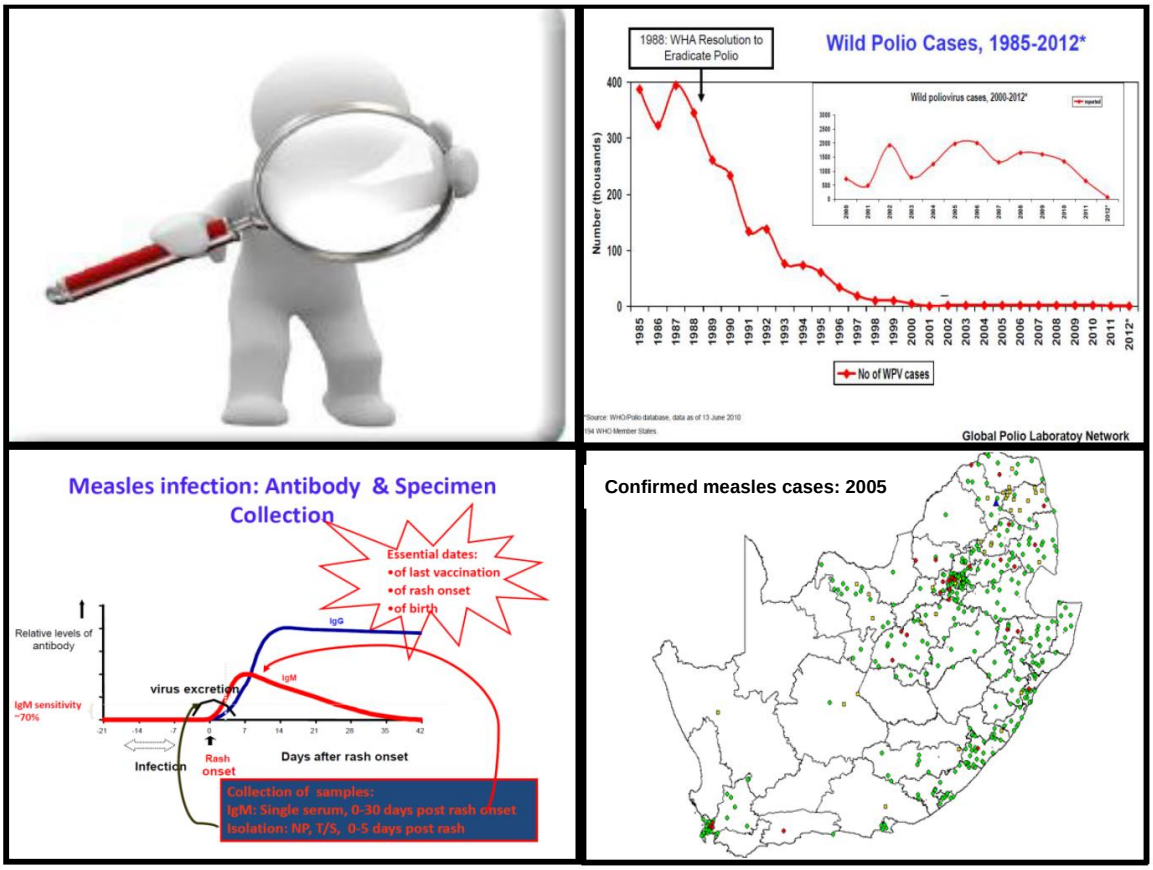
EPI Diseases Surveillance Guideline 3rd Edition (2015)

Guidelines for Detecting, Reporting, Investigating and Responding to EPI Priority Diseases

Expanded Programme on Immunisation in South Africa (EPISA)



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LIST OF ABBREVIATIONS

AEFI	Adverse Events Following Immunisation
AFP	Acute Flaccid Paralysis
AIDS	Acquired Immuno Deficiency Syndrome
BCG	Bacillus Calmette Guerin
CDC	Communicable Diseases Control
CIF	Case Investigation Form
DOH	Department of Health
DPT	Diphtheria, Pertussis, Tetanus
DTaP-IPV-HB-Hib	Diphtheria, Tetanus, acellular Pertussis,-Inactivated Polio Vaccine, Hepatitis B, Haemophilus influenzae type b
EDL	Essential Drug List
EDR	Event Description Report
EMG	Electromyography
EPI	Expanded Programme on Immunisation
EPI SA	Expanded Programme on Immunisation of South Africa
EPID	Epidemiological Identification
GBS	Guillain-Barré Syndrome
Hib	Haemophilus influenzae type b
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IPCN	Infection Prevention & Control Nurse
IU	International Unit
IST	Inter-country Support Team
MCC	Medicine Control Council
MCV	Measles Containing Vaccines
MNT	Maternal Neonatal Tetanus
NHLS	National Health Laboratory System
NICD	National Institute of Communicable Diseases
NID	National Immunisation Day
NNT	Neonatal Tetanus
OPV	Oral Polio Vaccine
PAB	Protected at Birth
PEC	Polio Expert Committee
RNA	Ribonucleic Acid
RTHC	Road To Health Card/Booklet
SA	South Africa

SIA	Supplementary Immunisation Activity
SMC	Suspected Measles Case
SOP	Standard Operating Procedure
SSPE	Sub-acute Sclerosing Pan Encephalitis
TAG	Technical Advisory Group
TB	Tuberculosis
TBA	Traditional Birth Attendant
Td	Tetanus -diphtheria (lower strength)
TT	Tetanus Toxoid
UNICEF	United Nations Children's Fund
VAPP	Vaccine Associated Paralytic Polio
VDPV	Vaccine Derived Polio Virus
VPD	Vaccine Preventable Diseases
VTM	Viral Transport Medium
VVM	Vaccine Vial Monitor
WHO	World Health Organization
WHO AFRO	World Health Organization Africa Regional Office

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FOREWORD TO THE THIRD EDITION

Surveillance plays a key role in disease control, elimination and eradication strategies. It is for close monitoring and evaluation of public health intervention programmes, like the Expanded Programme on Immunisation (EPI). Surveillance allows *hands-on-the-pulse* monitoring of disease incidence and detection of outbreaks.

This 3rd Surveillance Guideline comes at an appropriate time; in 2012, the 65th World Health Assembly (WHA) declared polio eradication a "programmatic public health emergency". This is a critical time in the history of polio eradication, as we implement the Polio Endgame Strategic Plan 2013 to 2018. This period not only requires the intensification of surveillance activities, but also that the infrastructure developed for polio eradication is used to strengthen health systems in general. It is for this reason that WHO in the Africa region has set the target for detection of Acute Flaccid Paralysis cases at 4 per 100 000 children below the age of 15 years.

This is also a time of intensified efforts directed at accelerated measles control, backed by the launch of the "Global Measles and Rubella Strategic Plan 2012 - 2020". The monitoring of milestones and targets for measles and polio eradication plans must be based on surveillance and data.

The 3rd edition of the EPI Surveillance Guideline will guide and support programme managers at different levels to monitor progress towards the attainment of national and global surveillance goals; help monitor the impact of EPI in the control of vaccine-preventable disease; direct limited resources, plan and help prioritise intervention measures. This document must be used as the basis for training in surveillance for EPI targeted conditions,

It is hoped that this Guideline will be a useful tool in monitoring surveillance performance and in our efforts to control vaccine-preventable diseases and protect South Africans from infections that can be prevented through vaccination.

MS MP MATSOSO (DIRECTOR GENERAL: HEALTH)

DATE:

1. INTRODUCTION AND PURPOSE OF THE FIELD GUIDE

1.1 Objectives

The information in this Field Guide forms the technical basis for the establishment of surveillance activities within districts and provinces; and for monitoring and responding to the targeted Expanded Programme on Immunisation (EPI) conditions. The Guide may be used for basic in-service training, field supervision and for monitoring surveillance performance.

In keeping with the global targets for control, elimination and eradication of EPI targeted conditions and the established disease control strategies, the Field Guide contains detailed steps to establish and monitor surveillance for Acute Flaccid Paralysis (AFP), Neonatal Tetanus (NNT) and Measles. The section on Adverse Events Following Immunisation (AEFI) is relevant and applicable to all vaccines used in the EPI programme. Surveillance for AEFI is for monitoring immunisation safety and contributes to the credibility of the programme. Even though surveillance for the other EPI diseases is not included in this Guide, the principles of surveillance discussed in the Guide are relevant and applicable to them.

After studying this Field Guide, readers will know:

1. The South African national EPI goals, objectives and targets;
2. South African EPI disease control strategies;
3. The definition and purpose of surveillance of vaccine preventable diseases (VPDs) and other priority communicable diseases and actions to be taken in response.

And be able to:

1. Detect, report and investigate conditions targeted for EPI surveillance: Measles, AFP, NNT and AEFI;
2. Collect and ship faecal specimens from an Acute Flaccid Paralysis case;
3. Collect and send blood (and throat swab where indicated) specimens from a Suspected Measles Case SMC;
4. Collect and ship vaccines and / or other specimens as part of investigating an AEFI;
5. Analyse and interpret data on district communicable disease patterns and trends;
6. Take appropriate action in response to a case or outbreak;
7. Monitor surveillance indicators;
8. Review and take corrective measures to improve the surveillance system;
9. Provide feedback to all appropriate parties;
10. Compile and submit weekly/monthly reports to the next level;
11. Conduct active case search and report timely.

1.2 Target Audience

This Field Guide is intended for all healthcare workers involved in EPI targeted conditions and vaccine preventable disease (VPD) surveillance, including: Infection and Prevention Control Nurses (IPCN) at facility level; Communicable Disease Control (CDC), EPI, Primary Health Care (PHC) and Maternal, Child and Women's Health (MCWH) coordinators, at all levels; surveillance officers and public health specialists. However, all health professionals involved in the delivery of immunisation services will benefit from this Guide. Provincial EPI and CDC officers should ensure that the guideline is distributed and used by all relevant officials at all levels within a province.

All districts should have district outbreak-response teams that should be composed of some or all of the following:

- District public health officers (environmental health practitioners, communicable disease coordinators, health promotion and communication officers, epidemiologists);
- Focal persons for EPI activities, such as EPI or MCWH or PHC coordinators;
- Appropriate health workers from health facilities, such as public health specialists, medical officers, epidemiologists, communicable disease control coordinators, senior nurses, ward supervisors, etc.

1.3 The Functions of Surveillance

The use of surveillance as a public health management tool should not be limited to a single programme. The principles and steps of a fully functional surveillance system can be applied to control any of the communicable conditions and other non-communicable conditions.

A surveillance system provides baseline data and forms the basis for trends, natural history, clinical spectrum and epidemiology of conditions. Possible benefits of a good surveillance system include prediction of who is at risk, when and where a condition occurs and the risk factors critical for its occurrence. When appropriately used, this knowledge may lead to the development of improved measures for disease prevention and control. It also provides information that can be used to assess, monitor and evaluate prevention and control measures.

