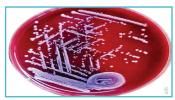


SURVEILLANCE FOR DIPHTHERIA, PERTUSSIS AND NEONATAL TETANUS





















SURVEILLANCE FOR DIPHTHERIA, PERTUSSIS AND NEONATAL TETANUS

India I Field Guide

FIRST EDITION 2020

Ministry of Health and Family Welfare

Government of India

CONTENTS ____

Acronyms and Abbreviations	
INTRODUCTION	1
PATHOGEN AND DISEASE	
Pertussis:	4
LABORATORY DIAGNOSIS	9
Diphtheria:	9
Pertussis:	
IMMUNIZATION AND IMMUNE RESPONSE	11
Components of DPT-containing vaccines (pentavalent, DPT, Td):	12
CASE SELECTION	
Diphtheria:	
Pertussis:	
Neonatal Tetanus:	15
CASE INVESTIGATION	16
Description of case investigation form:	16
ASSIGNING A UNIQUE IDENTIFICATION CODE	18
SAMPLE COLLECTION AND TRANSPORTATION	19
Procedures for collecting samples:	19
CASE CLASSIFICATION	21
CASE MANAGEMENT AND PUBLIC HEALTH INTERVENTIONS	23
Diphtheria: Case Management:	
Pertussis: Case Management:	
Neonatal Tetanus: Case Management:	
Active Case Search, Contact Tracing and Management:	
Diphtheria:	
Pertussis:	
Neonatal tetanus:	30

MONITORING AND SUPERVISION	32
Monitoring indicators:	32
Data Analysis:	
Active supervision:	37
Making supervision more effective:	37
Dissemination of surveillance data:	
REPORTING NETWORK AND CASE NOTIFICATION	40
Structure:	40
Functions:	41
Collaboration and sensitization of health facilities:	43
ROLES AND RESPONSIBILITIES	45
Implementing authority:	45
Technical advice and capacity building:	46
Monitoring and Evaluation:	46
Public health interventions and system strengthening:	46
ANNEXURES	
Annexure 1: Case investigation form	48
Annexure 2: VPD-ACS DTH/PTS form	50
Annexure 3: VPD-ACS NT form	51
Annexure 4: Diphtheria antitoxin (DAT) administration	52
Annexure 5: Surveillance forms	53
Annexure 6: Supportive supervision form – VPD surveillance	58
Annexure 7: Vaccine preventable disease (VPD) surveillance during the COVID-19 pandemic	59
References:	63

ACKNOWLEDGEMENT

Diphtheria, pertussis and neonatal tetanus surveillance operational guideline has been prepared in consultation with WHO National Public Health Surveillance Project (NPSP).

Advisors:

Ms Vandana Gurnani, Joint Secretary, Ministry of Health and Family Welfare, Government of India

Dr Manohar Agnani, Joint Secretary, Ministry of Health and Family Welfare, Government of India

Dr Pradeep Haldar, Deputy Commissioner (UIP), Ministry of Health and Family Welfare, Government of India

Dr M K Aggarwal, Joint Commissioner, Ministry of Health and Family Welfare, Government of India

Dr Sunil Bahl, WHO South-East Asia Regional Office

Dr Pauline Harvey, WHO Country Office for India

Dr Pankaj Bhatnagar, WHO Country Office for India

Authors:

Dr Sudhir Joshi, WHO South-East Asia Regional Office

Dr Lucky Sangal, WHO Country Office for India

Dr Arun Kumar, WHO Country Office for India

Support in reviewing the manuscript:

CDC: Christopher S Murril; Kristie E. N. Clarke; Maria L Tondella; Tejpratap Tiwari

Immunization Technical Support Unit: Dr Prem Singh

MoHFW: Dr Disha Agarwal, Dr Ashish Kumar

WHO Country Office for India: Dr Kristin VanderEnde, Dr Preeti Nigam, Dr Rachana Kathuria, Dr Danish

Ahmed, Dr Mandeep Rathee, Dr Sachin Rewaria

ACRONYMS AND ABBREVIATIONS ____

ACS	active case search
AFP	acute flaccid paralysis
aP	acellular pertussis (vaccine)
ATS	antitoxin tetanus serum
BCG	Bacillus Calmette-Guérin
CFR	case fatality rate/ratio
CIF	case investigation form
CMO	Chief Medical Officer
COVID-19	Coronavirus Disease 2019
DAT	diphtheria antitoxin
DIO	District Immunization Officer
DNA	deoxyribonucleic acid
DPT	diphtheria, pertussis and tetanus
EPI	Expanded Programme on Immunization
Hib	Haemophilus influenzae type b
IgG	immunoglobulin G
IPC	infection prevention and control
IPV	inactivated polio vaccine
IU	informer unit
IVIG	intravenous immunoglobulin
JE	Japanese encephalitis
JRF	Joint Reporting Form
M&E	monitoring and evaluation
MHA	Ministry of Home Affairs
MO	medical officer
MOIC	medical officer in-charge
MR	measles-rubella
NPSP	National Public Health Surveillance Project
NT	neonatal tetanus
OPV	oral polio vaccine
PCR	polymerase chain reaction

PEP	post-exposure prophylaxis
PPE	personal protective equipment
RI	routine immunization
RU	reporting unit
SM0	Surveillance Medical Officer
ТВ	tuberculosis
Td	tetanus–diphtheria (vaccine)
TIG	tetanus immune globulin
TT	tetanus toxoid
UIP	Universal Immunization Programme
UNICEF	United Nations Children's Fund
VPD	vaccine-preventable disease
WH0	World Health Organization
wP	whole cell pertussis (vaccine)

INTRODUCTION

Vaccination against childhood communicable diseases through the Expanded Programme on Immunization (EPI) is one of the most cost-effective public health interventions. Vaccination contributes substantially to the achievement of Sustainable Development Goals (SDGs) by reducing mortality and morbidity among children. The progress and impact of vaccination programmes can be effectively assessed by surveillance for vaccine preventable diseases (VPDs). It is also important to have country-specific epidemiological data to be able to formulate vaccination strategies.

Surveillance is the basic tool for understanding the epidemiology of a disease. The key objectives of surveillance are to trigger public health control measures, identify outbreaks and assess the effectiveness of prevention programmes. The burden and epidemiology of VPDs may vary by country because of differences in immunization coverage, nutritional status, population density, geosociocultural diversity, environmental factors and possibly, genetic differences in populations. Therefore, establishing an active surveillance system is essential to monitor an area more closely and directly in order to generate reliable surveillance data of programmatic importance.

The pentavalent vaccine which provides protection from five diseases including diphtheria, pertussis and tetanus forms the backbone of the current EPI schedule. Many of the newer vaccines are provided either in combination with or during the same visit as for DPT containing vaccine. Hence, surveillance for at least three VPDs — notably diphtheria, pertussis and neonatal tetanus (NT), together with poliomyelitis, measles and rubella will provide important information on the status of control of these diseases and on the overall performance of the immunization programme. Further, it will also help in identifying pockets of susceptible individuals to guide vaccination strategies.

Following an increase in incidence of pertussis in a few countries using acellular pertussis (aP) vaccines, and concern about the potential for global resurgence of pertussis, a review was conducted by World Health Organization (WHO) in 2014. Overall, data from 19 high- and middle-income countries provided no evidence of a widespread resurgence of pertussis. In most countries where increasing numbers of pertussis cases were noted over several recent years, it was mainly attributed to naturally occurring cyclic patterns. Factors that have probably contributed to the increasing numbers of recorded cases include higher disease awareness, improved surveillance sensitivity and the enhanced diagnostic sensitivity of the now widely used polymerase chain reaction (PCR) test. However, there is evidence that a true resurgence has occurred in five of the 19 countries reviewed, four of which were exclusively using aP vaccines. The observed increase in cases in the fifth country, which used whole-cell pertussis (wP) vaccine, was considered to be primarily related to factors other than the vaccine, such as changes in surveillance and laboratory methods and recent decreases in vaccination coverage (1,2). India has been using wP vaccine since the beginning of EPI in the country in 1978.

In India, the availability of quality surveillance data for VPDs is limited. WHO disease burden estimates are based on information available from a variety of sources such as demographic data, immunization coverage levels, vital registration data, mortality data and mathematical models using numerous

assumptions. The degree of accuracy of these estimates depends upon the quality of surveillance data available in the country. In 2018, India reported 8788 cases of diphtheria, 13 208 cases of pertussis and 129 cases of NT to WHO and United Nations Children's Fund (UNICEF) through the Joint Reporting Form (JRF). However, the quality and completeness of these reports is not known.

This manual describes various operational strategies for strengthening surveillance for diphtheria, pertussis and NT, building on the already existing acute flaccid paralysis (AFP) surveillance system, with the objective of generating reliable epidemiological information about the above mentioned diseases. It also focusses on key components of monitoring and evaluation plans necessary for maintaining an effective and efficient surveillance and response system. This field guide is designed primarily for the district health officials of government and implementing partners. The WHO National Public Health Surveillance Project (NPSP) field units will provide technical support for establishing a functional laboratory-supported surveillance system for VPDs. Their primary functions will be capacity-building of health-care providers/surveillance staff, monitoring and evaluation of the key components of surveillance, data analysis and providing feedback. The information generated will be used locally to guide control measures and strengthen the evolving surveillance system.

PATHOGEN AND DISEASE

Diphtheria

Diphtheria is derived from the Greek word diphthera meaning "skin" or "hide", which describes the pathognomonic pseudo-membrane associated with the disease.

Aetiopathogenesis

Diphtheria is a bacterial disease caused by exotoxin producing *Corynebacterium diphtheriae*. *C. diphtheriae* is a slender, club-shaped, gram positive bacillus that exists in four biotypes (gravis, mitis, belfanti and intermedius). Rarely, other Corynebacterium species (*C. ulcerans or C. pseudotuberculosis*) may produce diphtheria toxin and may cause classic respiratory diphtheria-like illness.

The pathogenesis of diphtheria involves bacterial exotoxin as well as cell wall components such as the O- and K- antigens. The most important virulence factor of *C. diphtheriae* is the exotoxin, a bacteriophage mediated, highly conserved polypeptide encoded by the bacterial chromosome. Outside the host cell, the exotoxin is relatively inactive, but following cellular attachment and internalization by its non-toxic fragment B, a highly toxic fragment (A) is detached that kills cells through inhibition of cellular protein synthesis. Diphtheria exotoxin causes both local and systemic cell destruction (3).

Transmission and communicability

Transmission is most often person-to-person spread from the respiratory tract through droplets or direct contact with respiratory secretions. Rarely, transmission may occur from skin lesions or articles soiled with discharges from lesions of infected persons (fomites). The incubation period of diphtheria is 2–5 days (range 1–10 days).

A person is infectious as long as virulent bacilli are present in discharges and lesions. The period of infectivity is variable, but organisms usually persist for two weeks, and seldom more than six weeks without antibiotics. Chronic carriers may shed organisms for six months or more. Effective antibiotic therapy promptly terminates shedding (3).

Reservoir

Humans are the only known reservoir of *C. diphtheriae*. In most cases, transmission of *C. diphtheriae* to susceptible individuals results in transient pharyngeal carriage rather than in disease. During outbreaks, high percentages of children are found to be transient carriers.

Occurrence

The disease has almost disappeared from developed countries as a result of high immunization coverage. Continued foci of epidemicity and endemicity exist in some parts of the world with low immunization coverage, including the Indian subcontinent and South East Asia.

Clinical features and complications

Most infections are asymptomatic or run a relatively mild clinical course. The onset of respiratory

diphtheria is relatively slow and is characterized by moderate fever and a mild exudative pharyngitis leading to sore throat and difficulty in swallowing. The exudate organizes into a tough, asymmetric, greyish-white pseudo-membrane over the tonsils, the pharynx, larynx and/or nose. The pseudo-membranes are strongly attached to the underlying tissue and attempts to dislodge it usually result in bleeding. They may extend into the nasal cavity and the larynx, causing obstruction of the airways. Laryngeal diphtheria, which sometimes occurs even without pharyngeal involvement, is a medical emergency that often requires tracheostomy. Accompanying inflammation of the cervical lymph nodes and surrounding soft-tissue swelling of the neck give rise to a "bull neck" appearance and are signs of moderate to severe disease.

Exotoxin absorbed from the mucosal (or cutaneous) lesions may account for toxic damage to organs such as the myocardium, kidneys and nervous system. The extent of toxin absorption depends largely on the extent of the mucosal lesions. The following WHO-defined clinical conditions are associated with increasing risk of toxin-induced systemic disease:

- Catarrhal: erythema of pharynx, no membranes
- Follicular: patches of exudates over pharynx and the tonsils
- Spreading: membranes covering the tonsils and posterior pharynx
- **Combined**: more than one anatomical site involved, e.g. throat and skin.

Most complications of diphtheria, including death, are attributable to effects of the toxin. The most frequent complications of diphtheria are myocarditis and neuritis. Neuritis may lead to bulbar dysfunction (which includes palatal, pharyngeal and facial paralysis), oculomotor paralysis and may also progress to peripheral neuropathy. Pneumonia occurs in more than 50% of fatal cases of diphtheria. Other complications include otitis media and respiratory insufficiency due to airway obstruction, especially in infants.

Prognosis

Most cases of diphtheria develop in non-immunized patients. The attack rate, severity of disease and risk of complications are much lower in immunized patients. Mortality increases with the severity of local disease, the extent of pseudo-membrane formation and delay between onset of local disease and administration of antitoxin. The death rate is highest during the first week of illness among patients with bull neck, myocarditis and laryngeal or tracheo-bronchial involvement. The case fatality rate (CFR) from respiratory tract diphtheria has been 2–20% with an average of 10% for patients receiving good medical care.

Pertussis

Pertussis is an acute infectious disease of the respiratory tract. It is commonly known as whooping cough. The name pertussis means "violent cough", which aptly describes the most consistent and prominent feature of the illness.

Aetiopathogenesis

Pertussis is a bacterial disease caused by *Bordetella pertussis*. Bordetella spp. are aerobic, gram negative coccobacilli. In addition to *B. pertussis*, three other Bordetella species can cause disease in

humans: *B. parapertussis*, *B. holmesii* and *B. bronchiseptica*. *B. parapertussis* causes a milder pertussis-like illness. Coinfection of *B. pertussis* and *B. parapertussis* is not unusual.

The pathogenesis of pertussis is incompletely understood. It is multifactorial. The factors like filamentous haemagglutinin, pertactin and fimbriae type 2 and type 3 facilitate attachment to targeted host cells. Other factors like pertussis toxin, tracheal cytotoxin and adenylate cyclase toxin enable the bacterium to destroy the epithelial lining and evade the host's immune system (1).

Transmission and communicability

B. pertussis is a human-specific pathogen and is unable to survive outside its human host. It is highly infectious and spreads by aerosolised droplets. The incubation period of pertussis is commonly 9–10 days, with a range of 6–20 days (1).

Pertussis is highly communicable. The secondary attack rate for susceptible household contacts is 80–100%. Untreated cases are infectious for three weeks following symptom onset. Antibiotics can reduce the period of infectivity.

Reservoir

Pertussis is a human disease. No animal or insect source or vector is known to exist. There is no evidence of prolonged carrier state. Asymptomatic individuals have been identified during epidemics. Adolescents and adults are an important reservoir for *B. pertussis* and are significant sources of transmission of *B. pertussis* to unvaccinated infants.

Occurrence

Pertussis occurs worldwide. Outbreaks were first described in the Sixteenth century. The disease is endemic in all countries with epidemic peaks occurring every 2 to 5 years (typically 3 to 4 years), even after the introduction of effective vaccination programmes and the achievement of high vaccination coverage. Following introduction of vaccine in the 1940s the incidence of reported pertussis and deaths in children have decreased. However, pertussis remains one of the principal VPDs even in countries with high vaccine coverage (1).

Classical pertussis is most often seen in pre-school and school-aged children. It is an important cause of death in infants worldwide. Pertussis may be responsible for between 12% and 32% of chronic cough in adults.

Clinical features and complications

The illness begins less dramatically with non-specific symptoms and then progresses in the following three stages:

Catarrhal: initially, patients develop catarrhal symptoms including cough. Other nonspecific symptoms are rhinorrhoea, sore throat and conjunctivitis. This stage typically lasts two weeks. Fever is present in less than 20% cases.

Paroxysmal: later, during the course of 1–2 weeks, coughing paroxysms occur, ending in characteristic whooping. In typical cases, cough is frequently followed by vomiting. Paroxysms can

occur more than 30 times in 24 hours and are more common at night. They occur spontaneously or are precipitated by external stimuli such as noise and cold air. Between coughing episodes, there are few clinical signs unless complications develop. This stage also typically lasts two weeks.

Convalescent: the coughing gradually subsides. Relapse can occur if another respiratory infection is acquired. This stage can last from two weeks to several months.

Pertussis in infants, adults and partially immunized individuals may not present with its typical clinical signs and symptoms.

Other common features of pertussis are:

Infants:

- Apnoea
- Cough (no whoop)
- Cyanotic episodes
- Vomiting
- Poor feeding
- Fever
- Seizures
- > Sudden infant death syndrome

Partially immunized:

- Duration of catarrhal phase may be reduced
- Whoop may not occur

Adults:

- Prolonged cough
- Paroxysmal cough
- Whoop
- Post-tussive vomiting
- Intracranial haemorrhage.

The most common complication is secondary bacterial pneumonia that causes most of pertussis-related deaths. Neurological complications such as seizures and encephalopathy may occur as a result of hypoxia from coughing, or possibly from toxin. Infants are at the highest risk for developing pertussis-related complications.

Other less serious complications of pertussis include otitis media, anorexia and dehydration. Complications resulting from pressure effects of severe paroxysms include pneumothorax, epistaxis, subdural haematomas, hernias and rectal prolapse.

