MINISTRY OF HEALTH & WELLNESS

JAMAICA

MOH-DOC-800-7-V3

Expanded Programme on Immunization Field Guide for Health Workers

Volume 3: Surveillance of Events Supposedly Attributable to Vaccination or Immunization (ESAVIs) and Vaccine-Preventable Diseases (VPDs)

Family Health Unit

Health Services Planning and Integration

March 2024

6	03/2024	Issue for Use	SS	JRP	NW
5	07/2020	Draft	JRP	ME	
4	07/2018	Draft	JRP	ME	
3	07/10	Issue for use	RR	KLB	DDG
2	05/5	Draft	RR	KLB	DDG
1	04/5	Draft	RR	KLB	DDG
Revision Issued	**Date**	**Issue description**	**Prepared by**	**Checked by**	**Approved by**

MINISTRY OF HEALTH AND WELLNESS, JAMAICA

EXPANDED PROGRAMME ON IMMUNIZATION

FIELD GUIDE FOR

HEALTH WORKERS

Volume 3: Surveillance of Events Supposedly Attributable to Vaccination or Immunization (ESAVIs) and Vaccine-Preventable Diseases (VPDs)

MARCH 2024

Approved by:

Dr. Julia Rowe-Porter
Director, Family Health Unit (Acting)

Dr. Naydene Williams
Director, Health Services Planning and Integration Branch

Dr. Jacquiline Bisasor McKenzie
Chief Medical Officer

Table of Contents

List of Figures

List of Tables

Abbreviations & Acronyms

AEFI	Adverse Events Following Immunization
AESI	Adverse Events of Special Interest
AFP	Acute flaccid paralysis
AIDS	Acquired Immune Deficiency Syndrome
Anti-HBc	Hepatitis B core antibody
Anti-HBs	Hepatitis B surface antibody
ARV	antiretroviral
BCG	Bacillus Calmette–Guérin
CARPHA	Caribbean Public Health Agency
CDC	Centre for Diseases Control and Prevention
cm	centimetre
CMO	Chief Medical Officer
CRS	Congenital Rubella Syndrome
CSF	Cerebrospinal fluid
DPT/Hep B/Hib	Diphtheria Pertussis Tetanus/Hepatitis B/Haemophilus Influenzae type b
DT	Diphtheria Tetanus
DTaP	Diphtheria Tetanus and Acellular Pertussis
DTwP	Diphtheria Tetanus and Whole Cell Pertussis
DT(A)	Diphtheria Tetanus (adult)
DT(P)	Diphtheria Tetanus (paediatric)
EPI	Expanded Programme on Immunization
ESAVI	Events Supposedly Attributable to Vaccination or Immunization
HBIg	Hepatitis B immunoglobulin
HBsAg	Hepatitis B surface antigen
HBcAg	Hepatitis B core antigen
HBV	Hepatitis B Vaccine
HCW	Health Care Workers

HepA	Hepatitis A
HepB	Hepatitis B
HHE	Hypotonic-hyporesponsive episodes
Hib	Haemophilus Influenzae type b
HIV	Human immunodeficiency virus
HPV	Human Papillomavirus
IgG, IgM, IgA	immunoglobin G/M/A
IPV	Inactivated Poliomyelitis Vaccine
IU	International Units
IV	intravenous
kg	kilogram
KPH	Kingston Public Hospital
mg	milligram
mL	millilitre
MO(H)	Medical Officer (Health)
MOHW	Ministry of Health and Wellness
MMR	Measles-mumps-rubella vaccine
MPV	Meningococcal polysaccharide vaccine
NPHL	National Public Health Laboratory
NSU	National Surveillance Unit
OPV	Oral Polio Vaccine
ORT	oral rehydration therapy
PAHO	Pan American Health Organization
PCR	polymerase chain reaction
PCV	Pneumococcal Conjugate Vaccine
PHN	Public Health Nurse
PPV	Pneumococcal Polysaccharide Vaccine
RN	Registered Nurse
TB	tuberculosis
VAPP	Vaccine-Associated Paralytic Polio
VJH	Victoria Jubilee Hospital
VPD	vaccine-preventable disease
VVM	vaccine vial monitor

VZV	Varicella Zoster Virus
WHO	World Health Organization
°C	degrees Celsius
<	less than
>	greater than

Foreword

Infectious disease such as measles, polio, diphtheria, tuberculosis, influenza, pneumonia, yellow fever and cholera were the prevailing causes of morbidity and mortality in the early 1900's. At that time in Jamaica, life expectancy at birth was as low as 38 years with an alarming infant mortality rate of 100-200 deaths per 1,000 live births. Mass immunization campaigns were instituted as measures to control frequent outbreaks of measles and poliomyelitis, especially among children being the vulnerable population most affected.

The Expanded Programme on Immunization (EPI) was established by the World Health Organization (WHO) in 1974 to reduce illness and death due to vaccine-preventable diseases through the provision of routine vaccination services in the primary care system. The Pan American Health Organization (PAHO) launched the EPI throughout the Americas, including Jamaica and the English-speaking Caribbean, in September 1977.

Over the decades, vaccination has proven to be the most effective tool globally against infectious diseases, saving millions of lives annually. Through the successful national immunization programme, Jamaica recorded the last cases of:

- Poliomyelitis (Polio) in 1982
- Locally transmitted Measles in 1991
- Diphtheria in 1995
- Congenital Rubella Syndrome in 1998
- Rubella (German Measles) in 2000
- Newborn Tetanus in 2001

Jamaica is grateful for the health workers in the public and private sectors that have worked assiduously over the years to maintain robust surveillance of vaccine preventable diseases, safeguard the integrity of vaccines through maintenance of the cold chain, raise the awareness in the community on vaccination, administer vaccines and manage the immunization programme – all these efforts have enabled the achievement of high vaccination coverage rates in our children and ultimately a reduction of the impact of vaccine-preventable disease on our population. International agencies, such as the PAHO and United Nations Children's Fund (UNICEF), should also be congratulated for the continuous technical cooperation and financial support, which has contributed to the success of the programme.

The national immunization programme continues to evolve in various respects, including: expansion of vaccination services beyond the main target of children to

accommodate the life course approach; introduction of digital solutions for enhanced efficiency of programme administration and management; and widening of the stakeholder network to strengthen advocacy and mobilization. The policy framework must therefore evolve in tandem with the changing landscape on the immunization programme to maintain and sustain its achievements, especially if the face of the growing threat of vaccine hesitancy globally and locally.

The ***Expanded Programme on Immunization Field Guide for Health Workers*** was developed as a reference document for health workers participating in the national immunization programme. The field guide seeks to establish standards, support training and provide guidance for health workers in key components of the immunization programme, namely: disease surveillance; vaccine supply, quality and logistics; advocacy, communication and service mobilization; monitoring and evaluation; and service delivery.

This version of the field guide is produced as three volumes:

- *Volume 1: Vaccine Administration and Programme Management*
- *Volume 2: Cold Chain and Vaccine Logistics Management*
- *Volume 3: Surveillance of Events Supposedly Attributable to Vaccination or Immunization (ESAVIs) and Vaccine-Preventable Diseases (VPDs)*

Thanks to the PAHO and UNICEF for their support in the preparation and production of this manual and special thanks to the co-opted members in the Ministry of Health and Wellness and Regional Health Authorities that participated in the revision of this document.

Special thanks to Mrs. Sannia Sutherland, short-term consultant to the Ministry of Health and Wellness, Jamaica that assisted in the final preparation and compilation of this manual.

Dr. Julia Rowe-Porter
Director, Family Health Unit (Acting)

Chapter 1: Vaccine-Preventable Diseases

Vaccine-preventable diseases (VPDs) are infectious diseases for which an effective preventative vaccine exists. VPDs addressed in this chapter are:

- Tuberculosis
- Diptheria
- Pertussis
- Tetanus
- Hepatitis B
- Haemophilus influenzae type b
- Poliomyelitis
- Measles
- Mumps
- Rubella
- Yellow Fever
- Varicella
- Pneumococcal disease
- Influenza
- Human papillomavirus
- Meningococcal disease
- Rotavirus enteritis
- Other VPDs

Details on surveillance, prevention and control of VPDs can be obtained from Chapter 3.

1.1 Tuberculosis

What is tuberculosis (TB)?

- Tuberculosis is caused by a bacterium (*Mycobacterium tuberculosis*)
- It is usually a disease of the lungs and respiratory tract
- It can affect almost any organ in the body, e.g. brain, kidneys and spine
- It can cause an asymptomatic (latent) infection or active disease
- Only people who have active disease can spread the infection to others

How is it spread?

- It is spread through the air when a person with TB disease of the lung or throat coughs or sneezes. Another person inhaling that air may then become infected
- Spread is facilitated by crowded living conditions, malnutrition and poor access to care
- People of any age can contract TB, but children under five years of age, older adults, persons with diabetes, and persons with HIV or AIDS are at higher risk of developing the disease
- A person with the disease can infect others for several weeks after beginning treatment

What is the incubation period?

- Usual incubation period (time from exposure to onset of symptoms) is 4 – 12 weeks, but infection may last for months or years before the disease develops. Some people who are infected may never develop the disease

What are the signs and symptoms?

- These include generalized weakness, fever, weight loss, decreased or lost appetite and night sweats
- In the lungs, TB causes persistent cough, the coughing up of blood, and chest pain; however, young children may not have these symptoms. The only sign of pulmonary TB may be stunted growth or failure to thrive
- Other signs and symptoms depend on the part of the body that is affected

What are the complications?

- Complications include weakening of the body, increased susceptibility to other diseases, disability and death
- These may develop more rapidly in persons infected with HIV

How is TB treated?

- TB is treated with two or more anti-TB drugs for at least 6 – 9 months
- If the drugs are not taken properly or if they are stopped too early, they will not work. Ineffective treatment can also lead to multidrug-resistant TB, which is very difficult to treat
- Consult the MOHW Tuberculosis guidelines for further information

How is TB prevented?

Primary prevention:

- Immunization of infants with Bacillus Calmette–Guérin (BCG) vaccine is used to prevent severe and disseminated TB infection, and tuberculous meningitis

Secondary prevention:

- Control of spread centres upon early diagnosis and adequate treatment of cases, as well as the investigation and treatment of contact(s)

- TB is a Class I notifiable disease. Suspected cases should be reported to the parish health department within 24 hours so that a case investigation may be done and disease prevention and control measures put in place
- Health departments should notify the regional epidemiologist/surveillance officers and the National Surveillance Unit immediately by telephone or fax/email.

1.2 Diphtheria

What is diphtheria?

- Diphtheria is an acute bacterial disease of the mouth, throat, nose or skin caused by *Corynebacterium diphtheria*
- Diphtheria produces a toxin (poison) that destroys nearby tissues and can spread through the body, causing severe illness
- It affects people of all ages, but mostly unimmunized children less than 15 years of age

How is diphtheria spread?

- It is spread through contact with infected secretions produced by coughing, sneezing or skin ulcers
- Many can carry the disease without symptoms and can pass it on to others for 2-6 weeks

What is the incubation period?

- The incubation period is usually 2 – 5 days with a range of 1 – 10 days

What are the signs and symptoms?

- Persons with diphtheria of the throat and tonsils develop fever, sore throat, loss of appetite, and malaise two to five days following exposure. A few days later, an adherent coating, bluish-white, grey or black in colour, forms on the throat and tonsils. This coating can obstruct the airway and can cause death. The throat may bleed if one tries to remove this coating
- Diphtheria of the skin causes painful red sores

What are the complications?

- The main complications are airway obstruction, inflammation of the heart muscle (myocarditis), or arrhythmia, neuritis, thrombocytopaenia and proteinuria
- Paralysis and death may also occur

How is diphtheria treated?

- Diphtheria is treated with antibiotics (erythromycin or penicillin) and diphtheria antitoxin
- About 2 days after starting antibiotic treatment, patients are no longer infectious
- Patients should also be isolated to avoid exposing others to the germ

How is diphtheria prevented?

Primary prevention:

- Diphtheria infection can be prevented by immunization with diphtheria toxoid, which is a part of the following vaccines: Pentavalent (**D**PT/Hib/Hepatitis B), **D**PT, **D**T(P), **D**T(A) and **D**TaP (which is given in the private sector)
- Three primary series doses plus three booster doses of diphtheria-containing vaccine provide protection throughout adolescence and adulthood

Secondary prevention:

- This is done by:
    - early diagnosis and adequate treatment of cases
    - investigation, prophylactic treatment and immunization of contact(s)
- Diphtheria is a Class I notifiable disease. Suspected cases should be reported to the parish health department within 24 hours to initiate a case investigation
- Health departments should notify the Regional Epidemiologist/Surveillance Officers and the NSU immediately by telephone or fax/email.

1.3 Pertussis

What is pertussis (whooping cough)?

- Pertussis is a very contagious respiratory disease caused by *Bordetella pertussis*, a germ (bacterium) that lives in the mouth, nose and throat
- It is common in non-immunized children everywhere, but young infants are at highest risk

How is it spread?

- It is spread through contact with, or inhalation of, infected droplets produced by coughing or sneezing
- Transmission occurs from seven days after exposure until three weeks after coughing begins

What is the incubation period?

- The incubation period is usually 7 – 10 days with a range of 4 – 21 days

What are the signs and symptoms?

- There are usually three stages of the illness. High fever is uncommon at any stage.
- **Stage 1:** The child appears to have a common cold. This is accompanied by runny nose, watery eyes, sneezing, fever and a mild cough. The cough worsens gradually for one to two weeks
- **Stage 2:** Coughing spells begin. Bursts of rapid coughing are followed by the child taking in air with a high-pitched "whoop". (Infants younger than six months may have apnoeic spells instead of a whoop). Because of these coughing spells, the child may turn blue (because he or she cannot breathe), vomit after coughing, and may become very tired. This stage usually lasts from 1 - 6 weeks but can last up to 10 weeks. The attacks become milder with the passage of time
- **Stage 3:** Coughing slows down and usually stops in 2 - 3 weeks but can range from weeks to months

What are the complications?

- Serious complications include pneumonia, seizures (convulsions), encephalopathy, apnoea or death

- Less serious complications include loss of appetite, dehydration, and ear infections
- Complications are most frequent and harmful in children under one year old

How is pertussis treated?

- Antibiotics (usually erythromycin) reduce severity and prevent infection of others
- Plenty of fluids should be given to prevent dehydration
- Isolation to avoid exposing others to the germ

How is pertussis prevented?

Primary prevention:

- Pertussis infection is prevented by immunization with pertussis vaccine, which is a part of the following:
    - vaccines with whole cell pertussis (wP): Pentavalent (DT**wP**/Hib/HepB), DT**wP**
    - vaccines with acellular pertussis (aP) – usually given in the private sector: DTa**P**; DT**P**/Hib; DTa**P**/Hib/HepB/IPV; DTa**P**/Hib/IPV

Secondary prevention:

- This is done by:
    - early diagnosis and adequate treatment of cases
    - investigation, prophylactic treatment and immunization of contact(s)
- Pertussis is a Class I notifiable disease. Report suspected cases to the parish health department within 24 hours to initiate a case investigation
- Health departments should notify the Regional Epidemiologist/Surveillance Officers and the NSU immediately by telephone or fax/email.

1.4 Tetanus

What is tetanus (lockjaw)?

- Tetanus is an acute disease caused by a neurotoxin (nerve poison) released by the bacterium *Clostridium tetani*
- It causes a person's muscles to contract, making the body stiff

- *Clostridium tetani* bacteria can be found throughout the environment (e.g. in soil and manure)
- People of all ages can get tetanus, and almost all babies who get the disease die

How is tetanus spread?

- Tetanus is spread through infected soil or dung entering a wound by way of a contaminated object (e.g. knife, nail, thorn)
- It cannot be spread from person to person
- Newborn babies can get neonatal tetanus when:
    - the umbilical cord is cut with a dirty instrument
    - the umbilical cord is dressed with contaminated cow dung or ash
    - contaminated hands or instruments are used to deliver or circumcise an infant
    - dirt, charcoal or other unclean substances are rubbed into a wound
    - the skin is pierced with an unclean object

What is the incubation period?

- The incubation period is 1 – 21 days for adults and 4 – 14 days for newborns

What are the signs and symptoms?

- In the most common type of tetanus (generalized tetanus), stiffness begins in the jaw and neck and then descends. Difficulty in swallowing follows, as well as stiffening of the stomach muscles, muscle spasms lasting several minutes, sweating and fever
- Newborn babies with tetanus look normal at birth but stop sucking 3 – 10 days later. They develop a progressive inability to feed because of stiffness in their jaw. The entire body becomes stiff, fits develop, and they will usually die if not treated

What are the complications?

- Fractures of the spine or other bones may result from muscle spasms and convulsions
- Abnormal heartbeat, high blood pressure, difficulty breathing, pneumonia and coma may also occur

- Death can occur particularly in the very young and older (over 60 years) age groups

What is the treatment for tetanus?

- Patients should be admitted to hospital for supportive therapy (e.g. antibiotics, airway maintenance, etc.)
- all wounds must be cleaned and dead tissues removed
- Tetanus immunoglobulin (TIG) should be given as soon as possible (see Chapter 3 for dosing).
- Once the patient is stable, vaccination should begin or continue with tetanus toxoid-containing vaccine

How is tetanus prevented?

Primary prevention:
Tetanus infection can be prevented by

- immunization with tetanus toxoid-containing vaccines:
  - Pentavalent (D**T**wP/Hib/Hepatitis B), D**T**wP**,** D**T**(P), D**T**(A)
  - D**T**aP, DaP**T**/HepB, **T**T, D**T**aP/Hib/Hepatitis B/IPV (private sector only)
- proper wound care
- immunization of women of childbearing age with tetanus toxoid-containing vaccine, either during pregnancy or outside of pregnancy. This protects women and their newborns against tetanus
- hygienic practices especially when a mother is delivering a child, even if she has been immunized
- passive immunization with TIG, which may be required when an injury occurs

Secondary prevention:

- Tetanus is a Class I notifiable disease. Report suspected cases to the parish health department, regional epidemiologist or surveillance officers and NSU within 24 hours.

1.5 Hepatitis B

What is hepatitis B?

- It is an infection of the liver caused by the Hepatitis B virus
- It occurs worldwide and affects all age groups
- Infants and children are more likely to become chronic carriers (chronic infection with Hepatitis B) than are adults

How is hepatitis B spread?

- The hepatitis B virus is found in blood and other bodily fluids, such as the saliva, semen, and vaginal fluids of acutely infected individuals and chronic carriers
- The virus can survive outside of the body for seven days and still be able to infect people
- It is usually spread by mucosal or percutaneous exposure to blood and bodily fluids from these persons. For example:
    - during sexual intercourse with an infected partner
    - from an infected mother to baby during delivery
    - from person-to-person through contact with cuts, scrapes or scratches
    - to others in a household by sharing toothbrushes or razors with an infected person
    - by injection with unclean needles or syringes (e.g. IV drug use)
    - contact with blood or open wounds of an infected person
    - needle sticks or sharp instruments exposure (e.g. HCW)

What is the incubation period?

- The incubation period is from 6 weeks to 6 months with an average of 60 – 90 days

What are the signs and symptoms?

- Infants, children and 50% of adults generally do not show acute signs or symptoms. Chronic carriers may also be asymptomatic. As such, infected persons may pass the disease to others without knowing
- In persons with symptoms, the immediate presentation is that of acute viral hepatitis:

- The prodrome consists of malaise, anorexia, nausea, vomiting, arthritis or arthralgia, skin rashes, fever, headache, dark urine lasting 3 – 10 days
- It is followed by yellowing of the skin or eyes (jaundice), pale stool, enlargement and tenderness of the liver (all lasting 1 – 3 weeks)
- Fatigue and malaise may persist for weeks to months following the jaundice, but in most adults, full recovery can be expected
- Fulminant hepatitis can occur in a small percentage and lead to death

- Children are far more likely to become chronic carriers and develop the serious complications associated with hepatitis B than adults

What are the complications?

- Complications include chronic hepatitis (liver inflammation), cirrhosis (permanent liver damage), liver failure, liver cancer and death

What is the treatment for hepatitis B?

- There is no treatment for the acute condition
- In chronic infection, the disease process can sometimes be stopped by antiviral medications such as entecavir, tenofovir alafenamide, or tenofovir D, interferon and lamivudine

Drug	Dose	Time
Pegylated interferon alfa-2a	135–180 ug/week	48 weeks
Pegylated interferon alfa-2b	1.5 mg/kg/week	48 weeks
Lamivudin	100 mg	*
Telbuvidin	600 mg	*
Entecavir	0.5-1 mg	*
Tenofovir disoproxil fumarate	245 mg	*
Tenofovir alafenamid	50 mg	*

CHB: chronic hepatitis B
**When oral antivirals disappear HBsAg (anti-HBs positive or negative).*

Table1.5. 1 Dosage for Hepatitis B treatment

First-line medications Interferon alfa 2/Pegulated interferon alfa Entecavir Tenofovir Second-line medications Lamivudine (3TC) Adefovir dipivoxil Telbivudine (LdT) Medications licensed by the Food and Drug Administration but not approved for hepatitis B virus Emtricitabine (FTC) Truvada (tenofovir + emtricitabine)

Table1.5. 2 First and Second Line Treatment for Hepatitis B

How is hepatitis B prevented?

Primary prevention:

- Hepatitis B infection can be prevented by immunization with hepatitis B vaccine, which may be given on its own or as part of the Pentavalent (DPT/Hib/hepatitis B) vaccine, or other combinations available in the private sector
- A birth-dose of hepatitis B vaccine is given to the newborn to prevent mother-to-child transmission
- Persons with hepatitis B virus should not donate blood and should not allow other persons to come in contact with their blood or other body fluids. They should use barrier methods (e.g. condoms) when engaging in sexual intercourse and should not share toothbrushes, needles or razors with other people. During a meal, they should avoid sharing eating utensils with others.
- To prevent the spread of hepatitis B, acutely infected persons and carriers must be identified. Passive and active immunization of contacts depends on the type of exposure:
    - To prevent transmission from mothers to infants, pregnant women may be tested to determine whether they carry the hepatitis B virus in their blood.
    - Babies of mothers who are carriers should receive an injection of hepatitis B immunoglobulin if available and a dose of hepatitis B vaccine at birth at separate anatomic sites. (See Volume 1 for more information on post-exposure prophylaxis).

- Healthcare workers should be vaccinated against the disease and use universal infection-control precautions with all patients. A health care worker who is not hepatitis B immune and is accidentally exposed to the virus (e.g., needle-stick injury; or contact with mucous membrane or non-intact skin with blood, tissue, or other body fluids that are potentially infectious) should receive hepatitis B immunoglobulin and hepatitis B vaccine at separate anatomic sites as soon as possible. This should be followed with completion of the hepatitis B series. (See Volume 1 for more information on post-exposure prophylaxis).
- Household contacts and sexual partners of hepatitis B infected persons should be vaccinated and will require HBIG under certain circumstances. (See Volume 1 for more information on post-exposure prophylaxis).

Secondary prevention:

- Hepatitis B is a Class I notifiable disease. Suspected cases should be reported to the parish health department within 24 hours to initiate a case investigation.
- Health departments should notify the Regional Epidemiologist or Surveillance Officers and the NSU immediately by telephone or fax/email.

1.6 Haemophilus Influenzae Type B (Hib)

What is *Haemophilus influenzae* type b (Hib)?

- It is a bacterium that can cause inflammation or infection of many different organ systems (e.g. brain, skin and lung)
- It should not be confused with the influenza virus, which causes the flu
- It causes serious diseases in children less than five years of age. Children who are less than 18 months of age, live in crowded conditions, attend daycare, and have low socio-economic status are particularly at risk

How is Hib spread?

- It is spread through contact with discharges from the eyes, nose and mouth of infected persons

What is the incubation period?

- The incubation period is unknown but may last 2 – 4 days

What are the signs and symptoms?

- In children less than 5 years old, Hib most commonly causes:
    - Meningitis (inflammation of the coverings of the brain), which presents with drowsiness, poor feeding, high fever and neck stiffness. Older children may present with headaches and vomiting
    - Epiglottitis (inflammation of the epiglottis), which presents with stridor (inspiratory wheeze), drooling and respiratory obstruction. The child will lean forward to keep the airway open
    - Pneumonia (infection of the lungs), which causes respiratory distress and fever.
    - Skin, ear and joint infections
- Symptoms may appear as early as 27 – 72 hours after exposure

What are the complications of Hib infections?

- The complications of Hib infection are the complications of the diseases it causes (meningitis, epiglottitis, pneumonia and other infections)
- Before the introduction of the vaccine, Hib was the leading cause of bacterial meningitis among children less than 5 years old
- Both meningitis and epiglottitis will lead to death if not treated

What is the treatment for Hib infections?

- Immediate antimicrobial therapy is needed, usually a 3rd generation cephalosporin such as cefotaxime or ceftriaxone, or chloramphenicol in combination with ampicillin
- The type of antimicrobial is dependent on the sensitivity pattern of the organism

How are Hib infections prevented?

Primary prevention:

- Hib infection can be prevented by immunization with Hib vaccine, which may be given on its own or as part of the Pentavalent (DPT/**Hib**/HepB) vaccine

Secondary prevention:

- Meningitis and sepsis, which are often caused by Hib, are Class I notifiable diseases. Suspected cases should be reported to the parish health department within 24 hours to initiate a case investigation
- Health departments should notify the Regional Epidemiologist or Surveillance Officers and the NSU immediately by telephone or fax/email.

1.7 Poliomyelitis

What is poliomyelitis (polio)?

- It is a paralyzing disease caused by poliovirus
- Polio mostly affects children, but also can affect adults
- The last poliomyelitis cases in the English-speaking Caribbean were in Jamaica in 1982
- There are three different types of poliovirus disease:
    - Wild poliovirus (WPV)
    - vaccine-derived poliovirus (VDPV)
    - Sabin

How is polio spread?

- It is spread via faecal-oral transmission (i.e. from person-to-person, when people eat food or water that has been contaminated with infected faeces)
- The disease is more likely to spread in areas where there is poor sanitation

What is the incubation period?

- The incubation period is 7 – 21 days with a range of 4 – 40 days

What are the signs and symptoms?

- Many infected persons may not feel ill at all. If they do develop symptoms, they may have:
    - fever and sore throat
    - loose stools, upset stomach, headache
    - stiffness in neck, back or legs
    - paralysis

- Paralytic polio is the severe form of the disease, which affects less than 1% of infected children. It occurs because the virus gets into certain types of nerve cells and damages or destroys them. Patients who develop paralysis may not be able to walk or even breathe by themselves. The degree of recovery varies from person to person. An increased rate of paralysis is found among pregnant women

What are the complications of polio?

- Permanent paralysis is the major complication of polio
- Death can also occur if respiratory muscles are affected and no respirator is available to support breathing

How is polio treated?

- There is no treatment for polio, but supportive therapy can be given (e.g. respirator, symptomatic treatment of fever and muscle pain, physical therapy for paralysis)

How is polio prevented?

Primary prevention:

- Immunization should be given with oral poliovirus vaccine (OPV) and/or inactivated poliovirus vaccine (IPV)
    - OPV is given in combination with IPV
    - IPV is given to immunodeficient or immunosuppressed persons and their close contacts instead of OPV
    - IPV may be given on its own or (in the private sector) as part of DTaP/Hib/Hepatitis B/**IPV** vaccine.
- Vaccine virus from the Oral Polio Vaccine may be transmitted from vaccinated persons to unvaccinated persons (horizontal transmission) through the faeco-oral route. This is of benefit in producing herd immunity

Secondary prevention:

- Jamaica has been certified polio free, however, surveillance is still required.
- Acute flaccid paralysis (AFP)/poliomyelitis is a Class I notifiable disease. Suspected cases should be reported to the parish health department within 24 hours to initiate a case investigation and appropriate containment activities (see Appendix G).

- Health departments should notify the Regional Epidemiologist/Surveillance Officers and the NSU immediately by telephone or fax/email.

1.8 Measles

What is measles?

- This is a systemic illness caused by the highly contagious measles virus (rubeola)
- It kills more children than any other vaccine-preventable disease
- The measles virus circulates worldwide in areas where there are unimmunized persons and the risk of imported cases exists
- The last case of indigenous measles in the Caribbean occurred in 1991. However, cases have been imported to the Caribbean sub-region, including Jamaica, since that time

How is it spread?

- It is spread by contact with the nasal and throat secretions of an infected person, and in airborne droplets released when an infected person sneezes or coughs
- An infected person can infect other people before and after developing symptoms

What is the incubation period?

- The incubation period is 11 – 12 days. The time from exposure to rash onset is 7 – 21 days

What are the signs and symptoms?

Symptoms begin 7 – 18 days after exposure to the virus and occur in two stages:

- **Stage 1:** High fever (greater than 100°C) lasts from 1 – 7 days and may be accompanied by cough, runny nose (coryza) and red watery eyes (conjunctivitis) sensitive to light. Small white spots (Koplik spots) may develop on the inside of the cheeks but will usually disappear before the second stage

- **Stage 2:** A slightly raised, red maculopapular rash appears on the hairline and face and spreads down the body to the hands and feet. It lasts from 5 – 6 days. Loss of appetite and loose stools may also occur

What are the complications?

- The main complications are pneumonia, laryngotracheobronchitis (croup), ear infections, severe diarrhoea, encephalitis (swelling of the brain), seizures, subacute sclerosing panencephalitis (SSPE), blindness and death
- Complications are most likely in adults and children less than five years old
- Children who are immunocompromised or malnourished, particularly those depleted in Vitamin A, are at greatest risk
- Complications of infection during pregnancy include premature labour, spontaneous abortion and low-birth-weight infants

What is the treatment?

- Give fluids and feed the child adequately
- Give antibiotics for complicating infections such as pneumonia and ear infections
- All infected children should receive two doses of Vitamin A 24 hours apart. Giving Vitamin A can help prevent eye damage and blindness. Vitamin A supplementation reduces the number of deaths from measles by 50%

How is it prevented?