The main purpose of surveillance as described in this guideline will be identification and response to AFP (for detection of Polio), Measles, NNT and AEFI. However, throughout the appropriate sections the usefulness of surveillance for other purposes is described.

1.4 Vaccine Preventable Disease (VPD) Surveillance

The purpose of the Expanded Programme on Immunisation (EPI) is to prevent childhood infections by using vaccines and eventually to reduce the burden of diseases by preventing the circulation of these infectious agents in the community. In South Africa, the number of vaccines used for childhood immunisation has increased from six vaccines in 1994 to eleven in 2015. The eleven vaccines protect against the following conditions: Tuberculosis, Polio, Rotavirus, Diphtheria, Pertussis, Tetanus, Haemophilus influenzae type b (Hib), Hepatitis B, Pneumococcal Infections, Measles and Cervical cancer. In communities where children are not protected through vaccination programmes, vaccine preventable infections can cause outbreaks. Through strong immunisation and surveillance programmes with adequate investment of time, money and hard work, it is possible to control outbreaks, eliminate and even eradicate some of these infections.

Because of the potential for rapid spread of VPDs, control requires prompt action at a local level. The opportunity to control outbreaks and prevent unnecessary illness and deaths depends on how fast control measures are put into effect. Routine monthly disease reporting is important to monitor disease trends, but is not rapid enough for disease control, prevention and early response to outbreaks. It is therefore crucial to conduct active case-based surveillance and notify the district and provincial health authorities immediately when a case of a targeted condition is detected. This will allow rapid response and ensure that appropriate measures are taken. The national office should be notified immediately for specific cases and under special conditions this will be highlighted in the relevant sections.

If cases and deaths of VPDs are to be identified and disease transmission has to be interrupted in a particular district, then rapid action at operational level (that is, within the district itself) must be organised. The role of national and provincial health authorities will be to train, monitor and provide supportive supervision to district teams to adequately carry out disease surveillance and response.

The Field Guide will provide district, sub-district and facility health workers involved in surveillance with the knowledge and skills needed to confidently identify and respond

appropriately to a case or outbreak of an EPI targeted condition, and to enable national, provincial and district health workers to train, monitor and supervise field workers. This Field Guide should therefore form the basis for training workshops.

1.5 EPI Disease Control Strategies

EPI disease control strategies include:

- Delivery of safe, potent vaccines to appropriate target groups using effective vaccination strategies;
- Effective disease surveillance and control measures to permit early detection and investigation of cases and outbreaks, and implementation of appropriate responses;
- Political commitment at all levels with partner agencies helping to ensure that sufficient sustainable financial, human and material resources are available on time;
- District level commitment, ownership and capacity for interventions, monitoring and the appropriate adaptation of the programme to local needs;
- Strong link with the community to create awareness, active participation and support in surveillance and response activities.

2. PRINCIPLES OF DISEASE SURVEILLANCE AND RESPONSE

2.1 Definition and Purpose of disease surveillance and response

Disease surveillance is the on-going systematic *collection, collation, analysis* and *interpretation* of information on where, when and in whom a diseases occurs and the dissemination of *information* to those that need to know, so that they can take appropriate *action* to prevent further occurrence.

> *Surveillance is information for public health action.*

Surveillance is essential for planning, implementation and evaluation of public health programmes. Effective surveillance identifies high-risk populations and areas where additional interventions may be required in order to achieve disease control objectives. It also shows trends over time and helps to demonstrate the impact of immunisation services.

A good surveillance system must be able to:

- Detect the minimum number of targeted cases timeously;
- Determine whether disease control strategies are effective;
- Identify challenges in immunisation service delivery;
- Identify high risk areas and population groups;
- Demonstrate the impact of immunisation services.

The information gained in EPI surveillance should be used to:

- Evaluate the impact of immunisation on the targeted conditions in the immunisation schedule;
- Identify, investigate and control EPI disease outbreaks;
- Analyse disease trends in certain areas and groups in order to identify those areas and groups that are at high risk;
- Plan and implement immunisation activities to reduce or eliminate risk;
- Satisfy the international requirements, for example Polio Free Certification.

2.2 Types of Surveillance

Passive surveillance:

This is a surveillance system where there is a routine reporting of disease data by all institutions that see patients (or test specimens) and are part of a reporting network. It involves passive notification by surveillance sites / health facilities through a monthly report of all cases of specified conditions on a standard form. There is no ongoing active search for cases.

Passive surveillance is less expensive than other surveillance strategies and covers wide areas (whole country or provinces). However, because it relies on an extensive network of health workers, it can be difficult to ensure completeness and timeliness of data. Some of the limitations of a passive reporting system are:

- Under-reporting of disease;
- Lack of representativeness of cases;
- Lack of timeliness of reporting;
- Lack of accuracy of the diagnosis.

Sentinel surveillance:

Sentinel surveillance is a surveillance system used when high-quality data are needed about a particular condition from selected reporting units with a high probability of seeing cases of the condition in question. Sentinel sites normally include sites with experienced well-qualified staff and good laboratory facilities where these are needed for diagnosis.

Unlike passive surveillance systems, a sentinel system deliberately involves only a limited network of carefully selected reporting sites. A sentinel surveillance system may be used in instances where high quality laboratory-based data is needed as for example in surveillance for invasive bacterial disease caused by *Haemophilus influenzae* type b. In South Africa, it is the system used for the HIV Antenatal Survey.

Sentinel surveillance data can be extrapolated to signal trends, indicate outbreaks and monitor the burden of disease in a community. Though it provides a rapid, economical alternative to other surveillance methods, it may not be effective for detecting rare conditions or conditions that occur outside the specific catchment areas of the sentinel sites.

Active Surveillance:

Active surveillance is the active ongoing search for suspected cases of targeted conditions under surveillance. It involves surveillance staff that − at regular intervals − visit health facilities, talk to healthcare providers and review medical records. When a case is detected, it is investigated, clinical and epidemiological data is collected, and appropriate specimens are collected and sent to the laboratory. The information and reports are sent to all relevant bodies. It is usually used when a condition is targeted for control, elimination or eradication; when every possible case must be detected and investigated. Active surveillance is also useful for detection and investigation of outbreaks.

Active surveillance is more difficult to set up and expensive to conduct. It does not replace, but complements passive surveillance. It has the following advantages:

- Helps to improve the timeliness and accuracy of case detection and reporting;
- Enables rapid case investigation, including taking laboratory specimen;
- Is closely linked to the laboratory system through individual case investigation;
- Enables timely action in response to the detected cases.

The type of surveillance appropriate for a specific vaccine-preventable disease depends on the attributes of the disease and the objectives of the disease control programme. To

institute appropriate control measures, complete case count is not necessarily required. However, it is required for:

- Surveillance of rare conditions;
- Conditions targeted for elimination (e.g. neonatal tetanus and measles)
- Conditions targeted for eradication (e.g. polio).

> ***Control*****:** The reduction of disease incidence, prevalence, morbidity or mortality to a level that is locally acceptable as a result of deliberate efforts. Continued intervention measures are required to maintain the reduction. Example: diphtheria, pertussis.
>
> ***Elimination:*** Reduction to zero of the incidence of a specified disease in a defined geographical area as a result of deliberate efforts. Continued intervention measures are required. Example: polio on certain continents. Elimination of neonatal tetanus is defined in the relevant section.
>
> ***Eradication*****:** The reduction to zero of the worldwide incidence of infection caused by a specific agent, the complete interruption of transmission and the extinction of the causative agent so that it no longer exists in the environment. As a result, intervention measures are no longer needed. Example: smallpox.

A good surveillance system need not be complicated. It should avoid spending much time in collecting information and filling out long, complicated forms so that little time is left for taking action to prevent the spread of cases. Therefore, only the needed data should be collected.

In South Africa, in addition to the case-based active surveillance for AFP, Measles and NNT, sentinel types of surveillance for Haemophilus influenzae type B, pneumococcal and rotavirus diseases are conducted in collaboration with the National Institute for Communicable Diseases (NICD) in Johannesburg.

2.3 Types of Data

Aggregated data:

The number of cases of many vaccine-preventable diseases can be reported on one form, a disease surveillance report. Aggregated data give a quick summary of the magnitude of the problem, covering several diseases, but are not detailed enough to enable case tracking. Aggregated data can be useful for analysis and display when full details are not required and are often used for reporting monthly data from passive surveillance systems.

A line list:

A line list is convenient for consolidating information on a number of cases of the same disease; it includes more details than aggregated data. The data acquired from case

investigation forms should be entered as soon as possible into a line list, thereby allowing prompt analysis, visual assessment and identification of possible clustering of cases.

Case-based surveillance data:

Case-based collected data is expected to provide details of individual cases of vaccine-preventable diseases. Case-based surveillance requires the use of a standard case definition and a case investigation form to record information, such as the patient's name, age, immunisation status, date of last immunisation against the suspected disease, address, date of disease onset, suspected diagnosis and laboratory results (when available). Case-based data are often used for diseases that require urgent public health action or are subject to accelerated disease control goals or during suspected outbreaks of epidemic-prone diseases, such as diphtheria, measles, meningitis and yellow fever.

2.4 Frequency of Reporting

The control objectives for each disease determine the frequency of surveillance reporting and the types of reports needed. Reports are usually sent from the level where the disease was detected first through each administrative level to provincial and national authorities. When immediate reporting is required, the priority is to notify a higher level as soon as possible, although the report should be copied to other levels, for information and to avoid duplication.

Monthly reports:

This is the usual schedule for reports, and most data collected through passive surveillance and sentinel sites are reported in this way. Monthly reports comprise aggregated data (the total number of cases of each disease) rather than providing details of each case, except for sentinel surveillance of some diseases.

Weekly reports:

Weekly reporting is usually used for diseases for which an active surveillance system is in place or when the disease control objective is elimination or eradication, such as for polio or measles. These data are often sent in the form of a summary or in some cases as a line list.

Immediate reporting:

Immediate notification is usually indicated for epidemic-prone diseases or if the disease is subject to eradication or elimination initiatives. These diseases are defined by national policy and related regulations. In South Africa, the notifiable conditions, which should be reported immediately, include measles, polio, maternal and neonatal tetanus, and severe AEFI. These conditions should be reported immediately to the local authority, the designated

district and provincial health officer, using the GW17/5 forms (*Annex 1.1*) as required. This can be done by e-mail, fax, telephone, short messaging service (SMS) or any other rapid means available. The maximum possible essential information should be conveyed, including a provisional diagnosis, location and age of the case. An immediate report should be followed as soon as possible by a case investigation report.