Prognosis

The infection gradually resolves over a period of weeks, but the coughing paroxysms can persist for several months. Most of the older children and adults have a full recovery from pertussis; however, infants need careful monitoring to avoid complications. The prognosis is worse when complications such as bacterial pneumonia develop. Most deaths from pertussis have occurred in children who have

not been vaccinated or who are too young to have received the vaccine. In high mortality countries, CFR is estimated to be 4% among infants and 1% among older children (4).

Neonatal tetanus

Tetanus, also known as lockjaw, is derived from the Greek word tetanos and teinein, which literally means 'a stretching, tension', and 'to stretch' respectively. It is a serious but preventable disease that affects the body's muscles and nerves.

Aetiopathogenesis

Tetanus is an infectious bacterial disease caused by *Clostridium tetani*. *C*. tetani is a gram-positive, strictly anaerobic bacillus that may develop a terminal spore, giving it a drumstick appearance. The bacterium itself can survive only in strict anaerobic conditions, but its spores are much more resistant and survive normal disinfection and heating. If a wound is contaminated with tetanus spores, they are able to germinate, allowing bacterial multiplication.

The bacilli may produce tetanospasmin, an extremely potent neurotoxin. This toxin blocks inhibitory neurotransmitters in the central nervous system and causes the muscular stiffness and spasms typical of generalized tetanus (5).

Transmission and communicability

Maternal tetanus is a consequence of unclean delivery or abortion practices. Neonatal tetanus occurs when unclean instruments are used to cut the umbilical cord or when contaminated material is used to cover the umbilical stump in susceptible babies.

The incubation period of tetanus usually varies between 3 to 21 days (median 7 days, range 0–>60 days). In most cases, NT starts 3–14 days after birth (6).

Reservoir

Spores are prevalent in the environment, particularly in the soil of warm and moist areas and may be carried in the intestinal tracts of humans and animals.

Occurrence

The majority of tetanus cases occur in developing countries and are birth associated, occurring among newborn babies or in mothers following unclean deliveries and poor postnatal hygiene. Tetanus in children and adults following injuries may also constitute a considerable public health problem.

In countries with effective immunization programmes and good standard of hygiene, maternal and neonatal tetanus (MNT) has been largely eliminated (<1 case per 1000 live births at the district level). On rare occasions, tetanus may affect inadequately immunized people, primarily among the elderly.

Clinical features and complications

In most cases, tetanus presents as a generalized spastic disease. Characteristic features are early spasms of the facial muscles (trismus or "lock-jaw" and risus sardonicus) followed by spasm of the back muscles (opisthotonos) and sudden, generalized tonic seizures (tetanospasms). Spasm of the glottis may cause sudden death. In NT, generalized spasms are commonly preceded by inability to suck or feed and excessive crying.

Prognosis

Neonatal tetanus is associated with a high mortality rate, despite intensive care. It can be prevented by immunization of expectant mothers and by good hygiene and asepsis during delivery. A short incubation period and low birth weight are associated with a high mortality rate and are poor prognostic factors. The CFR for NT ranges from 40% in developed countries to 80% in the poorest developing countries.

The overall tetanus CFR varies between 10% and 70%, depending on treatment, age and general health of the patient. Without hospitalization and intensive care, fatality is almost 100% among the oldest and the youngest patients. In settings with optimal care, it may be reduced to 10–20% (7).

LABORATORY DIAGNOSIS

Laboratory diagnosis of suspected cases of diphtheria and pertussis disease is essential for confirmation of cases and to guide the programme in the right direction. For VPD surveillance, efforts should be made to establish laboratory diagnosis of all suspected cases of diphtheria and pertussis. Confirmation of suspected cases of tetanus will be done only on a clinical basis and does not require any laboratory diagnostic test.

Bacterial culture is considered to be the gold standard laboratory test for bacterial pathogens. The specificity of culture for diphtheria and pertussis is considered 100%; however, in the antibiotic era, the sensitivity of culture method for bacterial pathogens is pretty low, more so for pertussis because it is a fastidious organism to grow. Further, its sensitivity decreases with use of antibiotics prior to sample collection. Molecular tests (PCR) are gaining more importance because of increased sensitivity and faster reporting of results. PCR does not require viable organisms and can detect genes of dead bacteria, so results are not affected by prior use of antibiotics. PCR is however less specific than culture.

Various serological methods have also been described but are not considered to be highly specific. Serological test has also been described for diagnostic purposes, but its use is limited to the diagnosis of pertussis cases during the convalescent phase.

Various laboratory tests available for establishing diagnosis of diphtheria and pertussis are discussed below.

Diphtheria

Gram stain

Diagnosis of diphtheria based on direct microscopy of smear is not advisable as false positives and false negatives may occur.

Culture

The clinical specimen for culture should be taken from the nose, throat or diphtheritic membrane. *C. diphtheriae* requires special culture media containing tellurite to grow and forms grey to black colonies. The four biotypes (gravis, mitis, belfanti, or intermedius) of *C. diphtheriae* can be distinguished by colonial morphology and biotyping. Certain biochemical tests are required to differentiate pathogenic *C. diphtheriae* from corynebacteria of the normal flora (diphtheroids) in the throat.

Toxigenicity test

All isolates of *C. diphtheriae* should be subjected to toxigenicity testing to determine the production of diphtheria toxin. Toxigenicity testing can be done by Elek test or PCR. Elek test is based on the double diffusion of diphtheria toxin and antitoxin in an agar medium. The production of diphtheria toxin can be detected within 18 to 48 hours by the formation of a toxin—antitoxin precipitin band in the agar. Demonstration of toxin production confirms a case as diphtheria.

Polymerase chain reaction

Isolation of *C. diphtheriae* may not always be possible because many patients will have received antibiotics before a diagnosis of diphtheria is considered. PCR allows for detection of the regulatory gene for toxin production (dtxR) and the diphtheria toxin gene (tox) in nonviable organisms. Additionally, primary isolates can also be screened rapidly for the presence of tox gene by PCR. Some strains of *C. diphtheriae* carry inactive toxin gene giving rise to false positive results in this test.

Pertussis

Culture

Culture of nasopharyngeal secretions is considered best for diagnosis of pertussis. *B. pertussis* is highly sensitive to drying; therefore, the specimen should be inoculated without delay onto the culture media. Regan-Lowe agar or freshly prepared Bordet-Gengou medium is generally used for culture. Fastidious growth requirement makes *B. pertussis* difficult to isolate.

Isolation of the organism declines if:

- specimen collection has been delayed beyond the first two weeks of illness (catarrhal stage)
- patient has received appropriate antibiotic therapy
- patient has been vaccinated.

Since the maximum chances of isolating the organism are during the catarrhal phase, when the aetiology of the infection is not suspected, there is only a small window of opportunity for culture proven diagnosis.

Polymerase chain reaction

PCR is an important tool for timely diagnosis of pertussis. It detects deoxyribonucleic acid (DNA) sequences of the bacterium and does not require presence of viable bacteria in the specimen. The optimal sensitivity of the test is during the first three weeks of cough, as bacterial DNA is present in the nasopharynx during this time. After the fourth week of cough, the amount of bacterial DNA diminishes rapidly.

Serological testing

This can be a useful tool for diagnosis of pertussis in cases with more than four weeks of cough onset. As serology confirmation is based on estimation of immunoglobulin G (IgG) titres, history of pertussis-containing vaccine in past two years makes the serological testing an unreliable tool. In children over 10 years of age, serological confirmation could be used more confidently (8). Enzyme immunoassay detecting immunoglobulin A (IgA) and IgG antibodies to pertussis toxin, filamentous haemagglutinin, pertactin and fimbriae are gaining increasing importance as a diagnostic tool for *B. pertussis*.

Neonatal tetanus

There is no diagnostic laboratory test for tetanus; the diagnosis is entirely clinical. *C. tetani* is recovered from wounds in only about 30% of cases, and the organism is sometimes isolated from patients who do not have tetanus.

IMMUNIZATION AND IMMUNE RESPONSE

Under the Universal Immunization Programme (UIP), the Government of India (GoI) currently provides vaccination to prevent 12 VPDs across the country (nationally against ten diseases and sub-nationally against two disease). These are tuberculosis (TB), polio, hepatitis B, diphtheria, pertussis, tetanus, *Haemophilus influenzae* type b (Hib), measles, rubella, rotavirus diarrhoea, pneumococcal pneumonia and Japanese encephalitis (JE). In children <1-year old, diphtheria, tetanus, pertussis, hepatitis B and Hib are provided as a combination vaccine called pentavalent vaccine. Children in the age group of 1–7 years receive diphtheria, pertussis and tetanus vaccine in the form of DPT. In addition, for adolescents and pregnant women, tetanus and diphtheria vaccine (Td) is given as a stand alone vaccine.

Three doses of the pentavalent vaccine, starting at 6 weeks of age and given at least 4 weeks apart, are recommended for primary immunization of infants. The primary vaccination series is extended by a booster dose of DPT vaccine at 16–24 months of age. To further promote immunity, a second booster of DPT vaccine has been recommended at 5–6 years of age.

Tetanus beyond the neonatal period is still a public health problem, particularly among children, adolescents and young adults. Two additional doses of Td are recommended at 10 years and 16 years of age. To address maternal and neonatal tetanus, immunization of all eligible pregnant women with two doses of Td is recommended (one dose if previously vaccinated within three years).

The GoI has introduced JE vaccine for endemic districts while pneumococcal conjugate vaccine is being introduced in a phased manner.

Table 1. Immunization schedule as per UIP in India

S.No	Vaccine & its presentation	Protection	Route	Dose(s)	Vaccination schedule
1.	BCG (Bacillus Calmette-Guérin) – lyophilized vaccine	ТВ	Intradermal	1	At birth (up to 1 year if not given earlier)
2.	OPV Oral polio vaccine (OPV) – liquid vaccine	Poliomyelitis	Oral	5	Birth dose for institutional deliveries, primary three doses at 6, 10 & 14 weeks and one booster dose at 16–24 months of age
3.	Hepatitis B – liquid vaccine	Hepatitis B	Intramuscular	1	Birth dose (within 24 hours) for institutional deliveries
4.	Pentavalent – liquid vaccine	Diphtheria, pertussis (wP), tetanus, hepatitis B and Hib	Intramuscular	3	At 6, 10 and 14 weeks of age
5.	Fractional inactivated polio vaccine (IPV) – liquid vaccine	Poliomyelitis	Intradermal	2	At 6 and 14 weeks of age
6.	Rotavirus – liquid or lyophilized vaccine	Rotavirus	Oral	3	At 6, 10 & 14 weeks of age

11

7.	Pneumococcal conjugate vaccine – liquid vaccine	Pneumococcal pneumonia, meningitis and other complications	Intramuscular	3	At 6 and 14 weeks of age and booster at 9 months of age
8.	Measles-rubella (MR) -lyophilized vaccine	Measles and rubella	Subcutaneous	2	At 9–12 months of age and second dose at 16–24 months
9.	JE– lyophilized vaccine	Japanese encephalitis	Subcutaneous	2	At 9–12 months of age and second dose at 16–24 months
10.	DPT – liquid vaccine	Diphtheria, pertussis (wP) and tetanus	Intramuscular	2	At 16–24 months and 5–6 years of age
11.	Td – liquid vaccine	Tetanus and diphtheria	Intramuscular	2	At 10 years and 16 years of age For pregnant women, two doses given (one dose if previously vaccinated within last 3 years)

OPV- oral polio vaccine; wP- whole-cell pertussis; IPV- inactivated polio vaccine; MR- measles-rubella; JE- Japanese encephalitis; DPT- diphtheria, pertussis and tetanus; Td- tetanus-diphtheria

Components of DPT-containing vaccines (pentavalent, DPT, Td)

Diphtheria toxoid: a modified bacterial toxin that induces protective antitoxin. The conventional steps of vaccine production include the growth of toxin-producing *C. diphtheriae* in liquid media, sterilization of exotoxin-containing supernatant, formalin-induced conversion of toxin to toxoid, adsorption to aluminium salt and addition of thiomersal as a preservative in multidose vials. The resulting product is tested for potency, toxicity and sterility. As per WHO requirements, the potency of diphtheria vaccine should be at least 30 IU per single human dose.

Tetanus toxoid: a modified neurotoxin that induces protective antitoxin. Conventional production includes growth of toxigenic strains of *C. tetani* in a liquid medium that favours toxin production, toxin harvest by filtration and detoxification by formaldehyde, followed by several steps of purification and sterilization. To increase immunogenicity, the toxoid is adsorbed to aluminium or calcium salts. According to WHO, the requirement for the potency of tetanus toxoid should be at least 40 IU per dose (0.5ml).

Whole-cell pertussis vaccine: whole-cell pertussis (wP) vaccine contains whole non-viable bacterial cells in various amounts. Selected *B. pertussis* strains are cultured and then killed by heat and treated with formalin to form the vaccine. The methods used for production vary among manufacturers and hence wP vaccines are relatively heterogeneous. Each lot of vaccine undergoes extensive testing to assess potency, toxicity, sterility and bacterial concentration. All pertussis vaccines contain aluminium salts as adjuvant and thiomersal as preservative for multi-dose formulations.

12 _

Another formulation available commercially is aP vaccine. This is based on highly purified selected components of the bacterial agent. The exact components and quantity of the antigens, method of antigen production, purification and detoxification vary with the manufacturers. The aP vaccines have lower initial efficacy, faster waning of immunity and possibly a reduced impact on transmission relative to currently internationally available wP vaccines, but aP vaccines show less local and systemic side-effects.

Immune response

The duration and level of protection following primary immunization by DPT-containing vaccines varies considerably depending on factors such as local epidemiology, immunization schedule, choice of vaccine and host factors. Immunity depends mainly on the presence of antibodies of IgG type. Antibodies passed through the placenta provide passive immunity to the newborn during the first few months of life. The natural course of a disease is influenced by the age-specific proportion of susceptible and resistant persons in the community. Neither infection nor primary vaccination confers long-lasting immunity to subsequent infection or disease. Multiple boosters are required for long term protection against these diseases.

Following primary immunization, infants aged 6 weeks or older develop protective titres of antibodies against the three diseases. A booster dose given during the second year of life improves protection and prevents early accumulation of susceptible individuals. In countries that are rendered non-endemic through high immunization coverage, revaccination of adults every 10 years with an age-appropriate vaccine may be necessary to sustain immunity in some epidemiological settings.

In 1998, WHO recommended that TT be replaced by Td vaccine. This is reiterated in the 2017 WHO tetanus vaccine position paper. The rationale for replacing TT with Td vaccine is the need to sustain protection against diphtheria due to waning diphtheria immunity following the primary series of DPT-containing vaccine given in the first year of life. By replacing TT with Td, additional protection against diphtheria can be obtained without major changes to the immunization programme and schedule. When pregnant women receive the recommended doses of Td at least two weeks before delivery, both mother and child are protected against birth-associated tetanus because maternal tetanus antitoxin passes via the placenta to the foetus (9).

13.

CASE SELECTION

A case definition defines a disease by a set of criteria to report suspected cases of that disease for public health surveillance. It enables consistent reporting of cases by the reporting network and improves specificity of reported cases.

Diphtheria

Suspected case definition

A suspected case of diphtheria is defined as an illness of the upper respiratory tract characterized by the following:

• laryngitis or nasopharyngitis or pharyngitis or tonsillitis

and

adherent membranes of tonsils, pharynx, larynx and/or nose (10).

Description of 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 **Nasopharyngitis**: runny nose, nasal congestion and sneezing

Membrane: initially isolated spots of grey or white exudate 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 colour. 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.

Other associated signs and symptoms

The other clinical features that should raise an alarm for the probability of diphtheria infections are dysphagia, difficulty in breathing, headache, change of voice (hoarseness or thick speech), nasal regurgitation and sero-sanguineous nasal discharge. Some patients may also present with "bull neck" diphtheria where there is massive cervical lymphadenopathy with oedematous swelling of the submandibular region and surrounding areas. Patients with diphtheria may also present with systemic manifestations of diphtheria toxin like myocarditis and polyneuritis.

Date of onset

The date of onset for diphtheria should be considered as date of onset of sore throat, i.e. pain or scratchy sensation in the throat that worsens with swallowing or talking.

Pertussis

Suspected case definition

A suspected case of pertussis is defined as a person of any age with a cough lasting ≥ 2 weeks, or of any duration in an infant or any person in an outbreak setting without a more likely diagnosis and with at least one of the following symptoms on observation or parental report:

paroxysms (i.e. fits) of coughing

- inspiratory whooping
- post-tussive vomiting, or vomiting without other apparent cause
- apnoea in infants (< 1 year of age)

or

clinician suspicion of pertussis (8).

Description of case definition

Paroxysms of cough: cough becomes more frequent and spasmodic with repetitive bursts of five to ten coughs, often within a single expiration. During a paroxysm there may be a visible neck vein distension, bulging eyes, tongue protrusion and cyanosis. Frequency of paroxysmal episodes varies from 5–10 per day to several per hour. Episodes are often worse at night and interfere with sleep.

Whoop: sound produced due to rapid inspiration against closed glottis at the end of a cough paroxysm.

Post-tussive vomiting: vomiting immediately after coughing occasionally with a mucous plug expelled at the end of an episode.

Without other apparent causes: exclude other causes of chronic cough like TB, asthmatic episodes, chronic bronchitis, etc.

Other associated signs and symptoms

In young infants, apnoea and cyanosis may be the only presenting symptoms. The clinical features due to increased intra-thoracic pressure generated due to paroxysms of cough are frequently associated with pertussis cases. These are subconjunctival and intracranial haemorrhages, rectal prolapse, hernias, pneumothorax, petechiae or rib fracture.

Date of onset

The date of onset for pertussis should be considered as date of onset of cough.

Neonatal tetanus

Suspected case definition

A suspected case for NT is a case that meets either of these two criteria:

 any neonate who could suck and cry normally during the first 2 days of life and who cannot suck normally between 3 and 28 days of age, and becomes stiff or has convulsions/spasms, i.e. jerking of the muscles or both

or

any neonate who dies of an unknown cause during the first month of life (11).

