by a member of the hospital Infection Prevention and Control (IPC) team. After completion, a copy should be kept in the hospital in a dedicated folder for healthcare worker Diphtheria infections and a copy emailed to the NCDC (tochi.okwor@ncdc.gov.ng). The findings of each investigation should be discussed with the hospital IPC committee, head of the clinical unit and senior hospital management staff.

**Name of health facility_____ Date of Interview: ____/____/_____ (dd/mm/yyyy)**

| **Section 1. Details of Investigator(s) i.e, the personnel administering the form (if multiple, list all)** | | | |
|---|---|---|---|
| **Name** | **Designation/Role** | **Phone number** | **Email Address** |
| | | | |
| | | | |
| | | | |
| | | | |

**Section 2. Source of information regarding HCW infection**

Was the HCW interviewed directly? **Yes** **No**

If yes, skip to section 3

If no, state reason_____

Who provided the information?

| **Name** | **Relationship with patient** | **Phone number(s)** | **Email address** |
|---|---|---|---|
| | | | |
| | | | |
| | | | |
| | | | |

**Section 3. Demographics of infected HCW**

Name: DOB/ Age:

Sex:

Phone number(s):

Profession: Designation (eg: Medical officer):

Residential address with LGA:

Place of work/State: Hospital Ward/unit:

Facility Type (Private/Public):

Facility Type (Tertiary, Secondary, Primary)

**Section 4. Illness and hospitalisation details of infected HCW**

A. Date of onset of symptoms: ____/_____/_____ **(dd/mm/yyyy)**

List the initial symptoms:

_____

B**.** Any history of contact with suspect or confirmed case(s) or their bodily fluids? **Yes** **No** **Unknown**

If yes, please specify_____

C. Any delay in HCW seeking medical attention after suspecting Diphtheria? **Yes** **No**

If yes, select reason: **Unsure** **Self medication** **Denial** **Others**_____

D. Was the health worker admitted? Yes ( ) No ( )

Date of admission to Diphtheria Isolation Centre: ____/_____/_____ **(dd/mm/yyyy)**

E. Date HCW commenced treatment for Diphtheria: ____/_____/_____ **(dd/mm/yyyy)**

F. HCW outcome (Discharged, Death, Transferred): _____

Date of outcome: ____/_____/_____ **(dd/mm/yyyy)**

**Section 5 . History of HCW contact with Diphtheria patient while providing care.**

Did the HCW provide care for a suspected or confirmed case of Diphtheria:

**Yes No Unknown**

(If yes complete section a only. If no complete section b only)

**Section a. (In situations where more than one confirmed patient was cared for outside the Isolation center, please print this section in duplicate and attach).**

Details of the confirmed Diphtheria patient the HCW had contact with

i. Epid No of Patient: _____ **No. Epid no.**
ii. Age: _____ **Month** **Years**
iii. Sex: _____
iv. Date of admission/presentation to healthcare facility: ____/_____/_____ **(dd/mm/yyyy)**
v. Name of healthcare facility:_____

A. Did the HCW use medical mask (droplet transmission precautions) while providing care to the suspected or confirmed case of diphtheria? Yes ( ) No ( )

B. Did the HCW use medical gloves and gown/apron (contact transmission precautions) while providing care to the suspected or confirmed case of diphtheria? Yes ( ) No ( )

C. What kind of clinical care did the HCW provide to the confirmed Diphtheria patient?

**Nursing Medical Surgical Obstetric Midwifery Dental Anaesthetic Others _____**

**If surgical care, give details**

Procedure:

_____

Duration of surgery: _____ hours

Complications of surgery, if any**:**_____

D. Which wards/locations did the HCW provide care? Please specify in space below

_____

E. Which date did the HCW first provide care for a Diphtheria case?
**____/____/____(dd/mm/yyyy)**

F. Which date did the HCW last provide care for the Diphtheria case?
**_____/_____/_____(dd/mm/yyyy)**

G. During that period, how many times did the HCW interact with the patient? (state number of estimated number of times **e.g 6** ) [ ]