2.5 EPI Surveillance System in South Africa

A surveillance system needs to define the process of surveillance for it to be operational. This includes the designation of a surveillance focal point at each level, the tasks, the data and specimen flow and appropriate tools for data collection, communication, specimen kit and transport. The process should be supported with training and consensus on standard performance indicators for monitoring and evaluation of the activities.

In South Africa, EPI disease surveillance is based on the following structure:

- Reporting sites include all health facilities (private and public) and doctors;
- All districts and facilities should have a surveillance focal person to conduct active surveillance and submit weekly reports. During active surveillance visits, the focal point will review records, visit relevant wards and departments and interview doctors, nurses and other health workers;
- Case detection is based on the standard case definitions;
- On detection of a case, investigation forms are completed and the next level is immediately notified. The process of specimen collection should start immediately;
- Reports are sent every week to the next level, even when no case is detected (Zero report);
- Laboratory results and final classification of the case recorded after getting the data from the provincial/national level;
- Surveillance data must be analysed regularly to detect patterns, clustering or outbreaks;
- Performance is monitored regularly, using standard indicators for the specific disease and action taken on time to improve weakness.

2.6 Steps in EPI disease surveillance and response

There are six distinct steps in the cycle of disease surveillance and response (Table 1).
These steps are used in all disease surveillance and control activities and can be adapted from this manual to serve in the control of non-EPI diseases.

Table 2.1: Six steps used in disease surveillance and control activities

Step 1	Detecting and reporting a case or an outbreak
Step 2	Investigating a case or an outbreak
Step 3	Analysing district EPI disease surveillance data and producing report
Step 4	Preparing and responding to a case or an outbreak
Step 5	Monitoring and evaluating of disease surveillance system
Step 6	Providing feedback to local staff and feed forward to next level

The following sections describe general aspects of each of these steps and detailed descriptions are provided in the sections specific to the control of suspected polio, neonatal tetanus, measles and AEFI.

Step 1: Detecting and reporting a case or an outbreak

Recognising and reporting a case of disease is one of the most important tasks a health worker carries out besides the healthcare function. The initial diagnosis and reporting of EPI diseases must be based primarily on careful observation of the clinical picture and the recognition of a disease fitting the standard case definition.

Every health worker should know the signs and symptoms of EPI target diseases as described in the standard case definition and be able to detect and notify these cases. South Africa has adopted the standard case definitions for EPI priority diseases developed by WHO. In view of the different backgrounds and training of the different cadres of health workers, case definitions are available in two forms: standard case definitions and case definitions for use at community level.

Standard case definitions:

Medical officers and nurses, primarily for hospitals, health centres and other health facilities, where cases may present in the outpatient ward, use standard case definitions to identify cases. The definition specifies an agreed-upon set of clinical criteria to decide if a person has a particular disease or condition. Using standard case definitions ensures that every case is diagnosed in the same way, regardless of where or when it occurred, or who identified it.

The District Medical or Public Health Officer should ensure that all staff likely to see AFP, NNT, measles or AEFI cases are knowledgeable on these case definitions and know that they have an obligation to report immediately (for example, staff in paediatric, neurological, outpatient or physiotherapy departments).

It is important to understand that these definitions are designed for disease control programmes and therefore differ somewhat from what is found in medical textbooks. For disease control, it is critical that every suspected case of a disease is reported, even if this means that a few doubtful cases get included. For surveillance purposes, over reporting of suspected cases is acceptable, whereas underreporting compromises efforts of disease control.

The district health authorities should meet with personnel in charge of public and private hospitals and health centres to organise brief seminars for medical officers and nurses. They should explain the national EPI disease reduction strategies and the importance of prompt reporting using standard case definitions.

The case definitions should be posted prominently in outpatient clinics and routinely applied when health workers see patients. Each time medical officers and nurses see a case, which manifests the symptoms described in the case definition; they should ensure that this case comes to the immediate attention of the district public health authorities responsible for taking appropriate action. Specific notification forms are available for this purpose.

Prompt case investigation and response actions, rapid reporting using telephone, short messaging service (SMS), fax, e-mail or other means, should be set up in advance and mobilised when the occasion arises. Clear guidelines for a **reporting chain** should be defined from all health facilities where cases may be seen to the authorities responsible for case investigation and response.

For various reasons, not all cases of EPI priority diseases are seen at hospitals and health centres. For example, worried parents sometimes bring AFP case first to community-based rehabilitation centres, physiotherapy units or other facilities. It is vital that these cases should not be missed. These facilities and other healthcare providers should also be visited regularly by the district public health authorities, where the staff should be trained and updated in case definition, detection and notification procedures.

Many EPI priority conditions, especially NNT and measles, are never brought to the attention of staff at health facilities. In some societies, measles is not considered a serious disease. Similarly, many families just accept neonatal illness and death and bury the body without seeking medical assistance. The detection of these cases, which may be more numerous than those seen at health facilities, poses a special challenge for disease control activities.

Case definitions for community-based surveillance

Simple definitions of the EPI priority disease have been developed to ensure that cases may be readily recognised at the community level. The description of signs and symptoms is simple and clear, and should be translated into a local language, which is clearly understood by the community and widely disseminated.

Community health workers, traditional birth attendants (TBAs) and traditional health practitioners (THPs), in addition to traditional and religious leaders, teachers, policemen and other persons, who are respected in the communities they serve and who know the families and their children intimately, should be trained to know and use these simple case definitions.

For example, if local leaders or other community members (non-health workers) hear of a neonatal death or a child with sudden paralysis in the village or township, the staff at the nearest health facility should be informed immediately. These local leaders or community informants should then lead the health facility staff directly to the home where this occurred to collect basic information so that the district surveillance team can be alerted to carry out a prompt case investigation.

Community meetings should be held and the benefits of detecting such cases in the community and the response actions they provoke explained in clear terms to community members. A **reporting chain** from local leaders and community informants to the authorities responsible for case investigation and response should be defined.

Standard case definitions for use by professionals and simple case definitions for non-health workers are detailed in the sections for poliomyelitis, NNT and measles. A list of trigger events for use by professionals and the community for detection of adverse events following immunisation (AEFIs) appears in the section for AEFIs.

Step 2: Investigating a case or outbreak

The district surveillance team must investigate each reported case of AFP (suspected polio), NNT, measles and AEFI. The purpose of each case or outbreak investigation is to answer the following questions:

- **When** did the case or outbreak occur?
- **Where** did the case or outbreak occur?
- **What** is the nature of the case or outbreak (Is it really polio? Is it really NNT? Is it really measles? Is it a true AEFI and not a side effect from another drug?)

- **Who** is affected by the case or outbreak?
- **Why** did the case or outbreak occur?
- **How** can the case or outbreak be prevented from spreading? Or **how** can the same programme-related or vaccine-related AEFI case be prevented?

Answers to these questions will provide the basis for selection and planning of appropriate response activities. It is important that each case or outbreak investigation is performed as soon as possible to ensure prompt outbreak response in order to reduce or prevent the occurrence of further cases. This is especially relevant for highly contagious diseases such as measles and polio because − if the current outbreak control strategies are implemented rapidly − they will permit the interruption of disease transmission.

The investigation procedure includes examining the patient (if possible) and interviewing the parents or close relatives and health facility staff managing the case. This may be initiated in a health facility if the patient is admitted, but a home visit is essential in all cases to collect epidemiological data, to conduct an active search for additional cases and to see the site where a supplemental vaccination activity may subsequently be carried out. Immunisation cards and clinical records must be reviewed if available. Case investigation forms should be used to facilitate collection of complete and relevant information.

Standard procedures have been developed and adapted for the investigation of AFP, NNT, measles and AEFI. Provincial or district surveillance teams should practice performing case or outbreak investigations using these standard case investigation forms.

In general, a health worker should follow the order of data collection on the form and *fill in all the information* required based on interviews, reviews of medical and other records and the patient examination. The investigator of the case or outbreak should provide his or her name and contact details on the applicable section of the form.

- Visit the case and the area concerned;
- Verify the diagnosis and confirm if an outbreak exists;
- Search for additional cases;
- Describe the outbreak;
- Plan and implement appropriate response;
- Analyse the lessons learnt and compile a report.

Step 3: Analysing district EPI disease patterns and trends

Analysis of surveillance data should include:

- Observing trends over time and alerting health staff about emergent events or unusual patterns (time);
- Identifying geographic areas of higher risk (place);
- Characterising personal variables such as age, gender or occupation that place a person at higher risk for the disease or event (person/s).

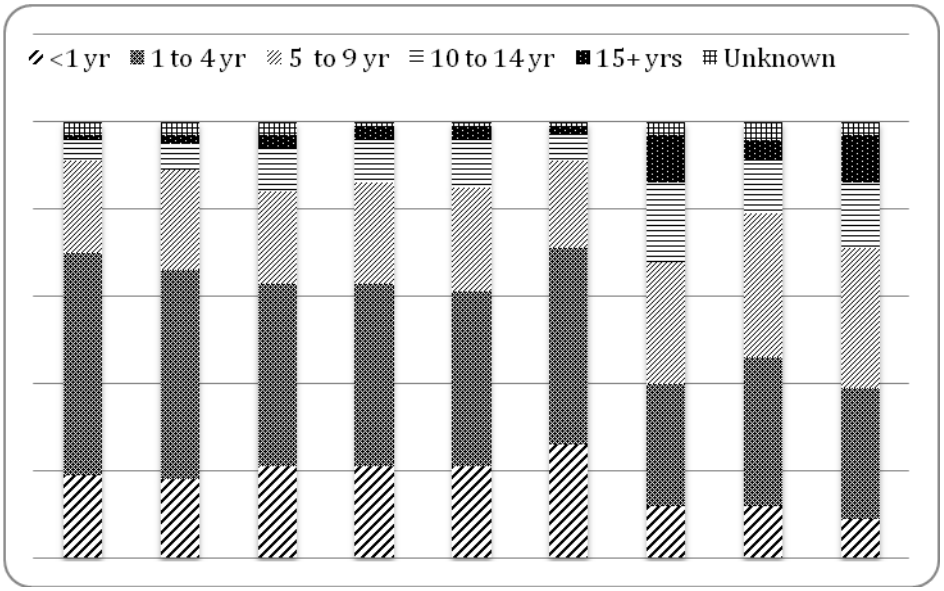
Purposes of analysing EPI disease patterns and trends:

- In the short term, to monitor disease activity and detect any unexpected changes, either downwards or upwards. In order to prevent a disease from getting out of control, it is vital to detect sudden changes in disease patterns and trends. Routine notification forms must therefore be received from all reporting units at least once per week and then analysed within a few days of receiving the forms. In this way, areas and populations at high risk for outbreaks may be identified and appropriate rapid action taken. When analysing the data, other factors affecting interpretation must be considered. Reported cases in a district may not include all the cases that are occurring, unless it is known that the completeness of reporting is 100%. A low reported *incidence* of cases might mean either that the disease is truly rare or that there is underreporting. If an increase in reported cases of a certain disease occurs following a training course, it is possible that this increase is due to the increased case detection by trained staff rather than a true rise in the occurrence of the disease.
- Secondly, in the long-term, the purpose is to evaluate the overall impact of EPI strategies and to plan future EPI activities in light of the findings. This requires a detailed analysis of data and disaggregation of reported cases by age group, gender, time (seasonal variation) and place.