Description of case definition

Spasm: initially, increased tone of facial muscles (lockjaw, grimace) is seen. Inability to suck, stiffness in the neck, shoulder and back muscles appear concurrently. Subsequent involvement of other muscles produce rigid abdomen and stiff proximal limb muscle. These spasms occur repetitively and may be spontaneous or provoked by even the slightest stimuli.

Date of onset

The date of onset for neonatal tetanus should be considered as date of onset of inability to suck.

All suspected cases of diphtheria, pertussis and neonatal tetanus having date of onset within the past three months should be notified immediately to the programme.

CASE INVESTIGATION

Quality case investigations are critical for obtaining accurate epidemiological and clinical information from cases. The details documented in the case investigation form (CIF) provide the basis of data analysis and monitoring of indicators (Annex 1). Any suspected case of diphtheria, pertussis and/or NT notified by the reporting system should be investigated as soon as possible, preferably within 48 hours. An early investigation will provide opportunities for sample collection and timely intervention. For example, medical aid provided early in the course of illness will reduce the morbidity and mortality from the disease and prevent or decrease its transmission in the community.

A CIF has been designed for the investigation of suspected cases of diphtheria, pertussis and NT. The CIF can be used as a guide to obtain all desirable and specific information of a suspected case.

Description of case investigation form

The initial sections of the CIF collect information on case reporting, identification, hospitalization and immunization details.

Clinical signs and symptoms of the suspected case should be documented as "yes/no" in the CIF. As the date of onset is critical information, it should be documented accurately in the CIF. Specifically, various performance and monitoring indicators are calculated from the date of onset, so it is extremely important to specify the correct date of onset of illness.

The date of onset for the three diseases should be considered as follows:

- Diphtheria: date of onset of sore throat
- Pertussis: date of onset of cough
- Neonatal tetanus: date of onset of inability to suck.

The use of antibiotics and partial immunization may change the natural course and presentation of diphtheria and pertussis illness. Therefore, efforts should be made to elicit a proper immunization history and history of antibiotic use. In suspected diphtheria cases, timely administration of diphtheria antitoxin (DAT) could be lifesaving.

The presence of greyish-white adherent membrane in the throat is pathognomonic of diphtheria. All clinicians should be advised to proactively examine the throat under sufficient light to identify the membrane in all cases presenting with fever and sore throat.

While pertussis presents primarily with classical symptoms in children aged 1–5 years, it may be unrecognized in infants, older children, adolescents and adults because of atypical presentation. In young infants, pertussis may cause apnoea and cyanosis without cough, whereas in adolescents and adults an uncharacteristic persistent cough may be the only manifestation. As India is endemic for TB and has a high disease incidence, it is important to exclude the diagnosis of TB in patients presenting with chronic cough.

The duration of protection following primary immunization against diphtheria and pertussis varies considerably. In view of the highly infectious nature of diphtheria and pertussis, information about similar symptoms in household contacts/neighbourhood/school/workplace should also be actively elicited.

Additional cases of similar illness in the community help to identify clustering of cases. While conducting active case searches (ACSs), the teams should look for such cases in all age groups. Attempts should be made to conduct an ACS as soon as possible after the identification of a suspected case, preferably within seven days of the case investigation. The details of conducting an ACS in the community are described in the chapter on "Case management and public health interventions". The information on ACS in the community (form: VPD-ACS) should then be summarized in the CIF.

If the ACS is for pertussis, children presenting with onset of cough of less than two weeks duration should be noted and followed by a local health worker (personal visit/telephonically) for persistence of illness for more than two weeks after onset. All cases with persistent cough should be reported as suspected cases of pertussis.

For all cases of diphtheria and pertussis, information on sample collection and laboratory confirmation should be entered and updated in the CIF.

Each suspected case of diphtheria, pertussis, or NT should be classified as laboratory confirmed, epidemiologically linked, clinically compatible, confirmed NT or rejected.

All cases of diphtheria, pertussis and NT should be followed up telephonically after 60 days from date of onset and outcome of follow up should be entered in the CIF.

17 _

ASSIGNING A UNIQUE IDENTIFICATION CODE

Assigning a unique identification code is an important way of assuring the quality of epidemiological data. The unique identification code is important for generating a computerized line list of cases, as personal identification information can be the same for two or more cases. Allotment of this code will facilitate electronic merging of information collected in the field with that generated in the laboratory.

The unique case identification code is a 16-character alphanumeric code allotted to each case of DPT. The first three characters are related to the suspected disease of the case; these are — DTH for diphtheria, PTS for pertussis and NNT for NT. The remaining 13 characters determine time, place and person identification. The first eight characters define the geographical location of the case by allotting a unique identification code for country, state and district. The universally accepted country code for India (IND) will be used here. To maintain uniformity and facilitate data analysis, it is mandatory to use the pre-defined state and district codes which are annexed in this manual. The last five characters of case identification code will depict the year of onset and serial number of the case of a district.

For example, if Bulandshahar district of Uttar Pradesh is reporting the first diphtheria case of 2019, the identification code allotted will be DTH-IND-UP-BLS-19-001, where:

- DTH- Suspected diphtheria code
- **IND** Country code
- **UP**—State code
- BLS District code
- 19 Year of onset
- 001 Serial number of diphtheria case of the district in that year.

The identification code, once allotted to a case of VPD, should not be repeated for any other case. In order to avoid re-allotment of the code, it should only be assigned by the District Immunization Officer (DIO) or Surveillance Medical Officer (SMO) in coordination with each other.

SAMPLE COLLECTION AND TRANSPORTATION

Laboratory confirmation of diphtheria and pertussis is considered the gold standard for case classification of clinically suspected cases. Suspected cases of tetanus do not require any laboratory test; the typical clinical presentation is considered pathognomonic. The recommended sample for diphtheria and pertussis should be collected as early as possible during the course of illness of the suspected cases. The chances of isolating the organism fall rapidly after 2–3 weeks of onset or by use of appropriate antibiotics. The diphtheria and pertussis bacteria have fastidious growth requirements and are susceptible to drying; therefore, the use of transport media is recommended to enhance positivity of laboratory tests.

The prerequisites for sample collection and conditions of sample storage and transportation for diphtheria and pertussis are described in Table 2.

Table 2: Prerequisites and conditions for sample collection

Prerequisites/conditions	Diphtheria	Pertussis*		
Window period from onset	Within 4 weeks	Within 4 weeks	Within 12 weeks	
Type of specimen	Throat swab or pieces of membrane	Nasopharyngeal swab	Serum	
Number	2	2	1	
Transport media	Amies transport media	Regan-Lowe/Amies transport media with charcoal	Not required for serum	
Storage and transportation	2–8°C	2-8°C	2–8°C	

^{*} Within four weeks both nasopharyngeal swab and serum will be collected

Procedures for collecting samples

Throat swab sample collection

- Use any throat swab made of cotton, polyester or dacron
- Check the expiry date on the tube and transport media to ensure acceptability of the material to be used for sample collection
- Label the Amies transport tube with the unique identification code, patient's name and date of collection
- Swab the inflamed area of tonsils and posterior pharynx without touching any other parts of the mouth. If membrane is visible, then rub the swab beneath the membrane
- Piece of membrane can also be collected on the swab
- Immediately place the throat swab sample in Amies transport media
- Immediately insert the swab till the bottom of the media

- If capped swab, then throw the cap of the tube. If uncapped swab, then cut the shaft of the swab to fit into the tube and cap it securely
- Ship the sample to the laboratory at 2–8°C.

Nasopharyngeal swab sample collection

For identification of pertussis, it is mandatory to collect nasopharyngeal swab or aspirate. Throat swab sample is not recommended for laboratory confirmation of pertussis.

- Obtain a thin flexible nasopharyngeal swab made up of dacron or nylon. Cotton and calcium alginate swabs are not to be used
- Check the expiry date on the tube and transport media to ensure acceptability of the material to be used for sample collection
- Label the Amies transport tube with charcoal with the unique identification code, patient's name and date of collection
- Have the patient sit in the mother's lap or with head against a wall or a support as patients have a tendency to pull away during this procedure
- Explain the procedure to the parents or patient
- Measure the distance between anterior nares to the lower lobe of the ear of one side
- Mark the swab with half of the above measured distance
- Ask the patient to blow the nose forcefully to remove any mucous plug
- Position the head slightly upwards and insert the swab along the base of the nose up to the distance marked. Avoid insertion of swab in upward direction
- Do not force swab if obstruction is encountered before reaching the nasopharynx. Remove swab and try the other side
- Try to leave the swab in place for 5–10 seconds to increase sensitivity
- Immediately place the swab in Regan-Lowe transport media/Amies transport media with charcoal and tighten the cap of specimen collection container
- Ship at 2–8°C.

Serum sample collection for serological diagnosis of pertussis cases

It is recommended that one serum sample should be obtained from pertussis suspected cases.

- Arrange the site for serum separation and obtain a serum collection kit before going for sample collection
- Use of standard precautions is recommended when collecting any biological specimen
- Properly label a blood collection tube with name, identification code and collection date
- Using acceptable venepuncture technique, collect 2 to 3 ml whole blood
- Rest the tube undisturbed at room temperature for a minimum of 15 minutes to allow clot to form
- After this, the tube can be transported at 4–8°C to the centrifugation site
- Centrifuge sample to separate serum from clot. This can also be accomplished by storing the whole blood sample in an upright position overnight in the refrigerator (2–8°C)
- Properly label a 2 ml plastic storage tube in which serum is going to be collected
- Serum samples should be stored and transported at 2–8°C.

CASE CLASSIFICATION

Case classification is important to group a disease for apt use of resources in case management and public health interventions. It also supports epidemiological analysis and exchange of information with policy-makers, health officials and in providing feedback.

Case classification diphtheria and pertussis

Every reported case that has been investigated, irrespective of sample collection, should undergo case classification as per Fig. 1.

Suspected case reported **Diphtheria/Pertussis Case investigation Typical signs & symptoms** No Yes Sample Yes No Lab result **Epidemiological** Pos Neg linkages Yes No **Clinically Laboratory Epidemiologically** Rejected confirmed linked compatible

Fig. 1: Algorithm of case classification of a suspected case of diphtheria and pertussis

Laboratory confirmed

A case that meets the clinical case definition, where samples are collected and laboratory results are positive for the suspected disease through culture and/or PCR.

Epidemiologically linked

Diphtheria: a case that meets the definition of a suspected case and is epidemiologically linked to a laboratory confirmed case. In this situation, a person has had intimate respiratory or physical contact with a laboratory-confirmed case within 14 days prior to onset of sore throat (10).

Pertussis: a case that meets the definition of a suspected case and is epidemiologically linked to a laboratory confirmed case. In this situation, a person has had close contact with a laboratory-confirmed case within three weeks prior to onset of cough (8).

Clinically compatible

A case that meets the suspected case definition but is neither laboratory confirmed nor epidemiologically linked.

Rejected

A case that does not meet the suspected case definition on case investigation.

Laboratory confirmation of diphtheria and pertussis is important because other pathogens can cause similar symptoms. A laboratory test can be negative even when the patient has these diseases. The case classification helps to increase the sensitivity for detecting such cases when confirmatory laboratory testing is not done or is negative.

Case classification neonatal tetanus

Confirmed neonatal tetanus

A confirmed case is any suspected NT case found during case investigation to have all three of the following:

normal ability to suck and cry during first two days of life

and

could not suck normally between 3 and 28 days of age

and

developed muscle stiffness and/or spasms (jerking) (11).

Rejected

A case that has been investigated and does not satisfy the clinical criteria for confirmation, or has an alternate diagnosis.

CASE MANAGEMENT AND PUBLIC HEALTH INTERVENTIONS

To reduce morbidity and mortality of VPDs, detected cases must receive prompt and appropriate medical care. Additionally, necessary public health interventions must be taken to restrict the spread of the disease. The initiation of specific therapy during the early phase of clinical illness tends to be more effective for rapid recovery of cases. As mortality rates are higher in younger age groups and in unimmunized children, detection of even a single case of diphtheria and pertussis should target identification of such high-risk groups and their protection by appropriate measures. Case management and subsequent public health interventions following detection of DPTs are discussed below.

Diphtheria: case management

The clinical outcome in diphtheria is improved by prompt initiation of specific therapy; therefore, physicians should act on clinical suspicion after collecting appropriate specimens for laboratory diagnosis. Although CFRs have reduced in developed countries, morbidity and mortality is still high in many developing countries. Urgent treatment of diphtheria is mandatory to reduce complications and mortality. Discovery of diphtheria antitoxin has revolutionized case management of diphtheria and resulted in a reduction in CFR.

Diphtheria case management has the components described here.

Isolation

Respiratory droplet isolation of patients with respiratory diphtheria is required till 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 (10).

Collection of throat swabs for culture

Swabs should be taken as soon as possible after diphtheria is suspected, and treatment should not be delayed while waiting for laboratory results.

Administration of diphtheria antitoxin

Intravenous or intramuscular administration of equine derived DAT (polyclonal IgG antibody) is highly effective and is the gold standard for diphtheria treatment. Diphtheria toxin that has already entered the host cells is unaffected by DAT. Therefore, to reduce complications and mortality, DAT should be administered as soon as possible after disease onset, preferably intravenously in serious cases.

The entire therapeutic dose should be administered at one time. The amount of antitoxin recommended varies between 20 000 to 100 000 units, with larger amounts recommended for persons with extensive local lesions and with longer interval since onset. The dose is the same for children and adults (12).

Antibiotic therapy

Antibiotic therapy is recommended in case management of diphtheria. Antibiotics have no impact on already established toxin-induced lesions but limit further bacterial growth and the duration of

corynebacterial carriage that often persists even after clinical recovery. Penicillin 0.6–1.2g 6-hourly, or erythromycin 0.5g 6-hourly is recommended. Antibiotic therapy should be continued for 14 days.

Supportive measures

Supportive management of complications, with particular attention to the airway and cardiac manifestations are an important part of case management. Patients should be nursed in strict isolation and should be attended by staff with documented immunization histories.

Early in the illness, respiratory and cardiac complications are the greatest threat. These can be minimized by close monitoring (including regular electrocardiogram [ECG]) and early Intervention (e.g. pacing for conduction disturbances, drugs for arrhythmia). Some experts recommend tracheostomy or intubation at an early stage to ensure continued patency of a compromised or potentially compromised airway, and mechanical removal of any tracheobronchial membrane.

Immunization as needed during convalescence

Protective immunity does not always develop after recovery from disease. Therefore, individuals recovering from diphtheria should complete the age-appropriate recommended course of diphtheria toxoid vaccination during convalescence.

Pertussis: case management

Treatment is most effective in lessening symptoms if offered early in the disease during the first 1–2 weeks before coughing paroxysms occur, but during this time pertussis is most difficult to diagnose. Most previously immunized adults or adolescents recover even without antibiotics because of milder illness than that seen in infants and young children.

Treatment in later stages is important to eliminate *B. pertussis* from the nasopharynx and prevent transmission to more vulnerable populations. Treatment is recommended at any time within 3 weeks of cough onset for those over 1 year of age, and within 6 weeks of cough onset for those less than 1 year of age. The period of communicability is reduced to 5 days after treatment with antibiotics. Coughing (symptomatic) household members of a pertussis patient should be treated as if they have pertussis. Early treatment and prevention of transmission may reduce the considerable burden of adult pertussis: loss of work, prolonged symptoms and multiple provider visits.

There are no proven treatments for pertussis-induced cough; steroids and beta-agonists are not effective. Macrolide antibiotics eradicate *B. pertussis* within 5 days. Recommendations include azithromycin (for 5 days) or clarithromycin (7 days). These have fewer gastrointestinal side effects, easier dosing and better compliance than erythromycin (which is recommended for 14 days). In infants <1 month of age, azithromycin is preferred due to concerns for infantile hypertrophic pyloric stenosis, which is associated with erythromycin.

Trimethoprim/sulfamethoxazole for 14 days is an alternative for patients who cannot tolerate macrolides and who are not pregnant, nursing, or <2 months of age.

No work or school is recommended for patients with suspected pertussis until completion of at least 5 days of antimicrobial therapy.

The primary DPT vaccine series is essential for reducing severe disease in young infants. Even one dose of DPT may offer some protection against fatal pertussis disease in infants.

Immunity to pertussis from vaccine or disease wanes over time, and persons who have been vaccinated or had prior infection can become infected. New data on the duration of protection from acellular pertussis vaccines suggest that significant waning of immunity occurs within 2–3 years of vaccination, particularly in persons who never received any doses of whole cell vaccine. Recommended treatment for pertussis is given in Table 3.

Table 3: Recommended treatment and post-exposure prophylaxis for pertussis, by age group (13)

Age group	Azithromycin	Erythromycin*	Clarithromycin	Alternate agent: TMP-SMX†
<1 month	Recommended agent for infants <1 month of age; 10 mg/kg per day in a single dose x 5 days#	40–50 mg/kg per day in 4 divided doses x 14 days	Not recommended	Contraindicated in infants <2 months of age (risk for kernicterus)
1–5 months	10 mg/kg per day in a single dose x 5 days	40–50 mg/kg per day in 4 divided doses x 14 days	15 mg/kg per day in 2 divided doses x 7 days	Contraindicated in infants <2 months of age. For infants aged >2 months of age, TMP 8 mg/kg per day; SMX 40 mg/kg per day in 2 divided doses x 14 days
Infants aged ≥6 months and children	10 mg/kg as a single dose on Day 1 (maximum 500 mg); then 5 mg/kg per day as a single dose on Days 2–5 (maximum 250 mg/day)	40–50 mg/kg per day in 4 divided doses x 14 days	15 mg/kg per day in 2 divided doses x 7 days	TMP 8 mg/kg per day; SMX 40 mg/kg per day in 2 divided doses x 14 days
Adolescents and adults	500 mg as a single dose on Day 1 then 250 mg as a single dose on Days 2–5	2g/day in 4 divided doses x 14 days	1g/day in 2 divided doses x 7 days	TMP 320 mg/day, SMX 1600mg/day in 2 divided doses x 14 days

^{*}Some experts prefer erythromycin estolate over erythromycin stearate or ethylsuccinate because it achieves higher serum levels with equal doses.