Primary prevention:

- Immunization should be done with the MMR (measles-mumps-rubella) vaccine

Secondary prevention:

- This is done by:
  - isolation of cases
  - investigation, prophylactic treatment and immunization of contact(s)
- Fever with generalized rash or suspected measles is a Class I notifiable condition. Suspected cases should be reported to the parish health department within 24 hours to initiate a case investigation and appropriate containment activities (See Appendix E).
- Health departments should notify the Regional Epidemiologist/Surveillance Officers and the NSU immediately by telephone or fax/email.

1.9 Mumps

What is mumps?

- It is an acute viral illness caused by the mumps virus
- It causes inflammation of different glands in the body (salivary glands, testes, ovaries and pancreas) and of the coverings of the brain (meninges)
- Usually, it is a mild childhood disease affecting children 5-9 years old
- In adults, complications of mumps are more likely to be serious
- Mumps virus is present throughout the world

How is it spread?

- It is spread by airborne droplets released when an infected person sneezes or coughs, or by direct contact with infected nose and throat secretions
- It then multiplies in the nose, throat and lymph nodes
- After 2 – 3 weeks, the virus enters the blood and spreads to organs like the salivary glands, the ovaries and the testes
- Inflammation in infected tissues leads to the symptoms of parotitis, orchitis or oophoritis, and aseptic meningitis

What is the incubation period?

- The incubation period is on average 16 – 18 days with a range of 12 – 25 days

What are the signs and symptoms?

Symptoms usually begin 2 to 3 weeks after a person is infected.

- The first symptoms include muscle pains, loss of appetite, headache, fever and fatigue
- After this, the salivary glands – usually the parotid glands – become swollen (parotitis), causing pain behind the ears when chewing and swallowing. The gland (located near the jawbone) will be painful to touch. One or both glands can be affected
- About a third of children infected with the mumps virus have no symptoms

What are the complications?

- The most common complication is meningitis. The symptoms of meningitis include headache, vomiting, stiff neck, back pain and high fever

- Other complications include swelling and tenderness of the testes or ovaries (orchitis or oophoritis); pancreatitis; and hearing loss
- Meningitis and orchitis are relatively more common in adults
- Infections in the first trimester of pregnancy can be associated with spontaneous abortion

How is mumps treated?

- There is no specific treatment for the disease. Symptoms are treated as they occur

How is mumps prevented?

Primary prevention:

- Immunization should be given with the MMR (measles-mumps-rubella) vaccine

Secondary prevention:

- This is done by:
  - investigation of cases
  - identification and protection of contacts
- Mumps is a Class III notifiable disease. Health care providers should report suspected cases to the parish health department as soon as possible Class III diseases are reported by the parish health department to the NSU and regional epidemiologists or surveillance officers as monthly case totals.

1.10 Rubella

What is rubella (German measles)?

- Rubella is an acute, usually mild viral infection that causes a rash and lasts only a few days
- It affects people of all ages, but most seriously affects the developing foetus of a pregnant woman

How is it spread?

- It is spread by direct contact with secretions from the nose and mouth of an infected person

- If a woman is pregnant, it can spread from the mother's blood to the unborn child through the placenta causing Congenital Rubella Syndrome (CRS)

What is the incubation period?

- The incubation period is 12 – 23 days

What are the signs and symptoms?

- Rash is usually the first sign of infection in children. It starts on the face, spreads quickly to the rest of the body, and usually disappears by the third day. The rash may be hard to see and is sometimes itchy
- Older children and adults will usually have fever, swollen glands and symptoms of a cold about a week before the rash appears. The rash may last only a few days.
- The disease can be very mild; many people will not come in to see health care workers

What are the complications?

- The main complication are joint aches and pains, brain inflammation and bleeding problems
- Babies born to mothers who had rubella in their first trimester (0 – 12 weeks) of pregnancy have a very high chance (up to 85%) of developing CRS. Maternal rubella infection in the second and third trimesters poses a lesser risk of CRS. CRS babies can have the following:
    - a small head, mental retardation and meningitis
    - low birth weight
    - cataracts, glaucoma or eye inflammation
    - blood thinning
    - deafness in one or both ears
    - lung problems
    - heart conditions
    - thyroid disease
    - hepatitis or a large liver or spleen

How is rubella treated?

- There is no treatment for the disease. Supportive therapy is given to relieve symptoms

How is rubella prevented?

Primary prevention:

- Immunization should be given with the MMR (measles-mumps-rubella) vaccine

Secondary prevention:

- This is done by:
  - investigation of cases of suspected rubella or CRS
  - isolation of cases and immunization of contacts as needed
- Infants with CRS shed large quantities of virus in their pharyngeal secretions and urine for up to 1 year and therefore may infect their contacts. Babies suspected of having rubella should be managed under contact isolation precautions and placed in a private room or isolation area
- CRS and Rubella are Class I notifiable diseases. Suspected cases should be reported to the parish health department within 24 hours. Health departments should notify the Regional Epidemiologist or Surveillance Officers and the NSU immediately by telephone or fax/email.

1.11 Yellow Fever

What is yellow fever?

- Yellow fever is an acute illness caused by the yellow fever virus, which is found in the tropics of South America and Africa. It is not endemic to the Caribbean, except for Trinidad and Tobago, Guyana and Suriname
- It can affects people of all ages

How is yellow fever spread?

- The virus is spread through the bite of an infective *Aedes aegypti* mosquito
- Mosquitoes may acquire the virus for life by biting either infected monkeys or infected humans
- It is not spread from person to person

What is the incubation period?

- The incubation period is usually 3 – 6 days

What are the signs and symptoms?

- Symptoms may be mild and go unnoticed, or severe, affecting many organ systems
- Symptomatic illness begins with fever, chills, headache, backache, general muscle pain, upset stomach and vomiting
- If the disease progresses, weakness, jaundice, bleeding of the gums, haematemesis (vomiting of blood) and blood and protein in the urine may occur
- Bleeding occurs because of problems with clotting of blood. This is why yellow fever is referred to as a 'haemorrhagic fever'
- Illness usually lasts two weeks, after which the patient either recovers or dies. Persons who recover from yellow fever have lifelong immunity
- Diagnosis of yellow fever is difficult because its signs and symptoms are similar to those of other diseases, such as hepatitis, malaria, dengue, and typhoid fever
- Any person who develops jaundice within 2 weeks of a fever, and has recently returned from travel in a yellow fever endemic area, or has been in contact with a return traveler, should be tested for yellow fever

What are the complications?

- Complications include liver and renal failure, and death

How is yellow fever treated?

- There is no specific treatment for yellow fever
- Dehydration and fever can be corrected with oral rehydration solution and acetaminophen/paracetamol respectively. Any superimposed bacterial infection should be treated with an appropriate antibiotic

How is yellow fever prevented?

Primary prevention:

- This is done by:
    - immunization with yellow fever vaccine
    - control of *Aedes aegypti* mosquitos

Secondary prevention:

- Vigilant surveillance is critical for prompt recognition and rapid control of outbreaks.
- Yellow Fever is a Class I notifiable disease. Suspected cases should be reported to the parish health department within 24 hours, so that a case investigation and disease prevention and control measures may be put in place.
- Health departments should notify the Regional Epidemiologist or Surveillance Officers and the NSU immediately by telephone or fax/email.

1.12 Varicella

What is varicella?

- This is caused by infection with varicella zoster virus (VZV)
- Primary varicella infection causes chickenpox. VZV may lie dormant in the nervous system following initial infection and reactivate as shingles later in life

How is varicella spread?

- It is spread by contact with, or inhalation of, infected respiratory secretions or vesicular fluid from skin lesions
- Chickenpox is highly communicable. It is contagious from 1 – 2 days before the rash appears until 5 days after the appearance of the first crop of vesicles
- Nine out of ten susceptible household contacts will develop chickenpox
- Contagiousness may be prolonged in patients with altered immunity
- Shingles is transmissible for a week after the appearance of lesions. Susceptible individuals should be considered infectious for 10 – 21 days following exposure

What is the incubation period?

- The incubation period is usually 10 - 21 days

What are the signs and symptoms?

- The main manifestation is a generalized, pruritic rash, which starts as macules. Lesions progress to papules and then vesicles before crusting over

- Lesions may be observed at different stages. They usually appear on the scalp then descend to the trunk and the extremities
- Lesions may also occur on mucous membranes (e.g. oropharynx, vagina and cornea)
- Fever and malaise may occur 1 – 2 days before the rash and continue for a few days

What are the complications?

- Bacterial infection of skin lesions, pneumonia, dehydration, meningitis, encephalitis, hospitalization and death are more common in infants, persons older than 15 years, and persons who are immunosuppressed
- Congenital varicella syndrome (low birth weight, limb hypoplasia, scarring, muscular atrophy and brain abnormalities) occurs occasionally when a woman has chickenpox in the first 20 weeks of pregnancy
- Neonatal varicella, which has a 30% fatality rate, can result when a woman has chickenpox 5 days before or 2 days after delivery
- Reye's syndrome has occurred when aspirin is given during the illness

How is varicella treated?

- Therapy is supportive
- Antiviral medications are sometimes given to reduce severity and length of illness

How is varicella prevented?

Primary prevention:

- Immunization can be given with varicella vaccine (in the private sector)

Secondary prevention:

- Varicella is a Class III notifiable disease. Health care providers should report suspected cases to the parish health department as soon as possible. Class III diseases are reported by the parish health department to the NSU and regional epidemiologists or surveillance officers as monthly case totals

1.13 Pneumococcal Disease

What is pneumococcal disease?

- This is a group of illnesses (pneumonia, bacteraemia, meningitis and otitis media) caused by the bacterium, *Streptococcus pneumoniae*
- *Streptococcus pneumoniae* is also known as pneumococcus

How is pneumococcal disease spread?

- Humans are the natural reservoir for *Streptococcus pneumoniae* and may asymptomatically carry the organism in their nasopharynx. Carriers may develop disease by autoinoculation
- It is spread from person to person by direct contact with infected droplets
- Crowded living conditions and the presence of upper respiratory tract infections facilitate spread

What is the incubation period?

- The incubation period of pneumococcal pneumonia is very short, lasting about 1 – 3 days

What are the signs and symptoms?

Signs and symptoms of pneumococcal disease depend on the organ system(s) infected:

- Pneumococcus causes pneumonia, bacteraemia (bacteria in the blood), meningitis and otitis media (inflammation of the middle ear). These conditions may occur at the same time or on their own
- The pneumonia comes on quickly, 1 – 3 days following exposure, and is characterized by fever, chills, pleuritic chest pain, productive cough, shortness of breath, poor oxygenation, increased heart rate, weakness and malaise
- Bacteraemia leads to fever, increased heart and respiratory rates, and an abnormal white blood cell count
- Pneumococcal meningitis causes fever, photophobia, drowsiness, neck stiffness, headache, vomiting and irritability
- Otitis media causes fluid to accumulate in the middle ear and results in ear pain, drainage of fluid from the ear, hearing loss and generalized symptoms of infection (fever, lethargy and irritability)

What are the complications?

- Pneumococcal disease may lead to empyema, pericarditis, endobronchial obstruction (with atelectasis and lung abscess formation), mastoiditis and hearing loss
- In severe cases of bacteraemia, blood oxygenation and urine output decline because of poor organ perfusion. Death may follow
- Pneumococcal meningitis can lead to seizures, coma and death

How is pneumococcal disease treated?

- Penicillin is the drug of choice
- Cephalosporins, erythromycin, chloramphenicol are alternatives in case of allergy

How is pneumococcal disease prevented?

Primary prevention:

- Immunization can be done with pneumococcal polysaccharide vaccine (PPV) or pneumococcal conjugate vaccine (PCV)
- Penicillin prophylaxis is another method of preventing pneumococcal infection

Secondary prevention:

- Pneumococcal meningitis is a Class I notifiable disease. Suspected cases should be reported to the parish health department within 24 hours. Health departments should notify the Regional Epidemiologist or Surveillance Officers and the NSU immediately by telephone or fax/email.

1.14 Influenza

What is influenza disease?

- Influenza is a highly contagious acute viral infection of the respiratory tract
- It affects all age groups, but the very young and very old are more susceptible
- There are three types of influenza virus – Types A, B and C
- Influenza A and B mainly cause disease in humans, including epidemics and pandemics
- Influenza A is most often the cause of pandemics and epidemics

How is influenza spread?

- It is spread by contact with, or inhalation of, infected respiratory secretions (aerosolized or droplet transmission)

What is the incubation period?

- The incubation period is 1 – 4 days

What are the signs and symptoms?

- Symptoms may be mild and go unnoticed, or severe
- Symptoms include sudden onset of fever, chills, headache, myalgia and malaise
- Sore throat and a dry cough may also occur
- Gastrointestinal symptoms such as nausea, vomiting or diarrhoea may accompany respiratory symptoms
- The illness usually lasts 3 – 7 days

What are the complications?

- Persons with chronic conditions (e.g. diabetes, heart, kidney and lung disease), pregnant women and the elderly are more at risk of complications
- The main complications are:
    - bronchitis
    - secondary bacterial pneumonia
    - otitis media
    - worsening chronic conditions (e.g. heart conditions and diabetes)
    - Reye's syndrome in children who have ingested salicylates
    - death

How is influenza treated?

- Therapy is supportive
- Antiviral medications are sometimes given to reduce severity and length of illness

How is influenza disease prevented?

Primary prevention:

- This is done by:
    - immunization with influenza vaccine yearly

- handwashing
- covering coughs and sneezes

Secondary prevention:

- Influenza is a Class II notifiable disease. Health care providers should report suspected cases to the parish health department as soon as possible. Class II diseases are reported by the parish health department to the NSU and Regional Epidemiologists or Surveillance Officers as weekly line listings.

1.15 Human Papillomavirus

What is Human Papillomavirus (HPV)?

- This is a virus that infects epithelial cells primarily in the ano-genital region of the body (e.g., cervix, vulva, penis and anus), leading to warts, precancers and cancers. Infections may also occur in the oropharyngeal region, leading to warts and cancers of the head and neck.
- Although there are over 40 types of human papillomaviruses that affect the genitalia, only a few are known to cause cancer.
- HPV types 16 and 18 are high-risk types that cause the majority of cases of cervical cancer
- HPV types 6 & 11 are low-risk types, among others, that cause warts

How is HPV spread?

- HPV infection is spread through sexual contact

What is the incubation period?

- Most infections are asymptomatic and resolve in 1 to 2 years. If not detected and treated appropriately, persistent infection with high risk types may progress to invasive cancer

What are the signs and symptoms?

- HPV infection is often asymptomatic but may present as genital warts
- Bleeding from the vagina, including bleeding after sexual intercourse, may be signs of cervical cancer
- HPV can only be diagnosed by specific laboratory tests

What are the complications?

The main complications are:

- obstruction of the genital tract by warts
- persistent HPV infection may lead to cancer of the cervix, penis, anogenital or head and neck cancers
- death from cancer

How is HPV treated?

- Once diagnosed, HPV infection may be treated through cauterization

How is HPV prevented?

Primary prevention:

- This is done by:
    - safe sexual practices, such as having one faithful sexual partner and condom use
    - immunization against specific virus types with the HPV vaccine

Secondary prevention:

- This is done through early identification (through Pap smears and HPV testing) and treatment to prevent persistent infection

1.16 Meningococcal Disease

What is meningococcal disease?

- This refers to infections caused by the bacterium *Neisseria meningitides*, also known as meningococcus.
- *Neisseria meningitides* causes meningitis, sepsis (bloodstream infection), pneumonia, arthritis, otitis media and epiglottitis
- Five strains of *Neisseria meningitides* cause serious disease: serogroups A, B, C, Y and W-135
- The disease occurs globally and is most common in infants and children

- Persons with acute and chronic health conditions (e.g., hyposplenism) and immune deficiencies are also at greater risk of the disease. (See 'Special Populations' in Volume 1 for recommendations)

How is meningococcal disease spread?

- It is spread:
  - from person to person
  - by direct contact with infected nose and throat secretions
  - by contact with respiratory droplets released when an infected person sneezes or coughs
- Persons who carry the bacteria in their nose and throat without developing serious illness are called carriers. They may transmit the infection while being asymptomatic

What is the incubation period?

- The incubation period ranges from 1 – 10 days (average 3 – 4 days).

What are the signs and symptoms?

The symptoms depend on the site(s) of meningococcal infection

- Meningitis causes fever, headache, stiff neck, photophobia, nausea, vomiting and an altered mental state (e.g. lethargy, delirium and coma)
- Infants may not have these classic symptoms, presenting instead with irritability, reduced activity, vomiting, fever and poor feeding
- Sepsis causes fever, petechial or purpuric rash (small spots of bleeding into the skin), hypotension, shock and organ failure
- Pneumonia, arthritis, otitis media and epiglottitis are not as common

What are the complications?

- Complications include deafness, limb loss and neurologic sequelae (e.g. seizures, mental retardation)
- Death may also occur

How is meningococcal meningitis treated?

- Meningitis is treated as a medical emergency; urgent admission to hospital is indicated

- Initially, cultures should be obtained then treat with broad-spectrum antibiotics. Once the causative organism is confirmed to be *Neisseria meningitidis*, penicillin alone may be used
- Initially, cultures should be obtained then treat with broad-spectrum antibiotics. Once the causative organism is confirmed to be *Neisseria meningitidis*, IV ceftriaxone/cefotaxime should be given as soon as meningococcal disease is suspected. If unavailable, penicillin alone may be used

Drug	Children <30kg	Children >30kg & adults (MAX DOSE)
Ceftriaxone (first line treatment)	50 mg/kg IV or IM	2g IV or IM
Benzylpenicillin (second choice)	50 mg/kg IV or IM	2.4g IV or IM
** Patients allergic to penicillin who do not have a documented history of anaphylaxis to penicillin can be given ceftriaxone.		

Table 1.16. 1 Dosage for Meningitis Treatment

How is meningococcal meningitis prevented?

Primary prevention:

- Immunization with meningococcal vaccine is recommended
    - Meningococcal polysaccharide vaccine (MPV) protects against serogroups A, C, Y, and W-135. It is not effective in children < 2 years of age and, therefore, is not part of the routine childhood immunization schedule
    - Meningococcal conjugate (protein-polysaccharide) vaccines that protect against serogroup A, C, Y, and W-135 can protect infants and have been introduced into the routine infant immunization schedule in many countries
    - Vaccines against serotype B are not widely available

Secondary prevention:

- This is done by investigation of cases and identification and protection of contacts

- Meningococcal meningitis and septicaemia are Class I notifiable diseases. Suspected cases should be reported to the parish health department within 24 hours. Health departments should notify the regional epidemiologist or surveillance officers and the NSU immediately by telephone or fax/email.
- Close contacts of the case should receive antimicrobial prophylaxis within 24 hours of case identification after contact or identification of the pathogen; Rifampin (rifampicin) given orally twice daily for two days in a 10 mg/kg dose (600 mg maximum) remains the drug of choice for meningococcal prophylaxis of high-risk groups. Patients receiving rifampicin should be informed of the possibility of side effects such as urine, stool, sweat, or tears discolor in red or orange. Alternative to rifampin in adults over 18 years, ciprofloxacin is given as a single dose of 500 mg or 750 mg. Ciprofloxacin is contraindicated in children, pregnant women, and nursing mothers. Ceftriaxone is a first-line antibiotic recommended as chemoprophylaxis in pregnancy and nursing mothers.

1.17 Rotavirus Enteritis

What is rotavirus enteritis?

- This is very contagious diarrhoeal disease caused by the rotavirus
- The peak incidence is at 6 – 24 months of age

How is rotavirus spread?

- Transmission is primarily faeco-oral, that is, contact with food or water contaminated with stool/faeces
- Transmission may also be through the respiratory tract by droplet infection

What is the incubation period?

- The incubation period is 1 – 3 days

What are the signs and symptoms?

- Most first infections are symptomatic; later infections may be milder or asymptomatic

- Symptoms include abrupt onset of fever, vomiting and explosive watery diarrhoea
- The illness usually lasts 3–9 days and is often self-limiting

What are the complications?

- Severe dehydration with electrolyte imbalance and metabolic acidosis
- Death

How is rotavirus treated?

- Supportive therapy can reduce diarrhoeal mortality, if timely, through replacement of fluid and electrolyte losses
- Oral rehydration therapy (ORT) is > 90% effective for all cases of diarrhoea
- IV fluids are administered to children with intractable vomiting

How is rotavirus disease prevented?

Primary prevention:

- This is done by immunization with the rotavirus vaccine

Secondary prevention:

- Gastroenteritis is a Class II notifiable disease. Health care providers should report suspected cases to the parish health department as soon as possible. Class II diseases are reported by the parish health department to the NSU and regional epidemiologists or surveillance officers as weekly line listings.

1.18 Other Vaccine-Preventable Diseases

Vaccines have been developed to protect against other diseases such as[1]:

- Hepatitis A
- Hepatitis E
- Japanese encephalitis
- Tick-borne encephalitis
- Rabies

[1] http://www.who.int/immunization/diseases/en/

- Cholera
- Dengue
- Typhoid
- Malaria
- COVID-19

Chapter 2: Safe Vaccination

2.1 Introduction

Safe Vaccination is of paramount importance to the immunization programme. This chapter provides health care workers with the necessary information that must be followed in providing vaccinations and attending to public concerns related to the risks of vaccination and Events Supposedly Attributable to Vaccination or Immunization (ESAVI).

All vaccines are extensively tested by their manufacturers to ensure safety and efficacy. However, vaccines are drugs and, as such, may be associated with side effects and adverse events.

As vaccine-preventable diseases become less visible because of effective vaccination programmes that have significantly reduced the incidence of these diseases, many of which have been eliminated from Jamaica and are rare, more attention is paid to adverse events associated with vaccination. When controversy over the safety of vaccination arises, it can reduce public confidence in immunization and interfere with established vaccination programmes. The world has seen the dangers and effects of interrupting vaccination (as illustrated in the case description in Figure 2.1.1)

The occasional occurrence of an adverse event or series of adverse events linked to vaccination can therefore quickly become a serious threat to public health and to the immunization programme. Consequently, health care workers need information on safe vaccination. It is also essential to have a national monitoring system for adverse events following vaccination. Having a functioning ESAVI surveillance system is essential also to monitor real risks associated to vaccines, and to be able to differentiate those events that could have been really caused by the vaccine from those situations that were coincidental with the vaccination process.

Safe vaccination requires:

1. safe vaccines
2. safe handling of the vaccines that includes adequate cold chain management
3. safe injection practices
4. monitoring and investigation of adverse events (ESAVI)

Each of these factors is addressed in this chapter.

Case Description of Decreased Confidence in Vaccination and Increased Disease

A well-known situation occurred in the 1970s in the United Kingdom: concern over the risks of whooping cough (pertussis) vaccination provoked a rapid fall in pertussis vaccination coverage. Coverage had been higher than 80% with only 2,000-8,000 cases of whooping cough per year. When coverage fell to 30%, the number of cases of whooping cough rose to more than 100,000 annually, causing deaths and hospitalizations that could have been avoided. After two large epidemics and some education campaigns on the disease and the vaccine, people slowly recovered their confidence in the vaccine. In the middle of the decade, coverage rose to 95% and as a result, the number of cases of whooping cough fell to its lowest recorded level in the history of the United Kingdom.

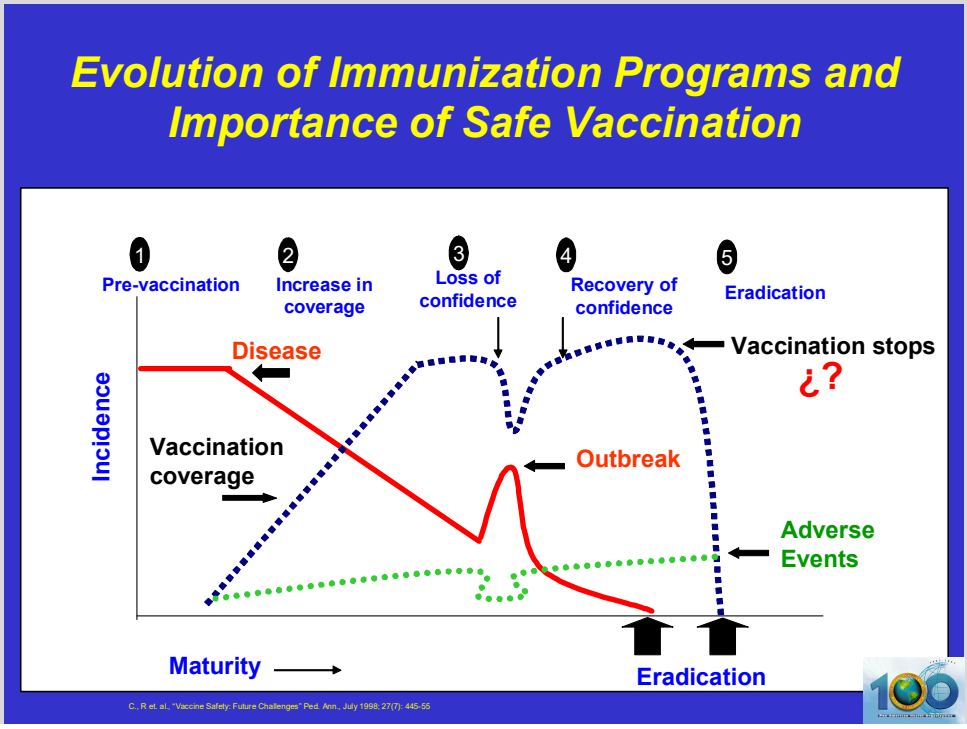


Figure 2.1 1: Evolution of Immunization Programmes and Importance of Safe Vaccination[2]

[2] Ołpiński, Marian. (2012). Anti-Vaccination Movement and Parental Refusals of Immunization of Children in USA. Pediatria Polska. 87. 381–385. 10.1016/j.pepo.2012.05.003.

2.2 Provision of Safe Vaccines in Jamaica

The Ministry of Health and Wellness (MOHW) guarantees safe, effective and high-quality vaccines for the population of Jamaica and takes into account international guidelines on the safety and quality of drugs and vaccines.

Jamaica purchases vaccines through the Pan American Health Organization (PAHO) Revolving Fund for Vaccines from manufacturers certified by the World Health Organization (WHO). The PAHO Revolving Fund for Vaccines is a pool of money maintained by PAHO that enables countries in the Region of the Americas that purchase through the fund benefit from "economy of scale" and receive high quality vaccination supplies that are pre-qualified by the WHO at significantly reduced costs. The main purpose of the fund is to ensure a uniformed and continuous supply of vaccines and supplies for country immunization programmes.

Vaccines purchased through the Revolving Fund for Vaccines undergo a rigorous regulatory process that evaluates their efficacy, safety and quality during manufacturing prior to receiving a marketing authorization. The WHO evaluates vaccine quality, safety and effectiveness to ensure compliance with the requirements of United Nations agencies, including those relating to good manufacturing practices.

Quality control documents and information on the final laboratory testing of each lot of vaccine accompany all shipments. These documents and the 'certificate for the release of vaccines acquired by United Nations agencies' are vetted by the Standards and Regulations Division of the MOHW. Systems are in place to ensure that all vaccines used in Jamaica are registered through the Standards and Regulations Division. Thus, the vaccines used in Jamaica's EPI must be safe and effective, and compliant with operational specifications regarding packaging and presentation.

2.3 The Regulatory Process

Figure 2.3.1 shows the regulatory process that vaccines undergo in countries where they are authorized by a national regulatory authority.

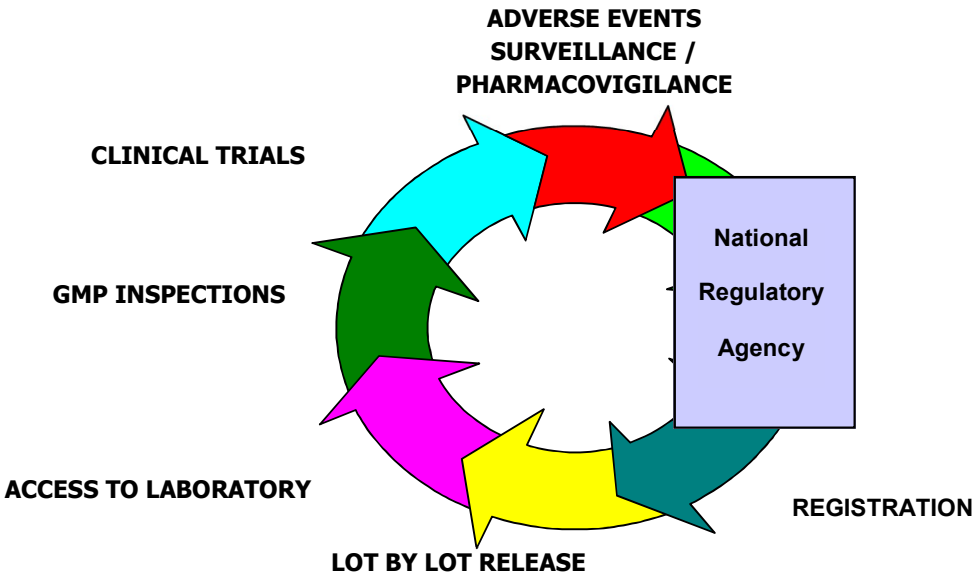


Figure 2.3 1: The Regulatory Process Vaccines Undergo[3]

Regulation of vaccines is a continuous process. Steps in the regulatory process are summarized as follows:

- In countries where they are authorized, vaccines are registered with the National Regulatory Authority (NRA), which has the responsibility for obtaining technical data on the vaccine and the manufacturer
- The NRA releases lots of vaccine, including the results of the quality-control tests carried out in its official laboratories, to evaluate their safety, efficacy and quality of manufacturing. At a minimum, release is based on an examination of the manufacturing protocol summaries of the lot, which give a detailed description of the production process
- In some countries, the function of the laboratory is to confirm the quality of the vaccines, by testing the finished product
- Manufacturers are inspected and granted licenses on the basis of their compliance with good manufacturing practices
- Distributors (importers, wholesalers and retailers/pharmacies) are also inspected and granted licenses to ensure that they comply with relevant regulations in order to acquire and retain their licenses
- Evaluation of the safety and effectiveness of vaccines are derived scientifically from randomized controlled clinical trails

[3] Source: ESAVI training materials, PAHO/WHO

- Before clinical trials, in-vitro and animals studies are performed to evaluate toxicity and biological effects of the vaccine
- Clinical Trials have four (4) phases:
    1. *Phase I,* with first-time use on humans
    2. *Phase II*, which usually focuses on comparison of safety between two groups (intervention and placebo) with some measures of efficacy
    3. *Phase III,* which decides the efficacy of the product. Usually the results of phase III enables or prohibits a product's submission for registration
    4. *Phase IV*, or the post-authorization surveillance stage, when the results on safety and effectiveness with the use of the product on the general population are obtained

Once a vaccine is placed on the market, the NRA continues to conduct after-sales surveillance, including:

1. periodic inspections of manufacturers
2. continual supervision of vaccine quality through lot release programmes and case-by-case evaluation of samples taken in the field
3. monitoring, checking and evaluation of the secondary effects (whenever necessary) associated with vaccination
4. collaboration in monitoring the effectiveness of vaccines in preventing targeted diseases
5. evaluation of the use of the vaccine

2.4 Safe Injection Practices

An injection is an invasive procedure that consists of puncturing the skin with a needle and injecting a substance from a syringe in order to introduce that substance to heal or prevent disease. Generally, injections can be administered by intravenous, intramuscular, intradermal or subcutaneous routes; note however that vaccinations are not given via the intravenous route.