H. While providing care, did the Patient wear a medical mask? Yes ( ) No ( )

I. If No, Why was the patient not wearing a medical mask?

i. Medical Mask not available: **Yes** **No**
ii. Under 5 age group: Yes No
iii. Was not aware that Medical Mask needed to be used: **Yes** **No**
iv. Forgot to use Medical Mask: **Yes** **No**
v. Had not been trained on how to use the Medical Mask: **Yes** **No**
vi. Other (give details):
_____

**Section 6. History of HCW vaccination for Diphtheria**

A. Did the HCW receive Diphtheria vaccination? **Yes** **No**

B. What year was the Diphtheria vaccination received? (state the year in the bracket *e.g. 1980*) [ ]

C. How many doses of Diphtheria vaccination were received? (state a number in the bracket *e.g. 4*) [ ]

**RRT Deployment Report Template-Preliminary**

**Administrative Elements**

**Report Type:** Preliminary report **Report Submission Date** Click or tap to enter a date.

**Disease/Event Investigated:** Click or tap here to enter text. (e.g Cholera)

**State:** Click or tap here to enter text. **LGA:** Click or tap here to enter text.

**SitAware ID:** Click or tap here to enter text.

**Date of Deployment:** Choose an item. **End of Deployment Date** Click or tap to enter a date.

**Reporting Authority** Choose an item.

**Outbreak Milestones**

| | |
|---|---|
| **Outbreak Start** (Date of onset for the index case for single-case disease outbreaks (e.g Lassa) or when the disease threshold was exceeded (e.g Measles, CSM)) | Choose an item. |
| **Date of Detection** (first suspected case/rumour; disease detected by clinical or public health authorities) | Choose an item. |
| **Date of Notification** (date of notification to the next level of public health authorities, e.g., from health facility to LGA or from LGA to state)) | Choose an item. |

| | |
|---|---|
| **Date of Laboratory Confirmation** | Choose an item. |

**Basic Epidemiology (Specified Dates)**

During the period of Choose an item. to Choose an item.

- **No of Suspected cases:** Click or tap here to enter text.
- **No of Confirmed cases:** Click or tap to enter a date.
- **No of Probable cases:** Click or tap to enter a date.
- **Case Fatality Ratio** Click or tap here to enter text.

---

**Background**

How was the problem identified/notified to NCDC RRT? [When was the index case identified, when was NCDC notified, when was team deployed and what's the team composition]

What were the objectives the investigation/response? Attach TOR as Annex 3

**Preliminary Report Outline**

- Investigation Name
- SitAware ID
- Date of investigation
- Location

Same as administrative text box on first page

- Names of the Investigation Team
- Duration of field trip
- Nature of the problem: copy the problem from the notification report and add specifics including mortality rates and severity of the disease

- Descriptive epidemiology– same as epidemiological situation in daily situation report. Tables, charts, maps and epidemic curve should be included in this section.
- Complete the Rapid Response Team Checklist (annex 2)

Recommendations

Name of supervisor notified:.....

Signature of supervisor.....

**NB:**

**This report should be sent between 24 to 48 hours of deployment**

**RRT Deployment Report Template- Daily**

**Administrative Elements**

**Report Type:** Daily **Report Submission Date** Click or tap to enter a date.

**Disease/Event Investigated:** Click or tap here to enter text. (e.g Cholera)

**State:** Click or tap here to enter text. **LGA:** Click or tap here to enter text.

**SitAware ID:** Click or tap here to enter text.

**Date of Deployment:** Choose an item.

**Reporting Authority** Choose an item.

**Outbreak Milestones**

| | |
|---|---|
| **Outbreak Start** (Date of onset for the index case for single-case disease outbreaks (e.g Lassa) or when the disease threshold was exceeded (e.g Measles, CSM)) | Choose an item. |
| **Date of Detection** (first suspected case/rumour; disease detected by clinical or public health authorities) | Choose an item. |
| **Date of Notification** (date of notification to the next level of public health authorities, e.g., from health facility to LGA or from LGA to state)) | Choose an item. |
| **Date of Laboratory Confirmation** | Choose an item. |

**Basic Epidemiology (Specified Dates)**

During the period of Choose an item. to Choose an item.