[†]Trimethoprim-sulfamethoxazole (TMP-SMX) can be used as an alternative agent to macrolides in patients >2 months of age who are not pregnant or nursing and are allergic to, cannot tolerate, or are infected with a rare macrolide-resistant strain of *Bordetella pertussis*.

[#]Preferred macrolide for this age because of risk of idiopathic hypertrophic pyloric stenosis associated with erythromycin

Neonatal tetanus: case management

The morbidity and mortality of tetanus patients admitted to the hospital decreased substantially in the 1960s and 1970s with the advent of mechanical ventilation and the introduction of benzodiazepines with their high efficacy and wide therapeutic index. Mortality rates of less than 20% are increasingly common for both neonatal and non-NT patients, if they have the benefits of care in a modern intensive care unit. Even in settings with limited resources, if basic medication, experienced medical supervision and high-quality nursing can be provided, mortality can be reduced to less than 50%. The greatest impediment to improved survival of tetanus patients in developing countries is the lack of access to appropriate medical care. Therapeutic approaches depend on the resources available in the facility to which the patient presents.

The specific objectives of tetanus treatment are to stop the production of toxin at the site of infection, with appropriate wound care and antibiotic use; to neutralize circulating toxin with antitetanus immunoglobulin; and to provide effective management of muscle spasm, respiratory failure, autonomic dysfunction and complications that arise during the course of illness.

Antibiotics

Intravenous penicillin G (100 000–200 000 IU/kg/day, given in 2–4 divided doses) and metronidazole (7.5 mg/kg IV every 6–8 hours) are first-line treatments in both maternal and NT cases.

Immunoglobulin

A single intramuscular dose of 500 units of human anti-tetanus immunoglobulin, also known as tetanus immune globulin (TIG) is recommended as soon as possible to prevent further progression of the disease. TIG can only help to remove unbound tetanus toxin. It cannot affect toxin bound to nerve endings. If TIG is not available, equine-derived antitoxin tetanus serum (ATS) can be given in a single intravenous dose, after testing for hypersensitivity. Alternatively, intravenous immunoglobulin (IVIG) may be used (5).

Symptom control and supportive care

In many developing countries, chlorpromazine and phenobarbitone (nasogastric or intravenous administration) remain the mainstay of treatment for NT because they are affordable sedatives.

Intravenous diazepam is used widely in neonates and adults to control spasms. In the absence of ventilator facilities, drugs such as intramuscular paraldehyde are used for further spasm control.

Active case search, contact tracing and management

Active case search and contact tracing in the community

ACS in response to identification of diphtheria and pertussis cases in the community is very important. Occurrence of a diphtheria case in the community indicates gaps in routine immunization (RI) coverage and build-up of a susceptible cohort. There is a very high probability of finding additional cases among contacts of diphtheria and pertussis cases due to the high attack rate of these diseases. Besides conducting ACSs in households and neighbourhoods, the workplace or school contacts should also be actively assessed for these illnesses. A thorough ACS in the community will identify any clustering of cases. Timely interventions have the potential to curtail the outbreaks and reduce case morbidity and mortality.

How to conduct ACS and contact tracing

ACS should be conducted after proper microplanning and training of team members. All the households of the village/tola/mohalla should be visited by the team. One auxiliary nurse midwife (ANM)/staff can visit 50 households in a day. Households can be allotted to each team member, using polio microplans. The team should mark house number/date on all the households visited. Logistics for sample collection and shipment should be arranged beforehand. The ACS team should be trained on VPD-ACS format, suspected case definition, how to identify close contact and identification of unimmunized and under-immunized children/person(s).

While conducting ACS, the teams should be primed to look for cases in all age groups. VPD-ACS forms (given at Annexure 2 and 3) are to be used to facilitate ACS in the community. This form will collate information on demographic profile and summarize the number of suspected cases identified during house-to-house searches. For a rapid assessment of pentavalent/DPT immunization status of the community, the form also captures total doses of these vaccines received by the youngest child (under 15 years of age) in the household. Once a suspected case has been identified, detailed information regarding the illness should be captured in the space provided in the form. Analysis of VPD-ACS forms will help in selecting cases that require detailed investigation, i.e. filling of CIF and intervention by a MO. A lab technician will collect specimens from suspected cases and will send them to the DIO/SMO office under cold chain.

The summary information of ACS should be entered in the VPD-CIF (Annexure 1) under the section "Active case search and response in community" for completeness of the information. Attempts should be made to conduct ACS soon after identification of a suspected case and preferably within seven days of case investigation.

Diphtheria

Management of contacts

Monitor close contacts for signs and symptoms for 10 days from the date of the last contact with a suspected case. At a minimum, close contacts are considered to be household members and others with a history of direct contact with a case. These may include caretakers, relatives, sexual contacts, fellow students and friends who regularly visit the home. Medical staff exposed to the case's oral or respiratory secretions or exposed to their wound should also be monitored. Ideally, surveillance staff should communicate daily with contacts to monitor for new symptoms, but the extent of monitoring is determined by public health resources (10).

Prophylactic antibiotics (penicillin or erythromycin) are indicated for close contacts. The number of contacts who received and completed their prophylactic antibiotics should be entered in VPD-ACS form.

Recommended post-exposure prophylaxis for diphtheria contacts is given in Table 4.

Table 4: Recommended post-exposure prophylaxis for diphtheria contacts

Age	Immunization		Proph	ylaxis					
		Antibiotic	Dose	Route	Duration				
<7 years old	Penta/DPT	Penicillin G 600 000 units IM Single dos benzathine							
		or							
		Erythromycin	40 mg/kg in 4 divided doses	P0	7–10 days				
>7 years old	Td	Penicillin G benzathine	1.2 million units	IM	Single dose				
		or							
		Erythromycin	1g/day in 4 divided doses	P0	7–10 days				

IM – intramuscular; PO – per oral

Note: Azithromycin (10 mg/kg body weight), a long acting oral antibiotic, is also being used as single daily dose for three days (14).

Diphtheria antitoxin is not recommended as post exposure prophylaxis (PEP) among contacts, as evidence of its benefit is limited.

Immunization of contacts

The contacts and susceptible cohort (un- and under-immunized) identified during ACS should be given a dose of diphtheria-containing vaccine appropriate to their age. All children less than 7 years of age should be immunized by a single dose of DPT if they have not received diphtheria-containing vaccine in the previous five years. Persons aged more than 7 years cannot be immunized with DPT vaccine that is used in RI due to the adverse effects of pertussis component. Such individuals should be given Td (tetanus with low dose diphtheria antigen) vaccine. The vaccination should be done through an outreach session site in the village. In areas with poorly vaccinated population, in-school vaccination can be planned. The number of susceptible persons receiving at least one dose of diphtheria-containing vaccine should be entered in the VPD-ACS form.

Surveillance, investigation and response in outbreak settings

Definition of an outbreak: a single laboratory confirmed case of diphtheria should trigger a public health response. Two temporally and geographically linked cases, of which at least one is laboratory confirmed, is considered an outbreak of diphtheria (10).

Surveillance during an outbreak: during outbreaks, identify additional cases using clinical diagnosis based on typical pseudomembranous pharyngitis without laboratory confirmation. However, laboratory investigation of suspected cases is strongly recommended. Investigation of contacts might reveal mild respiratory cases without psuedomembranes, these should be identified and counted as laboratory confirmed or epidemiologically linked cases. Do not delay treatment pending laboratory confirmation. All suspected cases should be line listed.

Public health response: conduct contact tracing, monitor for development of disease, collect specimens, treat with antibiotics and vaccinate as described above.

Medical Officer in-Charge (MOIC) of health facility to send report of activities done on a daily basis and then a final report should be sent after the fifteenth day of the start of outbreak response. The content of the report should be as given in Table 5.

Table 5: Reporting format following public health interventions in diphtheria

Name of village/tola/ mohalla	No. of households visited	No. of suspected diphtheria cases identified	Number of contacts/ susceptible to be vaccinated	No. of 0–7 year-olds received pentavalent/ DPT vaccine	No. of persons >7 years- old received Td vaccine	No. of close contacts of index case or suspected case	No. of persons received prophylactic antibiotics for diphtheria

Pertussis

Management of contacts

Contact investigation and management should focus on high-risk contacts at a minimum, and ideally all close and high-risk contacts. Close contacts are people who have had face-to-face exposure to an infected case, to include household or family contacts, people having stayed overnight in the same room with a case and people having direct contact with respiratory, oral or nasal secretions of a lab-confirmed case. High-risk contacts are not necessarily close contacts, but those that have been exposed to a suspected case and are themselves at increased risk of complications from pertussis or are at risk of transmitting the infection to other persons at risk of severe pertussis disease. These include infants, pregnant women in the third trimester of pregnancy, health-care workers working with infants or pregnant women and persons of any age working or sharing a house with infants (8).

Contacts should be tested only if they have symptoms consistent with pertussis infection. Asymptomatic contacts of confirmed cases should not be tested, and testing of contacts should not be used for post-exposure prophylaxis decisions.

Early treatment and post exposure prophylaxis: early treatment with macrolide antibiotics (such as erythromycin and azithromycin) should be administered to close contacts who are infants <6 months of age who develop symptoms of a respiratory infection.

Vaccination: under-vaccinated persons having contact with pertussis cases should be identified. Pertussis-containing vaccine should be given to any person who is not fully immunized according to the recommended immunization schedule. Vaccination might not prevent illness in a person who has already been infected with *B. pertussis*.

Surveillance, investigation and response in outbreak settings

Definition of an outbreak: an outbreak is an increase in incidence or number of cases over the reported

baseline in a specific geographical area. Pertussis outbreaks can be difficult to identify and manage, given the regular periodicity of pertussis and the existence of other respiratory pathogens causing similar symptoms. Epidemiological outbreak investigations can provide useful information on vaccine effectiveness and pertussis epidemiology, including the distribution of cases and CFR by age groups (8).

Specimens should be collected from five cases to confirm the outbreak. After this point, epidemiological linking should be done.

Public health response: during outbreaks, vaccination efforts should focus on the un- or underimmunized. At the same time, RI in the outbreak area should be strengthened. Vaccination campaigns are not part of pertussis outbreak response. Contact management is the same as mentioned above, with a focus on early treatment among infants <6 months of age with signs of respiratory illness. While antibiotics may prevent pertussis disease if given prior to symptom onset, there are no data to indicate that widespread use of post-exposure prophylaxis (PEP) among contacts effectively controls or limits the scope of community-wide pertussis outbreak.

Active screening for symptomatic patients with suspected pertussis should be done during outbreaks in settings such as schools, day-care centres and hospitals.

Notify all public and private health facilities in the affected and nearby areas of the outbreak and inform them to have a high index of suspicion for pertussis cases. Conduct health promotion activities and distribute education materials to provide basic information about pertussis and its prevention, particularly vaccination.

MOIC of health facility to send report of activities done on a daily basis and then a final report should be sent after the twentieth day of the start of outbreak response. The content of the report should be as given in Table 6.

Table 6: Reporting format following public health intervention in pertussis

Name of village/ tola/ mohalla	households visited	No. of suspected pertussis cases identified	Number of un- and under- immunized children	No. of children received pentavalent vaccine	No. of children received DPT vaccine	No. of close contacts of index case or suspected case	No. of contacts received prophylactic antibiotics for pertussis	Remarks

Neonatal tetanus

Contact tracing and management

As tetanus is not contagious, no contact tracing is needed.

Surveillance, investigation and response in outbreak setting

Tetanus is not considered an outbreak-prone disease. In general, NT outbreaks do not occur, but clusters linked to a single source of substandard clinical care have been observed.

Public health response for neonatal tetanus

Vaccination: the mother of the suspected NT case should receive two doses of Td at an interval of 4 weeks.

Rapid community assessment

Starting from the house where the confirmed NT case occurred, move house-to-house to interview 10–15 other mothers in the community who delivered in the last two years about their vaccination status, delivery place and attendant, application of substances to the umbilical cord, and the survival and vaccination status of their last born child. The VPD-ACS NT form Annexure 3 should be used to collect the information.

If at least 80% of mothers are protected (either through clean delivery and hygienic cord practices, or protection at birth immunization status), the response will be limited to vaccination of the mother of the NT case and promotion of clean birth and hygienic cord care practices.

If less than 80% of the mothers are protected, determine the cause of non-protection and formulate an appropriate intervention. Include this area for outreach sessions and ensure vaccination of pregnant women with tetanus toxoid-containing vaccine.

If less than 90% of the last born children received DPT3, strengthen RI services in the area (11).

Health education: provide information to the community and birth attendants about proper cord care. If a source of unclean deliveries is identified, training and education may be provided to the birth attendant to prevent further NT cases.

MONITORING AND SUPERVISION

Monitoring and supervision are important tools for establishing and maintaining efficient surveillance and response systems. Monitoring and supervision are used to assess the quality of the surveillance system over a time period against set norms and baseline data. The information should be used locally to address and resolve problems related to control of diseases and strengthen the evolving programme. Implementation of a surveillance system without a monitoring and supervision plan will result in no improvements in the system, thus leading to increased risk of failure.

Monitoring refers to the routine and continuous tracking of the implementation of planned surveillance activities. Evaluation is the periodic assessment of the relevance, effectiveness and impact of surveillance activities. Monitoring data should be collected through the system itself by the persons implementing the system with minimal resource implication. Evaluation ensures that the surveillance system meets its objectives. It documents the status of performance or any change in the system and provides an evidence base for any modification in the implementation strategies. Evaluation of the surveillance system should be conducted periodically by external experts to have a broader understanding of its functioning and bring a fresh perspective to the system. The inferences and recommendations of monitoring and evaluation should be acted upon in a timely and appropriate manner.

Supervision provides critical support for the delivery of health services. It serves numerous functions like strengthening capacity of staff, ensures that the right skills are used appropriately, necessary logistics are in place and that planned activities are implemented according to schedule. Supervisory activities should be included in the work plan and the proportion of planned supervisory visits can be documented to build confidence in the system.

A detailed monitoring and supervision plan is being described here as an integral part of the VPD surveillance implementation plan. The sources of information, methods and frequency of data collection, monitoring indicators, data analysis and use of information are inbuilt in this plan.

Monitoring indicators

Indicators are variables that can be measured repeatedly over time and provide measures of change in a system. They provide useful information on the status of the system and flag areas that need improvement. A good indicator should have a precise definition of the numerator and denominator that can be presented in a clear, concise and comprehensive way. The various monitoring indicators recommended for DPT surveillance are discussed hereafter.

Proportion of cases with timely notification

This indicator is most crucial in determining the speed and quality of a surveillance system. Timely notification of suspected cases has many advantages. Sample collection during the early phase of disease increases the probability of laboratory confirmation, early detection of impending outbreaks and case management. Timely public health interventions can reduce the morbidity and mortality rates.

Diphtheria: the date of onset in suspected diphtheria cases should be considered as the day of onset of sore throat. In most cases of diphtheria, a membrane appears in 2–4 days after onset, and due to severity of symptoms, there is more likelihood that patients will seek early medical care. The cases reported within seven days of disease onset should be considered as notified in a timely manner.

Pertussis: the date of onset in suspected pertussis cases should be considered as the day of onset of cough. Since the case definition of pertussis requires cough of more than two weeks duration and paroxysms occur late (≥2weeks of cough onset) during the natural course of illness, early notification of pertussis cases is not expected. The cases reported within four weeks of disease onset should be considered as notified in time.

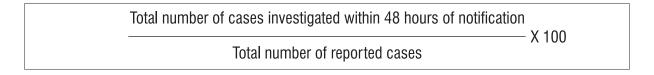
Neonatal tetanus: the date of onset in suspected NT cases should be considered as the day of onset of inability to suck. The disease progression in neonates is very rapid, with high CFR early in the course of illness; as such, cases reported within seven days of disease onset should be considered as notified in time.

$$\label{eq:Diphtheria} \mbox{Diphtheria} = \frac{\mbox{Total number of suspected diphtheria cases reported within 7 days of onset}}{\mbox{Total number of suspected diphtheria cases}} \mbox{ X 100 }$$

A target of \geq 80% should be achieved for timely notification. The reasons for delayed notification should be analysed. These could be due to lack of awareness among health-care providers, lack of understanding of reporting protocols, reporting network not tuned to pick early cases or communication channels provided for notification are not free or updated. Appropriate actions to achieve the target for this indicator will pay good dividends for classification of cases.

Proportion of cases with timely investigation

This indicator determines the alertness of the surveillance system to respond to notified cases. It is expected that the assigned MO at block level should be able to investigate all notified cases in his block within 48 hours of notification. It is calculated thus:



Efforts should be made to achieve a target of $\geq 80\%$ for timely investigation. Clinical training of assigned MOs at block level and tracking of cases after notification are important to achieve the target for this indicator. This indicator should be analysed at the block level to identify the areas which should be focussed on for active supervision.

Proportion of cases with adequate sample collection

This should be calculated disease-wise, as the sample collection in suspected cases of pertussis is more challenging, and for suspected cases of tetanus no sample will be collected. It is calculated thus:

Total number of cases in which adequate sample is collected

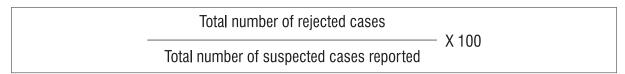
Total number of suspected cases reported – total number of rejected cases

If disease is suspected, then appropriate laboratory testing should be done to confirm (or rule out) that suspicion. If no testing is being done, it means that monitoring is inadequate or ineffective. Efforts should be made to achieve the target of collecting samples in $\geq 80\%$ suspected cases of diphtheria and pertussis.

If a large proportion of cases with no samples has been observed, the reasons could be multiple: late notification of cases outside the window period of sample collection, health-care provider not confident in sample collection procedure; lack of logistics; death; refusals and sample spoilt during storage and shipment. Appropriate actions should be taken to achieve and maintain the target.