Hazardous injection practices may lead to transmission of blood-borne pathogens (HIV, Hepatitis C virus and Hepatitis B virus) from one client to another, from client to health care worker, and rarely from health care worker to client. The community at large can also be exposed to serious infectious risks when injection equipment is not adequately discarded. Many epidemiologic studies in industrialized countries have

documented spread of Hepatitis B due to accidental needle pricks or the shared use of syringes and needles.

A safe injection does not:

- endanger the recipient's life
- expose the health care worker to any avoidable risk
- produce any waste that may be harmful to other people

A 'safe injection' is therefore safe for:

- the recipient
- the health care worker
- the community and environment

2.5 Safety of the Injection Recipient

Five interrelated aspects are fundamental in guaranteeing the safety of vaccine recipients:

2.5.1 Avoidance of Programmatic Errors (Operational Mistakes)

Programmatic errors are caused by human negligence or error. To a great extent, they can be prevented. Nevertheless, they occur more frequently than those caused by vaccines or technology. Prevention of programmatic errors requires adequate staff training and equipment, and proper supervision.

Inadequate vaccination practices may give rise to abscesses or blood-transmitted infections. The most serious case is toxic shock caused by the inappropriate manipulation of a reconstituted vaccine vial. In such a case, many infants vaccinated from the same vial may die soon after the injection has been administered.

The following are the basic rules to avoid programmatic errors:

- Use sterile needles and syringes for each injection
- Use the correct injection administration procedures
- Never leave a mixing needle in a vial
- Never pre-fill syringes prior to vaccination sessions

- Reconstitute vaccine only with the diluent provided by the manufacturer for the vaccine
- Discard reconstituted vaccines (MMR, yellow fever and BCG vaccines) within six hours after reconstitution
- Follow the WHO policy on the reuse of multiple-dose vials (Volume 2 Chapter 1)
- Do not store drugs, food, drinks, and other substances in a vaccine refrigerator
- Train and supervise workers appropriately in order for them to learn about safe injection practices
- Investigate any programmatic error so as to avoid its recurrence

Table 2.5.1.1 outlines common programmatic errors made and their consequences.

Table 2.5.1 1: Programmatic Errors and Their Consequences

Incorrect Practice	**Potential Reaction or Event**
Non-sterile injection: • Reuse of a disposable syringe or needle • Improperly sterilized syringe or needle (Jamaica does not use sterilized needles and syringes in the EPI programme) • Contaminated vaccine or diluent • Use of re-constituted vaccines for a period longer than indicated	• Infection such as abscess at the injection site, sepsis, toxic shock syndrome or death • Transmission of blood-borne infection, such as Hepatitis B/C or HIV
Reconstitution error: • Reconstitution with the wrong diluent • Drug substituted for vaccine or diluent • Inadequate mixing of vaccine	• Local abscess due to solid particles caused by improper mixing (agitation) • Adverse effect of a drug; for example, insulin • Death • Ineffective vaccine
Injection at incorrect site: • BCG applied subcutaneously • Very superficial administration of the DPT/DT/TT vaccine • Injection in the buttock	• Local reaction or abscess • Potential damage to the sciatic nerve
Incorrect transport/storage of vaccines • Cold chain not maintained • Freezing of vaccines which should be kept at +2°C to + 8°C	• Local reaction from frozen vaccine • Ineffective vaccine
Ignore vaccine contraindications	• Severe preventable reactions • Death

2.5.2 Adequate Vaccine Preservation

Vaccines and diluents must be stored within the required temperature ranges at all times to guarantee appropriate preservation. Cold Chain Management is discussed in detail in Volume 2 Chapter 1.

Health care workers should verify that vaccines are being kept under appropriate cold chain conditions at all times by following the steps outlined in Volume 2 Chapter 1, including:

- protecting vaccines and diluents from coming into direct contact with ice packs or cold water
- verifying the temperature of the refrigerator
- verifying the positioning of vaccines in the refrigerator and vaccine carrier
- continuously verifying the operational capacity of the cold chain equipment

2.5.3 Appropriate Handling of Opened Multi-Dose Vials

Vials containing multiple doses, which have been used to administer one or more doses during a vaccination session, may be used in subsequent immunizations, within a maximum period of four weeks (28 days), provided the following conditions are met:

- Vaccines have not expired
- Vaccines have been stored and preserved under appropriate cold chain conditions
- The rubber stopper has not been submerged in water
- Vaccine doses have been withdrawn using strict aseptic procedures (e.g. a minimal touch technique was used with hand washing between doses; the bung was not touched; no needle was left in the vial)
- Vaccines were not transported and opened for field use (i.e. outreach sessions)
- The vaccine vial monitor (VVM), if attached, has not reached the discard point

The revised policy does not modify the procedures recommended for vaccines that must be reconstituted, such as the BCG, MMR, Hib and Yellow Fever vaccines. These vaccines must be discarded six hours after having been reconstituted, or at the end of each vaccination session – whichever occurs first.

Death due to toxic shock syndrome has resulted when reconstituted live virus vaccines kept longer than the recommended period have been injected.

Refer to Table 2.5.3.1 for details regarding the allowable preservation time for opened vials.

Table 2.5.3 1: Allowable Preservation Time for Opened Vials

Biological	Formulation	Preservation time of the opened vials
OPV	Multiple-dose vial	Four weeks maximum
IPV	Multiple-dose vial	Four weeks maximum
IPV	Single- dose vial	Use immediately
BCG	Multiple-dose vial	Six hours
DPT	Multiple-dose vial	Four weeks maximum
Haemophilus Influenzae type b	Multiple-dose vial Single-dose vial	30-day maximum (M-d vial) Use immediately
Hepatitis B	Multiple-dose vial	Four weeks maximum
Pentavalent	Single-dose vial	Immediate use
Pediatric DT	Multiple-dose vial	Four weeks maximum
Adult DT	Multiple-dose vial	Four weeks maximum
Yellow Fever	Multiple-dose vial	1 hour if diluent is not kept at temperature between +2 to +8^{0}C as the vaccine. But 6 hrs if diluent is kept at temperature between +2 to +8^{0}C as the vaccine.
MMR	Multiple-dose vial	Six hours
Meningococcal Polysaccharide Vaccine (MPV)	Single-dose vial	30 minutes
Meningococcal Polysaccharide Vaccine (MPV)	Multiple-dose vial	10 days maximum
Influenza (inactivated)	Multiple-dose vial	Four weeks maximum
Rotavirus	Single-dose vial	Immediate use
HPV	Single-dose vial	Immediate use

N.B. Preservation temperature for all vaccines in +2 to +8^{0}C.

2.5.4 Administration Technique: Dose, Route, Injection Site and Syringe

As outlined in Volume 1 for Vaccine Administration, one must ensure:

- injection of the correct vaccine and dose
- administration of the vaccine with the correct syringe and needle
- application of the vaccine at the right site
- use of the correct route of administration

2.5.5 Appropriate Use of Syringes

See Volume 1.

2.6 Standard Precautions

Standard precautions should be used throughout the immunization programme.

2.6.1 Safety of the Health Care Workers

The safety of the health care workers depends on appropriate handling of disposable syringes and safety boxes.

- Do not recap the needle after administering the vaccine
- Do not remove the needle from the syringe after administering the vaccine
- Use a safety box (or other puncture-resistant container with a wide neck to allow insertion but not removal of the used needles and syringes) to dispose of syringes and needles immediately after use
- Never use plastic or paper bags or common garbage containers for disposal of syringes and needles

2.6.2 Safety of the Community and the Environment

The safety of the community and the environment requires the appropriate disposal of needles and syringes. This prevents the generation of waste that is hazardous to the community or the environment.

Although health centres may collect needles and syringes in safety boxes, eventually they must be destroyed.

- Incineration is the most reliable and safest means to dispose of this hazardous waste
- Incinerated waste should be buried at a site that is not accessible to the public
- Should an incinerator not be available, this waste may be burnt in a pit. Burying or dumping waste in an open field or in public or municipal dumps is not a recommended practice

2.7 Events Supposedly Attributable to Vaccination or Immunization (ESAVI)

An event supposedly attributable to vaccination or immunization (ESAVI) is defined as any untoward medical occurrence which follows immunization, and which does not necessarily have a causal relationship with the vaccination process or the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.

It is important to note that not all medical situations that occur after a vaccine is administered are related to the vaccine. As such, all ESAVI cases need to be followed up by a thorough investigation and classified into one of the specific causes below:

For the purpose of these guidelines ESAVIs are categorized into six categories, which are defined in Table 2.7.1

Vaccine product-related event:	An ESAVI that is caused or precipitated by a vaccine due to one or more of the inherent properties of the vaccine product (e.g., adjuvants, preservatives, or stabilizers).
Vaccine quality deviation-related event:	An ESAVI caused by deviations from vaccine quality specifications, including in devices used for vaccine administration, manufacturing processes, storage, or the distribution chain.
Event related to programmatic error:	An ESAVI caused by inappropriate vaccine handling, prescribing or administration and so is preventable.
Anxiety-related (or stress-related) event:	An ESAVI arising from anxiety or stress about the vaccination process and related sociocultural factors. It can occur before, during or immediately after vaccination.
Coincidental:	An event that is **not** caused by the vaccine, programmatic error or immunization stress, but which has a temporal relationship with the vaccine – a chance association.
Non-classifiable event:	The event cannot be classified, usually due to a lack of information

Table 2.7.1: Classification of Events Supposedly Attributable to Vaccination or Immunization (ESAVIs)

No biological or pharmaceutical product is totally innocuous, and occasional adverse effects related to vaccines occur. Vaccinators must know what to expect (type of event and frequency) when EPI vaccines are administered. In addition, vaccinators must know how to manage and report such reactions. Whenever any sign, symptom, abnormal lab or disease occur after inmmunization and vaccinators are doubtful if it might or not be related to the vaccine, the situation should be notified to follow an investigation and to assess the association with the vaccine or the vaccination process.

2.7.1 Classification and Rates of ESAVIs

ESAVIs are also classified according to their seriousness in the following manner:

- Non-serious (minor and more common)
- Serious (severe and less frequent)

Knowing the types of events to expect after vaccination can help health care workers to:

- educate parents and other caregivers about side effects
- prepare for treatment of patients
- monitor the occurrence of ESAVIs at their health centre
- prevent events that could arise in the immunization programme
- detect new adverse events that might be really related to the vaccines
- compare the rates occurring with those expected

Health care personnel are obliged to inform caregivers/clients of the more common events expected post-vaccination and how to manage them. It is also essential to inform them that in the event of any unknown or serious event appearing after vaccination, they must go to the nearest health centre or doctor.

A. Minor and More Common Adverse Events

Most reactions to vaccination are normal and mild. Local reactions, fever and other symptoms may be part of the normal immune response to vaccination. Recovery does not require treatment and there are no long-term consequences. The frequency of minor adverse events attributable to vaccination or immunization is summarized in Table 2.7.1.1.

Table 2.7.1 1: Summary of the frequency rates of minor events, attributed to vaccination or immunization and the times they take to appear.

Vaccine type	**Local reaction (pain, swelling, redness)**	**Fever**	**Irritability, malaise and non-specific symptoms**
Haemophilus influenzae type b (Hib)	5-15%	2-10%	-
Hepatitis B	up to 30% in adults up to 9% in children	1-6%	up to 20%
Measles/MMR	up to 10%	up to 5%	up to 5%
Oral poliovirus (OPV)	not applicable	less than 1%	less than 1% [a]
IPV	less than 0.1%	less than 0.1%	
TT/DT	up to 10% for boosters: 50-85%[b]	up to 10%	up to 25%
DPT[c]	up to 50%	up to 50%	up to 60%
BCG	90-95%[d,e]	-	-
HPV[4]	up to 10%	less than 10%	up to 10%

[4] HPV Manufacturers leaflet accessed at https://www.medicines.org.uk/emcmobile/PIL.20207.latest.pdf

(**N.B.** the rates corresponding to the administration of vaccines will be lower, given that these symptoms appear normally in children, regardless of vaccination).

a) Diarrhoea, headache and muscular pains
b) It is likely that the rates of local reaction increase with the booster from 50 to 85%.
c) Whole cell whooping cough vaccine. The rates for acellular whooping cough vaccine are lower.
d) Local reactogenicity varies from one vaccine to another as a function of the strain and number of viable bacilli.
e) The reaction consists of the appearance of a nodule and subsequent reaction.

B. Severe and less frequent adverse events

Serious reactions are much rarer and may require treatment. They produce few long-term problems. Anaphylaxis, though it can be fatal, produces no long-term complications if treated in time. The frequency and timing of the uncommon and severe adverse events associated with vaccination are detailed in Table 2.7.1.2.

Table 2.7.1 2: Summary of severe events attributed to vaccination or immunization, onset interval and rates

Vaccine	Event	Onset interval	Rates per 1,000,000 (million) doses
BCG	Suppurative lymphadenitis BCG osteitis Disseminated BCG	2-6 months 1-12 months 1-12 months	100-1000 1-700 2
Hib	Nil known	-	-
Hepatitis B	Anaphylaxis Guillan-Barré syndrome (vaccine obtained from plasma)*	0-1 hr 0-6 weeks	1-2 5
MMR[a]	Febrile seizures Thrombocytopenia (low platelet count) Anaphylaxis	5 -12 days 15-35 days 0-1 hr	333 33 1-50
Oral poliovirus (OPV) [b]	Vaccine-associated paralytic poliomyelitis (VAPP)/circulating Vaccine-Derived Polio Virus (cVDPV)	4-30 days	Less than 1
IPV	Anaphylaxis[5] Poly neuropathy[6] Apnea in very premature infants (less than 28 weeks gestation	0-1hr	Less than 1\ Less than 0.01%
TT/DT	Brachial neuritis Anaphylaxis Sterile abscess	2-28 days 0-1 hr 1-6 weeks	5-10 1-6 6-10
DPT [c]	Persistent screaming lasting for more than 3 hours. Seizures Hypotonic hypotensive episode (HHE) Anaphylaxis Encephalopathy	0-24 hours days 0-24 hours 0-1 hr 0-3 days (average)	1,000-60,000 570 570 20 0-1
Yellow fever	Post vaccination encephalitis Allergic reaction/anaphylaxis	7-21 days 0-1 hour	500-4,000 in infants under 6 months 5-20
HPV	Allergic reaction/anaphylaxis	0-1 hour	Less than 1

a) No reaction (except anaphylaxis) when there is immunity (~90% of those who receive a second dose); febrile seizures are very unlikely in children over six.
b) The risk of VAPP is higher for the first dose (1 in 1.400.000–3.400.000 dosage) than for subsequent doses and contacts, one in 5.900.000 and one in 6.700.000 doses, respectively.
c) Seizures are principally febrile and frequency depends on personal and family background and age, with the risk lower for children under four months.
d) Isolated cases with no denominator make evaluation of frequency more difficult for children and adults, but are extremely rare (less than one case in 8.000.000 doses.

[5] CDC Possible side effects of Vaccinations accessed at https://www.cdc.gov/vaccines/vac-gen/side-effects.htm

[6] IPV Manufacturers leaflet accessed at http://www.who.int/immunization_standards/vaccine_quality/pq_231_282_IPV_Bbio_PI_05_2015.pdf?ua=1

2.7.2 Approach to the Management of ESAVIs

The following steps should always be considered when faced with an ESAVI case:

1. treatment of the patient
2. subsequent conduct: indicate or contraindicate subsequent doses of the vaccine (as determined by a physician or specialist)
3. notification, reporting and investigation (if criteria are met)

Appropriate management of an ESAVI implies:

- rapid and adequate detection,
- evaluation,
- management and
- prevention of these events, as well as
- a sound communication plan.

Whenever a vaccinator faces an ESAVI, the following steps should be considered:

1. Detect the event and immediately offer adequate health care. Make sure a medical doctor evaluate the patient in case an unknown or serious event occurs or the patient requires medical treatment.
2. Completely notify the case. Fill out the reporting form with complete and accurate information.
3. Communicate adequately with the patient or his/her family. Provide information on the next steps, on the event duration and treatment. If it is an unknown or serious event, briefly indicate how the event is going to be reported, investigated and assessed by a national committee.

2.7.3 Management of Minor Vaccine-Related Adverse Events

The clinical management of minor vaccine-related adverse events in outlines in Table 2.7.3.1.

Table 2.7.3. 1: Clinical Management of Minor Vaccine-Related Adverse Events

ESAVI	Symptoms	Course/ Action needed	Treatment	Contra-indication for subsequent doses
Abscess at the injection site	Fluctuant lesion that contains liquid at the site of vaccine application; may or may not be accompanied by fever; pain at site of application or with movement of the affected limb	Requires a medical examination to determine treatment	-Analgesia (use non-aspirin containing pain reliever in children) -Cold or hot compress -May require incision and drainage -Requires antibiotics -May require drainage	None
Severe local reaction	Redness, oedema, or pain at the site of injection; pain may occur with movement of the affected limb.	Most cases get better on their own	-Analgesia (use non-aspirin containing pain reliever in children) -Cold or hot compress	None
Painless nodule	Lump at the site of the injection	Re-absorbs completely in a few weeks on its own	None	None
Fever	On average occurs 3-6 hours after vaccination. May occur up to 48 hours after vaccination with the exception of MMR vaccine. In the case of MMR, fever can appear between 5 to 12 days after vaccination.	Usually benign and self-limited Children must be examined to rule out another cause of the fever (e.g. inter-current infection)	-Fluids; rest -Administer antipyretics: preferably paracetamol, avoid the use of aspirin -Do not apply ice or alcohol -If persistent or associated with other symptoms, ensure thorough examination and lab test as required -Treat according to diagnosis	None, unless occurs with a more serious ESAVI

All medical situations that occur after vaccination and that anyone (i.e. vaccinator, the patient or his/her family, the medical doctor) suspects it might be related to the vaccine, must be recorded in the Adverse Events Register and reported to the MOHW using the Adverse Events Reporting Form (See Appendix C). Large increases in certain local reactions may be associated with errors in technique or a given lot of vaccine, so it is important that they are reported and investigated.

3.7.4 Management of Serious Vaccine-related Adverse Events

A physician should be consulted immediately to assist with the assessment and clinical management of all serious adverse events. Health care workers should familiarize themselves with the management of anaphylaxis, so that they can stabilize patients prior to the arrival of a physician or transfer to hospital. All serious adverse events must be reported to the Surveillance Unit/Family Health Unit immediately (see ESAVI Crisis Management Plan in Appendix I).

Management of the following major adverse events is outlined in this section:

a) BCG lymphadenitis
b) Persistent crying
c) Seizures
d) Shock-type syndrome (hypotonic hypotensive episodes – HHE)
e) Anaphylactic shock (anaphylaxis, anaphylactic reaction)
f) Encephalopathy and encephalitis
g) Exanthema
h) Thrombocytopaenic purpura
i) Vaccine-associated paralytic polio
j) Toxic shock
k) Peripheral neuritis (brachial or sciatic

a) BCG Lymphadenitis

Case definition:

- At least 1 lymph node greater than 1.5 cm in size, or a draining sinus over a lymph node

Clinical features:

- Usually occurs in the armpit within 2-6 months of BCG vaccination
- Occurs on the same side of the body as the vaccination

Management:

- Heals spontaneously over months
- Refer to pediatrician for observation and management
- Fistula requires surgical opinion
- Systemic treatment is ineffective

Contraindications for subsequent doses:

- None

b) Persistent Crying/Screaming

Clinical Features:

- Continuous inconsolable crying may last from ≥3 hours and sometimes up to 48 hours, post-vaccination (usually with DPT)
- Accompanied by screaming
- Thought to be associated with pain at the injection site
- Stops spontaneously

Management:

- Observe and verify the intensity of the local reaction
- If there is an intense local reaction give paracetamol
- The child should be taken to a hospital for evaluation and to rule out other causes of the crying

Contraindications for subsequent doses:

- Generally, inconsolable crying which lasts ≥3 hours after DPT vaccination is a contra-indication to further doses of DPT. A vaccine with acellular form of the pertussis antigen might be used to reduce the risk of this adverse reaction. Alternatively, DT can be given in the future. An alteration to this policy could be considered in the setting of an outbreak. History of persistent crying is a precaution, not a contraindication of further doses.

c) Generalized Convulsions

Clinical Features:

- Involuntary movements associated with loss of consciousness

- May be generalized (convulsions/fits) or local
- May be tonic and/or clonic
- Can occur up to 72 hours after administration of DPT or 5 to 7 days after administration of the MMR vaccine
- Often accompanied by fever
- Prognosis is good and no short or long-term complications have been shown

Management:

- Lay the patient on his/her side
- Do not place anything in his/her mouth or between his/her teeth so that the airway remains clear
- Transfer to hospital as soon as possible for assessment and observation. Seizures may recur
- Physicians can give diazepam if the crisis does not stop spontaneously. Phenobarbital can also be used as an alternative first line drug or as adjunctive treatment
- Additional emergency measures should be applied in cases of status epilepticus (maintain airway, breathing, circulation, including provision of 100% O_2)

Contraindications for subsequent doses:

- Generally, a seizure is not an absolute contraindication to further doses of DPT. If adequate evaluation of the case has been done and no risk factors for recurrent seizures have been identified, then the person can be revaccinated. Also the use of acellular pertussis may be considered. If there is a contraindication, DT should be given in the future
- If the seizure is a febrile seizure, post-MMR for example, consideration may be given to further MMR immunization with fever control (antipyretics)

d) Shock Type Syndrome (Hypotonic Hypotensive Episode: HHE)

Clinical Features:

- Sudden loss of colour, loss of muscular tone, loss of response to stimuli, occurring in the first 48 hours (usually less than 12 hours) after the vaccination
- The episode is temporary and disappears spontaneously without sequelae
- May be accompanied by respiratory depression, cyanosis, prolonged sleep or loss of consciousness

- Some cases described as HHE can be confused with anaphylaxis-type reactions or seizures. The presence of urticaria or angioedema, particularly in the larynx, indicates an anaphylactic reaction
- Prognosis is good; it is generally temporary and self-limiting. Studies of children who have had HHE do not show neurological sequelae in the short or long term

Management:

- Transfer to hospital
- Keep under close observation until the signs and symptoms have disappeared completely
- Take appropriate measures when hypotension, cyanosis or respiratory depression is present

Contraindications for subsequent doses:

- Generally, HHE is a contra-indication to further doses of DPT. DT should be given in the future. An alteration to this policy could be considered in the setting of an outbreak

e) Anaphylactic Shock (Anaphylaxis, Anaphylactic Reaction)

These are acute reactions that may occur after application of the vaccine. Their association with vaccines is very rare.

Clinical features:

According to the Brighton Collaboration Case Definition (2022)[7], anaphylaxis presents acutely and leads to a marked change in an individual's previous stable condition and is characterised by the following:

- Rapid progression of symptoms and signs which typically affects multiple body systems (skin/mucosa/respiratory/cardiovascular/gastrointestinal) at the same time or sequentially but occurring over a short period of time (within 1 h, from the onset of the first symptom and/or sign)

AND

- Major and/or minor symptoms and/or signs involving the following systems:
- Dermatological: pruritus, angioedema, generalized urticaria and/or erythema
- Respiratory: angioedema of the upper airway, stridor, wheezing, difficulty breathing, cough, dyspnea, respiratory distress

[7] Gold, M et al (2022). Anaphylaxis: revision of the Brighton collaboration case definition. Vaccine 41 (2023) 2605–2614. Accessed at https://zenodo.org/records/7427990

- Cardiovascular: pallor, hypotension, arrhythmia, shock, cyanosis, cold extremities, weak or absent pulses
- Gastrointestinal: new onset vomiting and/or diarrhea

> Anaphylactic reactions are very rare, unexpected, and can be fatal. All health care workers must, therefore, be able to distinguish anaphylaxis from convulsion and fainting. Fainting, while relatively common after immunization of adults and adolescents, is very rare in young children in whom sudden loss of consciousness should be presumed to be an anaphylactic reaction. There is no place for conservative management of anaphylaxis. Early administration of adrenaline is essential. All health care workers must be familiar with the practical steps necessary to save a life following an anaphylactic reaction. Rapid treatment is vital.

Prevention:

- Anaphylaxis may be avoidable if an allergy or prior vaccine reaction is known to be present
- Ensure there are no contraindications to immunization
- Ask the recipient or caregiver about known hypersensitivities or previous adverse reactions to vaccines
- If in doubt as to the advisability of administering the vaccine, consult the MO(H) or Director, Family Health, recipient's general practitioner or refer to a paediatrician
- If vaccine is given, keep the recipient under observation for 15-30 minutes after the injection

Preparation:

- All vaccination clinics must have an Emergency Tray with resuscitation equipment permanently available
- Medical and nursing personnel must be trained to recognize and treat anaphylactic shock and rehearse the procedures periodically
- Each vaccinator should have adrenaline available as adrenaline 1:1,000
- The expiry date of the adrenaline and other drugs should be written on the outside of the kit and the whole kit should be checked monthly or at least three or four times a year
- Adrenaline that has a brown tinge must be discarded

- Hydrocortisone and an injectable antihistamine for intravenous administration should be included in the emergency kit

Management:

- The main treatment of anaphylactic reactions is adrenaline
- Corticosteroids and antihistamines have a delayed effect, and though they may help to reduce the overall duration of a reaction and may prevent relapse, they must not be used to the exclusion of adrenaline in the management of anaphylaxis
- Adrenaline should be used early at the first suspicion of anaphylaxis. It is safe and effective
- The following four steps should be done rapidly or simultaneously, so that the administration of adrenaline is not delayed:
    1) Call for assistance, including an ambulance
    2) Lay patient in left lateral position to keep the airway clear and with legs elevated.
    3) Establish an oral airway if necessary and administer oxygen by facemask at a high flow rate (6L/min).
    4) Promptly administer adrenaline 1:1000 intramuscularly. This may be repeated at 5-10 minute intervals up to a maximum of three doses depending on the severity of the reaction. Recommended dosing for adrenalin is provided in Table 2.7.4.1.
- Avoid injecting adrenaline in the limb in which the vaccine was given
- A tuberculin syringe can be used to improve the accuracy of measurement when drawing up small doses
- If measurement of small volumes of adrenaline is a problem, use adrenaline 1; 10,000 in children up to 10 years of age. Recommended dosing for adrenalin at this concentration is provided in Table 2.7.4.2

Table 2.7.4 1: Adrenaline Dosage (one in one thousand) according to Age

Age (years)	Dose of adrenaline (1:1000)
Less than 1	**0.05-0.1 mL**
1-2 (approx. 10 kg)	**0.1 mL**
2-3 (approx. 15 kg)	**0.15 mL**
4-6 (approx. 20 kg)	**0.2 mL**
7-10 (approx. 30 kg)	**0.3 mL**
11-12 (approx. 40 kg)	**0.4 mL**
12 and over	**0.5 mL**

Table 2.7.4 2: Adrenaline Dosage (one in ten thousand) according to Age

Age (years)	Dose of adrenaline (1:10,000)
Less than 1	**0.5-1 mL**
1-2 (approx. 10 kg)	**1 mL**
2-3 (approx. 15 kg)	**1.5 mL**
4-6 (approx. 20 kg)	**2 mL**
7-10 (approx. 30 kg)	**3 mL**

- Establish intravenous line, if possible
- Monitor vital signs every 15-30 minutes for at least 4 hours
- Administer either:
  - intravenous or oral corticosteroid, e.g., hydrocortisone or prednisone
  - intravenous or intramuscular antihistamine, e.g., diphenhydramine
- If there is bronchospasm administer either nebulized salbutamol via face mask or intravenous aminophylline
- Make arrangements to transport patient to hospital immediately

- Never leave patient alone
- Keep patient rested, avoid heat, and provide reassurance
- All cases should be admitted to hospital for further observation and treatment

Contraindications for subsequent doses:

- If anaphylaxis occurs, the same vaccine would be contra-indicated in the future

f) Encephalopathy and Encephalitis

Clinical features:

- Encephalopathy is the acute appearance of one of the following conditions after vaccination:
  - Convulsive crisis
  - Severe alteration of consciousness lasting a day or longer
  - Behavioral disorder lasting a day or more
- It may occur in the seven days following vaccination and must be notified in the first 24-48 hours after discovery
- Encephalitis is characterized by the signs and symptoms described for encephalopathy and is caused by cerebral inflammation
- In addition, pleocytosis of the CSF may be observed
- Any encephalitis occurring in the four weeks after immunization must be investigated and reported immediately
- Caregivers should be informed of this during the pre-vaccination educational session
- Encephalopathy or encephalitis may occur within the first 48 hours although they may also appear up to seven days after a DPT vaccine (encephalopathy), and seven to twelve days after a measles/MMR or yellow fever vaccination (encephalitis)

Management:

- Patient must be taken to hospital for admission, evaluation and neurological treatment

Contraindications for subsequent doses:

- Encephalitis and encephalopathy are both contraindications for all doses of the implicated vaccine. In the event of a DPT vaccine being given, continue with DT

g) Exanthema

Clinical features:

- A maculopapular type of erythematous skin eruption, usually generalized
- 5% of vaccinees receiving the measles or rubella vaccine may present with exanthema 7 to 10 days after vaccination, lasting approximately two to four days

Management:

- Determine whether the event is post-vaccination or a case of measles, rubella, chicken pox or other skin condition and manage accordingly
- Notify the event and investigate as for fever and rash

Contraindications for subsequent doses

- None

h) Thrombocytopaenic Purpura

Clinical features:

- Haemorrhagic-type skin lesions (petechiae and ecchymoses) caused by a reduction in the number of platelets
- Blood may also be found in mucous membranes and internal organs
- May occur in the first two months after vaccination, in 1 in 30,000 to 1 in 40,000 vaccinees with the measles vaccine; infrequent with the Hib vaccine

Management:

- Specialist evaluation required

Contraindications for subsequent doses:

- In the event of post-vaccine purpura, the severity of the symptoms must be evaluated by a physician to decide whether a subsequent dose is indicated or not

i) Vaccine-Associated Paralytic Poliomyelitis (VAPP)

The risk of VAPP is higher for the first dose than for subsequent doses.