Analysis by affected population group:

Some valuable information may be hidden unless a careful analysis of data is carried out. In the example shown in Figure 2.1 below, if all measles cases are simply plotted in a graph with a bar for each year, the total number of cases may rise or fall and other patterns may not be detected. An additional graph with all the cases summed to 100% for each year and the bar divided into age groups reveals that the age of cases is increasing.

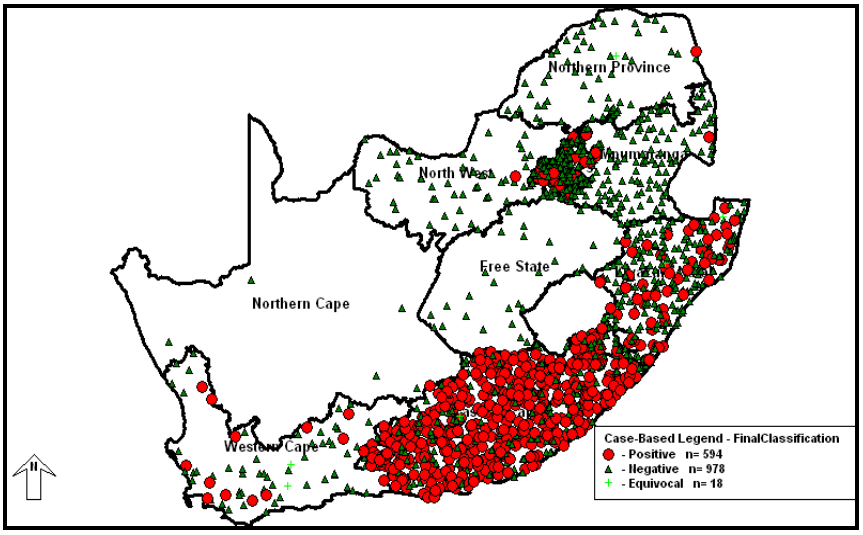
Figure 2.1 Measles cases by age group 1980-97



Analysis by place:

In general, a larger number of cases of a communicable disease occur in the bigger population groups. They also occur in the more densely populated areas such as the major cities. Therefore, if the number of cases on the map were plotted, the provinces with most cases would probably be those most densely populated.

Figure 2.2 Spot Map of CMC 2005



The number of cases per 100 000 inhabitants gives better information to study and compare the risk in different population sizes. For example, the number of measles cases in each

province divided by the number of inhabitants gives a more accurate reflection of prevalence and the risk of getting measles in any specific province.

Seasonal variation:

Plotting all cases by year may hide seasonal variations. Plotting the number of cases by month or week shows the peak season and illustrates how peaks vary in size between years and how additional peaks may occur in certain years.

To obtain more information, it is always better to group cases according to age:

- Infants < 1 year
- Children 1-4 years
- Children 5 years and older.

Doing so will reveal more information on the pattern in the different age groups. For example, even though the overall *trend* of measles during certain months shows a decline, the number of cases among children five years and older may be rising and this may be concealed unless the seasonal pattern is shown for the different age groups.

Such findings may be significant and deserve the careful scrutiny of the district EPI surveillance team. In such cases, the team should always investigate an unexpected change in disease patterns and trends should alert the district team to look carefully into possible factors, which might be due to changes in:

- Case detection and notification activities;
- Case or outbreak investigation activities;
- EPI procedures (cold chain, sterile technique, defaulter follow-up, etc.);
- District conditions (seasonal changes in temperature or rainfall, pre-harvest or post-harvest, industrial changes, etc.);
- District population (influx of migrant families, seasonal labourers and their families or refugees, changes in school or health facility catchment areas, etc.).

Pool of susceptibles:

Even in successful immunisation programmes, there will always be a proportion of children who will remain susceptible because of two main reasons:

- Unreached or unvaccinated children;
- Primary vaccine failure because vaccines are not 100% effective (e.g. measles vaccine efficacy is 85%).

As routine EPI coverage improves, the number of unvaccinated children in one cohort may not be large enough to cause outbreaks. However, with years to come there will be a gradual build-up of susceptible children and the number may be enough to cause outbreaks or epidemics. Typically, these kinds of outbreaks show a shift in the affected age group to involve older children because these are cohorts from previous years' vaccine / programme failure. Hence, measles elimination programmes, for example, use "follow–up" campaigns periodically to reduce the build-up of susceptibles.

Analysis by immunisation status:

Analysis of cases by immunisation status gives valuable information for the EPI programme. It will show the importance of high immunisation coverage in the prevention of disease outbreaks. The analysis should look further into factors or reasons for inadequate vaccination coverage in a particular area or community. The results of this analysis will assist in the long-term control of the disease causing the outbreak. The district team should set out a plan on how to improve immunisation coverage in all geographic areas.

Step 4: Responding to a case or outbreak

The objectives of responding to cases and outbreaks are:

- To contain the disease in a timely and effective manner;
- To prevent further spreading into other areas.

The scope and character of response activities will depend on the epidemiology of the disease and the magnitude of the outbreak.

An appropriate response should be:

- **Rapid enough** to reduce or prevent further spread of the disease or the event in the population;
- **Extensive enough** to cover the entire area at risk for disease spread or a repeat of the event;
- **Complete enough** to protect the entire target population at risk for disease spread or the repeat of the event.

When a case of polio, NNT, measles outbreak or AEFI occurs, the district EPI surveillance team is responsible for the immediate planning and implementation of effective case and outbreak response activities.

A plan for an appropriate response should specify -

- Objectives of the outbreak response;
- Strategies to be employed to achieve these objectives;
- Specific activities that will be carried out to contain the outbreak;
- Geographic area where these activities will be carried out;
- Persons at-risk who are being targeted for the outbreak response;
- Training of health / medical staff and volunteers involved in outbreak response;
- Resources required:
  - Human resources;
  - Transport;
  - Vaccines, cold chain equipment and supplies;
  - Information, education and communication materials;
  - Funds (per diem, travel costs, social mobilisation, etc.);
- Definition and role of each partner agency involved in the outbreak response;
- Timetable of activities;
- Evaluation and improvement of the outbreak response activities.

A standing committee should be formed at national, provincial, district and sub-district level for better planning and coordination of routine surveillance and outbreak response activities. In an outbreak, this committee should consist of the following: CDC, PHC, EPI coordinators, environmental health practitioners, port health officers, community health workers, the district authorities, police, military, teachers, students, Rotarians, and other governmental and non-governmental organisations for the planning and implementation of response activities.

Step 5: Monitoring disease surveillance; use of data for corrective action

Monitoring is the systematic and continuous examination of data to measure progress, identify problems and plan for corrective action. It should be conducted regularly and is best guided by a set of performance and quality indicators against which progress and accomplishments can be measured.

It is essential to check the performance of EPI disease control activities at least at the end of every month, ideally every week. This task should be carried out together with monitoring immunisation coverage as well as outbreak investigations and reporting.

In South Africa, the overall responsibility for ensuring the quality of disease surveillance, case investigation and outbreak response in the district, lies with the district public health authorities.

Under the supervision of the district medical or public health officer, one member of the district surveillance team should be formally assigned responsibility for routinely monitoring the performance of EPI activities. Although organisational structures vary, where possible, this responsibility should be assigned to the district EPI focal point or epidemiologist.

For each performance or surveillance quality indicator, data sources should be identified for both the numerator and the denominator. Though indicators may vary according to the specific disease (and will be discussed in the sections to follow on surveillance of polio, measles and NNT), and the level of surveillance programme (health facility, district, province or national) the most useful indicators for monitoring EPI disease surveillance and response are as follows:

I. Completeness of weekly/monthly reports

District surveillance officers must ensure that all important surveillance sites are included in the surveillance system. A review of the list of surveillance sites should be done every year to include new sites for active surveillance. Some aspects of quality of active surveillance that may not be captured by the indicators but through supervision, must also be reviewed and appropriate action taken.

In South Africa, each local authority or district office is required by law to compile and summarise the reports on all notifiable diseases. These are then submitted to the provincial office for compilation. To ensure complete reporting of EPI diseases targeted for elimination / eradication, a zero report should be sent if no cases were seen for the reporting period.

- **Purpose:** Measure of reports / surveillance forms submitted (including zero report) by surveillance sites;
- **Tool:** Weekly Active Surveillance Reporting Form (for Health Facility, District and Province);
- **Numerator:** The number of health facilities submitting weekly / monthly reports;
- **Denominator:** All health facilities / surveillance sites that are expected to submit weekly/ monthly report;
- **Target:** ≥ 90%.

II. Timeliness of weekly / monthly reporting:

All the reporting units should submit their disease notifications to reach the district no later than seven (7) days after the end of the reporting week. A reporting week is normally taken from Monday to Sunday. Thus, the weekly notifications are normally expected by the following Monday at the relevant, next higher health authority level (e.g. district or provincial office). It should reach the national office by Tuesday.

All reports received within that period are considered to be *on time*; any report received after that period is considered *late*.

- **Purpose:** measure of the practice of timely submission of surveillance data;
- **Tool:** Weekly Active Surveillance Reporting Form**/** Monthly reports;
- **Numerator:** The number of health facilities submitting weekly/monthly reports on time;
- **Denominator:** All health facilities /surveillance sites that are expected to submit weekly/ monthly report.
- **Target:** ≥ 80%.

III. Timeliness of notification of cases to the next higher level

It is required that AFP, NNT, SMC (measles) and AEFI cases or outbreaks should be reported within 2 days to the next higher level for prompt organisation of control measures.

- **Purpose:** Measure of early detection and timely reporting;
- **Tool:** Case-based investigation forms;
- **Numerator:** Number of cases or outbreaks reported within 48 hours;
- **Denominator:** Number of all suspected cases or outbreaks;
- **Target:** ≥ 80%.

IV. Investigation of case and outbreak reporting

All cases of diseases targeted for elimination, eradication and any other epidemic-prone diseases must be investigated immediately. The initial investigation is done on a Case Investigation Form (CIF) for a specific disease.

- **Purpose*:*** Measure of the reaction time by health/surveillance officers to a notification;
- **Tool:** Case investigation forms;
- **Numerator*:*** The number of cases investigated within 48 hours of notification;
- **Denominator:** the number of all suspected cases;
- **Target:** ≥ 80%.