Proportion of rejected cases

This measures the proportion of reported cases that do not meet the clinical case definition of the suspected disease. Disease-specific calculation and analysis of this indicator will be more useful. It is calculated thus:



This indicator helps in understanding the level of awareness among health-care providers. The number and type of reporting sites reporting such cases should be analysed, which helps to identify the training needs of the reporting network. Sensitization visits should be planned accordingly to reduce the proportion of rejected cases.

Proportion of timely ACS in the community

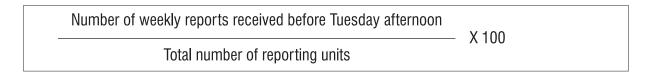
This indicator will help to monitor the preparedness of the government health system to build up a community response. It should be calculated for diphtheria and pertussis separately. This indicator will have little value in NT as it does not lead to outbreaks. The source of information to calculate this indicator will be the CIF. It is calculated thus:

Total number of ACS conducted within seven days of case investigation	X 100
Total number of suspected cases	Λ 100

A target of at least 80% should be achieved for this indicator. Monitoring of this indicator will promote timely ACS in the community and consequently, early identification of impending outbreaks. This indicator will also help in identifying the areas of complacency or areas requiring support or resources from the district level.

Timeliness of weekly reporting

This indicator determines the proportion of reporting units whose weekly reports are received on time at the district. Weekly report in VPD-H002 form received by Tuesday afternoon is considered as timely. Reports received after Tuesday afternoon but before next Monday are considered late, after which they are considered as not received. This indicator is calculated thus:



A target of \geq 80% timeliness of weekly reporting should be achieved. Its periodic analysis will reveal those reporting units that have failed to send the weekly report on time. This could have happened because of gaps in the system, change of human resources, logistic issues, etc. This indicator is an important tool to measure alertness of the reporting network.

Completeness of weekly reporting

This indicator determines the proportion of reporting units whose weekly reports have been received at the district. It is calculated thus:



The numerator includes all weekly reports received at the district before next Monday, irrespective of their timeliness. Target of \geq 90% completeness of weekly reporting should be achieved. The reporting units not maintaining the completeness indicator of weekly reports should be brought to the notice of district government officials for corrective action.

Data analysis

Ongoing analysis of surveillance data is important for detecting outbreaks, an unexpected increase or decrease in disease occurrence, monitoring disease trends and evaluating the effectiveness of disease control programmes and policies for identifying areas of improvement. Data analysis provides the basis for taking action, targeting communities at risk or modifying programme strategies. This information is critical to determine the most appropriate and efficient allocation of public health resources and human resources.

Computer technology has greatly facilitated the collection and analysis of surveillance data. Analysis should be performed at regular intervals using a standard approach. However, skilful interpretation of data is needed to determine any aberrations and to develop a focussed action plan. Therefore, both technology and human factors play important roles in the analysis of surveillance data.

Missing or inaccurate data may limit the usefulness of any analysis. Erroneous or incomplete data cannot be corrected through statistical procedures.

Processes and interpretation

Analysis of surveillance data begins with characterizing the pattern of disease reports by person, place and time. Knowledge of the specific pattern of disease occurrence in a geographical area is required to identify changes in disease occurrence and disease prevention. This knowledge can be obtained only through a continuous systematic process of consolidation and analysis of available surveillance data.

Time analysis: date of onset of symptom(s) is the most critical information which time analysis can be based upon. Basic analysis by time can be conducted in several different ways to detect changes in disease incidence, namely:

- comparing the number of cases occurring in the current week with the number in the preceding four weeks
- comparing the number of cases during the current period (month, quarter) with the number reported during the same period in previous years
- comparing the occurrence of disease by year to analyse long-term (secular) trends in a disease
- clustering of cases over the specified period (weeks, months) should immediately raise an alarm
- no cases during high transmission period should trigger an appropriate response for verification of information.

Some diseases, e.g. pertussis naturally occur periodically as epidemic years followed by non-epidemic years. An epidemic year will be followed by one or more years with relatively fewer number of cases of the disease until another epidemic year occurs. Increasing immunization coverage changes the epidemic pattern so that the time between epidemics increase.

Place analysis: the place where the case was residing at the time of onset of symptoms and during the incubation period must be determined for all cases. We should analyse disease occurrence simultaneously by time and place. Place analysis is best displayed by plotting the location of cases on a local map over a specified period of time. Any spatial clustering of cases or silent areas will immediately become visible to guide interventions. Repeated occurrence of cases in a particular geographical area over many years helps in identifying high-risk areas for disease transmission.

A map of the number of cases by geographical area does not adjust for population densities. Similarly, the number of cases in a specified geographical area over the past few years does not account for growing population. Therefore, any analysis on disease occurrence should be based on calculation of rates and not only on absolute number of cases occurring in a specified time and place.

Calculation of disease occurrence rate is done as follows:

Analysis of disease occurrence rate will help in analysing disease trends over time and place and identifying high-risk areas.

Person analysis: analysing surveillance data by characteristics of affected persons is also helpful. Age, sex and religion are the most basic variables on which person epidemiology is studied. Other variables such as vaccination status, hospitalization, associated risk factors for specific disease such as recent travel or exposure in school or work place should also be looked into for targeted interventions.

Active supervision

Supervision is a critical part of human resource management to ensure optimum functioning of the surveillance system. Supervision is the process of "directing and supporting staff so that they may effectively perform their duties".

Through supervision, the health staff are supported and guided by their supervisor(s) to help them perform better, and to ensure that planned activities are broadly on target. Supervision of the surveillance staff at different levels of surveillance provides opportunities for informal training, support and qualitative monitoring.

Supervision in health programmes traditionally used an inspection and control approach that is controlling the worker's adherence to policies and procedures. Health workers often receive little guidance or mentoring on how to improve their performance. The major flaw in traditional supervision is in its fault-finding approach rather than on problem solving to improve performance. However, active supervision should be a very participatory process that encourages effective two-way communication.

Supportive supervision has been used to promote sustainable and efficient programme management by strengthening relationships within the system.

Making supervision more effective

Advance planning

Prepare a plan for regular supervisory visits to health facilities: When supervisory visits are made routinely, supervisors are better able to monitor performance and can identify and address problems before a negative impact on the programme. Poorer performing health facilities should receive more visits.

Preparation for supervisory visits: Prepare updates, follow up recommendations of previous visits and feedback specific to the health facility.

Stick to the schedule and respect the time of the health facility: Plan to spend sufficient time to conduct supervisory visit.

Assess performance

Observe and note strengths and weaknesses together with the staff being supervised. Use information gathered during the visit to discuss progress with the health facility team and make adjustments as needed.

- Always ask for additional feedback
- Perform and document ACS in the facility by checking admission/OPD/emergency/ discharge registers for any unreported case
- Verify data from reports that have been sent to the district by the facility and also ensure quality of these reports
- Look for proper documentation of surveillance activities like case notification, investigation, follow up and results.

Discuss findings and strengthen capacity

- Always start by presenting the health staff and facilities' positive attributes "praise in public, correct in private"
- Provide staff with informational updates and new recommended practices
- Give constructive feedback: Facilitate staff to identify areas of strengths and weakness and help them to develop strategies for solving issues
- Discuss, listen and identify information/training needs together with the staff
- Develop a team approach to increase supportive supervision at a health facility and make it a
 routine procedure with or without frequent visits from central or district level. Health facility
 staff can develop supervision plans that fit their structures and conduct regular selfassessments to monitor their performance.

Dissemination of surveillance data

Dissemination of surveillance data to those who need to know is a critical component of the surveillance system. The phrase "information for action" implies that a surveillance system should be functionally linked with the public health programme. Clear communication and active dissemination of evidence to all relevant audiences in easy to understand formats are critical to generate awareness and for use of evidence.

Two types of audiences are benefitted by surveillance information: (i) those who are involved in operations of surveillance like health facilities, MOs, laboratory directors, etc.; and (ii) those who need to know for administrative, programme planning and decision-making purposes. Surveillance information should be disseminated in the most interpretable, persuasive and actionable manner. Clear graphical presentations tend to be more appealing and easily understood than detailed tables.

Surveillance information serves two primary purposes – information and motivation. Information on occurrence of the disease by time, place and person in the community informs local health providers

about the probability of their encountering the specific disease among their patients. A surveillance report can also be a strong motivational factor. It demonstrates that the programme managers actually look at the reported cases and surveillance data to take appropriate action. Such efforts are important in maintaining a spirit of collaboration among the public health and medical communities which in turn improves reporting to the surveillance system.

REPORTING NETWORK AND CASE NOTIFICATION

Efficient and reliable reporting network and notification systems are vital for any disease surveillance. In many developing countries, the number of cases that are reported into the system are underestimated for two main reasons:

- Community level: not all cases seek health care at the designated reporting sites (underascertainment)
- Health facility level: failure of a reporting site to adequately report suspected cases that have sought medical advice (underreporting). Common reasons for underreporting include lack of knowledge, lack of appreciation of its importance, lack of motivation, competing priorities and complexity of reporting procedures.

It is difficult to address under-ascertainment; however, underreporting can be addressed by diligently selecting the reporting sites, creating awareness of the importance of case reporting, and regular monitoring to verify the quality and completeness of reporting. The following criteria should be considered for selecting a health facility for VPD surveillance:

- the health facility is willing to participate in surveillance activities
- the health facility serves a relatively large population of interest
- the health facility has medical staff sufficiently specialized to diagnose, treat and report cases of the diseases under surveillance.

A widely accepted reporting system along with a convenient reporting mechanism is essential for effective surveillance of vaccine preventable diseases.

Structure

As part of the polio eradication initiative, a highly efficient surveillance system for AFP is already functional in the country with the support of WHO India National Public Health Surveillance Project (NPSP). Many of the weaknesses of a reporting network such as inadequate health facilities, poor awareness, superstitions and beliefs that discourage reporting, conscious or unconscious suppression of reporting have already been addressed in the AFP surveillance system. Thus, it is prudent to base the VPD surveillance activities through the already established AFP reporting network.

As the reporting of AFP cases does not require specialized medical skills, and to achieve the polio eradication goal, the AFP reporting network was expanded to include non-specialized community level health providers. Since reporting of suspected cases of diphtheria, pertussis and NT requires good clinical skills, the whole of the AFP reporting network cannot be adopted for DPT surveillance. If the non-specialized health providers are targeted for DPT reporting then it is expected that a huge number of non-specific illnesses of fever, sore throat and cough might be reported to the system. Non-specific reporting will be resource intensive and may unnecessarily burden the surveillance system.

The reporting network for DPT surveillance will consist of those AFP reporting sites that are government health facilities, and health facilities with personnel having medical skills to identify suspected cases of diphtheria, pertussis and NT.

The categorization of reporting sites as reporting unit (RU) and informer unit (IU) will remain the same as in the AFP surveillance system.

Reporting units

These include large government or private health facilities. Usually, these facilities have both outpatient and inpatient departments such as medical colleges, district hospitals, government health facilities and big private hospitals.

The reporting units (RUs) usually maintain documentation of all patients attending that facility. All RUs are required to send weekly reports to the district even when there are no cases of VPDs. Each RU already has a designated AFP surveillance nodal MO (nodal officer) who can be motivated to support the VPD surveillance activities.

Informer units

Informer units (IUs) are often smaller health facilities or clinics that are likely to see cases of VPDs. These facilities usually do not maintain detailed documentation of the patients visiting them, or have certain inhibitions in sending weekly reports. They notify the concerned official whenever they come across a case of VPD. They are not bound to send weekly reports.

Functions

Case notification

DPT surveillance is active surveillance of suspected cases of diphtheria, pertussis and NT. District health officials (DIO/SMO) actively solicit information or reports on VPDs directly from the reporting network. The reporting procedure is kept simple, as in the AFP surveillance system. Any reporting site should immediately notify a suspected case of VPD by any available mode of communication to the concerned official or office. The minimum information required to notify a case is suspected VPD, patient identifiers and contact details.

Weekly reports

All reporting units should notify the district of all VPD cases detected in a week through a mechanism of weekly reporting. The RUs are expected to submit their weekly reports in the form VPD-H002 to the DIO/SMO office every Monday. The district then compiles this information in form VPD-D001 and sends to the state every Tuesday. The state then collates information from VPD-D001 from all districts, prepares a state report in form VPD-S001 and sends to the national headquarters every Wednesday. The signed hard copies of the weekly reports or scanned copies are accepted as confirmation of reporting.

The weekly report contains basic information along with the contact details of notifiable cases during the previous week. When no cases are seen in a week, a weekly report is still required specifying that zero cases were seen. This is called "zero reporting" or "nil reporting". Nil reporting gives confidence

41

that the surveillance system is operational even if no disease is identified. This mechanism of submitting weekly reports ensures completeness of the reporting system and translates into an important monitoring indicator of performance of reporting sites. The timeliness of weekly reports can also be monitored to identify any complacency in the system. Informer units are not expected to send weekly reports.

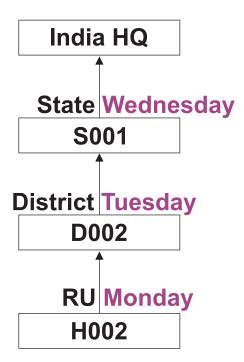
The forms used to compile and send weekly reports are:

Form VPD-H003/003A: It is important to seek and collect information about notifiable cases seen by individual clinicians or departments in an RU. This information is documented in this form by the nodal officer of that RU. It is desirable to obtain signatures of all concerned clinicians in this form for authentication of the weekly reports.

Form VPD-H002: This is the weekly reporting form which should be sent every Monday. The information contained in form VPD-H003/003A should be compiled to generate weekly reports.

Flow of weekly report is given in Fig. 2.

Fig. 2: Flow of weekly report



Collaboration and sensitization of health facilities

The awareness and skills of the health staff of health facilities included in the reporting network is a major contributor to ensuring a sensitive, high quality surveillance system. Increased awareness results in timely notification and investigation of suspected cases. Lack of knowledge regarding the components of notification (what, when, how and to whom to report) is the most common cause of under-reporting. Therefore, sincere efforts should be made to engage health staff of the selected health facilities in surveillance activities.

There are various methods to encourage involvement and to increase awareness among health-care providers of government and private sectors.

Introductory meeting

It is always useful to conduct an introductory meeting with the clinicians, hospital staff and health workers. The goal of this meeting is to improve knowledge about the disease and to explain the rationale for conducting surveillance. Standard case definitions, including all components of reporting a suspected case of VPD, should be introduced. It should be emphasized that all cases that fit the case definition should be reported, irrespective of diagnosis.

Regular visits

During regular visits to the reporting sites, it is preferable to first contact the nodal officer and take a brief account of activities and concerns regarding VPD surveillance. Any knowledge or communication gap, reluctance in reporting, poor accessibility and other barriers to active reporting should be appropriately addressed. Such visits should also be utilized to meet with the institution/department head, MOs and nursing staff of relevant departments. These visits should be used to build interpersonal relationships to achieve maximum cooperation from the reporting sites.

Feedback

Feedback is an important mechanism to obtain continued involvement and commitment of the reporting network. It can be a strong motivational factor for the reporting network, because it acknowledges their contribution and demonstrates that the information they submitted is analysed for action. It also improves the accuracy and promptness of reports. The feedback can be of three types:

General feedback: This includes summary information or updates on the epidemiology of the disease, any revisions in the recommendations for vaccination or control strategies, etc.

Specific feedback: These are laboratory results, final classification and updated information of the reported cases. The reason for any delayed or missed reporting by a reporting site should be politely addressed.

Urgent feedback: This is the confirmation of an outbreak or an individual case.

Feedback mechanisms can be improved if inferences and specific action points produced from in-depth data analysis are communicated. Graphical presentations tend to be more appealing and easily understood.

Sensitization workshops

These are an effective method of generating awareness among a group of health staff. This method can generate awareness throughout the reporting network within a short time span. Conducting frequent and quality sensitization workshops has the potential to give immediate impetus to improve the notification rate. Different medical platforms like the Indian Medical Association (IMA), the Indian Academy of Paediatrics (IAP), related conferences and monthly meetings of the government sector should be targeted to organize such workshops. All reporting sites should be sensitized through such workshops at least once in a year.

The quality of sensitization workshops depends largely on the training material and communication skills of the trainer. Since most of the target audience of these workshops will be medical specialists, the DIO and SMO should prepare and equip themselves with the latest information to be effective.

The training material should contain information about the current epidemiology of VPDs and rationale for surveillance. The operational components of notification and reporting should be clearly explained to prevent under-reporting. To increase the likelihood of timely reporting and specimen collection, particular attention should be paid to explaining case definitions, procedures for specimen collection and reporting formats.

ROLES AND RESPONSIBILITIES

VPD surveillance is useful both for measuring the need and effects of public health interventions by Ministry of Health and Family Welfare with support from allied Ministries such as Women and Child Development, Finance etc. Officials who decide to use public health surveillance as a management tool must recognize that they will need to commit political support and human and financial resources. For successful implementation of a surveillance system, roles and responsibilities need to be fixed, starting from the grass-root level health workers to the top managers at state and union levels.

Implementing authority

The quality and timeliness of surveillance operations is of prime importance to the effective functioning of disease surveillance. Since disease surveillance is an essential function of a public health system, its implementation becomes the responsibility of government health officials. District health officials (Chief Medical Officer [CMO]/DIO) need to take ownership of the programme by ensuring that cases of diphtheria, pertussis and NT are reported in time and responded to appropriately. Considering the population profile of districts in India and other administrative responsibilities of district health officials, a block-level MO should be designated and trained to carry out various activities related to VPD surveillance.

Roles and responsibilities of designated block level MO

Case investigation: All cases notified to the district should be properly investigated at the block level using the standard CIF. A detailed case investigation will reveal information about the case meeting the criteria of standard case definitions. All cases that do not meet the criteria of standard case definitions should be rejected, with proper reason and documentation on the CIF. The cases that meet the criteria of standard case definitions should be assigned a unique identification code in consultation with the concerned district official.