- **No of Suspected cases:** Click or tap here to enter text.
- **No of Confirmed cases:** Click or tap to enter a date.
- **No of Probable cases:** Click or tap to enter a date.
- **Case Fatality Ratio** Click or tap here to enter text.

---

**Background**

How was the problem identified/notified to NCDC RRT? [When was the index case identified, when was NCDC notified, when was team deployed and what's the team composition]

What were the objectives the investigation/response? Attach TOR as Annex 3

What recommendations do you have? E.g. for the different stakeholders- State, NCDC, partners

**Annex 1: Response Daily Situation Report Template**

| | |
|---|---|
| **Date/timing** | Reporting date and time |
| **Location/areas affected** | Village/town, LGA, State |
| **Summary** | When the index case was identified, when was NCDC notified, when was team deployed and what's the team composition, current status of the response |
| **Epidemiological situation** | Description of outbreak in time, place and person<br><br>No of cases-suspected, probable, confirmed, CFR |
| **Action Initiation** | What the RRT has done so far( data management, epidemiological surveillance- active case search, IAP development, risk communication, case management, laboratory support, etc) |
| **Contacts and coordination** | Stakeholders in the state involved in the response.<br><br>Response structure- EOC activation and structure |
| **Challenges** | Impediments to response and control |

| | |
|---|---|
| **Recommended actions (next steps for RRT and other levels)** | Based on response and challenges |
| **Resources needed (including staffing)** | |

***Table, charts, maps and epidemic curve should be included***

***Complete the Rapid Response Checklist (Annex 2)***

**RRT Deployment Report Template-Interim**

**Administrative Elements**

**Report Type:** Interim report **Report Submission Date** Click or tap to enter a date.

**Disease/Event Investigated:** Click or tap here to enter text. (e.g Cholera)

**State:** Click or tap here to enter text. **LGA:** Click or tap here to enter text.

**SitAware ID:** Click or tap here to enter text.

**Date of Deployment:** Choose an item. **End of Deployment Date** Click or tap to enter a date.

**Reporting Authority** Choose an item.

**Outbreak Milestones**

| | |
|---|---|
| **Outbreak Start** (Date of onset for the index case for single-case disease outbreaks (e.g Lassa) or when the disease threshold was exceeded (e.g Measles, CSM)) | Choose an item. |
| **Date of Detection** (first suspected case/rumour; disease detected by clinical or public health authorities) | Choose an item. |
| **Date of Notification** (date of notification to the next level of public health authorities, e.g., from health facility to LGA or from LGA to state)) | Choose an item. |
| **Date of Laboratory Confirmation** | Choose an item. |

**Basic Epidemiology (Specified Dates)**

During the period of Choose an item. to Choose an item.

- **No of Suspected cases:** Click or tap here to enter text.
- **No of Confirmed cases:** Click or tap to enter a date.
- **No of Probable cases:** Click or tap to enter a date.
- **Case Fatality Ratio** Click or tap here to enter text.

---

**Background**

How was the problem identified/notified to NCDC RRT? [When was the index case identified, when was NCDC notified, when was team deployed and what's the team composition]

What were the objectives the investigation/response? Attach TOR as Annex 3

**Interim Report Outline**

- Investigation Name
- SitAware ID
- Date of investigation
- Location

Same as administrative text box on first page

- Names of the Investigation Team
- Duration of field trip
- Nature of the problem: copy the problem from the notification report and add specifics including mortality rates and severity of the disease
- Descriptive epidemiology– same as epidemiological situation in daily situation report. Tables, charts, maps and epidemic curve should be included in this section.
- ***Investigation Method: what did you do to solve the problem***
    - Epidemiologic
    - microbiological
    - Toxicological
    - environmental
- ***Results: present the result in the same other as in the methods section***
- Recommendations
- Complete the Rapid Response Team Checklist (annex 2)