V. Proportion of cases for which adequate laboratory specimens were collected and sent to the laboratory (for conditions that require laboratory investigation)

- **Purpose:** Measure of the surveillance system in timely detection and laboratory investigation of case;
- **Tool:** Laboratory investigation form/ case investigation form;
- **Numerator:** The number of cases with adequate specimen collected;
- **Denominator:** The number of all suspected cases;
- **Target:** ≥ 80%.

VI. Percentage of reported cases and outbreaks with appropriate response

One of the important qualities of a good surveillance system is the ability to respond to confirmed cases and outbreak timely and appropriately as per the national guidelines and recommendations.

- **Purpose:** Measure of the capacity to respond appropriately as per the national recommendations;
- **Tool:** Outbreak or case investigation reports;
- **Numerator:** The number of cases or outbreaks with nationally recommended outbreak response;
- **Denominator*:*** The number of all confirmed cases or outbreaks;
- **Target:** ≥ 80%.

Table 2.2 Summary of surveillance monitoring tools

Indicator	Purpose	Data	Target
Completeness of weekly/monthly reports	Measure of reports / surveillance forms submitted (including zero report) by surveillance sites	The number of health facilities submitting weekly/monthly reports All health facilities / surveillance sites that are expected to submit weekly / monthly report	≥ 90%
Timeliness of weekly / monthly Reporting	The number of health facilities submitting weekly / monthly reports on time	The number of health facilities submitting weekly / monthly reports on time All health facilities / surveillance sites that are expected to submit weekly / monthly report	≥ 80
Timeliness of notification of cases to the next higher level	Measure of early detection and timely reporting	Number of cases or outbreaks reported within 48 hours Number of all suspected cases or outbreaks	≥ 80%
Investigation of case and outbreak reporting	Measure of the reaction time by health / surveillance officers to a notification	The number of cases investigated within 48 hours of notification The number of all suspected cases	≥ 80%
Proportion of cases for which adequate laboratory specimens were collected and sent to the laboratory for those diseases that laboratory investigation is indicated	Measure of the surveillance system in timely detection and laboratory investigation of case	The number of cases with adequate specimens collected The number of all suspected cases	≥ 80%
Percentage of reported cases and outbreaks with appropriate response	Measure of the capacity to respond appropriately as per the national recommendations	The number of cases or outbreaks with nationally recommended outbreak response The number of all confirmed cases or outbreaks	≥ 80%

Step 6: Providing feedback and feed-forward

Surveillance of any kind should form a closed loop. This information loop only closes if a report goes back to those that report first. Providing regular *feedback* to local health workers responsible for reporting, investigating cases and responding quickly and appropriately has a significant positive effect on their motivation and performance and on future reporting. They will be able to see the value of collecting and reporting information, and compare their performance in relation to others at the same level.

Feed-forward (forwarding results of data analysis to higher administrative levels) can help to promote accomplishments, highlight areas of concern and seek assistance with problems. Feedback should always be clear, honest, informative and encouraging. Feedback may be given in several forms, but those most effective and appreciated are:

- Written newsletters and newssheet;
- On-site supervisory visits;
- Quarterly meetings.

The collection, analysis and monitoring of surveillance data should lead to the implementation of corrective actions to improve the control of vaccine preventable diseases.

Newsletters and newssheets

The National Department of Health should provide feedback via the provincial offices to all districts, on reported cases, with appropriate analysis and interpretation. This should be through the distribution of a newssheet, dedicated solely to immunisation issues and diseases. At the provincial level, under the supervision of the Provincial EPI Coordinator, one member of the district surveillance team should be formally assigned the task of routinely preparing and distributing periodic feedback. A description of cases reported and any patterns or trends that emerge, such as clustering by person, place or time, should be highlighted. Reasons for cases or outbreaks of EPI priority diseases should be elaborated on, for example:

- Pockets of low coverage, frequent missed opportunities for vaccination or high drop-out rates;
- Possible cold chain failure;
- Social, religious or cultural practices (for example, birth practices) in the community.

The quality of the response that followed notification of these cases or outbreaks should also be evaluated. This information should form the basis of subsequent supervisory visits to local staff (see below), staff meetings and refresher training activities within the district. Hospital directors and persons in charge of health centres should actively pass on this information in order to motivate and inform staff who report cases and immunisation statistics within the areas their facility serves.

On-site supportive supervision

Supervision is both an art and a science based on effective interpersonal skills. Supportive supervision can boost staff morale and increase performance. Negative supervision or lack of supervision will demoralise or frustrate staff. The essential elements of good supervision are clarity, honesty, information sharing, encouragement and follow-up on problems identified. Good supervision aims to sustain good quality services rather than finding things that are wrong. Inclusion of surveillance in supportive supervision is encouraged because it is instrumental for early outbreak detection and response.

In a good system, supervisors and health professionals work together to review progress, identify problems, decide what has caused the problem and develop feasible solutions.

Supervisors need orientation and practice in these skills. There should also be a plan for supervision at all levels. This plan should include frequency, logistic arrangement and preparing a supervision checklist. A sample checklist for the purpose of EPI surveillance is attached in *Annex 1.2*.

During a supervisory visit by district staff to a hospital or health centre, the performance of that facility, as measured by the performance indicators, should be discussed in a positive, constructive manner and by discussing the areas of improvement together with the staff members.

Possible local causes of cases or outbreaks of EPI priority diseases, and the quality of the response that followed, should be discussed with the staff responsible for immunisation and communicable disease control.

Central to achieving these goals is accurate and timely reporting as well as a rapid response to the notification of an EPI priority disease. The training of sufficient staff at every level to manage the control of these diseases is therefore important.

Feedback to communities is also a very important part of the surveillance system. Local politicians, religious leaders, community leaders and parents should always be engaged in an immunisation and surveillance system. The media should be engaged to get public health messages to the community and, whenever possible, early information and close working relations with the media should be part of the activities as this determines public perceptions and participation.

Quarterly meetings should be held as part of the feedback process to allow discussions and establish intervention measures to improve surveillance. It is important that data be analysed in advance to facilitate the discussions.

2.7 Roles and Responsibilities

In the Republic of South Africa, surveillance and response is the responsibility of each sub-district, local municipality, district and province. The national department has a support function of developing guidelines for surveillance and outbreak control; training programmes; facilitating communication between provinces and publishing health information materials. Responsibilities for the different aspects of surveillance of EPI targeted diseases can be assigned to different levels.

Community level

With decreasing prevalence in some EPI diseases, especially those targeted for elimination or eradication, community sources play an important role in the detection and reporting of cases because the small number of persons affected may not seek healthcare. These community sources may include pharmacists, community health workers, traditional health practitioners, village leaders, school personnel, and so on. Training of these community sources on which diseases are reportable and how to recognise them, using simple case definitions, is critical. The use of promotional material in the community can also help in making the public aware of the symptoms and the need to report EPI target diseases. The community should be part of the response activities, and an effective response to a case notification may be the best incentive for community participation in disease surveillance.

Health facility level

Health care workers and surveillance focal persons are expected to:

- Detect, telephonically notify the district, investigate, confirm and record vaccine-preventable diseases using standard case definitions;

- Report case-based information on immediately notifiable diseases and summary report on others to the district;
- Collect and transport specimens for laboratory confirmation;
- Make simple data analysis, prepare graphs and charts to show time, place and person for diseases;
- Take early control measures, prepare and participate in response;
- Communicate with the community about outcome of reported cases, prevention measures and activities.

District level

The district surveillance team should:

- Review and update the list of reporting sites in the district periodically;
- Ensure all facilities and reporting sites have adequate supply of tools for recording, reporting and specimen collection;
- Make sure that health facilities use standard case definitions;
- Collect surveillance data from reporting sites;
- Ensure laboratory specimen are collected and shipped to NICD in good conditions (reverse cold chain)
- Report data on time to next level;
- Aggregate data from reporting sites and analyse data by person, time and place;
- Periodically update graphs, charts and tables to describe reported diseases and events, compare data with previous years, calculate rate and threshold;
- Lead detailed investigation of reported cases;
- Assign Epid Numbers;
- Support and ensure specimens are collected and transported in appropriate condition within the stipulated time frame to NICD;
- Receive and record laboratory results;
- Supervise and support active surveillance;
- Identify training needs for health workers;
- Convene emergency response committee and plan response;
- Organise and support rapid response teams and document response;
- Provide timely information to the community and ensure community involvement;
- Give regular feedback to facilities on surveillance and data quality;
- Conduct regular supervisory visits.

Provincial level

- Convene a provincial outbreak response team;
- Ensure full investigation of cases;
- Epid Numbers are allocated to all cases and inform / forward to national level;
- Follow up on case investigations;
- Support and facilitate the transportation of specimens;
- Regularly analyse provincial surveillance data;
- Identify and support districts at high risk for polio, NNT and measles;
- Follow up on “silent” districts;
- Identify training needs and train relevant staff on surveillance;
- Conduct supervisory visits;
- Give feedback to districts;
- Report to national level;
- Monitor and evaluate programme targets and surveillance indicators at provincial level.

National level

- Convene a national outbreak response committee;
- Receive surveillance reports from provinces;
- Analyse reports to detect trends and possible outbreaks;
- Take action in response to reports;
- Standardise and disseminate surveillance protocols and guidelines;
- Organise a system for transportation of specimens;
- Standardise training tools and materials;
- Conduct training at national level;
- Set surveillance policies and strategies;
- Decide whether to change immunisation strategies, procedures or policies;
- Draw supervisory plan and inform provinces ahead of time;
- Harmonise data with provinces and laboratory;
- Conduct supervisory visits, give feedback to staff; identify training needs;
- Monitor and evaluate progress towards programme targets and surveillance indicators;
- Ensure classification of cases is done within the specified time;
- Report to national and provincial senior management;
- Report to international agencies such as WHO and UNICEF.

3. ACUTE FLACCID PARALYSIS (AFP) SURVEILLANCE

3.1 Poliomyelitis: Disease background

Infectious agent and epidemiology

Poliomyelitis is an infectious disease caused by the poliovirus. There are three types of polioviruses, namely types 1, 2 and 3. Circulating wild type 2 poliovirus has not been isolated since October 1999. Type 1 is the cause of most epidemics, while most vaccine-associated cases are due to type 2 or 3. The virus mostly affects children below five years of age. However, a person of any age who does not have immunity to polio may be infected. Wild poliovirus infects only human beings. Before the implementation of the Polio Eradication Initiative, there was worldwide transmission of wild poliovirus; endemic transmission is now limited to only two regions.