Sample collection and shipment: Appropriate sample collection as per the disease syndrome and window period of sample collection should be done. The block level MO is responsible for arranging all logistics for quality sample collection and shipment to the designated laboratory. Sample collection kits for throat swab, nasopharyngeal swab and serum can be obtained from the district headquarters. Efforts should be made to collect the samples before initiation of antibiotic therapy.

Case management: The block MO has to ensure proper treatment of the cases as per the recommended guidelines. This can be best done through the reporting health facility by advising or capacity-building of health officials working in that facility. Treatment should be initiated at the earliest even in the absence of laboratory confirmation.

Sensitization efforts: For maintaining a sensitive system of disease surveillance, it is vital that the designated block level MO actively participates in sensitization of the reporting network in various ways. He or she should proactively pay sensitization visits to health facilities, especially facilities missing out on cases or those that are performing poorly due to other reasons. Other mechanisms such as sending text messages, phone calls or publishing newsletters to generate awareness can also be used for sensitization efforts.

Providing feedback: The designated block level MO should ensure that the feedback on case results is communicated to the reporting health facility and the case patient. Any unusual observation such as increase in disease occurrence, clustering, deaths, etc. should be immediately brought to the notice of the district health officials.

Technical advice and capacity building

Just as decision-makers require a competent, motivated economist to guide on budgetary planning and allocations, they also need a competent technical advisory body to provide scientifically valid surveillance analysis and communicate the result as information for action. WHO India (NPSP) will support the use of internationally gained experience in implementation and the operational translation of ideas into action. NPSP will play an important role in:

- dissemination of information and technical advice
- capacity-building of surveillance staff and reporting network
- creating a sense of urgency in taking actions for better translation of information from report to implementation
- advocacy for raising key technical aspects higher on the health agenda in the public and private sectors
- exercising quality standards and embedding M&E in the implementation process.

NPSP will support a qualitative leap towards establishing and maintaining a disease surveillance system that provides a scientific and factual database essential to inform decision-making and appropriate public health actions.

Monitoring and evaluation

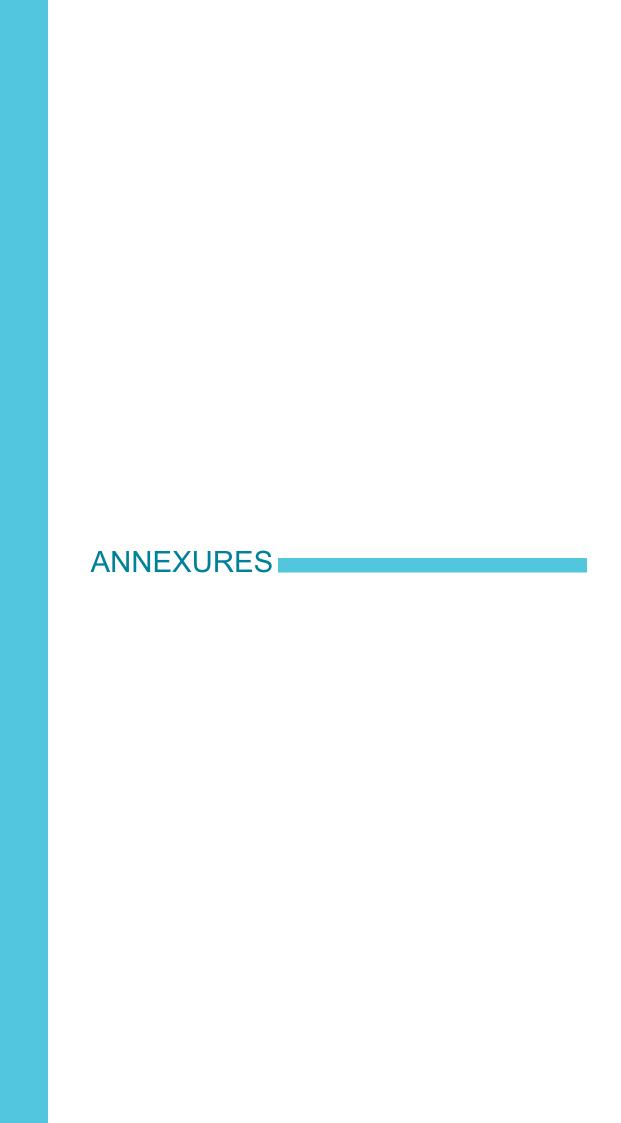
A structured approach of programme monitoring and evaluation function will strengthen the evolving surveillance system. Monitoring and evaluation generates valuable information that should be used locally to resolve problems. The district level unit offices of NPSP will proactively support their government counterparts in surveillance system performance assessment by implementing the monitoring and evaluation plan described in this field guide. Ongoing, systematic analysis of monitoring indicators will provide useful information on the status of the implementation of the VPD surveillance system and flag areas that need improvement.

Public health interventions and system strengthening

Completion of successful interventions determine the worth and effectiveness of the VPD surveillance system. Collection and analysis should not be allowed to consume resources if action does not follow. The key step for ensuring accountability and sustainability of the VPD surveillance system is to institutionalize the response and supportive supervision mechanism within the government system and other stakeholders. The District Task Force (DTF) meeting for immunization headed by the CMO under the chairmanship of the District Magistrate should adopt a systematic approach towards interventions and supportive supervision. Senior level managers of government and other prominent institutions/organizations/professional bodies should be involved to help in decision-making and system strengthening. The members of the district task force should be held accountable for their specific roles and responsibilities.

Roles and responsibilities of District Task Force for Immunization for VPD surveillance

- Take appropriate public health interventions in response to identification of cases or outbreaks
- Ensure involvement of the private sector in the surveillance activities, with special emphasis on quality
- Take immediate and appropriate actions based on the findings of monitoring and evaluation of the VPD surveillance system



Annex 1: Case Investigation Form

Vaccine Pre CASE INVES							DTH / PTS / NN syndrome)	NT - IND (matches Lab F	Request Form)	
1. Reporting / Investiga Date Case Reported: Date Case Investigated: Date Case verified:				Investigated by: _			Tifle:Tifle: DIO / DSO / Tifle: SMO / DIO	Medical Officer / I	Nodal Officer / SMC	O / Other
Reporting Health Facility:	Туре:	RU / Inf	former / Other /	ACS (facility) / Co	ommunity Search	Setup: Gov	t. Allopathic / Pvt A	Allopathic / ISM F	Pract. / Others	
2. Case Identification:		Patient's N	ame:			other given nan	nes:			
Sex: M/F/O	1	Date of birt	h (DOB):	<i>II</i>	[_] precise DOB	unknown (enter b	est estimate of age: y	ears mor	nths)	
Father's Name:					Mother's Name:_					
Father's Occupation:					Grandfather's Na	me:				
Address:					Religion: Hindu /	Muslim / Other		Caste:		
Landmark:					Village / Mohalla:			_ HRA per micro	olan?: Y/N	
Block /Urban area:					District		Setting: Urba	an / Rural		
State:							Alternate tel.			
Child belongs to migratory	y family/	'Communit	y : Yes/ No/ Unkr	nown	If yes, specify: Sli Others (specify):	•	/ Nomad/ Brick Kiln	/ Construction site	1	
3. Hospitalization:	Yes /	No	Name of Hospital	nl://		Date of Dischar	ge/LAMA/Death:		-	
4. Vaccination Status:	Has the	case ever	received one or	more vaccines (of	any listed helow) ir	n his or her lifetim	ne? Yes/No/Unki	nown		
41 Vaccination Status.				eceived irrespective			6. 10071107 CIIII			
	At bir	th	6 weeks	10 weeks	14 weeks	9 months	16 months	5 years	Others	7
	OPV (OPV 1	OPV 2	OPV 3	M1 / MR1 /	M2 / MR2 /	DPT Booster	Td 10	1
	BCG	,	DPT 1	DPT 2	DPT 3		MMR2 / MMRV2	DI I Doostel	Td 16	
	HepB	0	Pentavalent 1	Pentavalent 2	Pentavalent 3	JE 1	DPT Booster		Tdap	
	Перь	U	HepB 1	Hep B 2	HepB 3	PCV 3	OPV Booster		TT	
			FIPV 1	Пер в 2	f-IPV 2 / IM-IPV		JE 2		HPV	
			PCV 1		PCV 2		JL Z		ITEV	
				Dotovisuo 2	Rotavirus 3					
			Rotavirus 1	Rotavirus 2				ı		
Source of vaccination statu		•	•				,			
Date of last dose of diphthe In case of NNT - Vaccinati			· ·	: For diphtheria (Tetanus Toxoid (17.	. ,	,	p)// fTT/Td:/	
5. Clinical Symptoms:			Duration of illnes	ss in days:						
Date of Onset: /			Diphtheria:		Pertussis:		Neonatal Tetanu	s:		
			Sore Throat Y	es / No	Pertussis: Duration of cough:		Neonatal Tetanus: Child sucked and cried normally at 0-2 days: Yes / No			
			Fever: Yes / N		Cough >2 weeks		Child sucked and cried normally at 0-2 days: Yes / No Onset of following symptom(s) at 3-28 days of age:			
Diphtheria*:				dherent membrane	Paroxysms of co	ugh: Yes / No	_	suck and cry: Y		
Date of onset of sore throa	at		in throat: Yes /		Cough leading to	•	Stiffness:	Yes / No		
Pertussis*:			Bloody nasal dis	scharge: Yes / No	Yes / No	Ü	Spasms /	Seizures: Yes /	No	
Date of onset of cough			Hoarseness of	-	Whoop: Yes / N	No		s, precipitated by		
Neonatal Tetanus*:			Bull neck: Yes /	No	Apnoea: Yes /		Delivery: Institution)
Date of onset of inability to	suck		Nasal regurgitat		Cyanosis: Yes /		If home delivery, b		(-17:	
,				owing: Yes / No	History of active		Medical doctor / N	urse / ANM / Othe	er (Specify:	_)
			Difficulty in breat	=	chronic URTI: Y		Any substance ap	plied on cord: No	ne / Medicine / Oth	er
				3	Clinician suspicio Yes / No	n of pertussis:	If other substance,			
*Diphtheria: An illness of u pharynx and/or nose	ipper re	spiratory t	ract characterized	by the following:• I		haryngitis or pha	ryngitis or tonsillitis <i>i</i>	AND • adherent n	nembranes of tonsil	s,
*Pertussis: A person with a		-	•	•				ns (i.e. fits) of coug	hing • inspiratory v	whooping
*Neonatal tetanus: Any ne or has convulsions/spasm			•		•		•	•	normally,and beco	mes stiff
				all augmented VD	_					

CIF (Page 2)				EPID No.:	DTH / PTS / N	NT - IND		
6. Treatment History:	Antibiotic	given: Yes /No /	Unknown	if Yes: Antibiotic start	ed before specime	en collection: Yes /	No / Unknown	
(Ask if it is possible to see medication to confirm antibiotic type						zole/Clarithromycin/	Tetracydine/Doxycydine/	
	Diphther	ia Antitoxin (DAT)): Y / N / Unkno	own / Not Applicable (not a diphtheria ca	ise)	Dose of DAT:IU	
	Reason	for not giving anti	toxin: DAT not	available / Other		_		
7. Contact History:								
History of contact with a laborato Similar symptoms in other house Similar symptoms in other neighl	hold conta	act(s): Yes / No		If yes, EPID No of la If yes, No. of sick cor No. If yes, No. of sick c	ntacts:	details:		
8. Travel History:	Travel o	f suspected case	prior to onset (indicate dates and pla	ce of travel with ar	rows on date line)		
-21 -20 -19	-18	-17 -16 -15	-14 -13	-12 -11 -10	-9 -8 -7	-6 -5 -	4 -3 -2 -1 0	
			Diphtheria:				→	
Pertussis:				Incubation period (range	-)	Mart Plata a second at	to the state of an	
							getting infection	
Requires cross notification? Yes	s / No			On the control of the				
If yes, date of cross notification:				Block/ Urban are		• ,		
				(In case of Neonatal	Tetanus, block of	delivery)		
9. History of contacts with h	ealthcare	providers after	the date of c	onset (including re	porting health fa	acility):		
Name & address of Hospital/doctor:	1		2		3		4	
Phone no. / Email ID								
Dates case visited:								
Already RU/informer?	Yes/No Yes/No Yes/No		s/No	Yes/No				
Did they report this case?		Yes/No		Yes/No	Yes/No		Yes/No	
Date of sensitization visit/ Actions taken to improve case reporting								
10. Specimen Collection:								
	Number	Date Collected	Date Sent	Name of Lab	Date of Result	Condition	Laboratory Result	
Throat swab (Diphtheria)		!!				Good / Poor	Positive / Negative / Other	
Nasopharyngeal swab (DTH/PTS)		1 1	, ,		1 1	0.115	5 11 11 1 101	
Serum (Pertussis)						Good / Poor	Positive / Negative / Other	
If no specimen is collected, reason	on for not	collecting specime	en: Death	/ Notwilling / Lost	to follow-up / Lo	Good / Poor	Positive / Negative / Equivocal	
11. Active Case Search, Con	tact Trac	ing and Respor	nse in Commu	unity: Fill this in	nformation from VP	D-ACS format		
If yes, Date of search:/_ Number of contacts identified:	/_			ividuals verified: ntacts received antibio	ics:	Number of suspections Number of susceptions		
12. Final Classification:		Laboratory confi	irmed / Epi-li	nked / Clinically cor	mpatible / Rejec	ted / Confirmed NN	NT	
13. 60 Day follow-up (telepho	onic)	Date of follow-up	o://		Outcome: Alive	/ Lost / Death (Dea	th date:/)	
	: Myocardi Pneumonia 'etanus: F	tis / Paralysis (pala / Seizures / Encep Residual weaknes	ohalopathy / Otiti ss / Delayed m	s media / Pressure effec			s media / Respiratory insufficiency / Other atomas, hemias, rectal prolapse) / Other	

49 ___

Annex 2: VPD-ACS DTH/PTS Form

Active Case Search (ACS) and Public Health Response for Suspected Diphtheria and Pertussis Case

											1/2/		>7	yea
											2/3/4		1-7	year
	/										0/1/2/3/4/5/ 0/1/2/3/4/5/ 0/1/2/3/4/5/	⊃	<1 1-7 >7	year year yea
	/										1/2/			year year year year year
_											2/3/4		1-7	year
ng Uni	Date of visit										0/1/	⊃	1	year
PHC/Planning Unit	Date										4/5/		2<	year
PHC.											2/3/		1-7	year
											0/1/	⊃	<u>۲</u>	
											2/N		/ <	year
											13/4/			year
										_	0/1/2		<1 1-7	year year
	mbers										2/N		2<	year
	Team Members										2/3/4/		1-7	year
District	<u> </u>									_	0/1/2		^	year
Ä											12/N		2<	year
											2/3/4			
										_	0/1/		<1 1-7	year
State	Village/Area	Serial number of household	Name of head of the family	Religion (H/M/O)	Total members in family (all	age)	Number of suspected cases	found (provide details below)	Age of youngest child in family	(<15 yr) (Yr/Mon)	No. of pentavalent / DPT doses 0/1/2/3/4/5/U 0/1/2/3/4/5/U 0/1/2/3/4/5/U	to youngest child	No. of members are close	contact with index or suspected year year
-,		É	_	_	Ė.	٠٠	_	1		_	_	_	_	_

year

Details of suspected cases:

vaccine

No. of close contacts and/or unand under immunized in family

9

No. of members received

No. of close contacts received antibiotics

Hospitalization Diphtheria: Pertussis: Cough (Y/N) Sore throat of >2 weeks	Z >	N / >	N / X	N / >	N / X
Diphtheria: Sore throat	N / > N / >	N/A N/A	N / }	/	N / X N / X
Hospitalization (Y/N)	Z ->	N / X	N / X	N / X	N / X
Age (Yrs/Mnths)	/	<i> ,</i>	— / —	/	/
Sex	M / F	M / F	M / F	M / F	M / F
Name of school/ work place					
Phone Number					
Patient's name & Address					
SI. House No. No.					
Si. No.	_	2	3	4	5

Antibiotics prophylaxis (erythromycin/azithromycin) for seven days to close contacts which are household contacts, people with direct contact (e.g. caretakers, relatives, sexual contacts, friends Diphtheria: Vaccination - At least a single dose of age appropriate vaccine for close contacts, left outs, drop outs and persons who have not taken DPT containing vaccine in last 5 years. w ho regularly visit the home, students), health care worker; monitor close contact for sign and symptoms for 10 days from the date of the last contact with a suspected case.