**NB:**

**This report should be sent towards the end of the deployment. The difference between the preliminary report and interim report are:**

1. **The timing of submission**
2. **An investigation method is initiated, and results are reported.**

**RRT Deployment Report Template-Final**

**Administrative Elements**

**Report Type:** Final report **Report Submission Date** Click or tap to enter a date.

**Disease/Event Investigated:** Click or tap here to enter text. (e.g Cholera)

**State:** Click or tap here to enter text. **LGA:** Click or tap here to enter text.

**SitAware ID:** Click or tap here to enter text.

**Date of Deployment:** Choose an item. **End of Deployment Date** Click or tap to enter a date.

**Reporting Authority** Choose an item.

**Outbreak Milestones**

| | |
|---|---|
| **Outbreak Start** (Date of onset for the index case for single-case disease outbreaks (e.g Lassa) or when the disease threshold was exceeded (e.g Measles, CSM)) | Choose an item. |
| **Date of Detection** (first suspected case/rumour; disease detected by clinical or public health authorities) | Choose an item. |
| **Date of Notification** (date of notification to the next level of public health authorities, | Choose an item. |

| | |
|---|---|
| e.g., from health facility to LGA or from LGA to state)) | |
| **Date of Laboratory Confirmation** | Choose an item. |

**Basic Epidemiology (Specified Dates)**

During the period of Choose an item. to Choose an item.

- **No of Suspected cases:** Click or tap here to enter text.
- **No of Confirmed cases:** Click or tap to enter a date.
- **No of Probable cases:** Click or tap to enter a date.
- **Case Fatality Ratio** Click or tap here to enter text.

---

**Background**

How was the problem identified/notified to NCDC RRT? [When was the index case identified, when was NCDC notified, when was team deployed and what's the team composition]

What were the objectives the investigation/response? Attach TOR as Annex 3

**Final Outbreak Report Outline**

- **Introduction**: Date, time, description/primary objectives
- ***Background:*** Brief scientific background on disease and suspected etiologic agent
- **Investigation Methods**
  - Epidemiologic
  - microbiological
  - Toxicological
  - environmental

- **Results:** epidemiologic, microbiological, or toxicological and environmental
- ***Limitations of the study***: Any factor that limited the investigation e.g., late reporting, limited sample size etc.
- **Discussion**
    - Challenges
- **Conclusion**
- ***Public Health Interventions***
- ***Lessons learnt***
- ***Recommendations***
- ***Complete the Rapid Response Team Checklist (annex 2)***
- ***References***

***NB***

- ***Send Final report to NCDC within 1 week of departure from response site***
- ***Send electronic line list in MS excel along with report***

**Rapid Response Team Checklist (annex 2)**

**Instructions:** The purpose of this checklist is to document what has already been done and to help guide prioritization of the deployed RRT on how to support filling the gaps.

Use the checklist below to ensure that all initial response action items are completed as quickly as possible, ideally within 7 days. Document the dates each action item was completed as well as any bottlenecks that delayed implementation. If an action item was not applicate, write "N/A" in the Date Done column.

**Epidemiological Investigation:**

| **Date Done** | **If an action item is not applicable, write "N/A"** | **Action items** | **Public health authority that implemented the action- NCDC, State, LGA** | **Bottlenecks** |
|---|---|---|---|---|
| Click or tap to enter a date. | ☐ | Establish an information system for suspected and confirmed cases, contacts, and laboratory results. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |

| | | | | |
|---|---|---|---|---|
| | | | | |
| Click or tap to enter a date. | ☐ | Compile epidemiologic data, date of symptom onset, residence, age, symptoms, location of healthcare facilities visited, hospitalization, relevant diagnostic tests collected, test results, date of death, and any disease-specific exposures (e.g, travel, water, food sources) for hypothesis-generation regarding the source of infection. Enter this information for all suspected and confirmed cases into the information system. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |
| Click or tap to enter a date. | ☐ | As appropriate, conduct initial risk factor analysis using the epidemiologic data to generate hypotheses about the possible outbreak source. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |

| | | | | |
|---|---|---|---|---|
| Click or tap to enter a date. | ☐ | Initiate active surveillance for additional cases, if warranted. This can be done in the facility or the community. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |
| Click or tap to enter a date. | ☐ | Create a contact list, if applicable. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |
| Click or tap to enter a date. | ☐ | If indicated, complete initial severity and transmissibility assessment by calculating any available and applicable measures including case fatality ratios and attack rates. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |
| Click or tap to enter a date. | ☐ | Compile and analyze population-level data including the potential size of the susceptible population, vaccine coverage, and population movement, if applicable. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |

| | | | | |
|---|---|---|---|---|
| | | | | |

**Were all of the initial response activities completed within 7 days of notification?** ▫ **Yes** ▫ **No**

| **If no, explain why:** |
|---|
| |

**Laboratory:**

| **Date Done** | **If an action item is not applicable, write "N/A"** | **Current priority actions** | **Public health authority that implemented the action- NCDC, State, LGA** | **Bottlenecks** |
|---|---|---|---|---|
| Click or tap to enter a date. | Choose an item. | Collect relevant lab samples from suspected cases for diagnostic testing. | ☐ **LGAs**<br>☐ **State**<br>☒ **NCDC** | |

| | | | | |
|---|---|---|---|---|
| Click or tap to enter a date. | Choose an item. | Diagnostic test results received at the healthcare facility and shared with the clinical and public health teams. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |
| Click or tap to enter a date. | Choose an item. | Antimicrobial susceptibility results received at the healthcare facility, if applicable and feasible. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |
| Click or tap to enter a date. | Choose an item. | Arrangements for genomic sequencing begun, if applicable and appropriate. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |

**Were all of the initial response activities completed within 7 days of notification?** ☐ **Yes** ☐ **No**

| **If no, explain why:** |
|---|
| |

**Medical Treatment:**

| Date Done | If an action item is not applicable, write "N/A" | Current priority actions | Public health authority that implemented the action- NCDC, State, LGA | Bottlenecks |
|---|---|---|---|---|
| Click or tap to enter a date. | Choose an item. | Ensure suspected and confirmed cases are receiving appropriate clinical management. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |
| Click or tap to enter a date. | Choose an item. | Assess preparedness of healthcare facilities to safely treat additional cases: surge staffing, treatment commodities, appropriate clinical management, protocols for infection prevention and control employing the hierarchy of controls including personal protective equipment. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |
| Click or tap to enter a date. | Choose an item. | Initiate appropriate infection control protocols for suspected cases within healthcare facilities if applicable. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |

| | | | | |
|---|---|---|---|---|
| Click or tap to enter a date. | Choose an item. | Initiate training of supervisory and frontline healthcare providers in diagnosis, treatment, and/or containment strategy for the outbreak. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |

**Were all of the initial response activities completed within 7 days of notification?** ☐ **Yes** ☐ **No**

| **If no, explain why:** |
|---|
| |

**Medical Countermeasure**

| Date Done | If an action item is not applicable, write "N/A" | Current priority actions | Public health authority that implemented the action- NCDC, State, LGA | Bottlenecks |
|---|---|---|---|---|
| Click or tap to enter a date. | Choose an item. | Initiate contact tracing and culturally appropriate, supportive isolation and quarantine measures, if applicable. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |
| Click or tap to enter a date. | Choose an item. | Assess the need for community-based countermeasures. Mobilize and train public health staff, community members, and community health workers to obtain additional commodities for dispersal in the community to prevent outbreak spread. (e.g., vaccines, ORS sachets, antimicrobial agents, water treatment, soap, insect repellants, bed-nets). | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |

| | | | | |
|---|---|---|---|---|
| Click or tap to enter a date. | Choose an item. | Request and receive disbursement for additional PPE and disinfectants for clinical settings, if applicable. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |
| Click or tap to enter a date. | Choose an item. | Initiate distribution of prophylaxis, if applicable. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |
| Click or tap to enter a date. | Choose an item. | Initiate vaccination of the at-risk populations, if applicable and feasible. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |
| Click or tap to enter a date. | Choose an item. | Initiate food recall, if applicable. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |

**Were all of the initial response activities completed within 7 days of notification?** ☐ **Yes** ☐ **No**

| **If no, explain why:** |
|---|
| |

**Communications and Community Engagement:**

| Date Done | If an action item is not applicable, write "N/A" | Current priority actions | Public health authority that implemented the action- NCDC, State, LGA | Bottlenecks |
|---|---|---|---|---|
| Click or tap to enter a date. | Choose an item. | Identify key stakeholders at community level and engage in initial assessment of knowledge, attitude, and practices. Establish two-way communication to inform response. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |
| Click or tap to enter a date. | Choose an item. | Initiate social mobilization and messaging through community leaders and media, focusing on symptoms, appropriate treatment for early symptoms, the need to seek care, the need to report unusual deaths, preventive measures, and availability of vaccines (as applicable). | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |

| | | | | |
|---|---|---|---|---|
| Click or tap to enter a date. | Choose an item. | Implement public health and social measures to interrupt disease transmission - ensuring availability to and sensitively promoting acceptance by all potentially affected communities. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |

**Were all of the initial response activities completed within 7 days of notification?** ☐ **Yes** ☐ **No**

| **If no, explain why:** |
|---|
| |

**Response Coordination:**

| **Date Done** | **If an action item is not applicable, write "N/A** | **Current priority actions** | **Public health authority that implemented the action- NCDC, State, LGA** | **Bottlenecks** |
|---|---|---|---|---|
| Click or tap to | Choose an item. | Establish an incident management system with relevant pillars and coordination mechanisms. | ☐ **LGAs**<br>☐ **State** | |

| | | | | |
|---|---|---|---|---|
| enter a date. | | | ☐ **NCDC** | |
| Click or tap to enter a date. | Choose an item. | Make initial estimates of financial, human, and commodity needs and request these of the level of government/international agency which is capable of meeting these requests. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |
| Click or tap to enter a date. | Choose an item. | Protect the continuation of essential health and social services. | ☐ **LGAs**<br>☐ **State**<br>☐ **NCDC** | |

**Were all of the initial response activities completed within 7 days of notification?** ☐ **Yes** ☐ **No**

| **If no, explain why:** |
|---|
| |

## NRRT Debrief Template

Nigeria Centre for Disease Control
Protecting the health of Nigerians

**Title**
**Duration:**

Team members:

# Background

## Event, Location, Duration (1/2)

**Write a brief narrative**

- description of the event
- description of investigation
- key findings of the investigation
- actions taken
- public health implications and recommendations

3 NIGERIA CENTRE FOR DISEASE CONTROL

## Event, Location, Duration (2/2)

**Write a brief narrative**

- description of the event
- description of investigation
- key findings of the investigation
- actions taken
- public health implications and recommendations