Transmission is seasonal, being more common during the summer in countries with a temperate climate and during the rainy season in countries with a tropical climate. The major route of poliovirus transmission is faecal-oral. The virus spreads from person to person by contaminated hands, food and water. This mode of transmission is similar to that of cholera, dysentery and other diarrhoeal diseases. The transmission of a poliovirus is enhanced in crowded living conditions, especially in informal settlements where sanitation is poor and vaccination coverage is low.

Clinical course

The *incubation period* of polio lasts between 7-21 (range 3-35) days. During this period, the poliovirus multiplies in the throat and intestines. Polioviruses are excreted in a daily cyclical pattern, intensely for the first 14 days, then tapering off until about 30 days; thereafter excretions slow down, but continue to about 60 days after onset of illness. Not every child infected with a poliovirus becomes ill. Up to 90-95% of all infected individuals get asymptomatic infection and appear healthy.

About 4-8% of infections will result in minor illness also known as abortive polio. This disease usually starts after an incubation period of one to three weeks with some or all of the following initial symptoms: fever, headache, stiff neck, muscle pain, nausea, vomiting and diarrhoea. These symptoms are not specific and therefore, at this stage of polio, cannot be distinguished from other mild diseases. About 1% of infected individuals may even present signs of non-bacterial or *aseptic meningitis*.

The remaining 1-2% will go on to develop some degree of paralysis. The paralysis has a sudden rapid onset, often reaching complete paralysis within 72 hours. The paralysis is flaccid, meaning that muscles are relaxed, floppy and never stiff. In the most typical situation, patients wake up in the morning, try to stand up from the bed and find that they cannot stand or walk properly. In infants who are too young to walk, the mother may notice that one of the legs has assumed a different resting position, appearing "limp".

Polio paralysis is most usually, but not always, *asymmetrical*, affecting one side more than the other. It involves the legs more commonly than the arms, and affects the *proximal* muscles (those closer to the trunk) more commonly than the *distal* muscles (those further from the trunk). Involvement of all four limbs is almost never observed in infants, but may occur in older patients. Reflexes are decreased or absent in the affected muscles. The sensory nerves are usually not affected, and hence the senses of touch and pain are normal.

The risk of developing paralytic polio is not the same for all infected persons. Pregnant women are more likely to become paralysed when infected with a poliovirus. Injections given into the muscles, antibiotics for example, can also provoke paralysis in polio-infected individuals. In some cases, polio paralysis occasionally causes severe difficulty in breathing, swallowing or speaking when respiratory and other related muscles are involved (bulbar poliomyelitis). The risk of death from respiratory paralysis is high in such patients.

Over the years, the paralysed muscles, which do not get stimulated, will *atrophy (lose muscle bulk and get thinner)*, leaving the affected limb looking thinner or *wasted* compared to the other unaffected limb. With physiotherapy and other orthopaedic interventions, many patients recover significant movement of damaged limbs and go on to lead normal lives.

There are several other diseases that may initially look like polio and these diseases make up the bulk of the AFP (Acute Flaccid Paralysis) cases reported when wild polio is not found, such as in South Africa. The most common cause of AFP is Guillain-Barré Syndrome (GBS). Other conditions presenting as AFP include transverse myelitis, traumatic neuritis, other enterovirus infections and other causes of paralysis *(Annex 2.1).*

It is very important to understand that conditions such as GBS, transverse myelitis and others as above are cases of AFP. Therefore, all these cases should be investigated as AFP cases even if the person making the diagnosis is confident that it is not polio, and very confident that the diagnosis is accurate.

3.2 Goals and objectives of polio eradication programme

Following the success of the eradication of smallpox, poliomyelitis was targeted as the next disease to be eradicated at the 41st World Health Assembly in 1988. At that time, the goal was to eradicate polio by the year 2000. However, because of several challenges, including social and political issues, that goal could not be achieved and the revised target was to interrupt wild poliovirus transmission by the end of year 2012.

The Commission for the Certification of the Eradication of Poliomyelitis uses the following criteria to determine if polio eradication has been reached:

- There are no cases of clinical poliomyelitis associated with wild polio viruses;
- There is no wild poliovirus identified anywhere in the region, as determined by virological examination of stool specimens from AFP cases and environmental sampling;
- The process of independent certification of polio-free status must be initiated at national and sub-regional levels, leading eventually (approximately three years after the last polio cases are confirmed) to full regional certification.

To date, the following progress has been made in attaining these goals:

Globally:

- The number of cases have reduced from an estimated 350 000 cases in 1988 to 650 reported cases in 2011;
- Only 3 countries remain endemic for polio (Afghanistan, Pakistan and Nigeria) as compared to over 125 endemic countries in 1988. India had been free of polio for more than a year (from January 2011 to February 2012) and was officially removed from the list of endemic countries on 25 February 2012;
- Type 2 poliovirus has not been isolated since 1999 (has effectively been eradicated).

South Africa:

- Last virological confirmed case of polio was in 1989;
- AFP is a notifiable disease/syndrome since 1995;
- AFP case-based surveillance instituted in 1997
- Certification Standard AFP surveillance performance was attained in 2003, and has been maintained since then at national level;
- Excellent laboratory capacity, which is serving as regional reference laboratory for WHO AFRO.

3.3 Polio Eradication Strategies

Taking experience from the Americas where polio has not been isolated since 1991, the World Health Organization recommended the following basic strategies for polio eradication.

Basic strategies for polio eradication

- Achieving high routine coverage with polio vaccine (>90%) in all districts;
- Conducting National Immunisation Days (also referred as immunisation campaigns);
- High quality AFP surveillance with laboratory support;
- "Mopping-up" activities in low coverage and high-risk areas.

To achieve this, a high level of political and financial commitment needs to be sustained. AFP surveillance will be discussed at length in the sections below, while the improvement of routine coverage is dealt with in the *Vaccinator's Manual*. The other two strategies are briefly discussed below:

National Immunisation Days

National Immunisation Days or NIDs, also called mass immunisation campaigns, are conducted to provide all children or people in a targeted population a dose of polio vaccine regardless of their immunisation status. The aim of such a campaign is to vaccinate all targeted people all over the country within a short space of time (usually 2-3 days, but not more than a week) to interrupt transmission of the targeted organism, in the case of wild poliovirus.

Although sub-national campaigns may also be considered in some special situations, it is important to conduct the exercise over as wide a geographical area as possible, to interrupt wild poliovirus transmission in as large a population as possible.

In South Africa, NIDs are conducted to boost the routine immunisation coverage and population immunity in all districts, and should importation of wild poliovirus occur, there would be no further spread.

Polio campaigns are conducted in two rounds with a minimum interval of four weeks between the rounds during the low poliovirus transmission season (the cold season). Immunisation campaigns should ideally be completed within a short period, preferably in one week to a maximum of two weeks.

Seeing that South Africa started conducting polio immunisation campaigns long ago, these campaigns now generally target all children under the age of five years who should receive two doses of OPV with a minimum interval of four weeks, regardless of their previous OPV immunisation history.

Immunisation campaigns should be planned in detail at every level. It is the responsibility of relevant officials in the districts, including the EPI or MCWH, CDC and Primary Health Care coordinators to establish a team with other district officials like health information, health promotion, environmental health officers that will plan, coordinate and monitor implementation of immunisation activities within the district.

If epidemiologically justified and logistically feasible, other EPI antigens and child health interventions, such as measles vaccine, tetanus toxoid, Vitamin A, deworming and others could be delivered during mopping-up operations and National Immunisation Days. However, inclusion of the injectable EPI vaccines will require participation of qualified health staff, additional resources − especially syringes, needles and disposal equipment − and additional staff time to register doses on vaccination cards.

Integration of immunisation campaigns with other child health interventions results in substantial increases in the operational cost and time required to complete immunisation campaigns. Such a decision should be taken on a case-by-case basis; advantages should be clear and should not compromise the quality of the polio campaign.

Mopping-up

Mopping-up is the house-to-house vaccination of all children up to a specified age, usually five years, within a high-risk geographic area or population with two doses of OPV, regardless of previous vaccination history.

High-risk districts for polio transmission are:

- Districts with confirmed polio cases occurring during the last three years;
- Districts with unknown or low coverage of the third dose of polio vaccine;
- Geographic areas where the epidemiology of polio suggests a high risk of wild virus transmission, for example:
    - Peri-urban or high-density communities;
    - Communities with particularly poor hygiene;
    - Poor access to healthcare services;
    - Refugee or immigrant populations;

- Districts bordering countries where there is wild poliovirus circulation or importation.

Mopping-up should be conducted during the low poliovirus transmission season (usually in winter, May – August in South Africa). Mopping-up may be organised and implemented in a similar fashion to an outbreak response exercise.

3.4 AFP surveillance

To ensure the absence of wild poliovirus circulation, it is mandatory to establish a highly sensitive Acute Flaccid Paralysis (AFP) surveillance system. The key features of this system are:

- Active AFP surveillance;
- Detection and investigation of all cases of AFP;
- Collection of 2 stool specimens, 24 - 48 hours apart within 14 days of onset of paralysis;
- **PLEASE COMPLETE THE NEUROLOGICAL ASSESSMENT FORM (Annex 2.4) FOR <u>ALL</u> AFP CASES**
- 60-day follow-up examination of the case for residual paralysis when indicated;
- Perform virus isolation in a WHO-accredited laboratory;
- Classify cases according to WHO scheme.

Active AFP Surveillance

All provinces and districts should conduct active AFP surveillance. The implementation of active surveillance should be based on the following factors:

- Analysis of the situation to identify gaps in surveillance and high risk areas;
- Strategies and plans with prioritisation of reporting sites based on situation analysis;
- Regular monitoring of indicators, feedback and supportive supervision.

Prioritisation:

Each district should have a list of reporting sites for active surveillance. In each district, health facilities should be prioritised for active surveillance based on the assessment of the district surveillance team. Those facilities, which serve as referral centres, with a high rate of patient attendance and likely to be the centre where a child with AFP will seek healthcare, should be high priority and should be visited weekly (or the designated focal point should report weekly). The active surveillance report must be sent to the province every week from these centres. Other sites, which are not as big or busy, can be classified as medium or low priority sites and should be visited (or the designated focal point must report) twice or at least once monthly. The weekly active surveillance reports *(***Error! Reference source not**

found.*)* must be completed and sent weekly from the reporting sites to the next level up and all sites are expected to send the monthly surveillance report. These reports include zero reports when AFP cases or other conditions targeted for active surveillance were not identified in that week or month.