Clinical features:
Paralytic poliomyelitis associated with the OPV vaccine is characterized by:

- Appearance of acute flaccid paralysis (variable intensity, generally asymmetric, lower limbs usually) between 4 and 40 days after receiving the vaccine or between 4 and 85 days after contact with a vaccine
- Followed within 60 days of the motor deficit onset by neurological sequelae compatible with poliomyelitis

Management:

- Refer to specialist
- Treatment is symptomatic, with the aim of reducing sequelae
- The isolation of polio vaccine virus in faeces is necessary for the case to be confirmed as associated with the vaccine
- Two faecal samples must therefore be obtained as early as possible, in the first 15 days after onset of the paralysis with a minimum interval of 24 hours, for cultivation and isolation of the virus
- The Surveillance Unit and Family Health Unit must be notified immediately

Contraindication for subsequent doses of OPV:

- Further doses of OPV are contraindicated. Give IPV instead.

j) Toxic Shock

Clinical features:

- Sudden appearance of fever, vomiting and diarrhoea a few hours after vaccination
- Often leading to death in 24 to 48 hours

Management:

- This is an emergency and the patient must be taken to hospital for adequate treatment (rehydration, antibiotics, oxygen therapy, use of vasopressors and other intensive care measures)

Contraindications for subsequent doses:

- None, however the findings of the investigation and the report of the physician must be taken into account

k) Peripheral Neuritis (brachial or sciatic)

Clinical features:

- Pain in the affected area and limb (shoulder, arm, gluteus or thigh)
- Followed by weakness and reduction in muscle mass
- Loss of feeling is not prominent
- Occurs 2 to 28 days after vaccination and may be the manifestation of an infection, immunocomplexes or direct damage to a nerve at the time of injecting the vaccine

Management:

- Treatment is symptomatic
- Analgesics and evaluation by a specialist are indicated

Contraindications for subsequent doses

- None. Special attention must be paid to vaccination technique

2.7.5 Detecting, Reporting and Investigating ESAVI

See Chapter 3 (section 3.5) on ESAVI Surveillance.

2.7.6 Communicating with the Media about ESAVI

The media (newspaper, radio, and television) play an important role in public perception. Understanding what the media want for a story will assist communication with them.

In certain situations, media coverage is likely to raise public concern about immunization. In these situations, it is important to communicate with the Family Health Unit, prior to the information being disseminated to the media. The communication should include preparation on how to deal with the public concern on this issue, to minimize the potential harm. It is also useful to have other groups and individuals that have public respect and authority, e.g. Medical Association of Jamaica and Paediatric Association of Jamaica, make public comments to endorse and strengthen key messages.

Designating the spokesperson(s) to communicate with the media limits the possibility of conflicting messages coming from different sources. The spokesperson should have some training on media relations and be designated and trained before any vaccine safety issues arise, so that the spokesperson can develop a relation with key reporters. In general, the Chief Medical Officer (CMO) or the Director, Family Health Unit should communicate with the media on serious adverse events.

Decisions to suspend use of, or recall, a vaccine or specific lot is the responsibility of the Director, Family Health and needs to be made as swiftly as possible but should be very carefully thought out. The impact on the immunization programme, alternate sources of vaccine, and the reliability of the evidence on which the decision is based, need careful scrutiny. In particular, there needs to be consideration concerning the possibility of biased reporting resulting from an alert about a possible problem with a vaccine or lot. Consultation with the vaccine manufacture and PAHO/WHO is advisable before making the decision.

Refer to Appendix I for details regarding the Crisis Management Plan for ESAVIs.

Chapter 3: Surveillance

3.1 Introduction

Surveillance is the ongoing and systematic collection, interpretation and dissemination of health information essential for the planning, implementation and evaluation of public health activities. It can be described simply as 'information for action".

The three primary surveillance activities are:

1. collection of relevant health data for a specified population, time period and/or geographic area
2. meaningful analysis (interpretation) of data
3. routine dissemination of data with accompanying interpretation

The overall goal of surveillance is to reduce morbidity and mortality through the prevention and control of diseases and other adverse health events.

Each EPI Team Member is a Surveillance Officer!

Collect information on vaccination coverage and cases of vaccine-preventable disease, and submit it to the parish, regional and national levels, where it is analyzed and plans for the future are made based on interpretations of the data.

Surveillance is important to the EPI to:

- evaluate the effectiveness of the immunization programme on the occurrence of vaccine-preventable diseases (VPDs)
- identify high-risk groups and/or geographic areas where intensified immunization activities may be needed
- identify outbreaks so that control measures, including supplemental immunization activities (SIAs), may be implemented

Surveillance data must therefore be timely and complete to accurately reflect the occurrence and distribution of disease.

3.2 Surveillance Systems in Jamaica

The purpose of the National Surveillance System is to collect, collate, analyze and interpret data for action on:

a) reportable communicable diseases or health events as stipulated in the Public Health Act, Quarantine Act or gazette thereafter, and
b) syndromes under surveillance at sentinel sites

The surveillance system for VPDs is used to:

- monitor trends in VPDs
- define endemic levels and epidemic thresholds
- detect clusters of cases, outbreaks, epidemics and the potential for same
- document magnitude, distribution and spread of disease
- determine the need for public health action
- assist in planning of interventions to mitigate and control disease spread, and for disaster management
- assess effectiveness of public health programmes
- evaluate the effects of immunization services on the number of suspected cases and deaths from VPDs
- identify health disparities
- define natural history of disease
- facilitate research
- monitor changes in disease agents
- forecast future trends and events in diseases

Sources of surveillance data:

- Vital statistics
- Censuses
- Morbidity reports (hospital records)
- Mortality data
- Disease registries
- Sentinel Sites reports
- Case investigations
- Epidemic field reports
- Laboratory reports
- Special surveys (e.g. Jamaica Health and Lifestyle Survey)
- Biologics and drug distribution records
- Disease notifications
- Hospital Active Surveillance Reports
- Laboratory surveillance
- Hotel surveillance
- Port health surveillance (air and sea ports)
- Informal e.g. news, rumours, etc.
- ESAVI monitoring

Figure 3.2.1 outlines the levels of flow of surveillance information in Jamaica.

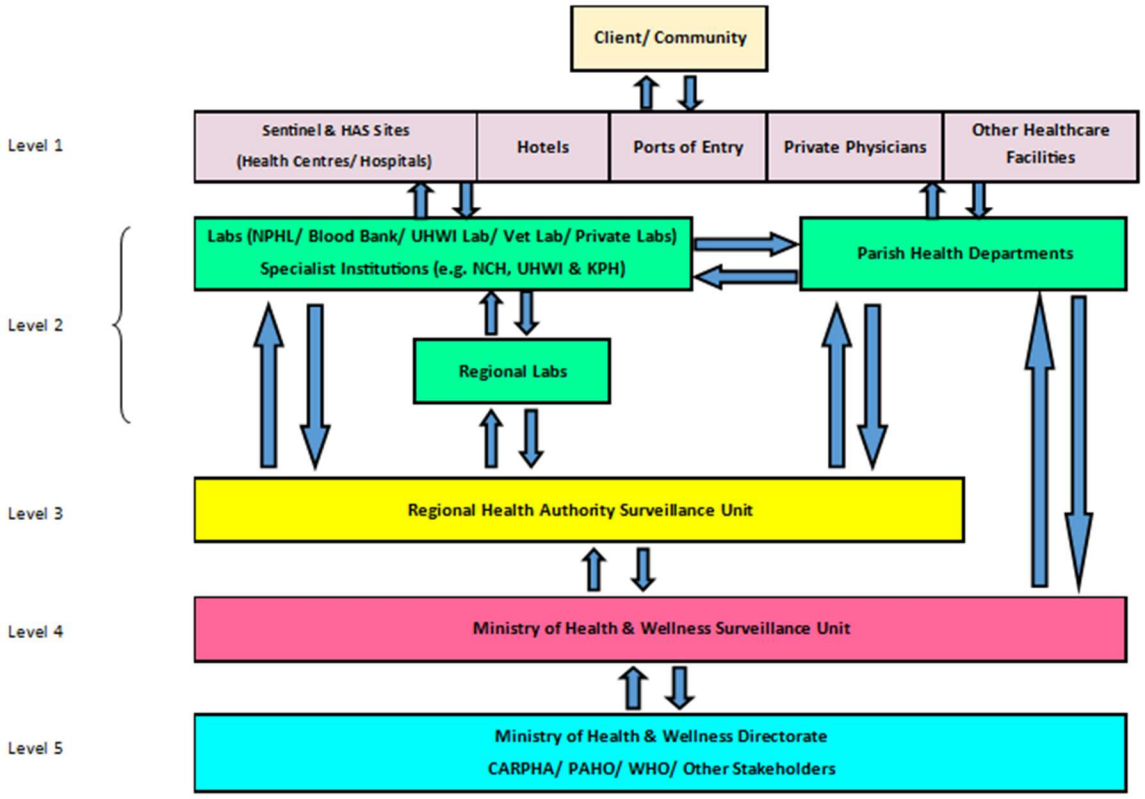


Figure 3.2 1: Levels of flow of surveillance information

Surveillance in Jamaica is conducted using active and passive surveillance systems:

1. *Passive surveillance* is a provider-initiated method of data collection on health events.
    - Health care providers send notifications and reports to a designated public health facility (e.g. the parish health department) in compliance with a known set of rules or regulations (e.g. the Public Health Act)
    - Passive surveillance requires timely and complete data
    - Health care providers ought to be aware of notifiable diseases/conditions and take relevant actions

2. *Active surveillance* is health-facility initiated.
    - Public-health personnel (e.g. hospital active surveillance or HAS officers) visit healthcare facilities or community sites to find suspected or confirmed cases of notifiable diseases/events
    - Active surveillance is costly and time-consuming

No single surveillance tool is perfect, and usually combinations of approaches work best.

Jamaica has three classes of notifiable diseases/health events. These are Class I, Class II and Class III.

3.2.1 Class I Disease/Health Events

Class I diseases/health events are of highest priority because of

1. their potential to cause high morbidity and/or mortality
2. their significance as diseases/events of national/international interest
3. the establishment of special programmes for these diseases/events

Class I diseases/health events are mainly infectious diseases, and include:

- those that are subject to international health regulations, such as cholera and yellow fever
- those under international surveillance, for example, HIV and AIDS, malaria, and VPDs such as measles, diphtheria, polio and tetanus
- any exotic or unusual disease, or occurrence of an unusual disease in unusually high numbers

Note that:

- if the number of cases exceeds its epidemic threshold, only the Chief Medical Officer can declare an outbreak or epidemic
- health care providers must report suspicion of Class I diseases within 24 hours to the parish health department and the NSU, as stipulated by the Class I Disease Order
    - the Class I Notifiable Diseases Reporting Form (See Appendix A) must be completed on suspicion, at first contact with the client. This facilitates timely initiation of case investigations and control measures
    - most VPDs are Class I, however Mumps is a Class III notifiable disease and Influenza is a Class II notifiable disease

Class I notifiable VPDs under the Public Health Act are:

- Acute Flaccid Paralysis (AFP)/Polio
- Congenital Rubella Syndrome
- Diphtheria
- Fever and Rash
- Hepatitis B and C
- Measles
- Meningitis
- Pertussis-like Syndrome
- Rubella
- Tetanus
- Tuberculosis
- Yellow Fever
- Zika
- Chikungunya
- COVID-19

The list of other notifiable diseases/events can be found in the MOHW National Surveillance Manual. Table 3.2.1.1 summarizes the Jamaica's reporting requirements for Class I notifiable conditions.

Table 3.2.1 1: Summary of Local Reporting Requirements for Class I Conditions

Entity	Reporting Content	To	Using	Timeline
Health Provider	Suspicious case of Class I condition or health event. Indicate: - demographic and contact information for the patient - symptoms - date of onset of symptoms - travel history - immunization history - laboratory information (date of sample collection) - other pertinent information to assist with case identification, investigation and data analysis	Medical Officer (Health) at the parish health department	Class I Notifiable Disease Form (NB fill out form at first contact with the patient)	Report on suspicion within 24 hours of contact
Parish Health Department	Class I notifiable disease/ health event	Regional Epidemiologist/ Surveillance Officer; National Surveillance Unit Parish Health Department in which patient resides, if it differs from the one in which he/she received healthcare	Telephone , faxed notification or email followed by hard copies	Immediately on receiving Class I notification

3.2.2 Class II Diseases/Health Events

Class II diseases/conditions are reported weekly in a line-listing format to the parish health department. Data captured on line lists should include:

- patient's full name
- address and landmark or means of locating the individual if the address is not available
- next of kin
- age/date of birth
- sex
- occupation
- work/school address
- date of onset of symptoms
- date of first report
- lab results (if available)
- case classification

Influenza is a Class II notifiable disease.

3.2.3 Class III Diseases / Health Events

Class III diseases/health events include sexually transmitted infections and are reported to the Parish Health Department, Regional Health Authority and National Surveillance Unit as monthly case totals.

Mumps is a Class III notifiable disease.

3.3 Roles and Responsibilities in the National Surveillance System

Parish

For each reportable disease/health event, the Parish Health Department:

1. verifies the diagnosis in order to confirm, discard the case, or request further investigation
2. searches for other cases (in the case of infectious diseases)
3. implements strategies to contain the spread of infectious diseases. This may include locating contacts

Region

The functions of the Regional Surveillance Unit include, but are not limited to, the following:

- collation, review and analysis of notification data
- transformation of notification data into information for action
- assistance with investigation on exceptional cases
- development of prevention strategies and actions
- provision of support and resources for surveillance at the local level
- monitoring and evaluation of parish health departments

MOHW Head Office

At the NSU, all notifications and investigation reports received should be routed to the desk of the MO(H) responsible for surveillance. He/She is responsible for assigning a Surveillance Officer to follow up on the investigation. The Surveillance Officer is responsible for:

- updating the notifiable diseases/health events electronic database
- ensuring that the relevant parish Health Department has initiated appropriate investigations
- ensuring that all relevant parish Health Departments have been notified, where more than one parish is involved, and that they are aware of their responsibilities in the investigation
- follow-up on the investigation periodically to ensure that investigation reports are completed and submitted to the NSU within the time frames specified

3.4 Surveillance of Class I Notifiable VPDs

The section discussed surveillance definitions, processes and procedures for the following Class I notifiable VPDs:

- AFP/Polio
- Fever and Rash/ Measles and Rubella
- Congenital Rubella Syndrome (CRS)
- Diphtheria
- Hepatitis B
- Pertussis
- Tetanus

- Tuberculosis

Areas discussed under each disease/condition are:

- Case definition and classification
- Case investigation
- Specimen collection and laboratory investigation (including handling, storage and transport of specimens)
- Prevention and control measures

The required reporting procedure is the same for all Class I notifiable diseases/conditions:

- Health care providers should report suspected cases to the parish Health Department within 24 hours using the Class I Diseases Notification Form (See Appendix A)
- Health Departments should notify the Regional Epidemiologist/Regional Surveillance Officer and the NSU immediately by phone or fax. Hard copies of the notification form must follow telephone/fax/email notifications
- NSU reports each case to the Family Health Unit and the EPI Regional Advisor

Note that patient information should not be transmitted over unsecured internet channels.

3.4.1 Acute Flaccid Paralysis (AFP)/Poliomyelitis

Polio has been targeted for worldwide eradication by the World Health Organization. In order to verify eradication, a robust surveillance system that is capable of detecting possible cases of polio should be in place. AFP surveillance is the gold standard for detecting cases of poliomyelitis.

Case Definition and Classification

AFP is the acute onset of a flaccid paralysis in the absence of trauma.[8]

[8] MOHW National Surveillance Manual 2009, page 24.

Suspected Case

- Any acute flaccid paralysis (AFP) in a person under 15 years of age, for which no cause can be immediately identified, or any case of suspected polio, regardless of age. This includes cases diagnosed with Guillain-Barré syndrome or Transverse Myelitis

Probable Case

- A suspected case in which the paralysis is flaccid and no other cause for the paralysis can be immediately identified

Confirmed Case

- A suspected or probable case, with or without residual paralysis, from which wild poliovirus is isolated from stool culture.

Classification as 'suspected' is temporary. Cases should be reclassified by the Surveillance Unit as 'probable' or 'discarded' within 48 hours of initial notification.

Case Investigation

The Public Health Nurse assigned to the case should:

1. initiate a case investigation within 24 hours of case identification:
    - obtain clinical history and laboratory test results from physician
    - obtain travel and immunization history
    - ensure appropriate specimen is collected and transported to the appropriate laboratory
    - visit the home, school, nursery or workplace as needed to search for other cases and obtain immunization history of close contacts
    - initiate community and hospital surveillance for additional cases
    - follow-up with attending physician/specialists for additional test results and clinical history, in preparation for completing the 60-day follow-up

2. complete and submit an Acute Flaccid Paralysis Case Investigation Form to the parish MO(H) within 48 hours of notification (see Appendix F)

3. complete a 60-day Follow-up Form (see Appendix G) based on a complete neurological examination to assess residual paralysis; information on this form should be based on consultation with the patient, physician, or physiotherapist

4. ensure that the patient is assessed by a physician at or after 60 days post the onset of paralysis

Specimen Collection and Laboratory Investigation

Confirmation of poliomyelitis is based on isolation of poliovirus from a clinical (stool) specimen.

Specimen Collection

- Collect two stool samples of approximately 12 grams (3 adult thumbnails) each at least 24 hours apart and within 14 days after the onset of paralysis
- Rectal swabs are not recommended because the amount of stool collected is inadequate for testing

Handling, Storage and Transportation of Specimens

- Place stool in a clean, dry, screw-capped container without any preservative
- The container should be labelled with the patient's name and date of collection
- Place specimen(s) immediately in a cold box or refrigerator at 4°C pending transport
- Transport on ice
- Specimens should be sent to the Enteric Section of the National Public Health Laboratory (NPHL), which forwards them to the WHO-accredited laboratory at the Caribbean Public Health Agency (CARPHA) in Trinidad
- The CARPHA Laboratory Form (see Appendix H) must accompany the specimen and should have (in bold across the top): 'For CARPHA'. The NPHL should be informed by phone that a specimen is en route

Note: If the patient dies before stool samples can be collected, an autopsy should be performed within 24 hours of death to determine cause of death and collect appropriate samples. These should be sent to CARPHA and the University Hospital of the West Indies (UHWI) Virology Laboratory in accordance with the surveillance manual.

Prevention and Control Measures

Containment activities are required as part of the outbreak response, following the identification of a suspected case. These include:

- intensified surveillance
- immunization of close contacts
- review of vaccination coverage and targeted immunization
- public education

3.4.2 Fever with Rash (Measles and Rubella)

Surveillance for Measles and Rubella is integrated into fever with rash surveillance. Although both diseases have been declared eliminated from Jamaica, the country remains on high alert for imported cases, and so surveillance is ongoing.

Case Definition and Classification

Suspected Case

- Any person presenting with, or giving a history of a body temperature ≥38°C (101.0°F) rectally or ≥38.6°C (101.5°F) axillary AND a generalized maculopapular rash
- Cases with fever and rash, for whom there is no obvious diagnosis or focus of infection, should be reported

Case Reclassification

- Suspected cases are re-classified as confirmed or discarded based on laboratory investigations for measles and rubella

- For cases lost to follow up, a review of the medical records by a physician should be done to classify the case

Figure 3.4.2.1 shows the scheme used in the Region of the Americas for case classification.

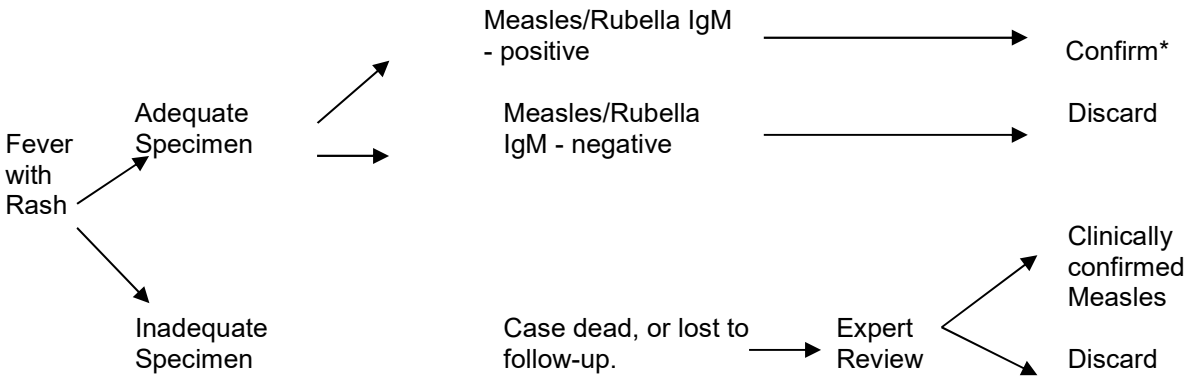


Figure 3.4.2 1: Scheme used in the PAHO Region for Case Classification.

* If a case has documentation of immunization with MMR 2 to 4 weeks prior to specimen collection, then discard as per advice from the CARPHA laboratory.

Case Investigation

Fever and rash requires the 'first contact strategy', that is, the case investigation is conducted by the first health care worker to see the case:

1. Initiate and submit a case investigation immediately:
    - Obtain clinical history and laboratory test results from physician
    - Obtain travel and immunization history
    - Ensure specimen collection and referral to the appropriate laboratory
    - The PHN assigned to the case should: visit the home, daycare, nursery, school or workplace to review immunization history of close contacts and search for other cases. All persons found to not be fully immunized, or not have documentation of immunization, should be vaccinated immediately with MMR
    - Initiate community and hospital surveillance for additional cases
    - Follow-up including review of the case with the attending physician/specialists to obtain the final diagnosis, and follow-up vaccinations at the home of the patient

2. Complete and submit a Fever and Rash Investigation Form to the parish MO(H) within 48 hours of notification

Specimen Collection and Laboratory Investigation

Laboratory testing for measles (and confirmation of rubella) must be done in a WHO accredited laboratory which uses standard methods and approved reagents, and which will have passed a recent proficiency test. At the writing of this document, the only WHO accredited laboratory within the Caribbean sub-region is located at the Caribbean Public Health Agency (CARPHA) in Trinidad.

The presence of IgM antibodies in serum indicates recent exposure to the virus, either through infection or immunization. Highly suspicious cases or confirmed cases should also have urine cultures processed for isolation of measles or rubella virus. This will assist in identification of the source of the virus.

Specimen Collection

- Approximately 5 to 10mL of blood should be collected in a red-top tube, i.e. one without any preservatives or anticoagulant
- An acute specimen should be collected at first contact (1-7 days after onset of symptoms) and a convalescent sample thereafter

- Blood – Convalescent:
  - Depending on the type of test done, a convalescent specimen may be requested
  - This should be taken 14 to 21 days after the onset of symptoms.

- Urine:
  - Urine specimen should be taken from high-risk individuals. The purpose of collecting a urine specimen is for virus isolation. This allows the laboratory to study the virus and obtain epidemiological information necessary to determine the original source.
  - High-risk individuals are any of the following persons:
    - visitors to Jamaica (especially from a country where measles is circulating)
    - locals who have been in contact with a visitor or have visited another country where measles is endemic recently
    - persons that form a cluster of suspected measles cases (random urine samples should be taken)
  - Urine should be collected within 10 days of rash onset (1-7 days is best)

- First-morning voided urine is ideal, but any urine specimen is adequate
- A volume of up to 100 mL of urine should be collected in an empty sterile specimen container

Handling, Storage and Transportation of Specimens

- Blood:
  - Blood specimens should be kept in an upright position for at least one hour to allow the blood to coagulate
  - If possible, the serum should be separated from the clot and placed into a clean receptacle i.e. a different red-top tube, a cryovial, or other suitable vial for safe transport of serum
  - The serum should be stored at 4°C or less until transportation to the laboratory
  - Storage of separated serum at –20°C is optimal
  - If serum separation is not possible at the collection site, the tube containing the clotted blood should be kept cool (but not frozen) and shipped to the laboratory within 24 hours after collection
  - The specimen should be transported to the Immunology Section of the National Public Health Laboratories for shipment to CARPHA. The laboratory form should have (in bold across the top): 'For CARPHA'. The laboratory should be informed by phone that a specimen is en route
  - At the Immunology Laboratory of the NPHL, the serum sample should be divided into two aliquots, each to be stored in cryovials approved by CARPHA. One aliquot is to be shipped to CARPHA and the second to be tested at the NPHL (also to serve as a backup in case of mishandling or loss of the sample sent to CARPHA)

- Urine:
  - The urine specimen must be kept cool at 4°C (ice packs or wet ice) and transported to the immunology section of the NPHL immediately or, in any case, within 24 hours
  - The laboratory and the NSU should be notified that a specimen is en route as these specimens require special handling
  - At the NPHL:
    - 50 mL of urine specimen should be transferred to a sterile plastic centrifuge tube and centrifuged at 1500rpm for 5-10 minutes at 4°C to pellet the sediment

- if no refrigerated centrifuge is available, an ordinary centrifuge will do
- the sediment should be re-suspended in 2 mL of viral transport media and stored at –70°C (if available) or –20°C pending shipment to CARPHA
- it is very important that the samples arrive at CARPHA within 5 days from the date of collection. This ensures optimal virus recovery

Prevention and Control Measures

- Public education and routine immunization are key to measles and rubella prevention
- Timely investigation of cases is critical for control of an outbreak and includes:
  - home visit within 48 hours of notification
  - adequate specimen collection
- Other control measures required following the identification of a suspected case are outlined below:
  - Suspected cases should be removed from the presence of young children and infants, until they have been classified as discarded
  - Highly suspicious (symptomatic high-risk) cases should be placed in respiratory isolation and treated until laboratory results are obtained
  - Confirmed measles cases should be treated appropriately and placed in respiratory isolation until day 5 after the onset of rash
  - A contact is a person that lives in the same household of the case or has close contact with the case 5 days before to 5 days after the onset of rash in the case:
    - Symptomatic close contacts of a confirmed or highly suspicious case should be placed in respiratory isolation and investigated as suspected cases
    - Asymptomatic close contacts of a confirmed or highly suspicious case should be quarantined at home until 21 days after last exposure when they can no longer infect others. They require vaccination against measles and rubella if not fully immunized or if evidence of immunization is not available

Data Management & Analysis

The following indicators for fever and rash surveillance must be monitored at both parish and national levels:

- percentage of sites (Sentinel and HAS) reporting every week (target is 90% or greater)
- percentage of sites reporting on time (target is 80% or greater)
- Fever with rash cases with investigations initiated in less than 48 hours after presentation to a health care facility (target is 80% or greater)
- cases with adequate blood specimens or epidemiological linkage to confirmed measles/rubella case (target is 80% or greater)
- specimens arriving at CARPHA within 5 days of collection
- proportion of total laboratory confirmed cases with source of infection identified (target is 80% or greater)
- number of cases with immunization history recorded and number with adequate immunization with MMR (i.e. 2 doses)
- number of cases confirmed and number discarded
- proportion of total cases with adequately completed investigation forms, which must include the following data points
    - unique identifier
    - address (community and parish)
    - name
    - date of birth
    - date of rash onset
    - date of notification
    - date of initiation of case investigation
    - date of specimen collection
    - date specimen sent to lab
    - number of doses of measles-containing vaccine received
    - date of last doses of measles-containing vaccine

3.4.3 Congenital Rubella Syndrome (CRS)

Region of the Americas was certified to have eliminated rubella and congenital rubella syndrome in 2015.

Case Definition and Classification

Suspected Case

- An infant less than one year of age clinically suspected of having CRS and presenting with one or more of the following: congenital cataracts, glaucoma, deafness, microphthalmia, microcephaly, congenital heart defects or meningoencephalitis

OR

- An infant born to a woman who had confirmed rubella infection during pregnancy or who received MMR vaccine during pregnancy

OR

- An infant less than one year of age with a positive result for Rubella IgM antibodies at a non-WHO accredited laboratory

Confirmed Case

- A suspected case of CRS with supportive laboratory evidence from a WHO accredited laboratory.

Case Investigation

The Public Health Nurse (PHN) assigned to the case should:

1. initiate a case investigation within 48 hours of case identification
- Obtain clinical history and laboratory test results from physician
- Obtain mother's immunization and travel history during pregnancy and history of illness/contact with rubella case during pregnancy
- Ensure appropriate specimen is collected and transported to the appropriate laboratory
- Visit the home to review immunization history of close contacts and search for other cases. All persons found to not be fully immunized or not have documentation of immunization should be vaccinated immediately
- Initiate community and hospital surveillance for additional cases
- Follow-up includes review of the case with the attending physician/specialists to obtain the final diagnosis

2. The CRS investigation should be completed, with the report submitted to the parish MO(H) within 48 hours of notification.