Pertussis: Vaccination - At least single dose of Penta/DPT to children who are left out or drop out; Antibiotic prophylaxis - To infants and close contacts (family contact, overnight stay in same room, direct contact with a lab confirmed case)

Annex 3: VPD-ACS NT Form	ll entered to the second of th
VPD-ACS_NT	Rapid Community Survey for Neonatal Tetanus Case and Response
State	District
PHC/Planning Unit	Village/Area
Team Members	Date of visit://

_	1 Serial number of household										
2	Name of head of the family										
3	Religion (H / M / O)										
4	Caste										
L	Name of mother who has										
C	delivered in last 2 years										
	No. of TTCV doses received	0/1/2/	0/1/2/	0/1/2/	0/1/2/	0/1/2/	0/1/2/	0/1/2/	0/1/2/	0/1/2/	0/1/2/
9	during last pregnancy	unknown	unknown	unknown	unknown	unknown	unknown	unknown	unknown	unknown	unknown
	(protected if 2 doses received)										
	No. of TTCV doses received in	0/1/2/3/	0/1/2/3/	0/1/2/3/	0/1/2/3/	0/1/2/3/ 0/1/2/3/	0/1/2/3/	0/1/2/3/	0/1/2/3/	2/3/	0/1/2/3/
7	all pregnancies (protected if 3	>3/	>3/	>3/	>3/	>3/	>3/	>3/	>3/	>3/	>3/
	or more doses received)	unknown	unknown	unknown	unknown	unknown	unknown	unknown	unknown	unknown	unknown
α	Place of delivery (home /										
0	hospital / other-specify)										
	If home delivery, birth attended										
6	by (doctor, nurse, ANM, Dai /										
	TBA, relative, other-specify)										
10	Any substance applied on cord	Yes/No	Yes/No	Yes/No	Yes/No	Ves/No	Yes/No	Yes/No	Yes/No	Yes/No	Yes / No
	If yes, write the name of										
7	substance (none, medicine, oil, other-specify)										
,	╫										
12	Date of birth of last born child										
4	Survival status of last born	Alive /	Alive /	Alive /	Alive /	Alive /	Alive /	Alive /	Alive /	Alive /	Alive /
2	child	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead	Dead
14	No. of doses of Pentavalent	0/1/2/3/	0/1/2/3/ 0/1/2/3/	0/1/2/3/	0/1/2/3/	0/1/2/3/	0/1/2/3/ 0/1/2/3/	0/1/2/3/	0/1/2/3/	0/1/2/3/	0/1/2/3/
<u>†</u>	vaccine received by child	unknown	unknown	unknown unknown unknown	unknown	unknown	unknown unknown unknown	unknown	unknown unknown	unknown	unknown

Summary: No. of mothers received 2 doses during last pregnancy or 3 or more doses during all pregnancies_		; No. of mothers vaccinated with TTCV following
community survey		
No. of mothers delivered at hospital		
No. of mothers did not apply any substance on cord		
No. of children who were eligible for Penta 3 vaccine		
No. of eligible children had not received Penta 3 vaccine	: No. of children vaccinated for the	: No. of children vaccinated for their missed doses following community survey

Annex 4: Diphtheria antitoxin (DAT) administration*

Route

The IV route is the preferred route of administration of DAT, especially in severe cases. The antitoxin dose should be mixed in 250–500 mL of normal saline and administered slowly over 2–4 hours, closely monitoring for anaphylaxis. The antitoxin may be given IM in mild or moderate cases.

Temperature

Antitoxin should be warmed to 32–34°C (90–95°F) before injection. Warming above the recommended temperature should be carefully avoided because the DAT proteins will denature.

Dosage

- A. Perform sensitivity tests, and desensitization if necessary.
- B. Give the entire treatment dose of antitoxin IV (or IM) in a single administration (except for series of injections needed for desensitization).
- C. The recommended DAT treatment dosage ranges are:

Pediatric and adult DAT dose

Diphtheria clinical presentation	DAT dose (units)
Pharyngeal or laryngeal disease of 2 days duration	20 000–40 000
Nasopharyngeal disease	40 000–60 000
Extensive disease of 3 or more days duration, or any patient with diffuse swelling of neck	80 000–100 000
Skin lesions only (rare case where treatment is indicated)	20 000–40 000

- D. Give children the same dose as adults.
- E. Repeated doses of DAT after an appropriate initial dose are not recommended and may increase the risk of adverse reactions.

Appropriate antimicrobial agents in full therapeutic dosages should be started immediately upon suspicion of respiratory diphtheria (and ideally after specimen collection). For cutaneous diphtheria, antitoxin is rarely required; attention should focus on wound hygiene and antimicrobial agent treatment. The antibiotic of choice for treatment of cutaneous diphtheria is erythromycin or penicillin.

Any person with clinical symptoms of diphtheria should receive DAT as soon as it can be made available, without waiting for bacteriologic confirmation of the diagnosis. Supportive treatment should be continued until all local and general symptoms are controlled.

(https://www.cdc.gov/diphtheria/downloads/protocol.pdf, accessed 26 August 2019).

^{*}Expanded Access Investigational New Drug (IND) Application Protocol: Use of Diphtheria Antitoxin (DAT) for suspected Diphtheria Cases, Version Number 7.0. Atlanta: Centers for Disease Control and Prevention; 2016

Annex 5: Surveillance forms

Form VPD - H001

ASSESSMENT OF HOSPITAL SURVEILLANCE FOR ENROLLMENT

	AS A REPORTING UNIT (RU) I Date of Visit:		
	Name and address of Hospital:		
			State:
3.	Is there a registry of all patients seen in the out	-patient department?	Yes / No
	If yes, does the registry include: suspected diag (Circle)	nosis / chief complaints / address of	current residence?
	If yes, does the registrar/staff know to report ca	ases of VPD?	Yes / No
	If there is a registry, review the past month Diphtheria; Pertussis	and enter no. of VPD found here	e: AFP; MR
ŀ.	Is there a registry of all patients admitted?		Yes / No
	If yes, does the registry include: suspected diag (Circle)	nosis / chief complaints / address of	current residence?
	If yes, does the registrar/staff know to report ca	ases of VPD?	Yes / No
	If there is a registry, review the past month and	enter no. of VPD found below:	
	AFP; M-R; Diphtheria	; Pertussis; Neonatal Tetanu	S
).	Is there a registry of all patients discharged?		Yes / No
	If yes, does the registry include: discharge diagr	nosis / address of current residence?	(Circle)
	If yes, does the registrar $/$ staff know to report $arphi$		Yes / No
	If there is a registry, review the past month and	enterno. of VPD cases found below	<i>i</i> :
	AFP; M-R; Diphtheria	; Pertussis; Neonatal Tetanu	S
i.	Are medical records filed by date of admission,	date of discharge, alphabetical, or o	ther method?
	(Circle)		
	If by date of discharge, enter the number VPD o	ases found in the last month here:	
	AFP; M-R; Diphtheria	; Pertussis; Neonatal Tetanu	s
	Are cases seen in the out-patient department re	eported to the district health office?	Yes / No
	Are admitted cases reported to the district heal		Yes / No
).	Are all VPD cases reported before diagnosis is c	onfirmed?	Yes / No
	Is there one person responsible for reporting		Yes / No
	If yes, who? Name:	_ Telephone No. :	
1	To whom are reports sent?		
	How are reports communicated? telephone/	fax / meeting / SMS /email / Whats A	
	Are "NIL" reports made?		Yes / No
.4	Number of VPD cases reported last year:		
	AFP; M-R; Diphtheria		nus
	Who is responsible for case investigation and		
	Name:	Telephone No.:	
16	i. Who is responsible for sample collection?		
	Name:	Telephone No.:	
	'. Sample collection kit available: AFP – Yes / No	; MR – Yes / No; Diphtheria & Pertu	
8	Meeting with Hospital Director		Yes / No
	Name:	Telephone No. :	
9	Meeting with Chief of Paediatrics?		Yes / No
	Name: Meeting with Chief of Neurology?	Telephone No. :	
20.	Meeting with Chief of Neurology?		Yes / No
	Name: Scheduled presentation of medical staff. Date	Telephone No. :	
	Scheduled presentation of medical staff. Date	· Time	

Form VPD-H002 ACUTE FLACCID PARALYSIS AND VPD SURVEILLANCE - WEEKLY HOSPITAL REPORT									
	After review of all wards and registry books, please send this report to the following person every Monday.								
Name:									
Address:									
Tel./Fax:				Mobile:	E-Mail:				
Name of Reporting Hospital: Year:									
Week No. Period included in the report: From: To:									
Number of AFP/ suspected VPD cases Identified: AFP Measles Diphtheria Pertussis Neonatal Tetanu If no cases were identified, write Zero (0)						tal Tetanus			
		#	AEFI: S	erious Severe					
Write the case det	tails of AFP o	ases	identified ar	nd reported this week					
Patient's name and Father's name	Age in months	Sex	Addre	ess / Village name and landmark	Block	name	District name		
	<u> </u>		<u> </u>						
Information on sus	spected case	s of \	/PDs (Measl	es, Diphtheria, Pertussis and Neonata	al Tetanus):				
Patient's name and Father's name	Age in months	Sex	Contact Number	Village name and landmark	Block name	District name	Outcome: Died? (Y/N/U) [#]	Type of VPD (M / D / P / T) ^{##}	
# Y=Yes, N=No, U=u	nknown		## M =M easles	s, D=Diphtheria, P=Pertussis, T=Neonatal Tetanus	3	<u>I</u>	l		
Name of person	filling this re	eport:							
Date report sent	to District:								
Approval of Med	ical Directo	r:							

Form VPD-D001											
FOIIII VPD-DUUT	ACUTE FLACCID PARALYSIS AND VPD SURVEILLANCE SYSTEM - WEEKLY DISTRICT REPORT										
Please send this r	eport to the following	•	-	•							
Tel./Fax:		Mobile:									
	ı district:			Year:							
Week No:	Period in	cluded in t	he report:	From:				То:			
Number of units e	expected to report:						Number	of units reporti	ing on time	::	-
Number of AFP/ s	uspected VPD cases	dentified	: AFP	Measles	DTH	PTS	NNT	AEFI	Seriou	ıs	
	dentified, write Zero								Sever	е	
Names of Reporti	Names of Reporting Units not reported on time this week:										
Write EPID num	bers of AFP cases	s identifie	d and rep	orted th	is week:						
Write EDID num	hara of augmented	d V/DD agai	oo idontif	ied end	ranartad	thic wook					
Measles	bers of suspected	Diphtheria		ied and	reported	Pertussis			Neonatal	Tetanus (NN	<u></u>
Fill up informat	ion on all suspec	ted measl	es cases	below							
	Plack non	Block name Numbe				of Dootho		Flagged for	r preliminaı	ry investigation	on
	DIOCK Hallie		Number of Cases		Number of Deaths		Y/N	If No, give re	ason If	f Yes, allot Οι	ıtbreak ID (#)
Blocks within											
the reporting											
district											
	District to										
Blocks outside	of reporting distr	ict						0 115	14 41	15:4	
District name	Block nan	ne	Number	of Cases	Number	of Deaths	Y/N If No, give reason			he concerned District? If Yes, date cross-notified to	
							1/13	II NO, GIVE IC	11	res, date ere	33-Hotilica to
Cases f	mber of measles dea rom previous week s s weeks should be o	should also	be consid				nary inve	estigation. Simil	larly deaths	s in cases rep	orted from
The reas	sons for not flaggin	• .	-	-							
	1 - there are less th4 - suspected meas	•									
	investigated ou							-	,		
Name of person fi	Name of person filling out report: Date report sent to State:										
	ct Immunization Off	icer			<u> </u>			_ 222 . 2 6 6 1 6 0 0 1			
	All c	listricts sho	ould report	weekly e	ven if no	cases of AF	P, MR or	VPD were ident	tified		

Form VPD-S001								
ACUTE FLACCID PARALYSIS AND VPD SURVEILLANCE SYSTEM - WEEKLY STATE REPORT Please send this report to the following person every Wednesday:								
		Address:						
Tel./Fax:		Mobile:		_	E-Mail:			
Name of reporting Names of Repor	state: ting Units not reported	Year: on time this week:						
Week No:	Period included	in the report: From	:			То:		
Number of units e	xpected to report:			Number o	f units r	eporting on time	e:	_
Number of AFP/ su	uspected VPD cases Identi	AFP Meas	sles DTH	PTS	NNT	AEFI	Serious	
If no cases were id	dentified, write Zero (0)]	Severe	
Names of Repor	ting Units not reported	on time this week:				L	Ocvere	
	g							
Write EPID num	bers of AFP cases ident	ified and reported	this week:					
Write EPID num	bers of suspected VPD	cases identified an	d reported th	is week:				
Measles		ria (DTH)	ia roportoa ti	Pertussis	(PTS)	N	eonatal Tet	anus (NNT)
								, ,
Fill up informati	ion on all suspected me	easles cases below	1					_
·			Number	Number	i laggou i		r preliminary investigation	
	District name	Block name	of Cases	of Deaths	Y/N	If No, give reas	son If Yes	s, mention Outbreak ID (#)
				Doutho				(#)
Blocks within								
the reporting								
state								
	21.1						_	
	State	total:						
Districts outside	e of reporting state:		1	Normalian	1	Cross notifies	l to the son	cerned State?
State name	District name	Block name	Number	Number of			If Yes	, date cross-notified to
			of Cases	Deaths	Y/N	If No, give reas	sonı	ne concerned State
Note: The num	show of manalog dooths abo	uld be sounted so m						
Note: The number of measles deaths should be counted as measles cases also. Cases from previous week should also be considered while flagging for preliminary investigation. Similarly deaths in cases reported from previous weeks should be considered. The reasons for not flagging for preliminary investigation are:								
 1 - there are less than 5 suspected measles cases and no deaths in a block in continuous 4 weeks 4 - suspected measles cases or death due to measles reported in this week belongs to an already investigated outbreak, In this case mention the outbreak Id. already allotted (#) 								
Name of person fil						Date report se	nt to GoI: _	
Approval of State	Immunization Officer							
All states should report weekly even if no cases of AFP, MR or VPD were identified								

DPT Surveillance

EPID Number:

LABORATORY REQUEST FORM

DTH / PTS / NNT-IND-__--_--_-

(To refer specimens to the laboratories)

(matches VPD Case Investigation Form)

PART I: Case detail	s to refer specimer	ıs :		
Case Information :				
Patient's name :		FatI	ner's name :	
Sex :	Date of birth :/_		Age: years	months
Address :			Village/City:	
District :		St	ate :	
Date of onset :/_		Diphtheria: sore throat/ P	ertussis: cough/ Neonatal Teta	nus: inability to suck)
Specimen collection :	Type of specimen	Number Date spe	cimen collected	Date specimen sent
	Throat swab			
	Nasopharyngeal swab	·		
	Serum			
Name of person investigation	ng & sending the specim	en :		
Address :				
DART III. Beceiving	at Laboratom.			
PART II: Receiving a	Lab ID Number	Date specimen recei	ved Condition of specim	en If poor specify
Throat swab 1			Good / Poor	p
Throat swab 2			Good / Poor	
Nasopharyngeal swab 1			Good / Poor	
Nasopharyngeal swab 2			Good / Poor	
Serum			Good / Poor	
Signature :		_		

Annex 6: Supportive Supervision Form – VPD Surveillance

Name of supervisor	Name of district
Facility reviewed	Block

Awareness of case definition and reporting protocol

- Number of health staff interviewed -
- Number of health staff aware of case definition and reporting protocol-
- Overall impression of awareness Good / Satisfactory / Needs improvement / Alarming
- Recommendations and follow up plans -

Assessment of records

- Number of unreported VPD case found -
- Status of documentation –
- Overall impression of record maintenance Good / Satisfactory / Needs improvement / Alarming
- Recommendations and follow up plans –

Availability of logistics

- Availability of logistics of sample collection –
- Availability of surveillance forms -
- Recommendations and follow up plans -

Quality of case investigation

- Quality and completeness of CIF (if possible visit a case to verify details) –
- Overall impression of case investigation Good / Satisfactory / Needs improvement / Alarming
- Recommendations and follow up plans -

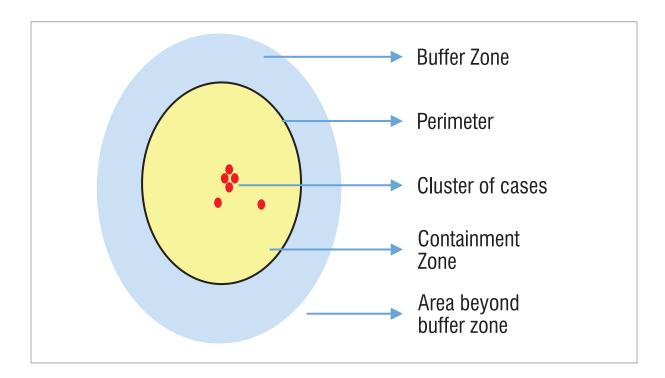
- 64					
Λ	ddi	tiona	TIM!	orma	tion
-					

Annex 7: VPD surveillance during the COVID-19 pandemic

The COVID-19 pandemic is challenging health systems across the world. Rapidly increasing demand for care of people with COVID-19 is compounded by fear, misinformation and restrictions on movement of people and supplies that may disrupt the health care delivery. When health systems are overwhelmed and people fail to access needed services, both direct and indirect mortality from vaccine preventable diseases are likely to increase. Hence, VPD surveillance should be reinforced to enable early detection, outbreak response and management of VPD cases.

Health services including immunization are deemed as essential and need to be functional across the country, as per Ministry of Home Affairs (MHA) order dated 15th April 2020. Depending upon the COVID-19 situation, areas are categorized as:

- Containment Zone: Areas where COVID-19 cases are reported
- Buffer Zone: Areas surrounding Containment Zone
- **Area beyond Buffer Zone:** Outside the Buffer Zone



The categorization of 'Containment Zone' and 'Buffer Zone' is a dynamic process based on active COVID-19 cases and is updated regularly.

Basic principles for delivery of services in the context of COVID-19 outbreak:

- 1. Guidelines from MHA and MoHFW pertaining to COVID-19 and related updates will be the primary reference points and no state should violate any COVID-19 guidance.
- 2. Practices of social distancing, hand washing, and respiratory hygiene need to be followed at all levels.

This guidance addresses specific aspects of conducting VPD surveillance activities, while also ensuring safety of health personnel in the context of COVID-19 and outlines basic principles and practical recommendations for the same.

- **Desk review of surveillance data:** is an important tool to monitor the ongoing activities and should be regularly carried out to provide feedback to the authorities during district weekly review meetings. Data reviews should drive actions such as increase in telephonic active case searches (ACS), feedback and directives to Medical Officer In-charges (MOIC). Key indicators for the review should include tracking of case investigation, flagging of outbreak and investigation, sample collection including adequacy, discard rate, weekly comparison of number of suspected cases and health facility contact analysis. Feedback from activities undertaken for quality assurance of case investigation form (CIF) and sample collection should be included. Monthly surveillance indicators and feedback on identified issues should be shared with district officials through WhatsApp/email.
- **Directive from District administration to blocks:** Relevant district authorities should send written communication (letter/email/WhatsApp) to blocks/health facilities to maintain surveillance and response to AFP, measles, rubella, diphtheria, pertussis and neonatal tetanus (NNT) cases while ensuring appropriate infection prevention and control measures as per MOHFW guidelines.