4 NIGERIA CENTRE FOR DISEASE CONTROL

## Epidemiological information

**Epi curve**

Period (start and end dates): MM/DD/YY – MM/DD/YY

Epi curve

5 NIGERIA CENTRE FOR DISEASE CONTROL

**Suspected**

Cases ####

Deaths ####

**Confirmed**

Cases ####

Deaths ####

**Probable**

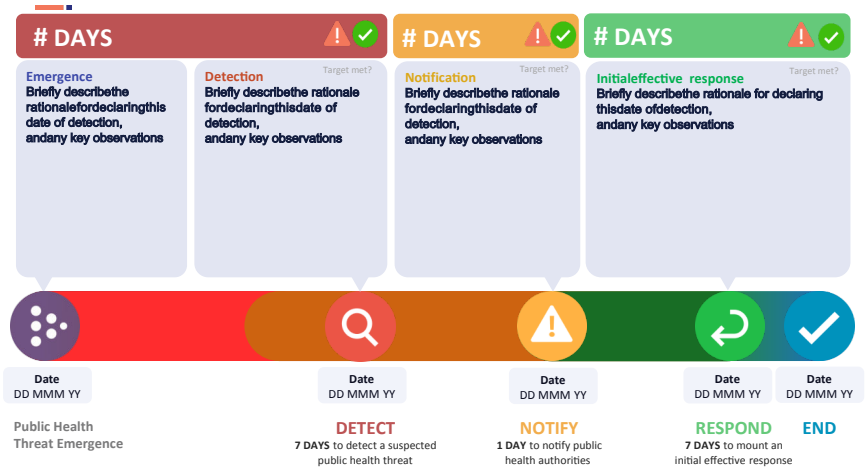
Cases ####

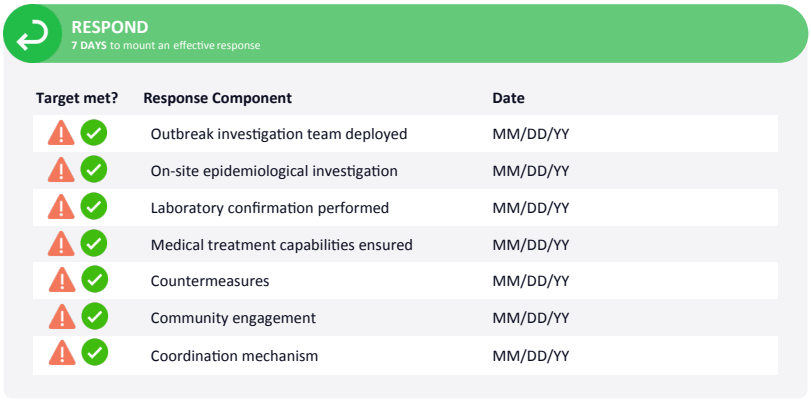
Deaths ####

**CFR among confirmed cases**

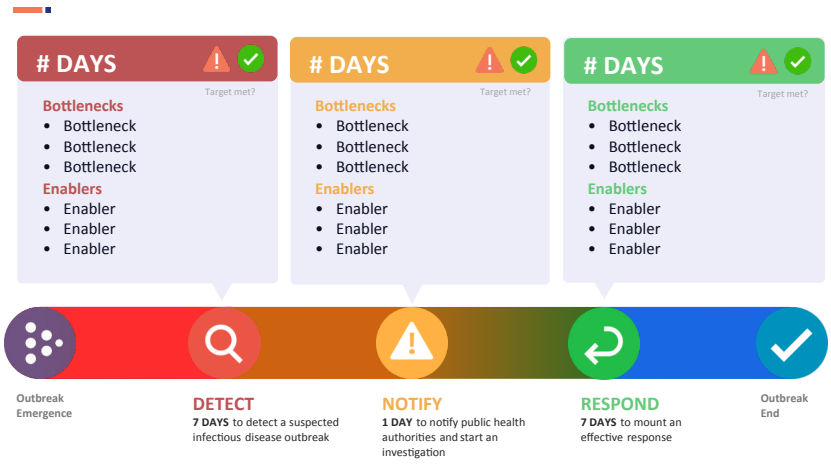
%

# 7-1-7 Metrics




# Bottlenecks and Enablers




## Recommendations

## Remediation plan

| | Priority bottlenecks | Remedial actions and recommendations | Responsible pers on or party | Resources or support required | Target completion date |
|---|---|---|---|---|---|
| 1 | Identify priority bottleneck | Identify immediate next step | Assign responsibility | List resource or support | MM/DD/YY |
| 2 | Identify priority bottleneck | Identify immediate next step | Assign responsibility | List resource or support | MM/DD/YY |
| 3 | Identify priority bottleneck | Identify immediate next step | Assign responsibility | List resource or support | MM/DD/YY |
| 4 | Identify priority bottleneck | Identify immediate next step | Assign responsibility | List resource or support | MM/DD/YY |

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NCDC
NIGERIA CENTRE FOR DISEASE CONTROL

## Thank you

**LIST OF CONTRIBUTORS**

| Name | Organization |
|---|---|
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