Focal points:

District surveillance officers should conduct active surveillance visits to high priority sites. In areas where visiting all high priority sites is not feasible, they should identify, train and designate a surveillance focal person (like an infection control nurse) in high priority facilities. During the **active surveillance visit**, the district surveillance officer and the focal persons will go through the records (outpatient and inpatient, paediatric department, neurology department, physiotherapy unit, intensive care, spinal unit), and interview clinicians and relevant health workers in these units or wards. The visit is also an opportunity for regular sensitisation and orientation of clinicians and relevant health workers on AFP surveillance and to provide feedback on AFP cases previously reported from the reporting site. Focal persons and district surveillance officers should document the active surveillance visit by recording findings and recommendations, and signing the supervisory book or admissions register. They are also responsible for sending reports weekly / monthly to the next level.

When checking registers or records, surveillance officers should look for **symptoms AND diagnoses.** A list of some of the most well-known diagnoses and symptoms is given in Table 3.1 below. If any symptoms or diagnoses like the ones listed in the table are found when reviewing logbooks and registers, then the medical records should be checked for details. In the event that the records are not satisfactory or indicate that the case may be an AFP, the facility health worker and the surveillance officer should examine the child again. If a case has been prematurely discharged or inadequately investigated, the surveillance officer (district / province) should immediately obtain the home address to visit and conduct a physical examination / collect the second sample (within expected time frame). Community contacts or persons who are not healthcare workers should be asked to report any child under the age of 15 years who has floppy paralysis that happened quickly (less than a week from start to full paralysis).

Table 3.1: Key symptoms and diagnoses to look for during health facility surveillance visits:

Symptoms that should alert further investigation	• Paralysis, paresis (weakness), flaccid (floppy) paralysis (in combination with any other words) • Weakness (of limb, of unclear origin, etc.) • "Frequent falls", "gait disturbance", "cannot walk", etc. • Muscle hypotonia (hypotonia means loss of muscle tone due to some other cause)
Diagnoses that should always be investigated as AFP	• Poliomyelitis, rule out polio, suspect polio • Guillain-Barre' Syndrome • Transverse myelitis • Traumatic neuritis
Diagnoses that sometimes present as AFP	• Hypokalemic paralysis • TB of the spines (Pott's disease) • Meningitis / encephalitis

Case detection:

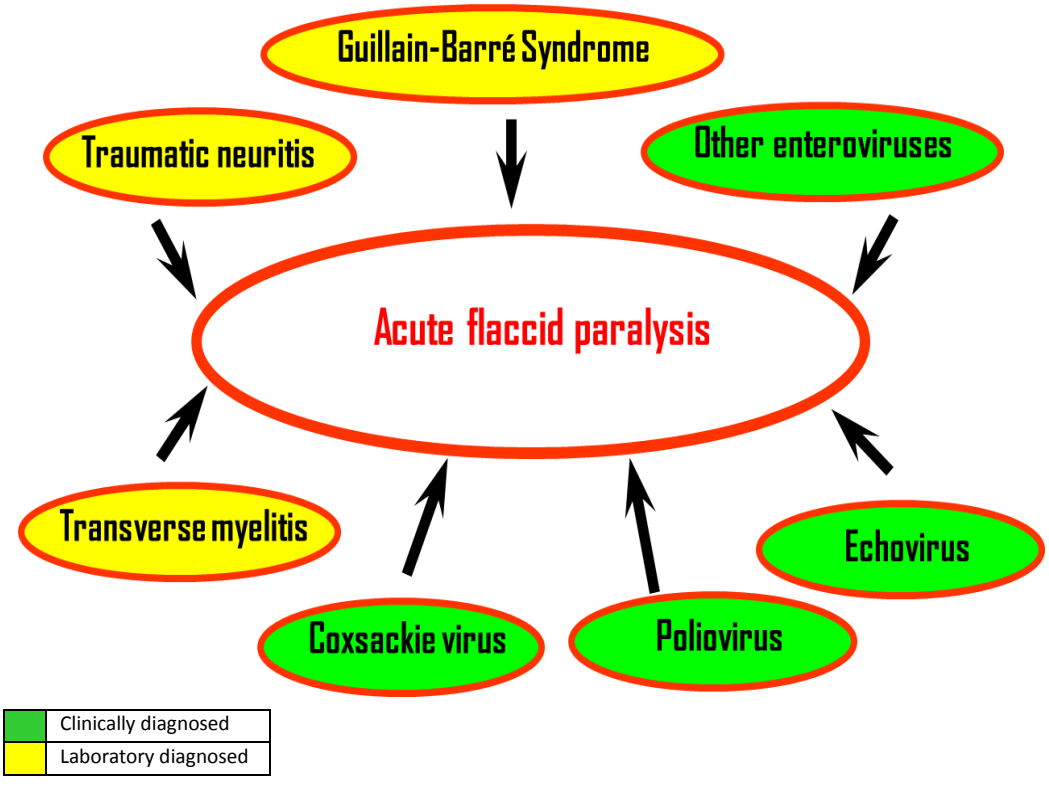
The standard **case definitions** are used for case detection and reporting. These standard case definitions are for use by professionals. A very simple version is also developed for community involvement and participation in surveillance. This allows for all community members, not only health professionals to detect and notify acute flaccid paralysis cases. These definitions should be distributed and displayed to draw the attention of health workers and the community.

Standard Case Definition
Any child under 15 years of age with acute flaccid paralysis, ***Or*** A patient of any age in whom a clinician suspects polio
<u>Acute:</u> Rapid progression of paralysis, (from onset to maximum paralysis) *<u>Flaccid:</u> Loss of muscle tone, "floppy" (as opposed to spastic or rigid)* *<u>Paralysis:</u> Weakness, loss or diminution of motion*
Simpler Case Definition for community participation
Sudden weakness or paralysis not caused by injury in a child under 15 years of age.

One main difficulty in AFP surveillance is to convince clinicians to report all paralysed children, including those that they are convinced are not polio cases, like cases with an established diagnosis. The best way to approach this is to explain the WHO certification process and the part that AFP surveillance plays in the global polio eradication programme. Clinicians must be urged to report all Guillain-Barré Syndrome (GBS) cases. These GBS cases may account for up to 50% of all AFP cases, and without reporting GBS, achieving an AFP detection rate of at least 4 per 100 000 children under the age of 15 years will be extremely difficult.

The figure below shows some of the causes of AFP, which should be included in the reporting and investigation, even if the clinician is very sure that the diagnosis is not polio.

Figure 3.1 AFP differential diagnosis (conditions which may present with AFP symptoms)



Upon detection, AFP cases must be notified immediately and investigated by the health worker. The case investigation form should also be completed immediately.

Although the responsibility of AFP surveillance lies in all health workers, all health facilities should have a focal person for VPD surveillance and this is normally the Infection Control Professional Nurse.

AFP Case investigation

Once an AFP case has been detected, the health worker should immediately investigate the case and telephonically notify or SMS the district. Within 24 hours of receiving notification of an AFP case, the district communicable disease control (CDC) coordinator should visit the patient (case) in hospital and reconfirm the AFP and the correctness of the data in the investigation form. The aim of the case investigation is to collect all the information required on first part of the AFP CIF (everything except for the 60-day follow-up part), as accurately as possible. The subsequent analysis of this information will facilitate planning of supplemental immunisation among targeted children in the affected area.

The District CDC coordinator should issue each AFP case with an Epid Number", a unique identification number. This should be done in coordination with the provincial EPI office. This number will include the country code, province code, district code, year of onset and chronological order of the case, for example: SOA-KZ*P-ETH-11-005* is the fifth AFP case reported in the KwaZulu-Natal Province, Ethekwini District in 2011. The three letter codes for the provinces to be used in the allocation of Epid Numbers are listed in Table 3.2 and districts should use the same pattern.

(Country code)	*(Province code)*	*(District code)*	*(Year)*	*(Case number)*
SOA	**KZP**	**ETH**	**11**	**005**

Table 3.2 Three letter codes for provinces in Epid Numbers

Province	**Code**	**Province**	**Code**
Eastern Cape	ECP	Northern Cape	NCP
Free State	FSP	Limpopo	LPP
Gauteng	GAP	North-West	NWP
KwaZulu-Natal	KZP	Western Cape	WCP
Mpumalanga	MPP		

The Epid Number must appear on the AFP Case Investigation Form (CIF*, Annex 2.3*) and the Neurological assessment form (*Annex 2.4)*. The Epid Number will link all field and laboratory investigations and final case classification and should be used in hospital records, at the District Medical or Communicable Disease Control Office, at the provincial and National Department of Health, and for reporting to the WHO.

The completion of the form requires careful compilation of data from different sources. This work should be assigned to the health worker who detects the case and a responsible health official at district level, mainly the CDC coordinator. In many cases, identification and clinical data on the case will be available at the hospital.

The CDC coordinator is the investigator of the case and should interview the examining doctor to ensure that the clinical data in the CIF is entered in full. The doctor's diagnosis is very important and should be entered on the space provided in the CIF. The final classification of AFP cases is not the responsibility of the CDC coordinator or the investigating official, it the responsibility of the Polio Expert Committee, an independent committee of experts that reviews and classifies AFP cases.

The investigator should ensure that all relevant clinical and epidemiological information is obtained, such as information on date of onset of paralysis, initial signs and symptoms, vaccination status, history of visits, visitors and other children in the neighbourhood with a similar illness. The attending clinician and the investigator should ensure that faecal specimens have been collected appropriately and sent / taken to the local health facility laboratory with the accompanying CIF, clearly marked that the specimen and CIF should be shipped to NICD in Johannesburg.

The case investigation form must be completed fully and a copy sent by fax, or e-mail to the EPI (SA), Department of Health. The e-mail address of the Department of Health episa@health.gov.za can be used to send electronic copies of case investigation forms or any information on EPI surveillance.

Accurate information on the address of the case is essential and when deemed necessary, a home visit is vital to confirm and find out if there are additional cases. It will also help simplify the task of tracing the case for the follow-up clinical examination, which should be done at 60 days after onset of paralysis for cases that were not fully investigated.

The results of virological analysis of stool specimens should be entered on the AFP Case Investigation Form at all levels that keep the record. When the final classification of the case is entered on this form after the Polio Expert Committee has assessed the case, the investigation is complete. For epidemiological analysis, the district, province and the national EPI office should all maintain and periodically review a line listing and a spot map of AFP cases under investigation and compatible cases after the case investigation is complete.

Clinical examination of AFP cases

Clinical examination of AFP cases includes the information on date of onset of paralysis, age, immunisation status, and presence of other similar cases, symptoms before or at the onset of paralysis as well as clinical examination, neurological assessment of affected limbs and the follow-up examination after 60 days of onset. The information in the table below allows the investigator to follow a systematic way to examine the patient and help during classification if stool specimens were not collected adequately. However, it should be clear that all cases that present with acute (sudden) onset of paralysis or limb weakness with a decreased muscle tone should be reported as AFP. Surveillance is not just for polio cases, but is for all cases that present with acute flaccid paralysis.