Specimen Collection and Laboratory Investigation

Diagnosis of CRS can be based on any one of the following:

- Detection of rubella-specific IgM antibodies in infant serum specimen(s)
- Maintenance or increase in IgG antibody titre between acute and convalescent samples
- Isolation of rubella virus from nasopharyngeal swab, urine, CSF or blood
- Detection of rubella virus in tissues by PCR

Specimen Collection

- Blood:
  - At first contact, collect 5 to 10 mL of blood in a red-top tube
  - Additional convalescent blood specimens may be requested and should be collected in the same way
- Urine:
  - Urine specimens should only be taken from highly suspected cases and from confirmed cases to isolate the rubella virus and determine its source
  - Collect up to 100 mL of urine in an empty sterile specimen container

Handling, Storage and Transportation of Specimens

- Blood:
  - Keep blood specimens in an upright position for at least one hour to allow the blood to coagulate
  - The serum should be separated and stored at 4°C or less and transported to NPHL within 24 hours
- Urine:
  - Keep cool at 4°C (ice packs or wet ice) until transported to the laboratory
- Transport specimens to the Immunology Section of NPHL for shipment to the Caribbean Public Health Agency (CARPHA)
- Notify the NSU and NPHL that the specimen is en route

Prevention and Control Measures

- Public education and routine immunization are key to CRS prevention
- Containment activities are required following the identification of a suspected case
- Babies suspected of having rubella should be managed under contact isolation precautions and placed in a private room
- Only health care workers who are not pregnant should be involved in their medical care.
- Medical providers should be notified immediately if the suspected case develops a rash
- Close contacts should be immunized if they are not already and should remain at home while they are still infectious
- Intensified surveillance, review of vaccination coverage and targeted immunization, and public education are all important parts of the response

3.4.4 Diphtheria

Diphtheria is a severe, acute and highly contagious disease caused by strains of the bacterium *Corynebacterium diphtheria*. This disease that has significant epidemic potential, and therefore remains a global public health concern.

Case Definition and Classification

Suspected Case

- A person presenting with acute pharyngitis, nasopharyngitis, tonsillitis or laryngitis AND a nasal, pharyngeal, tonsillar or laryngeal adherent pseudomembrane

Confirmed Case

- Cases may be confirmed in one of two ways:
    - A ***laboratory confirmed case*** is a suspected case from whom *Corynebacterium diphtheriae* was isolated from bacterial culture
    - An ***epidemiologically confirmed case*** is a suspected case that is epidemiologically linked to a laboratory confirmed case

Case Reclassification

- Suspected cases are reclassified as confirmed or discarded based on laboratory investigations.

Case Investigation

The Public Health Nurse assigned to the case should:

1. Initiate a case investigation within 48 hours of case identification
- Obtain clinical history and laboratory test results from physician
- Obtain travel and immunization history
- Ensure specimen collection and transportation to the appropriate laboratory
- Visit the home, day care, nursery or workplace to review immunization history of close contacts and search for other cases. All persons found to not be fully immunized, or not have documentation of immunization, should be vaccinated immediately
- Initiate community and hospital surveillance for additional cases
- Follow-up includes: review of the case to obtain the final diagnosis and outcome; home visit; check for additional cases; follow-up vaccinations

2. Complete and submit an investigation report to the parish MO(H) within 7 days of notification

Specimen Collection and Laboratory Investigation

Laboratory confirmation of Diphtheria is based on:

- Culture of *C. diphtheriae* (throat, nose, nasopharyngeal, skin)
- Gram stain may aid in diagnosis

<u>Caution: Ensure that personal protective equipment is used and that respiratory support is available for specimen collection.</u>

Specimen Collection

- Throat, nose, nasopharyngeal, skin swabs:
  - At first contact, swab the lesion with a cotton-tipped swab stick
  - Place swab in transport (Amies) medium and transport at room temperature
  - Parish Health Department should contact the Microbiologist at NPHL upon collection of the sample and verify the collection of the sample

Handling, Storage and Transportation of Specimens

- Transport specimens to the bacteriology section of NPHL accompanied by a copy of the completed CARPHA laboratory request form (see Appendix H)
- Age of the patient, clinical presentation, and site of the swab are mandatory fields

Prevention and Control Measures

- Public education and routine immunization are key to diphtheria prevention.
- Control of diphtheria is based on:
    - primary prevention of disease by ensuring high population immunity (target > 90% coverage)
    - secondary prevention of spread by conducting rapid investigation of close contacts, as well as isolation/quarantine
    - tertiary prevention of complications and death through early diagnosis and proper management
- Control measures are required following the identification of a suspected case
- Suspected cases should be placed in strict isolation and treated
- All articles in contact with the patient and all articles soiled by discharges of patient should be disinfected by terminal cleaning
- Close contacts should remain at home until they can no longer infect others, and should be vaccinated against diphtheria if they are not fully immunized

Prophylactic Treatment of Carriers

- All close contacts should have cultures taken for testing and should be kept under surveillance for 7 days
- A single dose of penicillin (IM) or a 7-10-day course of erythromycin (PO) is recommended for all persons exposed to diphtheria, regardless of their immunization status
- A single dose of benzathine penicillin G (IM) (600,000 units for persons <6 years of age and 1.2 million units for persons 6 years of age) or a 7-10 day course of erythromycin (PO) (40 mg/kg/d for children and 1 g/d for adults) has been recommended
- If cultures are positive, patients should be treated with antibiotics
- Contacts who handle food or work with school children should be excluded from work or school until bacteriologic examination proves them not to be carriers

- Previously immunized contacts should receive a booster dose of diphtheria toxoid, and a primary series should be initiated in un-immunized contacts, using Td, DT or DTP vaccine depending on age
- The search for carriers by use of nose and throat cultures is not ordinarily useful or indicated

Epidemic measures

- Immunize the largest possible proportion of the population group involved, with emphasis on protection of infants and preschool children
- In an epidemic involving adults, immunize groups that are most affected and at high risk. Repeat immunization procedures 1 month later to provide at least 2 doses to the recipients
- Identify close contacts and define population groups at special risk. In areas with appropriate facilities, carry out a prompt field investigation of reported cases to verify diagnosis, determine biotype and toxigenicity of *C. diphtheriae*

3.4.5 Hepatitis B

Hepatitis B is a potentially life-threatening liver infection caused by the hepatitis B virus (HBV). It is a major global public health problem as it can cause chronic infection and puts people at high risk of death from cirrhosis and liver cancer. Hepatitis B is also an important occupational hazard for health care workers.

Case Definition and Classification

Suspected case

- A person presenting with anorexia, abdominal pain, nausea, vomiting or jaundice;

OR

- A person, with or without symptoms, who has been in close contact with a confirmed case. Close contact includes sexual contacts, household contacts and children in nurseries/day-care centres.

Confirmed case

- A suspected case with laboratory confirmation of Hepatitis B infection using one of the following:
    - detection of Hepatitis B surface antigen in the serum
    - detection of serum antibodies to the Hepatitis B core antigen (HBcAg); OR
    - detection of serum antibodies to the Hepatitis B e antigen (HBeAg)

Case Reclassification:

- Reclassification of suspected or probable cases to 'confirmed' is based on laboratory evidence of infection

Case Investigation

- Case investigation is the responsibility of the public health nurse and the contact investigator as directed by the parish MO(H)
- In general, investigation involves:
    - taking of case history to attempt to discover the source of the infection e.g. history of sexual contacts, occupational risk, or other risk (history of obtaining a tattoo, injection drug use, recipient of donated blood or blood product, etc.)
    - counselling of sexual and household contacts re risk of exposure, symptoms, sequelae and disease spread
    - testing of contacts to determine if they have also been infected
- Cases should be investigated using the standard form provided by the Surveillance Unit. The time frame for submission of case investigation reports to the parish MO(H) is 6 weeks from identification of the case.

Further details on case investigation and counseling are provided in the Ministry of Health and Wellness's Contact Investigation Field Guide Manual.

Specimen Collection and Laboratory Investigation

Three clinically useful antigen-antibody systems have been identified for hepatitis B:

1. *Hepatitis B surface antigen (HBsAg) and antibody to HBsAg (anti-HBs)*

HBsAg can be detected in the serum from several weeks before onset of symptoms to

days, weeks or months after onset; it persists in chronic infections. HBsAg is present in serum during acute infections and persists in chronic infections. The presence of HBsAg indicates that the person is potentially infectious.

2. *Hepatitis B core antigen (HBcAg) and antibody to HBcAg (anti-HBc)*

Anti-HBc appears at the onset of illness and persists indefinitely. Demonstration of anti-HBc in serum indicates HBV infection, current or past; IgM anti-HBc is present in high titre during acute infection and usually disappears within 6 months, although it can persist in some cases of chronic hepatitis; thus, this test may reliably diagnose acute HBV infection.

3. *Hepatitis B e antigen (HBeAg) and antibody to HBeAg (anti-HBe)*

The presence of HBeAg is associated with relatively high infectivity.

Specimen Collection

- Approximately 5 to 10 mL of blood should be collected in a red-top tube i.e. one without any preservatives or anticoagulant
- Persons that test positive for HBsAg should be retested 6 months subsequently to differentiate persons who have cleared the virus from those with chronic infection

Handling, Storage and Transportation of Specimens

- Blood specimens should be kept in an upright position for at least one hour to allow the blood to coagulate
- If possible, the serum should be separated from the clot and placed into a clean receptacle i.e. a different red-top tube, a cryovial or other suitable vial for safe transport of serum
- The serum should be stored at 4°C or less until transportation to the laboratory
- Storage of separated serum at –20°C is optimal
- If serum separation is not possible at the collection site, the tube containing the clotted blood should be kept cool (but not frozen) and shipped to the laboratory within 24 hours after collection
- The specimen should be transported to the Immunology Section of the National Public Health Laboratory

Prevention and Control Measures

- There is no cure for Hepatitis B infection
- The majority of cases will develop antibodies to the HBsAg antigen and clear their infection in a few weeks or months. Some persons, however, will become chronically infected. The infection is considered chronic when HBsAg persists for longer than 6 months after the resolution of symptoms.

Preventive measures

Spread of this virus can be prevented using the following strategies:

- The general public should be educated on the nature of the infection – risk factors for acquiring the virus, the symptoms, and the value of immunization against it
- All health care workers (e.g. surgeons, dentists, oral surgeons, pathologists, operating room and emergency room staff, and clinical laboratory workers who handle blood are at highest risk) should receive the Hepatitis B vaccination series
- Health care workers should always employ standard precautions when handling blood, blood products, organs, tissue, semen or other body fluids
- Health care workers should practice the recommended procedures for safe disposal of used needles
- Health facilities should ensure that the proper containers are used for discarding of needles so as to decrease incidences of needle stick injuries
- Blood donors should be tested for Hepatitis B infection
- Infected persons should be educated on the nature of the disease and how it is spread. They should be educated on strict condom use for every sex act
- Infected persons should not donate blood, plasma, body organs or tissues, or semen until it can be demonstrated that the HBsAg test is negative
- Women who are infected should be made aware that if they become pregnant during the period that they test positive for the HBsAg, there is a high likelihood that they will pass the virus to their unborn child
- Universal hepatitis B vaccination of neonates within 24 hours of birth is highly effective at preventing perinatal transmission of Hepatitis B
- Infants born to women who are actively infected should be given Hepatitis B immune globulin along with a Hepatitis B vaccination series as soon as possible after birth
- Infected persons should be educated on methods of preventing spread to household contacts i.e. cuts or skin lesions should be covered; toothbrushes, utensils, razors etc. should not be shared with others
- Infected persons should be educated to always inform health care practitioners (e.g. dentists and physicians) of their infectious status

- All infants should be immunized with the Hepatitis B vaccine as per government schedule

Control measures

The main methods of control are:

- vaccination to prevent infection
- contact tracing of confirmed cases to identify new cases and prevent spread
- treatment of recent contacts of confirmed cases with immune globulin (e.g. infants born to infected mothers)

3.4.6 Pertussis

Pertussis, or whooping cough, is a disease of the respiratory tract caused by *Bordetella pertussis* bacteria that live in the mouth, nose and throat. Pertussis is a highly communicable disease that affects unimmunized infants in particular, and therefore remains a public health concern globally, including in countries where vaccination coverage is high.

Case Definition and Classification

Suspected Case

- [9]A person with a cough lasting at least 2 weeks with at least one of the following:
  - paroxysms (i.e. fits) of coughing
  - inspiratory "whooping"
  - post-tussive vomiting (i.e. vomiting immediately after coughing)
  - without other apparent cause

Confirmed Case

Cases may be confirmed in one of three ways:

- A *laboratory confirmed case* is a suspected case with positive laboratory findings
- An *epidemiologically confirmed case* is a suspected case that is epidemiologically linked to a laboratory confirmed case
- A *clinically confirmed case* is a suspected case that has been evaluated by a competent medical professional and diagnosed with Pertussis. Pertussis is commonly diagnosed based on history and physical examination findings

[9] WHO Recommended Surveillance Standards 2nd Edition (WHO/CDS/CSR/ISR/99.2) http://www.who.int/csr/resources/publications/surveillance/whocdscsrisr992.pdf

Case Reclassification

- Suspected cases are re-classified as confirmed or discarded based on laboratory investigations or evaluation by a competent medical professional

Case Investigation

The Public Health Nurse (PHN) assigned to the case should:

1) Initiate a case investigation within 48 hours of case identification

- Obtain clinical history and laboratory test results from physician
- Obtain travel and immunization history
- Ensure specimen collection and referral to the appropriate laboratory
- Visit the home, day care, nursery, school or workplace to review immunization history of close contacts and search for other cases. All persons under age 7 years found to not be fully immunized, or not to have documentation of immunization, should be vaccinated immediately
- Initiate community and hospital surveillance for additional cases
- Follow-up includes review of the case with the attending physician/specialists to obtain the final diagnosis, and follow-up vaccinations at the home of the patient

2) Complete and submit an investigation report to the parish MO(H) within 6 weeks of notification

Specimen Collection and Laboratory Investigation

Laboratory confirmation of pertussis is based on:

- Isolation of *Bordetella pertussis* from culture of the posterior nasopharynx
- Direct fluorescent antibody testing
- Polymerase Chain Reaction (PCR)
- Detection of pertussis-specific serum IgM may aid in diagnosis

Specimen Collection

- Nasopharyngeal swab:
    - Prior to sample collection, contact National Surveillance Unit and Consultant Microbiologist at NPHL
    - At first contact and as early in the cough as possible, swab the posterior nasopharynx with polyester (Dacron), rayon or nylon-tipped swab and place in Reagan-Lowe or Amies medium containing charcoal

- Blood:
    - In the event of a verified or suspected outbreak, collect blood in a red top tube

Handling, Storage and Transportation of Specimens

- Nasopharyngeal swab:
    - Transport to the laboratory between 15°C to 30°C (room temperature)
    - Contact the laboratory to ensure that blood agar plates are available and make alternative arrangements with NPHL or other laboratory if they are not
    - Rapidly transport the swab to NPHL (with correct media) at room temperature within 24 hours OR streak the swab onto Reagan-Lowe or Bordet-Gengou agar (with 15% defibrinated horse blood)
- Blood
    - Store blood samples upright for approximately 1 hour (or until blood has coagulated)
    - Separate the serum and place it in a sterile tube for transport to the laboratory
    - Serum samples should be sent to the Immunology Section of NPHL for shipment to CARPHA
    - NPHL should be informed by phone that the serum is en route
    - The laboratory form should have (in bold across the top): “For CARPHA”

Prevention and Control Measures

- Public education and routine immunization are key to pertussis prevention
- Control measures are required following the identification of a suspected case
- Suspected cases should be removed from the presence of young children and infants, until they have received at least 5 days of a minimum 14-day course of antibiotics
- Confirmed cases should be placed in respiratory isolation and treated
- Symptomatic close contacts should remain at home until they can no longer infect others. They should also receive a 14-day course of Erythromycin regardless of age and immunization status
- Asymptomatic contacts should be vaccinated against pertussis if they are below age 7 years and not fully immunized. Whole cell pertussis-containing vaccine is not given to persons older than 7 years of age. They should also receive a 14-day course of Erythromycin regardless of age and immunization status

3.4.7 Tetanus

Tetanus, also known as “lock jaw”, is a serious wound infection caused by the bacterium *Clostridium tetani*, found in soil, dust and animal faeces. The germ produces toxins that affect the brain and nervous system, resulting in muscle stiffness.

Case Definition and Classification

Suspected Case

a) Neonatal Tetanus – An infant between the ages of 3 to 28 days who, having been able to suck normally for the first few days after birth, develops an inability to suck**.**

> Death of a neonate between the ages of 3 and 28 days should be reviewed by a competent medical professional, given the possibility that tetanus is a differential diagnosis.

b) Non-neonatal Tetanus – Any person experiencing difficulty swallowing, contraction of the jaw and neck muscles, followed by muscle spasm and rigidity. History of an injury is supporting evidence of possible exposure but is not necessary.

Confirmed Case

a) Neonatal Tetanus – A suspected case with one or more of the following:
   - facial grimace
   - stiffness of the body and arching of back
   - generalized spasms or convulsions

   Figure 3.4.7.1 shows and image of a neonate diagnosed with tetanus.

Figure 3.4.7 1: Neonatal Tetanus

b) Non-neonatal Tetanus – A suspected case exhibiting the typical facial expression "risus sardonicus"

Figure 3.4.7.2 shows an image of an adult male diagnosed with tetanus, with the "risus sardonicus" facial expression.

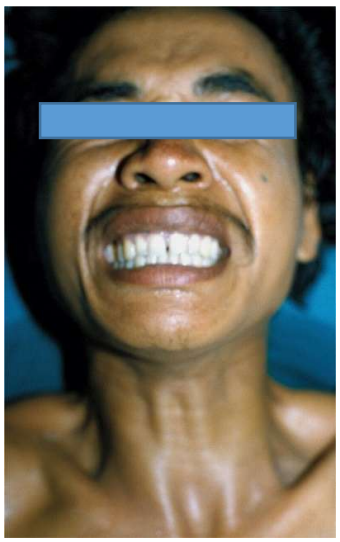


Figure 3.4.7 2: Risus Sardonicus in Non-neonatal Tetanus

Case Reclassification:

- Suspected cases are confirmed or discarded based on case history and clinical presentation

Case Investigation

1. The Public Health Nurse, along with the Public Health Inspector, is responsible for:
   - case review to obtain the clinical history, date and site of injury, date of illness onset, signs and symptoms, and current presentation;
   - obtain details of immunization history;
   - ensuring specimen collection and referral to the appropriate laboratory (optional depending on the case's history and presentation);
   - conducting a home visit to evaluate living conditions (this goes towards education for injury prevention, proper cleaning of wounds, etc.) and to review immunization status of household members, especially children and pregnant women. Follow-up of case review with physician to obtain final diagnosis;
   - follow-up home visit to review the case, ensure implementation of previous recommendations, and follow-up vaccinations as necessary.

2. Every suspected case of tetanus must be investigated within 48 hours using the appropriate investigation form

3. Completion of the form is the responsibility of a public health nurse assigned to the case by the parish MO(H) and must be done and submitted within 6 weeks of case notification

Specimen Collection and Laboratory Investigation

An appropriate specimen from debridement or wound swab should be collected and sent to NPHL or CRH (Bacteriology section) along with a copy of the investigation form. Note however that the diagnosis may be made without laboratory tests. The isolation of the organism from the wound is of little value since it may be recovered from the wounds of persons who show no signs of tetanus.

Prevention and Control Measures

There are three main lines of prevention:

- active immunization against tetanus
- antibacterial measures for wounds and deliveries of babies
- passive immunization of possible cases with immune globulin

a) Active Immunizations:

- Active immunization with tetanus toxoid is the most satisfactory method of preventing tetanus
- Ideally everyone should be given a course of active immunization, according to the national immunization schedule

b) Antibacterial Measures

- The general public should be educated on the hazards of puncture wounds, proper cleansing of wounds with soap and water, and seeking medical intervention when appropriate
- Medical institutions must employ appropriate measures for adequate cleaning of wounds and careful debridement as well as protection of wounds to avoid contamination
- Maternity personnel and institutions should institute/maintain clean delivery programmes to prevent cases of neonatal tetanus
- Antibiotics, especially long acting penicillin, can also be given to suppress bacterial multiplication. If the wound is old, i.e. more than 12 hours, tetanus may occur despite adequate doses of penicillin

c) Passive Immunization:

- Tetanus antitoxin (ATS) or Tetanus Immune Globulin (TIG) are used for treatment
    - Fifteen hundred (1500) units of ATS are given in the average case although a larger dose may be required for patients who present with heavily contaminated wounds
    - Note that a test dose of ATS should be given to patients in order to test for adverse reactions. Repeated doses are not recommended, as it will lead to sensitization of the patient thereby creating the hazard of allergic reaction. These later doses are also rapidly eliminated from the body and are therefore less effective for prevention and treatment
    - TIG is administered intramuscularly at a dose of 3000 to 6000 IU

3.4.8 Tuberculosis

The overall objective of tuberculosis control is to reduce morbidity, mortality and transmission of the disease until it no longer poses a threat to public health.

Case Definition and Classification

Suspected Case

- Persistent cough for greater than three (3) weeks.

Confirmed Case

- Bacteriologically confirmed case is one from which a biological specimen is positive by smear microscopy for acid fast bacilli, culture of Mycobacterium tuberculosis or WHO recognized rapid diagnostic test, e.g. Xpert MTB/RIF

- Clinically diagnosed TB case is one who does not fulfill the criteria for bacteriological confirmation but has been diagnosed with active TB by a medical practitioner who has decided to give a complete course of treatment

Classification

1. Pulmonary tuberculosis

- Bacteriologically confirmed or clinically diagnosed case of tuberculosis involving the lung parenchyma or the tracheobronchial tree
- Miliary tuberculosis is classified as pulmonary tuberculosis
- A person with both pulmonary and extrapulmonary tuberculosis should be classified as pulmonary tuberculosis

2. Extrapulmonary tuberculosis

- Any bacteriologically confirmed or clinically diagnosed case of tuberculosis involving organs other than the lungs, e.g. pleura, lymph nodes, joints, bones, meninges

Refer to the Tuberculosis Manual and the National Surveillance Manual for details on case investigation, specimen collection laboratory investigation, and prevention and control measures.

Interpretation of Tuberculin (Mantoux) Skin Test

Tuberculin testing in Jamaica is done using bioequivalent to 2 IUs of the International Standard of Purified Protein Derivative (PPD).

Immunocompetent Persons
In general, a skin reaction to tuberculin skin testing that results in an induration of 10 mm or more indicates exposure to Mycobacterium tuberculosis, M. africanum or M. bovis. This person should be classified as a suspected case of TB and investigated as such.

A person who has received BCG immunization can have a positive reaction (i.e. >10mm induration). It is therefore important to obtain documentation of BCG immunization on all persons being tested. This documentation, along with review of the person's risk factors for acquiring TB, chest x-ray and/or clinical examination, can be used to decide whether the person under investigation should be classified as a suspected case or cleared from further TB-related investigations.

Immunocompromised Persons
The Mantoux skin test in immunocompromised persons is not reliable as immune impairment may result in atypical reactions to the tuberculin antigens. The reaction may be suppressed:

- in tuberculosis patients with advanced disease
- during certain acute infectious diseases e.g. measles
- by immunization with live attenuated viruses
- in persons who are immunosuppressed by disease (especially AIDS), drugs or malnutrition

For these reasons, an induration of 5 mm or more should be considered indicative of tuberculosis infection for:

- symptomatic household contacts of infectious tuberculosis cases
- persons with an abnormal chest radiograph suggesting old healed tuberculosis
- persons with HIV infection

3.4.9 Other Vaccine Preventable Diseases

Please see the National Surveillance Manual for information on the surveillance of other VPDs such as Meningococcal meningitis, Yellow Fever and Gastroenteritis. These diseases should be investigated using the standard investigation forms provided by the Surveillance Unit and within the time frames specified by the manual.

3.5 ESAVI Surveillance

The primary purpose of ESAVI surveillance is to identify and respond to events that are temporally associated with vaccination and generate information on the safety of vaccines and the vaccination process. This section describes the key definitions and steps involved in ESAVI surveillance.

3.5.1 ESAVI case definition and classification

For the purposes of surveillance, ESAVI can be classified as serious or non-serious:

A Serious ESAVI meets ANY of the following crietria:

- Results in the death of a vaccinated individual
- Puts the life of the vaccinated individual in imminent danger
- Requires hospitalization or prolongation of existing hospitalization
- Results in persistent or significant disability/incapacity
- Is suspected of having caused a congenital anomaly or stillbirth
- Is suspected of having caused an abortion

A non-serious ESAVI meets ALL of the following conditions:

- ESAVI that does not put the life of the vaccinated person (or, when the vaccinated person is pregnant, the embryo, fetus, or newborn) at risk, and resolves without treatment or with symptomatic treatment
- Does not require hospitalization of the affected person
- Does not cause disability or long-term harm

3.5.2 ESAVI detection, notification and reporting

ESAVI detection primarily takes place through routine passive surveillance. This involves vaccine recipients, parents of immunized infants and children, health care workers and staff in immunization or healthcare facilities detecting and reporting them to any health care worker within the health care system.

In an effort to strengthen surveillance of ESAVI following COVID-19 vaccination, active surveillance of ESAVI and Adverse Events of Special Interest (AESI) was implemented at Kingston Public Hospital (VJH). Further details of active ESAVI/AESI surveillance at KPH/VJH can be found in the 'KPH/VJH protocol for sentinel surveillance of AESI and ESAVI from COVID-19 vaccination'.

All ESAVIs should be reported using the MOHW reporting form for Events Supposedly Attributable to Vaccination or Immunization (ESAVI) (See Appendix C). It is important to note that all ESAVI reports should include information on the vaccine such as, the brand name, manufacturer and batch number. The ESAVI reporting form is the primary source for populating the ESAVI line-list (See Appendix C), which provides key descriptive epidemiological data (person, time and place) that are critical for identifying clusters and for signal detection. The ESAVI primary reporter, the HCW or immunization provider are responsible for providing most of the information required for the ESAVI reporting form.

The following must be done for all ESAVI:

- An ESAVI report form must be filled out and directed to the parish Medical Officer of Health
- The MO(H) will request further investigations as deemed necessary for the normal, expected reactions
- The event should be recorded in the adverse events register and the client's medical record
- Statistics on adverse events should be provided to the Family Health Unit on a monthly basis as part of the routine EPI coverage reporting system
- All completed ESAVI reporting forms must be submitted to the Surveillance Unit/Family Health Unit
- Serious ESAVI should be reported immediately (within 24 hours) to the Family Health Unit, Ministry of Health and Wellness through the Medical Officer of Health responsible for the EPI Programme. Non-serious ESAVI should be reported no later than 7 days of detection

Remember that fever and rash needs to be completely investigated, including blood sample collection.

Table 3.5.2.1 provides a list of ESAVIs that should be reported and the time limits on the occurrence of each event.

3.5.2. 1: List of Reportable ESAVI

Occurring within 24 hours of immunization	Anaphylactoid reaction (acute hypersensitivity reaction) Anaphylaxis Persistent (more than 3 hours) inconsolable screaming Hypotonic hyporesponsive episode (HHE) Toxic shock syndrome (TSS)
Occurring within 5 days of immunization	Severe local reaction Sepsis Injection site abscess (bacterial/sterile) Fever and rash
Occurring within 15 days of immunization	Seizures, including febrile seizures (6-12 days for measles/MMR; 0-2 days for DTP) Encephalopathy (6-12 days for measles/MMR; 0-2 days for DTP)
Occurring within 3 months of immunization	Acute flaccid paralysis (4-30 days for OPV recipient; 4-75 days for contact) Brachial neuritis (2-28 days after tetanus containing vaccine) Thrombocytopaenia (15-35 days after measles/MMR)
Occurring between 1 and 12 months after BCG immunization	Lymphadenitis Disseminated BCG infection Osteitis/Osteomyelitis
No time limit	Any death, hospitalization, or other severe and unusual events that are thought by health care workers or the public to be related to immunization

(Note: this list has examples of conditions that can be reported, however any adverse event/condition following immunization should be reports)

In general, any change in the health of a vaccinated person within the first 30 days after administration should be suspected of being the result of administration of the vaccine; however, the occurrence of an event after 30 days does not exclude the possibility of its being associated with the vaccine. The safety profile of the vaccine and historical data in the region on the ESAVI in question need to be assessed in order to exclude a potential association. ESAVI should be reported if, after analyzing the clinical status of the vaccinated person, there is still a suspicion that there may be a relationship between the vaccine and the clinical findings.

3.5.3 ESAVI Investigation

The investigation must proceed in an orderly fashion in order to establish the cause of the ESAVI. Table 3.5.3.1 outlines the steps to be completed when investigating an ESAVI. The Medical Officer of Health must ensure that the investigation is completed and the report submitted to the Surveillance Unit/Family Health Unit.

Serious ESAVI, must be reported to the Surveillance Unit/Family Health Unit within 24 hours of notification of the event. Investigations of these events must be led by the MO(H)

with team members identified to support the investigation process. The MO(H) is expected to submit a preliminary report within 24 hours.

Non-serious ESAVIs need only be investigated in the following special cases:

- When case clusters (groups of two or more cases), either in time or in space, are identified
- When the frequency of the event is higher than expected
- When it is a new event, or one not previously described, or is a known event but with new or unexpected clinical or epidemiological characteristics (in terms of population group, geographic area, etc.)
- When there are findings indicating that the event was caused by a programme error or a defect in the quality of the vaccine, its diluent (if applicable), or the device used for administering the vaccine

Decisions to suspend use of, or recall, a vaccine or specific lot is the responsibility of the Director, Family Health Unit and needs to be made as swiftly as possible, but should be very carefully thought out.

The standardized PAHO ESAVI investigation form should be completed for all events that meet the criteria for investigation (See Appendix B). The investigation form and the supporting documents (autopsy, laboratory, diagnostic reports) should be forwarded to Surveillance Unit/Family Health Unit to facilitate causality assessment and final classification of the event.