Table 7. Guidance on Key Surveillance Activities in COVID-19 Defined Zones

	Activity	Containment & Buffer Zone	Areas beyond Buffer Zone
1.	Sensitization of reporting sites	Telephonic contact and other virtual platforms	Active surveillance visits in all priority reporting sites
2.	Surveillance workshops	Utilize virtual platform or small batches	Utilize virtual platform or small batches
3.	Case notification & tracking	✓	✓
4.	Case investigation by MOs	PPE Kits and other measures	✓
5.	Sample collection	PPE kits and other measures	✓
6.	Sample shipment	√	✓
7.	House to house searches	Limited with PPE kits and other measures	√

Following standard guidelines of COVID-19 like social distancing, mask, PPE use in containment zone

- 1.1 Sensitization of reporting sites by Surveillance Medical Officer/District Immunization Officer/Nodal Officer
 - Active Case Searches (ACS)
 - In areas beyond Buffer Zone: ACS as per existing guidelines
 - ▶ In Containment and Buffer Zones: telephonic ACS and other virtual platforms. Frequency of telephonic ACS will be as per routine norms

- Block wise reporting sites (RS) may be allocated to different staff for ACS to avoid duplication.
- DIO office/Administrative Assistant (AA) from WHO NPSP unit may conduct telephonic ACS in the low priority reporting sites while Health staff/Field Monitor /Immunization Field Volunteer (IFV), where applicable will conduct the ACS by visiting the low priority reporting sites (LPs), unqualified practitioners and potential informers. In areas with travel restrictions, Health staff/AAs/FMs/IFVs will ensure sensitization through telephonic ACS. The telephonic ACS thus conducted should be documented in the in D-004/modified D-003 and at the same time they should also track sample collection and shipment.

Surveillance workshops:

Workshops should be done using online video conferencing applications available at block level through personal computers/smart phones. Avoid physical gathering of large number of participants within a confined room. If unavoidable, then plan in small batches, ensuring physical distancing measures. Thermal screening of participants should be carried out before they enter the training venue, and any febrile person or having COVID-19 like symptoms should not attend the training.

1.2 Case notification/tracking register:

The register should be maintained at health facility for regular tracking of cases and thus identify reasons for delay in case investigation, sample collection, sample shipment from field to District Immunization Officer (DIO)/Surveillance Medical Officer (SMO) office and shipment from office to laboratory.

1.3 Case investigation by Medical Officers:

- In areas beyond buffer zone: standard IPC measures (wearing of triple layer mask/N-95 mask* and gloves) should be followed as per the available guidelines.
- In Containment and Buffer Zones: use PPE kits and other IPC measures should be followed
 - o **NOTE:** any medical staff having symptoms consistent with COVID-19 should not participate in case investigation, sample collection and transportation.
 - o Any case suspected to have COVID-19 should be encouraged to wear a mask.

1.4 Sample collection and transportation:

- In areas beyond Buffer Zone: standard IPC measures should be followed as per the available guidelines.
- In Containment and Buffer Zone: use PPE kits and other IPC measures should be followed.
- If transport is not available for shipment to district, it can be stored at the block level health facility either in sample carrier (daily change of icepack should be done) or in a freezer if available. Serum can be stored at 4-8°C for a maximum period of 7 days, beyond which it must be frozen at -20°C and subsequently should be transported to the designated laboratory. Repeated freezing and thawing should be avoided as it has detrimental effect on the stability of IgM antibodies. Use standard IPC measures including wearing triple layer medical mask and gloves along with hand hygiene measures.

1.5 Conducting house to house case searches

- In area beyond Buffer Zone: standard IPC measures should be followed as per the available guidelines. House to house case searches, including during outbreak investigations should be conducted with IPC measures, including physical distancing and hand and respiratory hygiene. Interview should be conducted outdoors or in a well-ventilated space
- In Containment and Buffer Zone: limited house to house searches. Use of PPE kits and other IPC measures should be followed.

1.6 Protecting self through infection prevention and control (IPC) measures

Physical distancing, hand and respiratory hygiene and the use of appropriate personal protective equipment (PPE) according to a risk assessment.

- Avoid touching any surface (e.g. door handle, handrails, etc.) in the hospital. If any surface is touched, immediately sanitize hands using alcohol-based hand rub.
- Wear gloves when touching blood, body fluids, secretions, excretions, mucous membrane or skin. Immediately perform hand hygiene in case of any such contact.
- Preferably do not sit anywhere within the hospital standing is a much better option.
- Follow the Guidelines on Rational Use of Personal Protective Equipment issued by Directorate General of Health Services [Emergency Medical Relief], Govt. of India

Table 8: Recommended PPE while doing VPD surveillance

S. No.	Setting	Recommended PPE	Remarks
1.	Telephonic interview of suspected/confirmed cases	No PPE required	
2.	In-person interview of suspect/ confirmed cases	Triple layer mask White coat (full-sleeved)	Physical distancing; hand hygiene Interview to be done outdoors Patient to wear triple layer mask
3.	Non-COVID field activities, like case investigations, concurrent monitoring etc.	Triple layer mask	Physical distancing; hand hygiene; Respiratory hygiene/ Cough etiquette Interview/examination to be done outdoors (if possible)
4.	Handling of clinical samples –	Triple layer mask	Hand hygiene after handling of
	stool, blood, serum, swab	Gloves	specimen

REFERENCES

- 1. Pertussis vaccines: WHO position paper. Wkly. Epidemiol. Rec. 2015;90(35):433–5 (http://www.who.int/wer/2015/wer9035.pdf?ua=1, accessed 26 August 2019).
- 2. WHO SAGE pertussis working group. Background paper. Geneva:World Health Organization; 2014 (www.who.int > sage > 2014 > april > 1_Pertussis_background_FINAL4_web, accessed 26 August 2019).
- 3. Diphtheria vaccine: WHO position paper August 2017. Wkly. Epidemiol. Rec. 2017;92(31):417–36 (http://www.who.int/immunization/policy/position_papers/wer_ 31_diphtheria_updated_position_paper.pdf?ua=1).
- 4. Crowcroft NS, Pebody RG. Recent developments in pertussis. Lancet. 2006;367:1926–36.
- 5. Tetanus vaccines: WHO Position Paper February 2017. Wkly. Epidemiol. Rec. 2017;92(6):53–76 (http://apps.who.int/iris/bitstream/10665/254582/1/WER9206.pdf?ua=1).
- 6. Roper MH, Vandelaer JH, Gasse FL. Maternal and neonatal tetanus. Lancet. 2007;370(9603): 1947–59.
- 7. Roper MH, Wassilak SGF, Tiwari TSP, Orenstein WA. Tetanus toxoid. In: Plotkin S, Orenstein W, Offit P, editors. Vaccines, sixth editon. Philadelphia: Sauders; 2013: 447–92.
- 8. Pertussis. In: Surveillance Standards for Vaccine-Preventable Diseases, second edition. Geneva: World Health Organization; 2018 (https://www.who.int/immunization/monitoring_surveillance/burden/vpd/standards/en/, accessed 26 August 2019).
- 9. WHO/UNICEF guidance note. Ensuring sustained protection against diphtheria: Replacing TT with Td vaccine: Geneva and New York. World Health Organization and United Nations Children's Fund. 2018.
- 10. Diphtheria. In: Surveillance Standards for Vaccine-Preventable Diseases, second edition. Geneva: World Health Organization; 2018 (https://www.who.int/immunization/monitoring_surveillance/burden/vpd/standards/en/, accessed 26 August 2019).
- 11. Neonatal Tetanus. In: Surveillance Standards for Vaccine-Preventable Diseases, second edition. Geneva: World Health Organization; 2018.
- 12. WHO Model Formulary 2008. Geneva: World Health Organization; 2009 (http://apps.who.int/medicines.docs/documents/s16879e/s16879e.pdf, accessed 26 August 2019).
- 13. Pertussis (whooping cough) Treatment [website]. Atlanta, USA: Centers for Disease Control and Prevention; 2017 (https://www.cdc.gov/pertussis/clinical/treatment.html, accessed 26 August 2019).
- 14. Surveillance Guide for Vaccine-Preventable Diseases in the WHO South-East Asia Region Module-4 Diphtheria. New Delhi: World Health Organization Regional Office for South-East Asia; 2017.

Additional References:

World Health Organization. Diphtheria Vaccine; WHO position paper. Weekly Epidemiological Record; 2006. p. 24-32.

World Health Organization. Pertussis Vaccine; WHO position paper. Weekly Epidemiological Record; 2010. p. 385-400.

World Health Organization. Revised guidance on the choice of pertussis vaccines. Weekly Epidemiological Record; 2014. p. 337-40.

World Health Organization. Tetanus vaccine: WHO position paper. http://www.who.int/wer:, 2006.p. 198-207

Early Warning and Response to Outbreaks and other Public Health Events: A Guide. World Health Organization Regional Office for South-East Asia; 2008.

Scheifele DW, Ochnio JJ. The immunological basis for immunization series: module 2: diphtheria - Update 2009: World Health Organization; 2010.

Wirsing von König CH. The immunological basis for immunization series: module 4: pertussis - Update 2009: World Health Organization; 2010.

Borrow R, Balmer P, Roper MH. The immunological basis for immunization series Module 3: Tetanus Update 2006. World Health Organization; 2007.

IHR Core Capacity Monitoring Framework: Checklist and Indicators for Monitoring Progress in the Development of IHR Core Capacities in States Parties: World Health Organization; 2011.

Tiwari TSP. Manual for the surveillance of Vaccine-Preventable Diseases, 5th edition, Chapter 1: Diphtheria. Roush SW, McIntyre L, Baldy LM, editors. Centers for Disease Control and Prevention, Atlanta, GA: Centers for Disease Control and Prevention; 2011.

Faulkner A, Skoff T, Martin S, Cassiday P, Tondella ML, Liang J et al. Manual for the surveillance of Vaccine-Preventable Diseases, 5th edition, Chapter 10: Pertussis. Roush SW, McIntyre L, Baldy LM, editors. Centers for Disease Control and Prevention, Atlanta, GA: Centers for Disease Control and Prevention; 2011.

Tiwari TSP. Manual for the surveillance of Vaccine-Preventable Diseases, 5th edition, Chapter 16: Tetanus. Roush SW, McIntyre L, Baldy LM, editors. Centers for Disease Control and Prevention, Atlanta, GA: Centers for Disease Control and Prevention; 2011.

Crespo I, Cardeñosa N, Godoy P, Carmona G, Sala MR, Barrabeig I, et al. Epidemiology of pertussis in a country with high vaccination coverage. Vaccine. 2011;29(25):4244-8.

Daley MF, Yih WK, Glanz JM, Hambidge SJ, Narwaney KJ, Yin R, et al. Safety of diphtheria, tetanus, acellular pertussis and inactivated poliovirus (DTaP-IPV) vaccine. Vaccine. 2014;32(25):3019-24.

Efstratiou A, Engler KH, Mazurova IK, Glushkevich T, Vuopio-Varkila J, Popovic T. Current approaches to the laboratory diagnosis of diphtheria. J Infect Dis. 2000;181 Suppl 1:S138-45.

Efstratiou A, George RC. Laboratory guidelines for the diagnosis of infections caused by Corynebacterium diphtheriae and C. ulcerans. World Health Organization. Commun Dis Public Health. 1999;2(4):250-7.

Frumkin K. Pertussis and persistent cough: practical, clinical and epidemiologic issues. J Emerg Med. 2013;44(4):889-95.

George RC. Diphtheria. Medicine. 2005;33(7):31-3.

Ghanaie RM, Karimi A, Sadeghi H, Esteghamti A, Falah F, Armin S, et al. Sensitivity and specificity of the World Health Organization pertussis clinical case definition. Int J Infect Dis. 2010;14(12):e1072-5.

Hewlett EL, Edwards KM. Clinical practice. Pertussis--not just for kids. N Engl J Med. 2005;352(12):1215-22.

Jacob John T, Samuel R, Balraj V, John R. Disease surveillance at district level: a model for developing countries. The Lancet.352(9121):58-61.

John TJ, Rajappan K, Arjunan KK. Communicable diseases monitored by disease surveillance in Kottayam district, Kerala state, India. Indian J Med Res. 2004;120(2):86-93.

Kent A, Heath PT. Pertussis. Medicine. 2013;42(1):8-10.

Keramarou M, Evans MR. Completeness of infectious disease notification in the United Kingdom: A systematic review. Journal of Infection.64(6):555-64.

Lambo JA, Anokye EA. Prognostic factors for mortality in neonatal tetanus: a systematic review and meta-analysis. Int J Infect Dis. 2013;17(12):e1100-10.

Leber AL. Pertussis: relevant species and diagnostic update. Clin Lab Med. 2014;34(2):237-55.

M M, M R. Diphtheria in Andhra Pradesh-a clinical-epidemiological study. Int J Infect Dis. 2014;19:74-8.

Murhekar MV, Bitragunta S. Persistence of Diphtheria in India. Indian Journal of Community Medicine: Official Publication of Indian Association of Preventive & Social Medicine. 2011;36(2):164-5.

Murphy JR. Medical Microbiology. 4th edition. Chapter 32 Corynebacterium Diphtheriae. Baron S, editor. Galveston TX: University of Texas Medical Branch at Galveston; 1996.

Nandi R, De M, Browning S, Purkayastha P, Bhattacharjee AK. Diphtheria: the patch remains. The Journal of Laryngology & Otology. 2003;117(10):807-10.

Narang M, Khurana A, Gomber S, Choudhary N. Epidemiological trends of tetanus from East Delhi, India: a hospital-based study. J Infect Public Health. 2014;7(2):121-4.

Nath B, Mahanta TG. Investigation of an outbreak of diphtheria in borborooah block of dibrugarh district, assam. Indian J Community Med. 2010;35(3):436-8.

Raza SA, Avan BI. Disposable clean delivery kits and prevention of neonatal tetanus in the presence of skilled birth attendants. Int J Gynaecol Obstet. 2013;120(2):148-51.

Rodgers L, Martin SW, Cohn A, Budd J, Marcon M, Terranella A, et al. Epidemiologic and laboratory features of a large outbreak of pertussis-like illnesses associated with cocirculating Bordetella holmesii and Bordetella pertussis--Ohio, 2010-2011. Clin Infect Dis. 2013;56(3):322-31.

Roper MH, Vandelaer JH, Gasse FL. Maternal and neonatal tetanus. Lancet. 2007;370(9603): 1947-59.

Sadoh AE, Oladokun RE. Re-emergence of diphtheria and pertussis: Implications for Nigeria. Vaccine. 2012;30:7221-8.

Saikia L, Nath R, Saikia NJ, Choudhury G, Sarkar M. A diphtheria outbreak in Assam, India. Southeast Asian J Trop Med Public Health. 2010;41(3):647-52.

Sailaja B, Manoj VM, Yvan JH, Padmanabha PP, Mohan DG. Persistence of Diphtheria, Hyderabad, India, 2003–2006. Emerging Infectious Disease journal. 2008;14(7):1144.

Shakib JH, Wyman L, Gesteland PH, Staes CJ, Bennion DW, Byington CL. Should the pertussis case definition for public health reporting be refined? J Public Health Manag Pract. 2009;15(6):479-84.

Sharma N, Banavaliker J, Ranjan R, Kumar R. Bacteriological & epidemiological characteristics of diphtheria cases in & around Delhi - a retrospective study2007 December 1, 2007. 545-52 p.

Singh SN, Singh A, Chandra S. Clinical profile and predictors of poor outcome of hospitalized diphtheria cases in children from Lucknow region of North India. Clinical Epidemiology and Global Health. 2014;2(2):75-9.

Children's Vaccine Program at PATH. Guidelines for Implementing Supportive Supervision: A step-by-step guide with tools to support immunization. Seattle: PATH (2003).

Sow I, Alemu W, Nanyunja M, Duale S, Perry HN, Gaturuku P. Trained district health personnel and the performance of integrated disease surveillance in the WHO African region. East Afr J Public Health. 2010;7(1):16-9.

Thwaites CL, Beeching NJ, Newton CR. Maternal and neonatal tetanus. Lancet. 2014.

Thwaites CL, Farrar JJ. Magnesium sulphate as a first line therapy in the management of tetanus. Anaesthesia. 2003;58(3):286.

Thwaites CL, Yen LM, Loan HT, Thuy TT, Thwaites GE, Stepniewska K, et al. Magnesium sulphate for treatment of severe tetanus: a randomised controlled trial. Lancet. 2006;368(9545):1436-43.

Vandelaer J, Birmingham M, Gasse F, Kurian M, Shaw C, Garnier S. Tetanus in developing countries: an update on the Maternal and Neonatal Tetanus Elimination Initiative. Vaccine. 2003;21(24):3442-5.

Wagner KS, White JM, Lucenko I, Mercer D, Crowcroft NS, Neal S, et al. Diphtheria in the postepidemic period, Europe, 2000-2009. Emerg Infect Dis. 2012;18(2):217-25.

Wood N, McIntyre P. Pertussis: review of epidemiology, diagnosis, management and prevention. Paediatr Respir Rev. 2008;9(3):201-11; quiz 11-2.

Wu Y, Gao Y, Zhu B, Zhou H, Shi Z, Wang J, et al. Antitoxins for diphtheria and tetanus decline more slowly after vaccination with DTwP than with DTaP: a study in a Chinese population. Vaccine. 2014;32(22):2570-3.

Training for mid-level managers (MLM) Module 8: Making disease surveillance work: World Health Organization; 2008.

Communicable disease surveillance and response systems. Guide to monitoring and evaluating. World Health Organization; 2006.

World Health Organization Checklist and indicators for monitoring progress in the development of IHR core capacities in states parties [cited 2012 Apr 19].

http://www.who.int/ihr/checklist/en/index.html

Edwards KM, Decker MD. Pertussis vaccines. In:Plotkin S, Orenstein W, Offit P, eds. Vaccines, 6th ed. Philadelphia, Saunders, 2013:447-492