Table 3.5.3.1: Steps in an ESAVI investigation

Step	Actions
1) Confirm information in report	□ Obtain patient's medical file (or other clinical record) □ Check details about patient and event from medical file and document information □ Obtain any details missing from ESAVI Report Form (see Appendix D) □ Identify any other cases that need to be included in the investigation
2) Investigate and collect data: About the **client:**	□ Immunization history □ Previous medical history, including prior history of similar reaction or other allergies or contraindications □ Family history of similar events
About the **event:**	□ History, clinical description, any relevant laboratory results about the ESAVI and diagnosis of the event □ Treatment, whether hospitalized, and outcome
About the **suspected vaccine(s):**	□ Conditions under which the vaccine was shipped, its present storage condition, state of vaccine vial monitor, and temperature record of refrigerator □ Storage of vaccine before it arrived at health facility, where it has come from higher up the cold chain, vaccine monitor card □ How it was mixed (if relevant); diluent used □ Dose given
About **other vacinees/people:**	□ Whether others received the same vaccine and developed illness □ Whether others had similar illness (may need case definition); if so exposure of cases to suspect vaccine(s) □ Investigate the local immunization service
3) Assess the service by: **Asking** about:	□ Vaccine storage (including open vials), distribution, and disposal □ Diluent storage and distribution □ Reconstitution (process and time kept) □ Use and sterilization of syringes and needles □ Details of training in immunization practice, supervision and vaccinator(s) □ Number of immunizations- greater than normal? e.g. outreach, mass campaign
Observing the service in action:	□ Refrigerator – what else is stored (note if similar containers stored next to vaccine vials which could be confused); which vaccines/diluents stored with other drugs; whether any vials have lost their label □ Immunization procedures (reconstitution, drawing up vaccine, injection technique, safety of needles and syringes; disposal of opened vials) □ Do any open vials look contaminated?
4) Formulate a working hypothesis:	□ On the likely/possible cause(s) of the event
5) Test working hypothesis	□ Does case distribution match working hypothesis? □ Occasionally, laboratory tests may help
6) Conclude investigation	□ Reach a conclusion on the cause. □ Complete ESAVI Investigation Form (see Appendix C) □ Take corrective action, and recommend further action □ Communicate with the patient and public as needed

3.5.4 Causality Assessment and Final Classification of ESAVI

Causality assessment is the systematic review of an ESAVI to determine the likelihood that the vaccine is the cause of the event. The quality of the causality analysis is highly dependent on the performance of the ESAVI surveillance in terms of responsiveness, effectiveness and quality of investigation and reports, the availability of adequate medical and laboratory services and the ESAVI review process.

The purpose of causality assessment is to establish the level of certainty with which it can be affirmed that the vaccine or the vaccination process was the origin or cause of the clinical picture and of the symptoms or signs observed in the vaccinated person. It requires the consideration of several criteria, not limited to the observation of a temporal relationship between the administration of the vaccine and the onset of symptoms, or to the observation of a mathematical relationship (association) in the pattern of the frequency of cases over time.

Individual level causality assessment

Causality assessment and final classification of ESAVI is carried out by a multidisciplinary team of experts who make up the National ESAVI Committee. It is done once the ESAVI investigation form and appropriate tests results or reports are completed and forwarded to the National Surveillance Unit/Family Health Unit.

As recommended by the WHO Global Vaccine Safety Group, causality assessment will follow a four step process:

- *Step 1: Eligibility.* The first step aims to determine if the ESAVI case satisfies the minimum criteria for causality assessment as outlined below
- *Step 2: Checklist.* The second step involves systematically reviewing the relevant and available information to address possible causal aspects of the ESAVI
- *Step 3: Algorithm.* The third step obtains a trend as to the causality with the information gathered in the checklist
- *Step 4: Classification.* The fourth step categorizes the ESAVI's association to the vaccine or vaccination on the basis of the trend determined in the algorithm

Step 1. Evaluation of eligibility

The case diagnosis must be confirmed and must meet standardized classification criteria, according to standard clinical practice, national or international clinical practice guidelines, or according to some standardized definition, as discussed in previous chapters. In addition, the vaccine involved and the temporal relationship with the case should be verified in order to ensure that the vaccine was administered before the onset of symptoms or signs of the event, with the exception of stress-related events that may be triggered immediately prior to administration of the vaccine.

In this step, it is suggested that the causality question be defined and formulated:

Is the _____ vaccine or the vaccination with _____ the cause of _____?

If multiple vaccines are given simultaneously, the reviewers will have to assess causality separately for each suspected vaccine

Step 2. Verification checklist

The causality assessment checklist should be used (see Appendix B) to evaluate the analytical elements and to ensure that all of the data collected during the investigation can be used. Questions, grouped into four areas, should be answered:

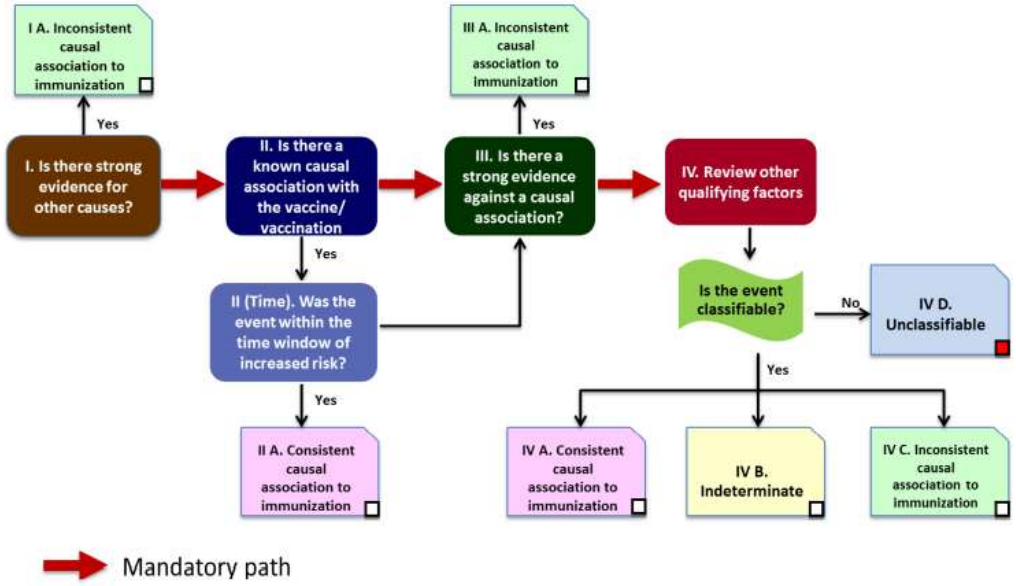
1. Is there evidence of other causes?
2. Is there a known association with the vaccine or vaccination that is described in the medical literature?
3. Is there evidence against a causal association?
4. Have other factors (e.g. baseline event rate, health history, potential risk factors, medications and biological plausibility) been considered?

The checklist includes four possible answers: (i) Yes; (ii) No; (iii) Not known; and (iv) Not applicable. If yes to any of the questions, comments and supporting evidence should be included.

Step 3. Causality assessment algorithm

Once the analytic questions have been answered, the algorithm in Fig 3.5.4.1 is applied.

Figure 3.5.4 1: Causality assessment algorithm



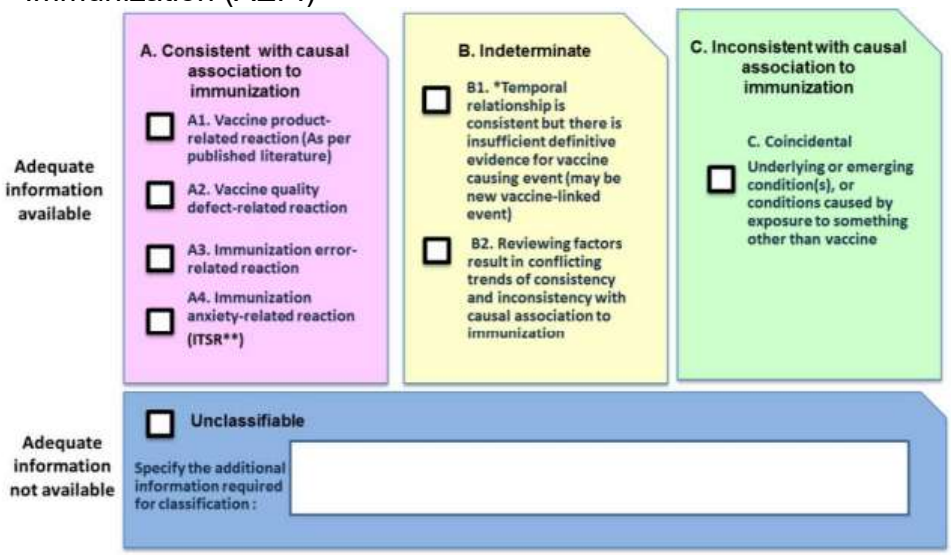
Source: WHO.Causality Assessment of an Adverse Event Following Immunization (AEFI). User Manual for the Revised WHO Classification (2nd edition. 2018)

If it is not classifiable after applying the algorithm, it is recommended that all possible measures be taken to collect all of the missing information needed to classify it. The algorithm does not make decisions based on who is performing the analysis, but, rather, serves only as a guide on what direction to pursue; it is up to the committee to make a decision and assess whether or not it agrees with the results of the algorithm.

Step 4. Classification of the event

The final classification is based on availability of adequate information. Fig 3.5.4.2 outlines the possible classifications:

Figure 3.5.4 2: WHO Causality Assessment of an Adverse Event Following Immunization (AEFI)



*B1: This is a potential signal and maybe considered for investigation
** Immunization Triggered Stress Response

Source: WHO Causality Assessment of an Adverse Event Following Immunization (AEFI). User Manual for the Revised WHO Classification (2nd edition. 2018)

Once each case has been classified, the appropriate interventions for each should be planned.

Bibliography/Works Cited

Amarasinghe, A., World Health Organization, & Global Advisory Committee on Vaccine Safety. (2014). Global manual on surveillance of adverse events following immunization: Vol. (revised March 2016). https://iris.who.int/handle/10665/206144

Australian Technical Advisory Group on Immunization of the Commonwealth Department of Health and Aged Care. (2000). The Australian Immunization Handbook 7t h Edition (7th ed.). Commonwealth of Australia. www.hic.gov.au.

Centers for Disease Control and Prevention. (2021). Epidemiology and Prevention of Vaccine-Preventable Diseases (E. Hall, P. A. Wodi, J. Hamborsky, S. Schillie, & V. Morelli, Eds.; 14th ed.). D.C. Public Health Foundation. https://www.cdc.gov/vaccines/pubs/pinkbook/index.html

Centers for Disease Control and Prevention. (2015). Epidemiology and Prevention of Vaccine-Preventable Diseases (Hamborsky J, Kroger A, Wolfe S, eds. 13th ed.). D.C. Public Health Foundation.

Clements CJ, Chandra-Mouli V, Byass P, Ferguson B.J. (1999). Global strategies, policies and practices for immunization of adolescents. Geneva: WHO.

Mackett M, Williamson J.D., *Human Vaccines and Vaccination*. Oxford: Bios; 1995

Ministry of Health, Jamaica. Clinical Management of HIV Disease: Guidelines for Medical Practitioners. 2017

Ministry of Health, Jamaica. (2014). Health Facilities Infection Control – Policies and Procedures Manual.

Ministry of Health, New Zealand. (1996). Immunization Handbook. Bios Scientific.

Ministry of Health, Jamaica. (2009). National Surveillance Manual.

Pan American Health Organization. (2021). Guidance for Implementing the Regional COVID-19 Vaccine AEFI/AESI Surveillance System. https://iris.paho.org/bitstream/handle/10665.2/53340/PAHOFPLIMCOVID-19210013_eng.pdf?sequence=2&isAllowed=y

Pan American Health Organization. (2022). Manual for Surveillance of Events Supposedly Attributable to Vaccination or Immunization in the Region of the Americas. In Manual for Surveillance of Events Supposedly Attributable to Vaccination or

Immunization in the Region of the Americas. Pan American Health Organization. https://doi.org/10.37774/9789275123867

Pan American Health Organization. (2017). Maternal and Neonatal Immunization Field Guide for Latin America and the Caribbean. https://iris.paho.org/bitstream/handle/10665.2/34150/9789275119501-eng.pdf?sequence=6&isAllowed=y

Pan American Sanitary Bureau, R. O. of the W. H. O. D. of V. and I. (HVP). (2000). Methodology for the Multidisciplinary Evaluation of the Expanded Programme on Immunization at the Country Level.

Technical Advisory Group Meeting on Vaccine-Preventable Diseases (12th: 1997: Guatemala City). SVI technical advisory group meets. EPI Newsl. 1997 Oct;19(5):1-4. PMID: 12348224.

World Health Organization. Department of Immunization, V. and B. (2015). Immunization in practice: a practical guide for health staff (2015 Update). WHO Press. https://www.who.int/publications/i/item/immunization-in-practice-a-practical-guide-for-health-staff

World Health Organization. (2019). Causality assessment of an adverse event following immunization (AEFI) User manual for the revised WHO classification (2nd ed.). https://iris.who.int/bitstream/handle/10665/340802/9789241516990-eng.pdf?sequence=1

World Health Organization. (2021). COVID-19 Vaccines: Safety Surveillance Manual Second Edition. https://iris.who.int/bitstream/handle/10665/345178/9789240032781-eng.pdf?sequence=1

World Health Organization. Department of Immunization, V. and B. (2015). Immunization in practice: a practical guide for health staff (2015 Update). WHO Press. https://www.who.int/publications/i/item/immunization-in-practice-a-practical-guide-for-health-staff

World Health Organization Department of Communicable Diseases Surveillance and Response. (1999). WHO Recommended Surveillance-Standards. https://cdn.who.int/media/docs/default-source/documents/publications/who-recommended-surveillance-standards17363eff-9860-48c1-9f5f-3c0c3a4f955d.pdf?sfvrsn=ee2893e4_1&download=true

World Health Organization. (2023). Table 1: Summary of WHO Position Papers-Recommendations for Routine Immunization Adolescents Adults Considerations

Recommendations for certain regions.
http://www.who.int/immunization/documents/positionpapers

World Health Organization. (2017). Weekly epidemiological record: Cholera vaccines: WHO position paper – August 2017. 34(92), 477–500. http://www.who.int/wer

World Health Organization. (2016). Weekly epidemiological record: Dengue vaccine: WHO position paper – July 2016. 30(91), 349–364. http://www.who.int/wer

World Health Organization. (2004). Weekly epidemiological record: Development of a vaccine effective against avian influenza H5N1 infection in humans. 4(79), 25–40.

World Health Organization. (2017). Weekly epidemiological record: Diphtheria vaccine: WHO position paper – August 2017. 31(92), 417–436.

World Health Organization. (2017). Weekly epidemiological record: Human papillomavirus vaccines: WHO position paper, May 2017. 19(92), 241–268. http://www.who.int/wer

World Health Organization. (2017). Weekly epidemiological record: Hepatitis B vaccines: WHO position paper – July 2017. 27(92), 369–392. http://www.who.int/wer

World Health Organization. (2007). Weekly epidemiological record: Malaria, Jamaica. 7(82), 49–60.

World Health Organization. (2013). Weekly epidemiological record: Haemophilus influenzae type b (Hib) Vaccination Position Paper – September 2013. 39(88), 413–428. http://www.who.int/wer

World Health Organization. (2015). Weekly epidemiological record: Hepatitis E vaccine: WHO position paper, May 2015. 18(90), 185–200. http://www.who.int/wer

World Health Organization. (2015). Weekly epidemiological record: Japanese Encephalitis Vaccines: WHO position paper – February 2015. 9(90), 69–88. http://www.who.int/wer

World Health Organization. (2017). Weekly epidemiological record: Measles vaccines: WHO position paper – April 2017. 17(92), 205–228. http://www.who.int/wer

World Health Organization. (2015). Weekly epidemiological record: Meningococcal A conjugate vaccine: updated guidance, February 2015. 8(90), 57–68. http://www.who.int/wer

World Health Organization. (2011). Weekly epidemiological record: Meningococcal vaccines: WHO position paper, November 2011. 47(86), 521–540.

World Health Organization. (2015). Weekly epidemiological record: Pertussis vaccines: WHO position paper – August 2015. 35(90), 433–460. http://www.who.int/wer2015,90,433-460No.35

Appendix A: CLASS I DISEASES NOTIFICATION FORM

CLASS I REPORTING FORM - INDIVIDUAL NOTIFICATION (ON SUSPICION)

Date of Report: _____ / ____ / _____ (DD/MM/YY) NEW CASE / PREVIOUSLY REPORTED CASE (Circle One)

Diagnosis: _____ _____

Case Demographic Information

Name (including pet name): _____ Sex: _____ Age: _____ D.O.B ____ /____ /____ (dd/mm/yy)

Address: (Include Landmark) Lot #: _____ Street: _____ (Name) Street Type: _____ (Drive, Road, Close etc)

Community: _____ Neighbouring Community/District: _____ Parish: _____

Workplace/School: _____ Occupation: _____

(H) Phone #: _____ (Wk) Phone #: _____ History of overseas travel in past 4-6 weeks? Y / N

Specify area/country: _____

Name of NOK/Parent: _____ Relationship to case: _____

Address of NOK/Parent: _____ Phone No.: _____

Clinical information:

Symptoms: _____

_____

Date of onset: ____ /____ /_____ (dd/mm/yy) Date seen: ____ /____ /_____ (dd/mm/yy)

Specimen Taken Y / N Type: _____

Specimen Date: ____ /____ /_____ (dd/mm/yy) Laboratory: _____

Result (s): _____

Hosp./Facility Name: _____

Medical Record # _____

Case admitted to Hosp?: Y / N (Circle one)

Date of Admission: _____ /_____ /_____ (dd/mm/yy)

Ward: _____

If dead, Date of Death: _____ /_____ /_____ (dd/mm/yy)

Notifier Information

Name of notifier: _____ Phone #: _____

Address: _____ Email: _____

Comments: _____

Received by MO(H) _____ /_____ /_____ (dd/mm/yy)

Parish MO(H} Signature _____

Forwarded to R.S.O _____ /_____ /_____ (dd/mm/yy)

Forwarded to Surveillance Unit _____ /_____ /_____ (dd/mm/yy)

Ministry of Health, Surveillance Unit. September 2006

Appendix B: ADVERSE EVENTS FOLLOWING IMMUNIZATION (AEFI) CAUSALITY ASSESSMENT

Worksheet for AEFI causality assessment

Mar 2019

Patient ID/ Name : **DoB/ Age:** **Sex: Male/ Female**

Step 1 (Eligibility)

Name one of the vaccines administered before this event	What is the Valid Diagnosis?	Does the diagnosis meet a case definition?

Create your question on causality here

Has the _____ vaccine / vaccination caused _____(The event for review in step 2 - valid diagnosis)

Is this case eligible for causality assessment? Yes/ No; If, "Yes", proceed to step 2

Step 2 (Event Checklist) ✓ (check) all boxes that apply

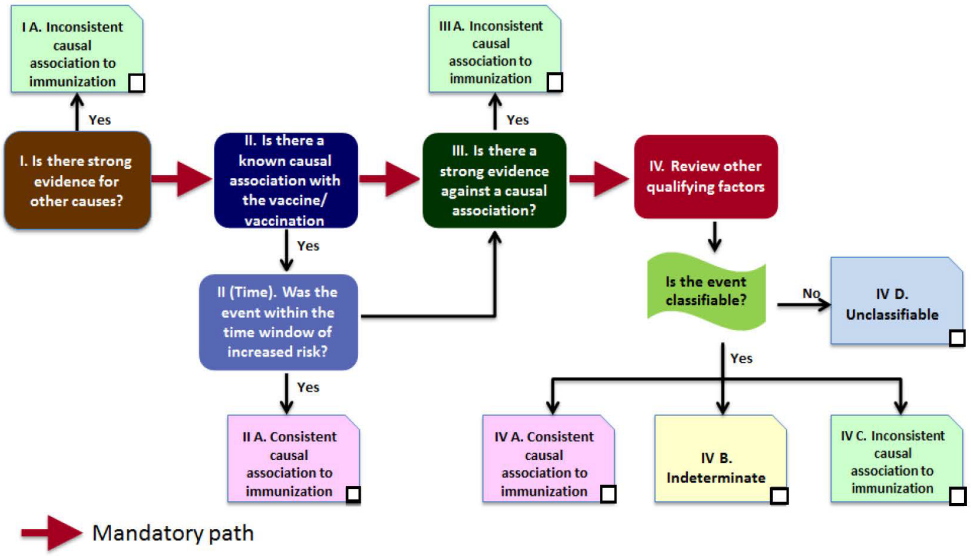
I. Is there strong evidence for other causes?	Y N UK NA	Remarks
1. In this patient, does the medical history, clinical examination and/ or investigations, **confirm** another cause for the event?	☐☐☐☐	
II. Is there a known causal association with the vaccine or vaccination?		
Vaccine product		
1. Is there evidence in published peer reviewed literature that this vaccine may cause such an event if administered correctly?	☐☐☐☐	
2. Is there a biological plausibility that this vaccine could cause such an event?	☐☐☐☐	
3. In this patient, did a specific test demonstrate the causal role of the vaccine?	☐☐☐☐	
Vaccine quality		
4. Could the vaccine given to this patient have a quality defect or is substandard or falsified?	☐☐☐☐	
Immunization error		
5. In this patient, was there an error in prescribing or non-adherence to recommendations for use of the vaccine (e.g. use beyond the expiry date, wrong recipient etc.)?	☐☐☐☐	
6. In this patient, was the vaccine (or diluent) administered in an unsterile manner?	☐☐☐☐	
7. In this patient, was the vaccine's physical condition (e.g. colour, turbidity, presence of foreign substances etc.) abnormal when administered?	☐☐☐☐	
8. When this patient was vaccinated, was there an error in vaccine constitution/preparation by the vaccinator (e.g. wrong product, wrong diluent, improper mixing, improper syringe filling etc.)?	☐☐☐☐	
9. In this patient, was there an error in vaccine handling (e.g. a break in the cold chain during transport, storage and/or immunization session etc)?	☐☐☐☐	
10. In this patient, was the vaccine administered incorrectly (e.g. wrong dose, site or route of administration; wrong needle size etc.)?	☐☐☐☐	
Immunization anxiety (Immunization stress related response - ISRR)		
11. In this patient, could this event be a stress response related to immunization (e.g. acute stress response, vasovagal reaction, hyperventilation, dissociative neurological symptom reaction etc)?	☐☐☐☐	
II (time): Was the event in section II within the time window of increased risk (i.e. 'Yes" response to questions from II 1 to II 11 above)		
12. In this patient, did the event occur within a plausible time window after vaccine administration?	☐☐☐☐	
III. Is there strong evidence against a causal association?		
1. Is there a body of published evidence (systematic reviews, GACVS reviews, Cochrane reviews etc.) **against** a causal association between the vaccine and the event?	☐☐☐☐	
IV. Other qualifying factors for classification		
1. In this patient, did such an event occur in the past after administration of a similar vaccine?	☐☐☐☐	
2. In this patient did such an event occur in the past independent of vaccination?	☐☐☐☐	
3. Could the current event have occurred in this patient without vaccination (background rate)?	☐☐☐☐	
4. Did this patient have an illness, pre-existing condition or risk factor that could have contributed to the event?	☐☐☐☐	
5. Was this patient taking any medication prior to the vaccination?	☐☐☐☐	
6. Was this patient exposed to a potential factor (other than vaccine) prior to the event (e.g. allergen, drug, herbal product etc.)?	☐☐☐☐	

Y: Yes N: No UK: Unknown NA: Not applicable or Not available

1

Mar 2019

Step 3 (Algorithm) review all steps and ✓ all the appropriate boxes



Notes for Step 3:

Step 4 (Classification) ✓ all boxes that apply

Adequate information available

A. Consistent with causal association to immunization

- ☐ A1. Vaccine product-related reaction (As per published literature)
- ☐ A2. Vaccine quality defect-related reaction
- ☐ A3. Immunization error-related reaction
- ☐ A4. Immunization anxiety-related reaction (ISRR**)

B. Indeterminate

- ☐ B1. *Temporal relationship is consistent but there is insufficient definitive evidence for vaccine causing event (may be new vaccine-linked event)
- ☐ B2. Reviewing factors result in conflicting trends of consistency and inconsistency with causal association to immunization

C. Inconsistent with causal association to immunization

- ☐ C. Coincidental
  Underlying or emerging condition(s), or conditions caused by exposure to something other than vaccine

Adequate information not available

☐ **Unclassifiable**

Specify the additional information required for classification : _____

*B1: This is a potential signal and maybe considered for investigation
** Immunization stress related response

Summarize the classification logic in the order of priority:

With available evidence, we could conclude that the classification is _____ because:

With available evidence, we could **NOT** classify the case because: _____

2

Appendix C: ESAVI REPORTING FORM

MINISTRY OF HEALTH & WELLNESS

ESAVI reporting ID number:

MINISTRY OF HEALTH AND WELLNESS

REPORTING FORM FOR EVENTS SUPPOSEDLY ATTRIBUTED TO VACCINATION OR IMMUNIZATION (ESAVI)

Patient Name: _____	***Reporter's Name:*** _____
Patient's full Address: _____	Institution: _____
_____	Post & Department: _____
Telephone: _____	Address: _____
Sex: ☐ M ☐ F Currently pregnant: ☐ Yes ☐ No	_____
Date of birth (DD/MM/YYYY): _ _ _ _ _ _ _ _ _ _	Telephone & E-mail: _____
OR Age at onset: _____Years _____Months _____ Days	Date patient notified event to health system *(DD/MM/YYYY)*: _ _ _ _ _ _ _ _ _ _
	Today's date *(DD/MM/YYYY)*: _ _ _ _ _ _ _ _ _ _

Health Facility (place or vaccination centre) name & address:

Vaccine						*Diluent (if applicable)*			
Name of vaccine	***Date of vaccination***	***Time of vaccination***	Dose (1st, 2nd, etc.)	***Batch /Lot number***	Expiry date	Name of diluent	***Batch /Lot number***	Expiry date	Date and time of reconstitution

Adverse event(s):

☐ Local reaction ☐ *>3 days* ☐ *beyond nearest joint*
☐ *pain* ☐ *redness* ☐ *swelling*
☐ Seizures
☐ *febrile* ☐ *afebrile*
☐ Headache
☐ Fever ≥ 38°C
☐ Abscess
☐ Myalgia
☐ Sepsis
☐ Encephalopathy
☐ Thrombocytopenia
☐ Anaphylaxis
Other *(specify)*
☐ .....
☐ .....
☐ .....

Date ESAVI started *(DD/MM/YYYY)*: _ _ _ _ _ _ _ Time _ _:_ _

Describe ESAVI (Signs & Symptoms) and Treatment *(if any)*:

Serious: ☐ ***Yes*** ☐ ***No;*** ➔ If Yes ☐ Death ☐ Life threatening ☐ Persistent or significant disability ☐ Hospitalization ☐ Congenital anomaly

☐ Other important medical event (specify).....

Outcome: ☐ Recovering ☐ Recovered ☐ Recovered with sequelae ☐ Not Recovered ☐ Unknown

☐ Died If Died, date of death *(DD/MM/YYYY)*: _ _ _ _ _ _ _ _ _ _ Autopsy done: ☐ Yes ☐ No ☐ Unknown

Past medical history (including history of similar reaction or other allergies), concomitant medication and other relevant information (e.g. other cases). *Use additional sheets if needed:*

Parish level to complete:

Investigation needed: ☐ Yes ☐ No	If Yes, date investigation planned *(DD/MM/YYYY)*: _ _ _ _ _ _ _ _ _ _

Reviewed and signed off by MO(H): _____ *Date (DD/MM/YYYY):* _ _ _ _ _ _ _ _ _ _

Name and Signature

National level to complete

Date report received at National level *(DD/MM/YYYY)*: _ _ _ _ _ _ _ _ _ _	ESAVI worldwide unique ID :
Comments:	

**** Compulsory field***

Appendix D: EVENTS SUPPOSEDLY ATTRIBUTABLE TO VACCINATION OR IMMUNIZATION (ESAVI) INVESTIGATION FORM

MINISTRY OF HEALTH & WELLNESS — PAHO Pan American Health Organization — World Health Organization Americas	**EVENTS SUPPOSEDLY ATTRIBUTABLE TO VACCINATION OR IMMUNIZATION (ESAVI) INVESTIGATION FORM**

This form complements the reporting form and should be completed with the data from that form. It should be used only in cases where the subnational technical level has decided to conduct a thorough investigation of a serious or non-serious event that meets the following criteria:

1. Temporal or geographic case clusters (groups of two or more cases) have been identified.
2. The frequency of the event is higher than expected.
3. It is a new or previously undescribed event, or it is a known event with new or unexpected epidemiological or clinical manifestations (in terms of population groups, geographic areas, etc.).
4. Some data indicate that the event was caused by a program error or a defect in the quality of the vaccine, its diluent (if applicable), or the device used in its administration.

This form is a guide for identifying all information considered relevant to analyzing the causality of the event. The analysis should be conducted by a national or subnational committee of ESAVI experts, and the factors that contributed to its appearance should be identified so that risk mitigation measures can be adopted.

Identification number of the ESAVI indicated on the reporting form _____

1. Indicate the sources of information consulted to obtain the information for the following investigation:

☐ Clinical history ☐ Interview of the person vaccinated ☐ Interview of health workers ☐ Vaccination records ☐ Autopsy report ☐ Community investigation report
☐ Immunization register ☐ Adverse events register ☐ Health record ☐ Interview with family/household contact ☐ Other 1.1 Indicate:_____

2. Patient Demographic Information

First Name: _____ Last Name: _____Sex: Male ☐ Female ☐

Date of Birth (dd/mm/yyyy): _____ Age: _____

Home Address: _____

Telephone Contact: _____

Name of Next of Kin/Emergency Contact: _____

Phone Number for Next of Kin/Emergency Contact: _____

Relationship to patient: _____

Section A. Basic information

3. Vaccination site: ☐ Public hospital ☐ Private hospital ☐ Vaccination post ☐ Private physician's office

☐ Campaign ☐ Other 3.1 Indicate:_____

3.2 If the vaccination was administered during a campaign, indicate where:

☐ Residence ☐ Fixed site ☐ Mobile unit ☐ Institutional ☐ Other 3.2.1 Indicate:_____

4. Complete address of the vaccination site:

City/town:	Parish:

5. Information on the investigation team:			
5.1 Full name	**5.2 Institution and position**	**5.3 E-mail**	**5.4 Mobile telephone**

6. Date this form was completed: dd/mm/yyyy	7. Date of investigation: dd/mm/yyyy
8. Hospitalization date: dd/mm/yyyy	9. This report is: ☐ Preliminary ☐ Interim ☐ Final

10. Status of the individual at the time of the investigation:

☐ Deceased ☐ Not recovered ☐ Recovering ☐ Fully recovered ☐ Recovered with sequelae

☐ Unknown

10.1 If the person is deceased, indicate the date of death: dd/mm/yyyy	10.2 Time of death: a.m./p.m.

10.3 Was an autopsy performed?

☐ Yes ☐ No ☐ Scheduled: **Expected autopsy date**: dd/mm/yyyy

10.3.1 If no, reason why an autopsy was not performed:

☐ Family refused ☐ The person who reported the event or treated the patient did not request one
☐ Clinical or forensic autopsy services were not available
☐ There are no regulations permitting an autopsy in cases of ESAVI
☐ Other
10.3.1.1
Indicate:_____

Enclose the autopsy report, if available.

11. If the patient had an infection or other medical condition at the time of the report, how severe did the infection/medical condition become, according to the clinical record? (If the patient had a SARS CoV2 infection, use the classification in Clinical Management of COVID-19. Interim Guidance, published by WHO[1], as a reference)

☐ Mild disease ☐ Moderate disease ☐ Severe disease ☐ Critical disease

☐ Generic Disease (please name): _____

From here on: DK = doesn't know NA = not applicable

[1] World Health Organization. Clinical Management of COVID-19: interim guidance, 27 May 2020. Geneva: WHO; 2020. Available from: https://apps.who.int/iris/handle/10665/332196.

Section B. Relevant information about the vaccinated person prior to immunization.		
Criteria	**Findings**	**Comments**
12. History of a similar event.	☐ Yes ☐ No ☐ DK	
13. Adverse events after previous vaccinations.	☐ Yes ☐No ☐ DK	
14. History of allergy to a vaccine, food, or medication.	☐ Yes ☐ No ☐ DK	
15. Acute disease diagnosed in the 15 days prior to vaccination.	☐ Yes ☐ No ☐ DK	
16. Preexisting disease (diagnosed earlier than 15 days prior to vaccination) or birth defect.	☐ Yes ☐ No ☐ DK	
17. History of hospitalization in the 30 days prior to the current vaccination.	☐ Yes ☐ No ☐ DK	
18. Family history of other disease (relevant to an ESAVI) or allergy.	☐ Yes ☐ No ☐ DK	
PERINATAL HISTORY (complete this section only in the case of children under 5, or over 5 when relevant).		
19. Delivery was: ☐ Normal ☐ Caesarean section ☐ By forceps ☐ With complications 19.1 Indicate:_____		
20. The birth was: ☐ At term ☐ Preterm ☐ Post-term	21. Birthweight:	
22. Was any medical problem or congenital or neonatal pathology diagnosed?	☐ Yes ☐ No ☐ DK	
22.1 Explain:		
QUESTIONS FOR WOMEN (mainly aged 15 to 49 or when pregnancy is suspected).		
23. Was the woman pregnant when she received the vaccine? ☐ Yes, gestational week: _____ ☐ No ☐ DK		23.1 If yes, indicate how the pregnancy was diagnosed:
24. Was a risk factor for a serious obstetric complications identified?	☐ Yes ☐ No ☐ DK	Explain:
If the pregnancy has ended, mark the respective obstetric-neonatal outcome:		
25. Delivery was: ☐ Normal ☐ Cesarean section ☐ By forceps ☐ With complications 26.1 Indicate:		
26. The birth was: ☐ At term ☐ Preterm ☐ Post-term	27. Birthweight:	

28. What was the pregnancy outcome? ☐ Healthy live birth ☐ Live birth with medical problem at birth ☐ Fetal death ☐ Early neonatal death ☐ Late neonatal death ☐ Miscarriage	28.1 If applicable, describe the newborn's medical problem:
29. Was the mother breastfeeding at the time of vaccination?	☐ Yes ☐ No ☐ Does not recall or DK
Section C. Details of the first review of the ESAVI.	
30. Source of information (mark all that apply). ☐ Review conducted by the investigator ☐ Documents ☐ Other 30.1 Indicate: _____	
31. Name of the individual who first examined or treated the person: 31.1 E-mail address of that individual: 32. Names of the professionals who treated the person (indicate below): First Name: Surname: 33. Other sources of information (specify):	
34. Signs and symptoms since vaccination, in chronological order:	
35. If the ESAVI was identified in a child or adolescent (birth to 18yrs), is abuse suspected? ☐ Yes ☐ No ☐ DK	35.1 If yes, explain:
36. If the ESAVI was identified in an adult, is there evidence of violence? ☐ Yes ☐ No ☐ DK	36.1 If yes, explain:
37. Other social background relevant to the case:	

38. Name and contact information of the person or persons familiar with the clinical details:

Name: _____Contact number: _____

Position or post: _____

Date/time: dd/mm/yyyy _____Time: ☐ a.m. ☐ p.m.

39. Has the person received medical attention for the ESAVI? ☐ Yes ☐ No ☐ DK

Instructions: Enclose a copy of ALL available documents (including the clinical history, discharge summary, case notes, laboratory or autopsy reports, concomitant drug prescriptions, vaccination record). In addition, include information UNAVAILABLE in the existing documents.

- ***If the person received medical attention***: include copies of all available documents and note here only the information not available in the attached documents.
- ***If the person did not receive medical attention***: question and examine him/her and enter your comments below. Include additional pages, if necessary.

40. Definitive or preliminary diagnosis:

40.1 ICD diagnostic code:

Section D. ESAVI-related information on the people vaccinated at the vaccination site.

41. Number of people vaccinated with each antigen at the vaccination site on **the day of the event**. Include the records, if available.

41.1 Name of the vaccine								
41.2 Number of doses								

41.3 Number of people vaccinated with the vaccine vial involved.	
41.4 Number of people vaccinated with the same antigen involved on the same day or session.	
41.5 Number of people vaccinated with the same lot of vaccine in other locations. 41.5.1 Indicate the locations:	

42. Vaccine vial information:

42.1 Batch no.								
42.2 Expiration date								
42.3 Manufacturer								

43. In the case of multidose vials, the vaccine administered was: ☐ Among the first doses of the vial administered ☐ Among the last doses of the vial ☐ Unknown

		Explanation and comments (provide for all affirmative responses)
44. Was there a prescribing error or failure to follow the vaccine's recommendations for use?	☐ Yes ☐ No ☐ Not assessable	
45. Based on your investigation, do you believe that the vaccine administered could have been contaminated?	☐ Yes ☐ No ☐ Not assessable	
46. Based on your investigation, do you believe that the physical condition of the vaccine (color, turbidity, extraneous substances, etc.) was abnormal at the time of administration?	☐ Yes ☐ No ☐ Not assessable	
47. Based on your investigation, do you believe there was an error in the preparation or reconstitution of the vaccine (wrong product, vaccine or diluent, mixture, syringe, or improper filling of the syringe, etc.) by the vaccinator?	☐ Yes ☐ No ☐ Not assessable	
48. Based on your investigation, do you believe there was an error in handling the vaccine (interruption in the cold chain during transport, storage, the vaccination period, etc.)?	☐ Yes ☐ No ☐ Not assessable	
49. Based on your investigation, do you believe the vaccine was improperly administered (wrong dose, site or route of administration; wrong-size needle, failure to follow good injection practices, etc.)?	☐ Yes ☐ No ☐ Not assessable	
50. Is this case part of a cluster?	☐ Yes ☐ No ☐ Unknown	
50.1 If yes, case cluster identification number:	50.2 How many additional cases have been detected in the cluster?	
50.3 Did all cases in the cluster receive the vaccine from the same vial?	☐ Yes ☐ No ☐ Unknown	
50.4.1 If not, number the vials used for the case cluster.		
Section E. Immunization practices at the locations where the vaccine in question was used (through interviews or observation of practices at the vaccination site).		
Syringes and needles used:		
51. Were auto-disable (AD) syringes used?	☐ Yes ☐ No ☐ DK	
51.1 If not, indicate the type of syringes used: ☐ Glass ☐ Disposable ☐ Recycled disposable ☐ Other 54.1.1 Which? _____		
State the key findings, additional observations, or comments:		

Reconstitution procedure:	
52. Was the same reconstitution syringe/needle used for each vial of vaccine?	☐ Yes ☐ No ☐ DK ☐ NA
53. Was the same reconstitution syringe/needles used for multiple vials of the same vaccine?	☐ Yes ☐ No ☐ DK ☐ NA
54. Was the same reconstitution syringe/needle used for different vaccines?	☐ Yes ☐ No ☐ DK ☐ NA
55. Was a separate reconstitution needle used for each vaccine vial?	☐ Yes ☐ No ☐ DK ☐ NA
56. Were the diluents and vaccines used recommended by the manufacturer? 56.1 If no, specify what was used:	☐ Yes ☐ No ☐ DK ☐ NA
57. State the key findings, additional observations, or comments:	
Section F. Cold chain and transport	
Last vaccine storage point	
58. Was the temperature of the last storage refrigerator monitored, and a daily a.m. and p.m. temperature record maintained?	☐ Yes ☐ No
58.1 If yes, were there any deviations from the 2°C-8°C range after the vaccine was placed in the refrigerator?	☐ Yes ☐ No
58.1.1 If yes, **separately** attach the monitoring data.	
59. Was the correct procedure for storing the vaccines, diluents and syringes followed?	☐ Yes ☐ No ☐ DK
60. Did the refrigerator or freezer contain anything other than vaccines and diluents?	☐ Yes ☐ No ☐ DK
61. Was any partially reconstituted vaccine in the refrigerator?	☐ Yes ☐ No ☐ DK
62. Were there any vaccines that were unusable (expired, lacking a label, or frozen) in the refrigerator/freezer?	☐ Yes ☐ No ☐ DK
63. Did the warehouse have any diluent that was unusable (expired, not recommended by the manufacture, broken or dirty)?	☐ Yes ☐ No ☐ DK
64. What are the expiration dates for the diluents and syringes? diluents: dd/mm/yyyy syringes: dd/mm/yyyy	
65. State the key findings, additional observations, or comments:	

Vaccine transport	
66. Type of vaccine carrier/cold box used	
67. Was the vaccine carrier/cold box sent the day of the vaccination?	☐ Yes ☐ No ☐ DK
68. Was the vaccine carrier/cold box returned the day of the vaccination?	☐ Yes ☐ No ☐ DK
69. Was a conditioned cold pack used?	☐ Yes ☐ No ☐ DK
70. State the key findings, additional observations, or comments (indicate the departure and arrival time of the vaccine carrier or cold box, if relevant):	
Section G. Community investigation (visit the locality and interview the family or neighbours of the affected person).	
71. Was a similar event reported in the same locality around the time the ESAVI occurred? ☐ Yes ☐ No ☐ DK 71.1 If yes, describe it:	
71.2 If yes, how many events or episodes were reported?	
72. Of the people effected, how many are: ▪ Vaccinated: _____ ▪ Unvaccinated: _____ ▪ Status unknown: _____ Generate the line list of vaccinated and unvaccinated casesand, if necessary, report the unreported vaccinated cases to the information system.	
73. Other comments:	
Section H. Other findings, observations, and comments.	
74. Note other findings, observations and comments:	

Section I. Final classification of the ESAVI	
75. Did the national or subnational committee that reviewed the ESAVI case arrive at a final classification?	☐ Yes ☐ No
75.1 If yes, what was the final classification issued by the national or subnational committee that reviewed the ESAVI?	
75.2 Indicate what entity assigned this causality:	
A. Causal relationship consistent with the vaccine or vaccination process.	
A1. Event related to the antigen or a component of the vaccine (as published in the specialized bibliography).	☐
A2. Event related to a defect in vaccine quality.	☐
A3. Event related to a program error.	☐
A4. Stress-related event occurring immediately prior to, during, or after vaccination.	☐
B. Undetermined.	
B1. The temporal relationship is consistent, but sufficient definitive evidence to assign the causality to the vaccine is lacking.	☐
B2. The factors for determining the classification show conflicting tendencies and are not uniformly favorable to a causal relationship with vaccination.	☐
C. Inconsistent causal relationship with the vaccine or vaccination (coincidental event).	☐
D. Unclassifiable according to WHO criteria.	☐
76. Comments on the causality classification:	

INSTRUCTIONS FOR COMPLETING THE EVENTS SUPPOSEDLY ATTRIBUTABLE TO VACCINATION OR IMMUNIZATION (ESAVI) INVESTIGATION FORM

The criteria for recommending a full investigation are indicated at the top of the form. Given the amount of resources needed to complete all the information required on this form, selective criteria should be employed to determine the cases where it is necessary.

Detailed instructions for answering some of the questions on the form are provided below:

Question	Instruction
Indicate the sources of information consulted to GATHER the information+ for the following investigation.	Mark all sources used in obtaining the information provided on this form.
Section A. Basic information	
Identification number of the ESAVI indicated on the reporting form.	This is the number assigned to the case on the reporting form. Make sure that the number is exactly the same as the one assigned and that it is not the same as the national identification document number of the affected person.
Vaccination site.	Mark the location where the vaccine was administered, as appropriate. If it none of the options applies, select "Other" and provide more details on the "Indicate" line. If the ESAVI occurred during a vaccination campaign, leave the first part blank and respond in the section on vaccination campaigns.
Information on the investigation team:	Use this box to provide complete information on the individuals who participated in the investigation. This information is important for keeping a record of responsible personnel and for long-term evaluation of the use of resources for this surveillance.
Date this form was completed.	Indicate the date the form was finally completed, using the dd/mm/yyyy format.
Date of the investigation.	Date on which ESAVI investigation began, using the dd/mm/yyyy format.
Date of hospitalization.	Date of the first day of hospitalization or hospital consultation, using the dd/mm/yyyy format.
Reason why an autopsy was not performed:	In the section on the diagnosis at death, if an autopsy was not performed, mark the reason. If there is more than one, mark all that are applicable. Even though a verbal autopsy was performed, explain why a clinical or pathological autopsy was not.
If the patient had the SARS-CoV-2 infection at the time of the report, how severe did the infection become according to the clinical record?	To learn the criteria for the severity of a SARS-CoV-2 infection, WHO's *Clinical management of COVID-19: interim guidance,* dated 27 May 2020, should be used. It can be accessed at the following link: https://apps.who.int/iris/handle/10665/332196.

Section B. Relevant information about the vaccinated person prior to immunization. This section is for all medically important background information on the vaccinated person.	
History of a similar event	If the affected person developed signs or symptoms, or had abnormal laboratory results that appeared to be similar to those currently observed and followed a similar course, mark "YES". Describe or explain them in detail in the "Comments" section.
Acute disease diagnosed in the 15 days prior to vaccination.	Indicate all diseases diagnosed in the 15 days prior to vaccination.
Preexisting disease (diagnosed before 15 days prior to vaccination) or birth defect.	Indicate all diseases diagnosed before 15 days prior to vaccination.
Family history of another disease (relevant for an ESAVI) or allergy.	If a family member has a history of a disease that could indicate a risk that the ESAVI is related to the clinical status of the affected person, mark "Yes".
PERINATAL HISTORY. This section applies only to ESAVIs in children under 5, and the questions are about their history.	
The delivery was:	Mark how the child was delivered. If there were complications, explain.
The birth was:	Indicate the term of the pregnancy at birth. In the next question, indicate the birthweight in grams.
Were any medical problems or congenital or neonatal pathology diagnosed?	If the infant was diagnosed with a congenital medical problem at birth or in the first 30 days postpartum, mark "Yes".
QUESTIONS FOR WOMEN. This section is applicable to all women, principally those of reproductive age (15 to 49 years), but bearing in mind that there is a real risk of pregnancy outside that age range. If pregnancy is suspected during the investigation, the following questions should also be asked.	
Confirm whether the woman was pregnant when the vaccine was administered.	If the pregnancy diagnosis was confirmed by a laboratory or health worker, mark "Yes" and indicate the weeks of gestation at the time of the investigation. In the "Comments" space, include information on the test used to confirm the pregnancy.
Was any risk factor for serious obstetric complications identified? Explain this in the comments space.	If a risk factor for some obstetric complication was identified, mark "Yes" and explain.
If the pregnancy ended, mark the obstetric-neonatal outcome, as appropriate:	Complete this section only if the pregnancy has ended at the time of the investigation. It should refer to the maternal outcome and that of the embryo, fetus, or neonate.
What was the pregnancy outcome?	Mark the most appropriate pregnancy outcome.
Was the woman breastfeeding at the time of vaccination?	Indicate whether she was nursing when she was vaccinated.

Section C. Details of the first review of the ESAVI.	
Source of information.	Indicate the source of the details on the affected person's clinical status.
Name of the individual who first examined or treated the person:	Include information on the identity of the professional who first had contact with the affected person.
Name of the professionals who treated the person:	Provide information on the identity of the other professionals who treated the affected person; this additional information may be useful in the future.
Other sources of information (specify):	If some source of information has not been included, indicate it in this field.
Signs and symptoms since vaccination, in chronological order:	In this field, create a timeline of relevant clinical events. This can guide additional investigatory measures and the final analysis.
If the ESAVI occurred in a child under the age of 18 years, is child abuse suspected?	This question is relevant, as other causes of the event need to be ruled out and the effects of abuse can often be confused with diseases or medical conditions that may have been classified as ESAVIs.
If the ESAVI occurred in an adult, is there evidence of family violence?	This question is relevant, as other causes of the event need to be ruled out, and the effects of abuse can often be confused with diseases or medical conditions that may have been classified as ESAVIs.
Other relevant social background of the case:	This type of background is highly relevant in cases of a suspected anxiety reaction. Socioeconomic status, educational level, etc. should be considered.
Definitive or preliminary diagnosis:	The diagnosis of the case should be indicated in free text.
ICD diagnostic code:	Include the appropriate ICD diagnostic code for the reported ESAVI.
Section D. ESAVI-related information on the vaccine and people vaccinated at the vaccination site. **Enter the results of the visit to the vaccination site in this section. This is for the identification of patterns that can shed light on the cause of the event.**	
Number of people vaccinated with each antigen at the vaccination site on the day of the event.	Indicate the total number of people vaccinated with each antigen or vaccine at the place where the affected person was vaccinated, including people vaccinated during off-site activities, if appropriate.
Number of people vaccinated with the same lot of vaccine in other locations.	To obtain this information, it is necessary to have traced the lot of vaccine indicated in the report. Enter the number of people vaccinated with the same lot as the affected person in the country where the ESAVI was reported.
Was there a prescribing error or failure to follow the vaccine's recommendations for use?	This and the other questions in this section require reasonable evidence to back the judgment of poor practice indicated. If sufficient evidence is lacking, "Not assessable" should be marked. Mark "No" if there is evidence that the error mentioned did NOT occur.

Is this case part of a cluster?	An association between two or more cases in time or location represents a cluster and should be studied as such. A cluster is defined as two or more cases of the same or similar event, related in time, geographical location, and/or vaccine administered (i.e., route of administration or lot). It can also be associated with the same distributor or health facility
Section E. Immunization practices at the locations where the vaccine in question was used.	
Syringes and needles used:	This section refers to the syringes used to administer the vaccine. If the vaccine is not administered parenterally, leave it blank.
Reconstitution procedure:	This section can be completed once the person who administered the vaccine has been interviewed and records of the vaccination site have been reviewed. The vaccination procedure can be observed and the details of the reconstitution and vaccination process can be observed.
Section F. Cold chain and transport.	
Last storage point.	This section involves inspecting the location where the vaccine and all vaccines at the vaccination site are stored. Verify temperature records at the vaccination site.
Vaccine transport.	This section refers to the transport of the vaccine in question on the day it was administered. This usually applies to cases in which the vaccination was off-site. The individual responsible for vaccine transport logistics should review the information on the transport and temperature control of the lot at every step after its arrival in the country.
Type of vaccine carrier or cold box used.	Describe in detail the type of vaccine carrier used to transport the vaccines on the day of administration, if applicable. If not, leave this section blank.
Section G. Community investigation.	
Was a similar event reported in the same locality around the time the ESAVI occurred?	This section requires reporting of events in the community that are potentially related to the case in question. It is important to review the surveillance data and assess this situation in advance. When answering this question, it is especially important to indicate the geographic location of all cases. The ideal would be to undertake a complete epidemiologic characterization of the cases.
Section H. Other findings, observations, and comments. In this section, enter any additional findings that you consider relevant and essential for analyzing the case.	
Section I. Final classification of the event In this section, final classification of case causality is recorded, following a review by the national or subnational committee. In the comments section, add a brief summary of how the case was assessed.	

Appendix E: INVESTIGATION FORM – FEVER AND RASH

MINISTRY OF HEALTH, JAMAICA

Investigation Form – Fever and Rash (Modified: February 12, 2015)

Complete this form for: Any person in whom a health care worker suspects measles or rubella infection or a patient with fever and rash. The health worker should attempt to collect epidemiological and clinical data, as well as a blood sample, on the first contact with the patient. This contact with the patient might be the only one.

I IDENTIFICATION OF THE REPORTING INSTITUTION

Initial Diagnosis: ☐ 1=Measles, 2=Rubella, 3=Dengue, 4=Other Rash illness, 8=Other Non-Rash illness, 99=Unknown

Case Number: _____
Country: _____
Province/State: _____
Municipality: _____
Locality/Neighborhood: _____

Health service name: _____
Health service telephone: _____
Reported by: _____
Date of consultation: ____/____/____ (Day Month Year)
Date Reported, Local: ____/____/____ (Day Month Year)
Date of home visit: ____/____/____ (Day Month Year)
Date Reported, National: ____/____/____ (Day Month Year)

Detected by: ☐ 1=Spontaneous consultation 2=Laboratory 3=Institutional Search 4=Community Case Search 5=Contact investigation 6=Community Report 88=Other 99=Unknown

Type of provider reporting: ☐ 1=Public 2=Private 88=Other, Specify _____

II PATIENT INFORMATION

Patient's first and last names: _____
Address: _____
Landmarks to locate the house: _____
Type of locality: ☐ 1=Urban 2=Periurban 3=Rural
Patient's sex: ☐ 1=Male 2=Female
Patient's Date of Birth: ____/____/____ (Day Month Year)

Name of the mother or guardian: _____
Telephone: _____
Patient's Occupation: _____
Work or school address: _____
If date of birth is unknown, age: _____ (Years) _____ (Months)

III VACCINATION HISTORY

Type of Vaccine*	Number of doses**	Date of last dose	Source of vaccination Information †
		____/____/____	
		____/____/____	
		____/____/____	

(*) 1=Measles, 2=Rubella, 3=Measles Rubella (MR), 4=Measles Mumps Rubella (MMR)
(**) 0=Zero dose, 1=One dose, 2=Two, 3=Three, etc., 99=Unknown
(†) 1=Vaccination card, 2=Health service record, 3=Verbal

IV CLINICAL DATA, FOLLOW-UP AND TREATMENT

Signs and Symptoms

Fever? ☐ 1=Yes 2=No 99=Unknown — If Yes, temperature (°): _____ — **Date of fever onset:** ____/____/____ (Day Month Year)

Rash? ☐ 1=Yes 2=No 99=Unknown — If Yes, duration of the rash (in days): _____ — Date of rash onset: ____/____/____ (Day Month Year) — Type of rash: ☐ 1=Maculopapular 2=Vesicular 88=Other 99=Unknown

Cough? ☐ Conjunctivitis? ☐ Coryza? ☐ Koplik Spots? ☐ Lymphadenopathy? ☐ **Arthralgia?** ☐ (1=Yes 2=No 99=Unknown)

Is the patient pregnant? ☐ 1=Yes 2=No 99=Unknown — If Yes, **Weeks of pregnancy (01-42):** _____ **Place where birth will likely take place:** _____

Hospitalized? ☐ 1=Yes 2=No 99=Unknown — If Yes, **Hospital name:** _____ Date of admission: ____/____/____ (Day Month Year) **Hospital record number:** _____

Death? ☐ 1=Yes 2=No 99=Unknown — If Yes, Date of death: ____/____/____ (Day Month Year) **Primary cause of death:** _____

Comments: _____

V SPECIMENS AND LABORATORY TESTING

Obtain an adequate specimen for viral isolation. Throat swabs are the first choice.

Specimen			Laboratory test							
Specimen number*	Type of specimen**	Date specimen obtained (Day/Month/Year)	Laboratory Name	Date specimen was sent to lab (Day/Month/Year)	Date Received (Day/Month/Year)	# specimen ID in lab.	Type of test †	Antigen ‡	Result §	Date of Results (Day/Month/Year)
		___/___/___		___/___/___	___/___/___					___/___/___
		___/___/___		___/___/___	___/___/___					___/___/___
		___/___/___		___/___/___	___/___/___					___/___/___
		___/___/___		___/___/___	___/___/___					___/___/___

If virus was detected, specify viral genotype: (Measles: A, B1, B2, B3, C1, C2, D1, D2, D3, D4, D5, D6, D7, D8, D9, D10, E, F, G1, G2, G3, H1, H2. Rubella: 1a, 1B, 1C, 1D, 1E, 1F, 1g, 2A, 2B, 2c) _____

Comments: _____

(*) **1**=First Sample, **2**=Second Sample, **3**=Third Sample (if appropriate)
(**) **1**=Serum, **2**=Nasopharyngeal aspirate/swab, **3**=Throat swab, **4**=Urine, **5**= Cerebrospinal Fluid, **88**=Other
(†) **1**=IgM EIA/Indirect, **2**=IgM EIA/Capture, **3**=Virus Isolation, **4**=PCR, **5**=IgM IF, **6**=IgG EIA/Capture, **7**=IgG IF, **8**=HI
(‡) **1**=Measles, **2**=Rubella, **3**=Dengue, **4**=Parvovirus B19, **5**=Herpes 6, **6**=Enterovirus, **88**=Other
(§) **0**=Negative, **1**=Positive, **2**=Inadequate specimen, **3**=Equivocal (indeterminate), **99**=Unknown (result not available)

VI INVESTIGATION

Were active case-searches conducted?	☐ 1=Yes 2=No 99=Unknown	If Yes,	**Number of suspect cases detected during active case-search:** _____
Was the patient in contact with any pregnant woman?	☐ 1=Yes 2=No 99=Unknown	If Yes,	**Name(s):** _____
Are there other cases present in the case's municipality of residence?	☐ 1=Yes, with measles	**2=Yes, with rubella 3=Yes, with both 4=No 99=Unknown**	
Did the patient travel outside his/her province/state of residence 7-23 days before rash onset?	☐ 1=Yes 2=No 99=Unknown	If Yes,: Cities/Countries	Date of arrival (Day/Month/Year) ___/___/___ **Date of departure (Day/Month/Year)** ___/___/___
			___/___/___ ___/___/___
Setting where infected?	**1=Household contact, 2=Community, 3=Health Center, 99=Unknown, 88=Others** _____		

VII RESPONSE MEASURES

Ring vaccination?	☐ 1=Yes 2=No 99=Unknown	If Yes,	Date started: ___/___/___ (Day Month Year) **Date Ended:** ___/___/___ (Day Month Year) **Number of doses given during ring vaccination:** _____
Was rapid coverage monitoring done?	☐ 1=Yes 2=No 99=Unknown	If Yes,	**What % of vaccinated persons was found?:** _____
Were the contacts followed for up to 30 days after the date of the rash onset of the case?	☐ 1=Yes 2=No 99=Unknown	If Yes,	Date of the last day of contact follow-up: ___/___/___ (Day Month Year)

VIII CLASSIFICATION

FINAL CLASSIFICATION:	☐ 1=Measles 2=Rubella 3=Discarded	Basis for Confirmation:	☐ 1=Laboratory 2=Epidemiological Link 3=Clinical	Basis for Discarding:	☐ 1=Measles/Rubella IgM-neg 2=Vaccine Reaction 3=Dengue 4=Parvovirus B19 5=Herpes 6 6=Allergic Reaction 88=Other Diagnosis _____ (specify)
For confirmed cases, Source of infection:	☐ 1=Imported 2=Import-Related 3=Unknown source 4=Indigenous	If Imported or Import-related	**Country of importation:** _____		
Contact of another case?	☐ 1=Yes 2=No 99=Unknown	**Contact of (or epidemiologically-linked to) case number:** _____			
Classified by _____				Date of final classification: ___/___/___ (Day Month Year)	

Appendix F: ACUTE FLACCID PARALYSIS CASE INVESTIGATION FORM

Investigation Form – POLIO (Modified: January 25, 2024)

Complete this form for any person aged <15 years with acute flaccid paralysis, and for a person of any age in whom polio is suspected.

I IDENTIFICATION

Case Number: _____
Country: _____
Province/State: _____
Municipality: _____
Locality/Neighborhood: _____
Detected by: ☐ 1=Spontaneous consultation 2=Laboratory 3=Institutional Search 4=Community Case Search 5=Contact investigation 6=Community Report 88=Other 99=Unknown

Health Service Name: _____
Health Service Telephone: _____
Reported by: _____
Date of Consultation: ___/___/___ (Day Month Year) Date Reported, Local: ___/___/___ (Day Month Year)
Date of Investigation: ___/___/___ (Day Month Year) *Date Reported, National* ___/___/___ (Day Month Year)
Type of provider reporting: ☐ 1=Public 2=Private 88=Other, Specify _____

II PATIENT INFORMATION

Patient's first and last name: _____
Address: _____
Telephone: _____
Name of the mother or guardian: _____
Landmarks to locate the house: _____
Type of locality: ☐ 1=Urban 2=Periurban 3=Rural
Patient Occupation: _____
Work or School Address _____
Patient's Sex: ☐ 1=Male 2=Female
Patient's date of birth: ___/___/___ (Day Month Year)
If date of birth unavailable, age: _____ Years _____ Months

III VACCINATION HISTORY

Type of Vaccine*	Number of doses**	Date of last dose (Day Month Year)	Source of vaccination Information †
		___/___/___	
		___/___/___	
		___/___/___	

(*) 1=OPV, 2=IPV, 99=Unknown
(**) 0=Zero dose, 1=One dose, 2=Two, 3=Three, etc., 99=Unknown
(†) 1=Vaccination card, 2=Health service record, 3=Verbal

IV CLINICAL DATA

PRODROME
Fever: ☐
Respiratory: ☐
Gastrointestinal: ☐
1=Yes 2=No 99=Unknown

PARALYSIS
Date of Onset: ___/___/___ (Day Month Year)
Fever at paralysis onset: ☐ 1=Yes 2=No 99=Unknown
Cranial pairs: ☐ 1=Yes 2=No 99=Unknown
Respiratory: ☐ 1=Yes 2=No 99=Unknown

SITE OF FLACCID PARALYSIS

	1=Yes 2=No 99=Unknown	1=Proximal 2=Distal 3=Both	REFLEXES 1=Increased 3=Absent 4=Normal 99=Unknown	SENSATION 2=Decreased 99=Unknown
Right arm	☐	☐	☐	☐
Left arm	☐	☐	☐	☐
Right leg	☐	☐	☐	☐
Left leg	☐	☐	☐	☐

SIGNS
Muscle pain: ☐
Meningeal: ☐
1=Yes 2=No 99=Unknown

PROGRESSION
Direction: ☐ 1=Ascending 2=Descending 3= Other
Number of days for paralysis to fully develop: _____

If hospitalized, hospital name: _____
Admission date: ___/___/___ (Day Month Year) Hospital Record. #: _____

Death?: ☐ 1=Yes 2=No 99=Unknown
If Yes, Date: ___/___/___ (Day Month Year) Primary cause of death: _____

Comments: _____

V LABORATORY TESTING

Sample		Laboratory Test												
		Virus Isolation						Intratipic Differentiation (ITD)						
Specimen #	Specimen obtained (Day/Month/Year)	Date sample sent to Lab. (Day/Month/Year)	**Name of Lab. processing the sample**	Date received (Day/Month/Year)	# Specimen ID in lab.	Result †	Date result (Day/Month/Year)	Date sent to Ref. Lab. (Day/Month/Year)	Ref. Lab. name	Date received by Ref. Lab. (Day/Month/Year)	Results ‡	Date ITD (Day/Month/Year)	Natl. vs Ref. discordance 1=Yes 2=No	Final result §
	__/__/__	__/__/__		__/__/__			__/__/__	__/__/__		__/__/__		__/__/__		
	__/__/__	__/__/__		__/__/__			__/__/__	__/__/__		__/__/__		__/__/__		

(†) 0=Negative, 4=Non Polio Enterovirus, 44= Poliovirus &NPEV, 5=Inadequate, 6=Other Virus, 77=Poliovirus

(‡) 1=P1Sabin, 2=P2Sabin, 3=P3Sabin, 5=Inadequate, 7=P1 Vacc. Derived, 8=P2 Vacc. Derived, 9=P3 Vacc. Derived, 10=P1 Wild, 11=P2 Wild, 12=P3 Wild

(§) Official Result

Comments: _____

Sample	Name	Age (YY/MM)	No. OPV Doses	Date of last dose
Contact 1				__/__/__
Contact 2				__/__/__

* Contacts should be <5 years of age and not vaccinated within 30 days. List additional contacts on separate page.

Contacts* (If necessary)

Laboratory Test														
	Virus Isolation							Intratypic Differentiation (ITD)						
Date taken (Day/Month/Year)	Date sample sent to Lab. (Day/Month/Year)	Lab. name	Date received (Day/Month/Year)	# specimen ID in lab.	Result †	Date Result (Day/Month/Year)	Date sent to Ref. Lab. (Day/Month/Year)	Name Ref. Lab.	Date received by Ref. Lab (Day/Month/Year)	Results ‡	Date ITD (Day/Month/Year)	Natl. vs Ref. discordance 1=Yes 2=No	Final result §
__/__/__	__/__/__		__/__/__			__/__/__	__/__/__		__/__/__		__/__/__		
__/__/__	__/__/__		__/__/__			__/__/__	__/__/__		__/__/__		__/__/__		

(†) 0=Negative, 4=Non Polio Enterovirus, 44= Poliovirus &NPEV, 5=Inadequate, 6=Other Virus, 77=Poliovirus

((‡) 1=P1Sabin, 2=P2Sabin, 3=P3Sabin, 5=Inadequate, 7=P1 Vacc. Derived, 8=P2 Vacc. Derived, 9=P3 Vacc. Derived, 10=P1 Wild, 11=P2 Wild, 12=P3 Wild

(§) Official Result

Comments: _____

VI FOLLOW-UP

Date of 60 days follow-up: ____/____/____ (Day Month Year)

Residual paralysis compatible with polio at 60 days: ☐ 1=Yes 2=No 99=Unknown

Atrophy: ☐ 1=Yes 2=No 99=Unknown

VII CONTROL

Date of mop-up vaccination begun: ____/____/____ (Day Month Year) Population <5 years: _____ Total <5 years vaccinated: _____

Estimated number of households in target area: _____ Number of households visited: _____

VIII CLASSIFICATION

FINAL CLASSIFICATION: ☐ 1=Confirmed Polio Wild 2=Confirmed Polio Vacc. Derived 3=Confirmed Polio Vacc. Associated 4=Polio Compatible 5=Discarded	CLASSIFICATION CRITERIA: ☐ 1=Laboratory 2=Lost to Follow Up 3=Death 4=With Residual Paralysis 5=Without Residual Paralysis	IF DISCARDED, DIAGNOSIS: ☐ 1=Guillain-Barré 2=Traumatic Neuritis 3=Transverse Myelitis 4=Tumor 99=Unknown 88=Other _____
Date classified: ____/____/____ (Day Month Year)		

IX INVESTIGATOR

Name of investigator: _____ Signature _____ Date: ____/____/____ (Day Month Year)

Title: _____ Office: _____

Comments: _____

Appendix G: ACUTE FLACCID PARALYSIS SURVEILLANCE 60 DAY FOLLOW UP

ACUTE FLACCID PARALYSIS SURVEILLANCE
NEUROLOGICAL EXAMINATION :

60 DAY FOLLOW-UP

Please complete and return promptly:

COUNTRY: _____

Hospital: _____ **Registration No.** _____

Ward/Clinic: _____ **Consultant:** _____

Name of Patient: _____ **Age:** _____

Sex: **Male** ☐ **Female** ☐

Address: _____

Tel. No.: _____ **Next of Kin:** _____

Paralysis Present: **Yes** ☐ **No** ☐

If yes, please complete the following:

SITE	DEGREE OF PARALYSIS	DEGREE OF PARESTHESIA
Left Leg		
Left Arm		
Right Leg		
Right Arm		
Face		
Respiratory Muscles		
Other Cranial Nerves		

Comments: _____

_____

_____

_____

Final Diagnosis: _____

Signature of Doctor: _____

Date: _____

Appendix H: CARPHA LAB INVESTIGATION FORM

JAMAICA : Laboratory Investigation Form

FOR-Q05-003-02

1. Patient Information

Client Patient ID: (if available) ⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊

First Name: ⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊

Middle Name: ⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊

Surname: ⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊⌊

Gender: ☐ M ☐ F

Date of Birth (DD/MM/YYYY): ⌊⌊/⌊⌊/⌊⌊⌊⌊⌊

Age: ⌊⌊⌊ ☐ years ⌊⌊⌊ ☐ months

Address: _____

Phone: _____ Country: _____

2. Residential Status

☐ Resident ☐ Visitor (Tourist) ☐ Visitor (Business)

Country of origin: _____

Country visited in the last 14 days: _____

3. Immunization History

EPI No:

☐ BCG	DD	MM	YYYY	☐ HBV	DD	MM	YYYY		
COVID-19	☐ 1st DD	MM	YYYY	☐2nd	☐ MMR	DD	MM	YYYY	
					☐ Polio	DD	MM	YYYY	
☐ DPT	DD	MM	YYYY	☐ YF	DD	MM	YYYY		

Other: _____

4. Referring Doctor

Name: _____

Reporting Address: _____

_____

Phone:

5. Date of Onset of Illness (DD/MM/YYYY)

⌊⌊/⌊⌊/⌊⌊⌊⌊

6. Signs, Symptoms and Syndromes

☐ AFP	☐ Genital lesions
☐ Altered mental state	☐ Haemorrhagic symptoms
☐ Chills	☐ Hepatomegaly
☐ Circulatory collapse	☐ HIV +ve
☐ Conjunctivitis	☐ Jaundice
☐ Convulsions	☐ Kernig's sign
☐ Coryza	☐ Lymphadenopathy
☐ Cough	☐ Nausea
☐ Diarrhoea, Acute	☐ Neck Stiffness
☐ Diarrhoea, Chronic	☐ Pain
☐ Failure to Thrive	☐ Paralysis
☐ Fever	☐ Rash
☐ Fever (Undifferentiated)	☐ Respiratory, Lower
☐ Fever And Haemorrhagic	☐ Respiratory, Upper
☐ Fever And Neurological	☐ Shortness of breath
☐ Fever And Rash	☐ Sore Throat
☐ Fever And Respiratory or Acute Respiratory Infection	☐ Vomiting
	☐ Weakness of limbs
☐ Gastroenteritis	☐ Weight Loss
☐ Genital discharge	

Other: _____

7. Case Status

☐ Outbreak ☐ Single ☐ Survey ☐ Unknown

8. Case Outcome

☐ Patient Died ☐ Patient Hospitalized ☐ N/A

9. Additional Notes/Provisional Diagnosis

[1] information on risk factors, lab findings, etc.

10. Food/Animal/Environment Sample Details

Type of food/env sample: _____

Where specimen(s) collected _____

☐ Outbreak ☐ Traceback ☐ Survey ☐ Other

Specimen Details		Specimen 1	Specimen 2	Specimen 3
	Date of Collection (DD/MM/YYYY)			
	* Sample Type			
	Client Sample ID			
	Lab Analyses/ Test(s) Requested			
	***Sample Type: Serum; EDTA blood; Blood smear; Sputum; CSF; Swab; Urine; Stool; Tissue; Plasma (PPT); if other specify**			

Nat. Lab Test(s) Performed				
	Date Received at Nat. Lab (DD/MM/YYYY)			
	Test(s) Performed			
	Date(s) Tested			
	Laboratory Diagnosis			

	(1)	(2)	(3)
CARPHA USE: Specimen ID			

Appendix I: CRISIS PLAN FOR THE MANAGEMENT OF EVENTS SUPPOSEDLY ATTRIBUTABLE TO VACCINATION OR IMMUNIZATION (ESAVIs)

CRISIS PLAN FOR THE MANAGEMENT OF EVENTS SUPPOSEDLY ATTRIBUTED TO VACCINATION OR IMMUNIZATIONS (ESAVIs)

Introduction

Immunization is one of the safest and most cost-effective interventions in health. Inexpensive vaccines have prevented millions child deaths per year and ensured that hundreds of thousands fewer children grow up mentally or physically handicapped. It is well known that immunization programmes have been the backbone of preventive primary health care services in most countries, benefiting large sections of the population. Immunization programmes have been very successful in many countries of the world including the English-speaking Caribbean, where most vaccine preventable disease have already been eradicated or eliminated.

However, as diseases preventable by vaccination become less visible because of effective vaccination programs, there is less fear about the diseases and more concern about the vaccinations. More attention is paid to adverse events after vaccination. Any severe or large scale occurrence of these events can rapidly threaten the integrity of the immunization programme, and consequently, the health of the public, especially children. Such events must therefore be carefully prevented as well as monitored and investigated in a timely and objective manner. Cases should also be managed appropriately and the public advised/educated accordingly.

National immunization programmes have the responsibility to procure safe, effective vaccines, educate the health staff about safe vaccination practices, educate parents/guardians and establish an effective system for the monitoring of such events.

No biological or pharmaceutical product is without risk and vaccines are no different. Manufacturers produce vaccines that are as safe and effective as possible using current technology, but occasional adverse effects related to vaccines always occur.

Most reactions to vaccines are normal and mild, disappear without treatment and have no long-term consequences. Serious reactions are much rarer.

A vaccine can also precipitate an event that would have occurred anyway; for example, the first feverish symptoms leading to seizures. Vaccines are also normally administered at certain stages of life in which both infants and children show viral symptoms with cough and colds that may be accompanied by fever. When these episodes occur whether vaccines are given or not, they are coincidences although parents may believe that they are directly related to the vaccine.

Events supposedly attributed to vaccination or immunization (ESAVIs)

There are a set of symptoms that occur after a vaccination has been given, which causes concern and is supposedly attributable to vaccination or immunization.These events can be classified according to their severity, either: (a) non-serious events (minor and/or normal); or (b) serious events (severe and/or less frequent or rare events).

a) Non-serious events

The purpose of a vaccine is to induce immunity (to form antibodies) by means of a reaction by the immune system of the vaccine. Local reaction, fever and symptoms in general may be part of the normal immune response. In addition, some of the components of the vaccine (for example, the aluminum coadjuvant, antibiotics or preservatives) can produce such events. These usually appear within the first 24-72 hours.

Table 1: Frequency rates of minor events attributed to vaccination or immunization.

Vaccine	Local reaction (pain, swelling, redness)	Fever	Irritability, malaise and non-specific symptoms
Haemophilus influenzae type b (Hib)	5-15%	2-10%	-
Hepatitis B	Up to 30% in adults Up to 5% in children	1-6%	-
Measles/MMR	Up to 10%	up to 5%	up to 5%
Oral poliomyelitis (OPV)	None	less than 1%	Less than 1% [a)]
TT/DT	Up to 10% [b)]	up to 10%	up to 25%
DPT [c)]	Up to 50%	Up to 50%	up to 60%
BCG[d)]	Common e)	-	-

(N.B the rates corresponding to the administration of vaccine will be lower, given that these symptoms appear normally in children, regardless of vaccination).

(a) Diarrhea, headache and muscular pains; (b) It is likely that the rates of local reaction increase with the booster from 50 to 85% (c) Whole cell whooping cough vaccine. The rates for acellular whooping cough vaccine are lower (d) Local reactogenicity varies from one vaccine to another as a function of the strain and number of viable bacilli. (e) The reaction consists of the appearance of a nodule and subsequent reaction.

b) Serious events

Almost all rare post-vaccination events (e.g. seizures, thrombocytopenia, hypotonic and hypotensive episodes and persistent inconsolable screaming) are characterized by spontaneous remission and cause no subsequent problems or sequelae. Anaphylaxis, though it can be fatal, produces no sequels if treated in time. Although encephalopathy is quoted as a rare event after measles and DPT vaccination, in reality no casual relation has been demonstrated.

Table 2: Severe events attributed to vaccination or immunization, onset interval and rates

Vaccine	**Event**	**Onset interval**	**Rates per 1,000,000 dosage**
BCG	Supparative lymphadenitis BCGG osteitis Disseminated BCG	2-6 months 1-12 months 1-12 months	100-1000 1-700 2
Hib	Nil known	-	-
Hepatitis B	Anaphylaxis Guillan-Barre' syndrome (vaccine obtained from plasma)*	0-1 Hour 0-6 weeks	1-2 5
Measles/MMR [a)]	Febrile Seizures Thrombocytopenia (low platelet count) Anaphylaxis	5-12 days 15-35 days 0-1 hour	333 33 1-50
Oral poliomyelitis (OPV)	Vaccine- associated paralytic poliomyelitis (VAPP)	4-30 days	Less than 1b)
TT/Td	Brachial neuritis Anaphylaxis Sterile abscess	2-28 days 0-1 hour 1-6 weeks	5-10 1-6 6-10
DPT	Persistent screaming lasting for more than 3 hours. Seizures Hypotonic hypotensive episode (HHE) Anaphylaxis Encephalopathy	0-24 hours 0-2 days 0-24 hours 0-1 hour 0-3 days (average)	1000-60,000 570c 570 20 0-1
Yellow fever	Post vaccination encephalitis Allergic reaction /anaphylaxis	7-12 days 0-1 hour	500-4.000 in infants under 6m 5-20

a) No reaction (except anaphylaxis) when there is immunity (~90% of those who receive a second dose); febrile seizures are very unlikely in children over six.
b) The risk of VAPP is higher for the first dose (1 in 1,400,000–3,400,000 dosage) than for subsequent doses and contacts, 1 in 5,900,000 and 1 in 6,700,000 doses respectively.
c) Seizures are principally febrile and the frequency depends on personal and family background and age, with the risk lower for children under 4 months.
d) Isolated cases with no denominator make evaluation of frequency more difficult for children and adults, but are extremely rare (less than 1 case in 8,000,000 doses).

The information in the tables of events expected after vaccination will be useful to:

- Prevent events that could arise in an immunization programme
- Detect events that are not linked to vaccines
- Compare the rates notified with those expected
- Start an investigation if the notified rates exceed the expected rates

Health care workers are obliged to inform parents of the more common events expected post-vaccination and how to manage them. It is also essential to inform them that in the event of any reaction appearing after vaccination, they must go to the hospital or the nearest health centre.

Determining the cause of ESAVIs

The casual relationship between a vaccine and an adverse event may be determined using three questions:

a) **Can it?** (Potential causality): Can the vaccine cause an adverse event, at least in a certain group of people under certain circumstances?
b) **Did it?** (Retrospective causality): If a person who received the vaccine developed an adverse event, was this caused by the vaccine?
c) **Will it?** (Predictive causality): Will the next persons who receive the vaccine develop the same adverse events because of the vaccine?

Monitoring for ESAVIs

All ESAVIs must be monitored on a daily basis by the parish and regional Immunization team as well as members of private medical associations who administer vaccinations. As some ESAVIs may first present in the hospital setting, staff of the Accident and Emergency Unit as well as the casualty Departments should also be educated on ESAVIs and sensitized to the possible presentations.

The standard Ministry of Health and Wellness forms for the reporting and investigation of ESAVIs (Appendices C and D) should be available at all times at health centres, hospitals and private doctors' offices. ESAVIs should be recorded in the Adverse Events Registers

at health centre and parish levels and notified to the Surveillance Unit, Ministry of Health or the Family Health Unit in the time frame specified. Reports should be made through the Parish Medical Officers of Health.

ESAVI Crisis Plan

A "crisis" under the ESAVI context is a situation in which there is an actual or potential loss of confidence in the vaccine or Immunization Programme that generally begins with a notification, report or rumor of an adverse event (real or alleged).

Crises can and must be avoided with the adequate promptness, care and training of the people involved in a Safe Vaccination programme. If the "crisis" is adequately handled, the programme will be reinforced, therefore increasing the public's confidence.

In order to prevent crises from occurring in the Immunization Programme, the following activities must be conducted on a regular basis with vigor and with close supervision and monitoring.

Public Education

This should be done to educate parents/guardians on the identification of possible adverse events to vaccination in order for them to promptly react to the events and immediately seek help at the hospital or nearest health centre. The main events that have to be recognized are: persistent crying (for more than three hours), incessant fever, sleepiness, prolonged irritability.

Prompt medical intervention starting from the identification of symptoms, will decrease the likelihood of an ESAVI leading to an undesired event, and will help to identify the cause of the event as soon as possible.

Training

Health care workers must be trained to know possible vaccine adverse events, identify “danger signs" and be equipped with the necessary skills to counsel parents. They should also be trained in the monitoring and timely investigation of ESAVIs in order to avoid any rapid spread of negative criticism of the programme.

Updated Guidelines / Protocol

This is to standardize the clinical management of ESAVIs. Immunization field guidelines must include the recognition and management of ESAVIs as well as the mechanism for monitoring, reporting and investigation of these events.

Communication

This is a very important strategy for the appropriate management of ESAVIs, especially when they are severe. It requires a plan that outlines:

- The information that is necessary / important to disseminate
- The person(s) designated to makes statements or speak to the press
- The person(s) designated to liaise with the media and the different stakeholders

ESAVI Crisis Management Team

At the first report or rumour of a Serious ESAVI or a cluster of ESAVI cases, the Ministry of Health and Wellness shall immediately (within 1 hour) establish its ESAVI Crisis Management Team. The team shall comprise of representatives from the following areas or associations:

- Family Health Unit
- Surveillance Unit
- Emergency, Disaster Management and Special Services Branch
- Public Relations and Communications Unit
- Standards and Regulations Division
- Regional Health Authorities
- Paediatric Association of Jamaica
- Medical Association of Jamaica
- Nursing Association of Jamaica

The members of the team shall comprise of the technical heads of the units or their designates. The legal officer of the Ministry of Health and Wellness shall also be an integral member of the team. The Director, Family Health Unit, shall be the team leader. The team should seek the guidance of a communications specialist in the preparation and dissemination of statements.

Reporting of ESAVIs

All ESAVIs shall be entered in the Adverse Events Registers at health centre and parish levels. The standardized form for the reporting of ESAVIs shall also be used for the reporting of any event related to vaccination and immunization including severe events. These forms should be submitted to the Surveillance Unit and Family Health Unit through the Parish Medical Officer of Health. The Surveillance Unit shall analyze the reports and immediately report clusters or severe events to the Director, Family Health Unit. All members of the Crisis Management Team shall monitor the media for reports or rumours

of clusters or Serious ESAVIs and report them immediately to the Director, Family Health Unit.

Investigation of ESAVIs

All events considered by the public, parents, the patient or health care workers as linked to the vaccine must be investigated locally. If the time frame and symptoms show a possible link between the event and the vaccine, a deeper investigation must be initiated immediately, with regional and/or national support.

The purpose of the investigation is to confirm or dismiss the reported event, and determine whether other possible causes are present; also, to confirm if this is an isolated event and thus inform the people involved.

All ESAVIs falling into the following categories must be monitored and investigated:

- Severe events:
  - Require hospitalization
  - Are life-threatening
  - Produce disability
  - Have fatal consequences
- Hearsay
- Events occurring in groups of people (clusters).
- Program-related (“programmatic”) events

Serious events – must be investigated within 24 hours.

Clusters – must be investigated within 48 hours.

Other events – must be investigated within 7 days.

Investigations of severe events and clusters should be conducted by the Parish Health Team consisting of the Medical Officer of Health, Senior Public Health Nurse and a Pediatrician from the regional hospital. Other members of the health team may be included as is necessary.

The purpose of the investigation is to:

- determine the validity of the ESAVI report- verify the information and confirm the ESAVI
- determine temporal association with vaccination classify the ESAVI
- classify the ESAVI

Classification of ESAVIs based on their origin:

Vaccine product-related event

Event caused or triggered by a vaccine, despite its correct administration, due to its inherent properties or components.

- Intrinsic reactions: Reactions of the patient's body to the biological product itself.
- Extrinsic reactions: Reactions of the patient's body to the formulation's co-adjuvants.
- Quality diversion: The deviation from the normal parameters that gave rise to the vaccine's license, i.e. increase in viral concentration.

Vaccine quality-related event

Event caused by deviations from vaccine quality specifications, including in devices used for vaccine administration, manufacturing processes, storage, or the distribution chain.

Event related to programmatic error

Event caused throughout the vaccine's life cycle, due to errors in storage (cold chain), preparation, handling or administration.

Anxiety-related (stress-related) event

Event due to anxiety or pain generated by the injection, not by the vaccine.

Coincidental event

Events occurring after vaccination but which are not caused by the vaccine: it is a random association, i.e. they occur at the same time but do not have a cause and effect relationship (they are independent).

Non-classifiable eventnknown

Events for which the cause is not known or has not yet been determined.

If an ESAVI is due to a vaccine or unknown reaction, it must be investigated in greater depth to be classified as a **certain/very likely, probable, or possible** cause in terms of causality classification. If not related to vaccination or the investigation is inconclusive, the event should be classified **as unlikely, unrelated or unclassifiable.**

The Process of Investigation

The investigation should focus on: the service, the vaccine, the user, the health care worker, the parents, the fieldwork and the legal area. This entails observation procedures, interviews, record reviews, facility inspection, postmortem reports, and home visits.

Area of Investigation	**Details to look for**
The service	Programmatic errors at some level of service provision at the vaccination site. Take a detailed and thorough look at the vaccination site, focusing on everything related to the programme – the refrigerator, the vaccine carrier, the vaccination room, the place where syringes and diluents are stored, the vaccine inventory log, the biosafety measures.
The vaccine	Identification of the vaccine and syringe used; Vaccine's name (label description), batch number, production and expiration dates, manufacturer, origin of the vaccine / syringe, shipment date and transportation data (cold chain), physical aspect of the vaccine / syringe, vaccine quality control results, review of the vaccine's production protocol.
The programme logistics	Vaccine storage, vaccine transportation and handling, movement records, stock controls and others.
The health care worker	The use of diluents, vaccine reconstitution and administration routes. The adequate dose. Syringe and needle availability and appropriate practices. Circumstances under which vaccination is being conducted, and how it is performed. The person who administered the vaccine (vaccinator). Administration technique. The cold chain. The work climate and work organization during vaccination.

The user (client)	Demographic data: age, sex, place of residence and references for location; family background; the recent clinical history (symptoms and signs, when they appeared, duration, clinical exam, auxiliary examinations diagnosed, treatment, evolution); event type, onset date, duration and clinical event treatment; client's pathological history and clinical history (at birth, prior reactions to vaccines, allergies to certain pharmaceutical preparations, preexisting neurological disorders, sleep apnoea, drugs he/she is currently taking, etc.); vaccination history: type of vaccine used and last dose's date, type of reaction (if appropriate).

Area Of Investigation	**Details to look for**
Field/Community	Interviews, home visits. Social and economic conditions: type of household, shelter, type of bed and sleep habit (in the case of a child, indicate who he/she sleeps with). In the event of death, indicate how the corpse was found (position, corpse temperature, if there were mouth or nasal secretions and their characteristics). Complete postmortem report. Follow-up of other children who received vaccines from the same batch or vial. Determine if the notified event was isolated or if there were other similar cases. • People vaccinated from the same batch during the same period and having the same symptoms. • Non-vaccinated people to determine whether a similar event was present in this population. • People vaccinated from a different vaccine batch (of the same or other manufacturer) having similar symptoms, to determine if a similar event occurred in the population vaccinated from another batch.

Postmortems

In cases of deaths supposedly attributable to vaccination or immunization, a postmortem should be arranged within the first 72 hours.

- If the child dies at home from no apparent cause, the physician must perform a verbal autopsy as soon as the child is taken to a health facility for pronouncement of the death. The mother or responsible relative must be

questioned, following the same steps of a clinical history and a physical exam on the dead child must be done to look for disease signs [i.e.: jaundice (yellowish skin and sclera), petechiae, hemorrhages, cyanosis, paleness].
- If possible, x-rays must be taken.
- A detailed postmortem should be performed by a trained pathologist with adequate tissue sampling before autolysis.

Samples of vaccines from the same manufacturer and batch may have to be collected for quality testing depending on the nature of the event and especially when unexpected ESAVIs occur, or when they exceed the expected rates.

After the investigation, the information must be analyzed to determine the cause, confirm the diagnosis or suggest other possible diagnoses.

Reporting of Investigation Results

The event is definitely not related to vaccination:

Co-incidental i.e. the event might have been produced even if the person had not received the vaccine. It is best to support this argument by showing that the same case or cases occurred in a group that was not immunized. Clinical and laboratory evidence will be needed to explain the reactions suffered by the person.

The event is related to vaccination:

If related to the operational aspects of the programme (Programmatic Error). A programmatic error may lead to a cluster of events, especially if a vaccinator does not comply with what was taught during training. Programmatic errors are generated by at least one of the following situations:

- Inadequate dosage.
- Incorrect administration method.
- Unsafe use of needles and disposable syringes.
- Lack of package supervision, ensuring needle and syringe sterility.
- Inadequate handling of needles and syringes.
- Vaccine reconstitution with the wrong diluent.
- Inadequate amount of diluent.
- Inappropriate vaccine preparation.
- Vaccine or diluent substitution with drugs or others.
- Vaccine or diluent contamination.
- Incorrect storing of vaccine and syringes.

- Vaccines and syringes used after their expiration date.
- Incorrect movement or administration records.

The investigation is not conclusive:

When causality cannot be determined, apart from notifying the interested parties on the investigation's results, details must be also reported as to why a conclusion cannot be reached and how far the investigation had gone.

Once the investigation has been concluded and the respective results have been reached, a written report must be prepared and sent to the Chief Medical Officer, Permanent Secretary, Minister of Health and Wellness and the Pan American Health Organization.

Clear communication is needed at this point and the parents, the community, the parish and regional health authorities as well as professional associations must next be advised. The general public may have to be informed, including mass media, only if appropriate.

The Chief Medical Officer or designate shall be the only person authorized to speak with the media and to issue statements on the ESAVI and investigation report.

Communication

The communication plan shall be developed by the Public Relations and Communication Unit. All press and media releases/ statements should be prepared by the Public Relations and Communications Unit and be signed off on by the Chief Medical Officer prior to release. The Permanent Secretary and the Minister of Health and Wellness should also sign off on the media releases.

For serious ESAVIs already in the public knowledge, the first media release shall be prepared within 24 hours and include a statement of the event as well as the status of the investigation thus far. Subsequent media releases shall be prepared in a timely manner as deemed appropriate by the Public Relations and Communications Unit. Where necessary, a press briefing may be organized with the Minister of Health and Wellness and the Chief Medical Officer as the designated speakers.

At all times, the success and benefits of the Immunization Programme must be re-iterated.

Management of ESAVIs

Clients

Cases of ESAVIs resulting from vaccination in the public health facilities shall be managed free of charge by the health teams in either the hospitals or the health centres, depending on the severity of the event. Management should be by a team headed by the regional Paediatrician/Internist and must be implemented immediately upon receipt of the report or presentation by the client. A clinical summary of the case must be presented to the investigation team as soon as is practicable.

Health workers

If ESAVIs were determined to be due to programmatic error, re-training of all the relevant health workers shall be done within 6 weeks. This re-training shall be co-ordinated by the Family Health Unit in collaboration with the Regional Health Authorities.