Table 3.3 Clinical features of poliomyelitis

Progression of Paralysis	24 to 48 hours onset to full paralysis
Fever at onset	high, always present at onset of flaccid paralysis,
Flaccid paralysis	acute, usually asymmetrical, principally proximal
Muscle tone	reduced or absent in affected limb
Deep-tendon reflexes	decreased to absent
Sensation	severe pain, backache, NO sensory loss
Cranial nerve involvement	only when bulbar involvement is present
Respiratory insufficiency	only when bulbar involvement is present
Autonomic signs & symptoms	Rare
Cerebro-spinal fluid	Inflammatory changes
Bladder dysfunction	Absent
Nerve conduction velocity: third week	Abnormal: anterior horn cell disease (normal during the first 2 weeks
EMG at three weeks	Abnormal
Sequelae at three months and up to a year	severe, asymmetrical atrophy, skeletal deformities developing later

Follow-up examination after 60 days

Each incompletely investigated AFP case that did not have two adequate stool specimens collected 24- 48 hours apart within 14 days of onset of paralysis that was transported on ice to NICD, must be evaluated again 60 days after the onset of paralysis. This examination follows the same basic clinical examination of the initial investigation. A health worker examines to see if the patient still has paralysis by checking reflexes and muscle tone. The intention is to find if there has been any improvement in the weakness since onset of the paralysis. As polio disease causes permanent damage to the spinal nerves, a true polio case

does not show any improvement of weakness, whereas most other diseases causing AFP such as Guillain-Barré Syndrome, often have completely resolved after 60 days.

A 60-day follow-up examination is critical in the final classification of incompletely investigated AFP cases. Therefore, all incompletely investigated cases should be called back for this review after 60 days (2 months) of onset of paralysis. It is preferable, but not necessary that a case be recalled to a health facility. A 60-day follow up can be conducted at home. *Complete residential address information is vital for tracing cases that are recalled for follow-up examination, but who do not come. If an* incompletely investigated AFP *case is lost to follow-up, a final classification of* ***compatible*** *polio may be assigned by the Polio Expert Committee (PEC), thereby possibly jeopardising the polio-free status* (See table 3.4 on Final Classification).

This 60-day follow-up examination is critical for the final classification and every effort should be made to conduct this examination when indicated. If after 60 days, an AFP case still has:

- Diminished or no reflexes, and / or
- Any sign of muscle weakness, and / or
- Diminished or no muscle tone,
- With or without muscle wasting,

Then it is said the case has “residual paralysis” and the Polio Expert Committee will take this into account in its final classification. If the stool specimens were not adequate and if residual paralysis is still present at 60 days in the absence of other evident medical reasons for the paralysis, the case can be classified as a **compatible polio case**.

When there is full recovery noted with no residual paralysis at 60-day follow up, the PEC will discard an incompletely investigated AFP case as not being a possible polio case.

Clinical notes and results of other investigations

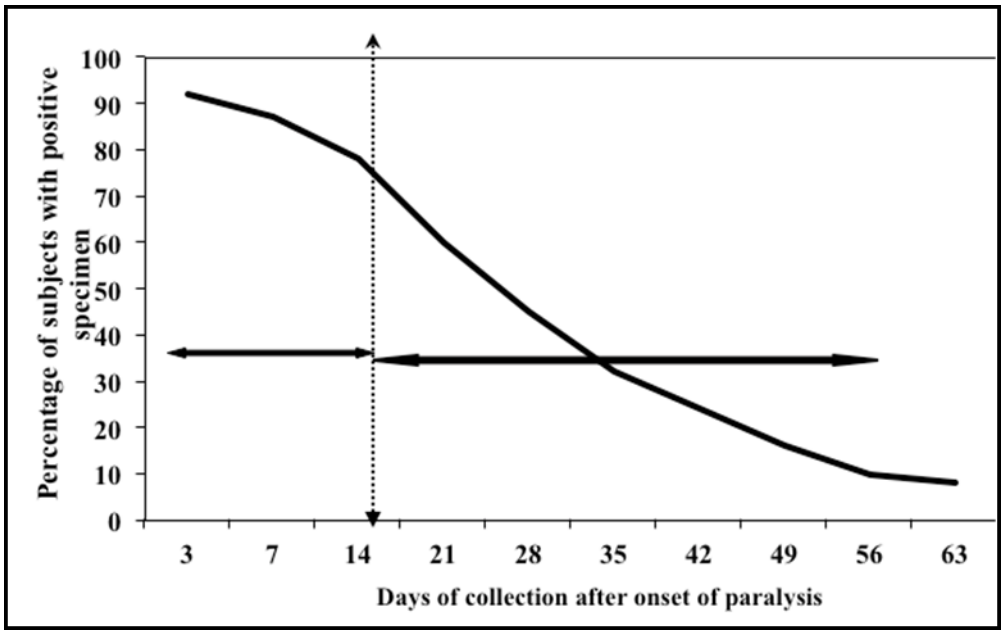
Apart from conducting the 60-day follow up, all incompletely investigated cases need clinical progress notes by the attending physician ,physiotherapist and all relevant information such as reports of special investigations conducted. This information includes CAT Scan results, cerebrospinal fluid (CSF) results, electromyogram (EMG) reports, nerve conduction studies, other laboratory and similar investigations conducted.

The PEC will discard a case, as not being a possible polio case only if good clinical notes and/or clear results of investigations points to a diagnosis other than polio as the cause of paralysis.

Laboratory investigation of stool specimens

Due to the intermittent excretion of the wild poliovirus, it is necessary to collect two stool specimens from each AFP case. The rationale for collecting two stool specimens is to increase the chances of collecting at least one of the specimens during the peak period of the viral excretion. The first stool specimen should be collected as soon as possible after admission and the second stool specimen 24-48 hours after the first specimen. Specimens must be collected within 14 days after the onset of paralysis because there is a dramatic fall in the load of virus excretion in faecal material after 14 days (*Figure 3.2*).

Figure 3.2 Faecal excretion of polioviruses



Procedure for the collection of the stool specimen:

The following procedures and steps must be followed in collecting and shipping specimens to the laboratory:

- Collect at least 1 adult “thumb sized” (8 g) amount of stool;
- Place in clean plastic container, such as a wide-mouthed plastic bottle with an external screw-on cap tightly closed;
- Side of container should be labelled with name, identification number of the case, number of specimen (1 or 2) and date of collection using a water-resistant pen;
- Place specimen container in sealed plastic bag;
- Fold the filled Case Investigation Form (CIF) and place it in a separate sealed plastic bag;

- Transport this specimen immediately to the local health facility laboratory or call the courier company to come fetch the stool after collecting the second stool specimen;
- Store separately from vaccines and other clean items;
- Store in refrigerator to maintain temperature below 8°C until shipment has been arranged;
- Transport the specimen in a cool box to ensure that temperature is still maintained below 8°C.

All specimens should be submitted immediately to the National Institute of Communicable Diseases (NICD) in Johannesburg, frozen and / or on ice, with an AFP case investigation accompanying the specimen. The laboratories also have timeliness indicators to reach, so the sample should arrive at the NICD within 72 hours after collection.

The AFP Case Investigation Form should be completed in full including the Epid Number. District CDC officers must ensure that the AFP case investigation forms are available in all health facilities at all times.

The specimen from each AFP case that has been collected and placed into a sealed plastic specimen bottle should be packed in a zip-lock plastic bag (or tied off with a string or a rubber band) together with the CIF.

The specimen should be put in a cooler box with ice and the courier should be contacted to transport the specimen to the NICD in Johannesburg. If the specimen has to be stored for some time to await the courier or transport to the local laboratory, it must be kept in the refrigerator until transport is available. The specimen must be kept in a cold box with ice packs during transport. Care must be taken to avoid faecal contamination of the refrigerator. Hand washing with soap must be practised meticulously after handling specimen containers.

Adequate Stool Specimen:

- Two stool specimens
- Collected at least 24-48 hours apart
- Collected $\leq$ 14 days of onset of paralysis
- Arriving within 3 days of collection at the laboratory in **good condition**
- Each specimen of adequate volume (8-10 g)
- Packed adequately – no desiccations, no leakage
- Well labelled
- Shipped in a cold box below 8°C

An arrangement should be made to send the specimens by the most secure methods. Since the specimens are in a cold-box, they cannot be delayed for more than 24 hours. Specimens may be sent

through a courier any day of the week. The laboratory should be followed up within reasonable time (between 12 and 24 hours from the time it was sent) to ensure that the specimen was indeed received at NICD.

IMPORTANT

The National Institute for Communicable Diseases (NICD) in Johannesburg is the only WHO approved laboratory in South Africa to perform poliovirus isolation. While other virological laboratories in the country may receive the specimen, the original specimen must reach the NICD within 72 hours of collection.

NICD contact information:

The National Institute for Communicable Diseases
01 Modderfontein Road, Sandringham, 2192
Private Bag X4, Sandringham 2131
Tel: 011 386 6421/ 6422 / 6438 / 6358 / 6361
Fax: 011 386 6458

Results of the virological investigations will be transmitted to the national EPI office and to the Provincial AFP Surveillance Officer. These officers are responsible for providing feedback to the district and the health facility where the case was detected. Laboratory results should be ready in no more than two weeks. The Provincial AFP Surveillance Officer and national EPI office should follow up if no results have been received from the laboratory after three weeks of receipt.

Within 24 hours of being informed of the outcome of the virological investigation, the Provincial AFP Surveillance Officer should convey the results to the district CDC officials where the case originated.

If a wild poliovirus was isolated from the stool specimen of an AFP case, this would be a national emergency that will require special intervention measures with the support of senior health managers at all levels. The National Outbreak Response Team will handle response to a wild poliovirus. Response to wild poliovirus is covered in another document "Wild poliovirus Outbreak and Importation Preparedness Plan."

Final classification of AFP cases

Final classification of all incompletely investigated AFP cases is independent of the investigator, the province or the national EPI unit to ensure impartiality. There is a committee of experts; the Polio Expert Committee (PEC) that regularly meets to classify all incompletely investigated AFP cases, cases that do not have two adequate stool specimens. The PEC may confirm or discard a diagnosis of poliomyelitis; request for additional clinical information and / or results of investigations conducted; or classify a case as compatible with polio.

If there is not enough clinical grounds (including results of investigations conducted) to discard the case as not being polio, then PEC requests additional information or a 60-day follow up; such a case is temporarily classified as pending, till the next PEC when its classification will be finalised. The process of classification of cases is time sensitive and should be done within 90 days. A case that is not classified at 90 days or later automatically becomes compatible with polio; this is irrespective of the underlying reasons. Therefore, health workers should support investigation of cases by providing the necessary documents, including clinical notes and results of investigations.

The Polio Expert Committee (PEC) makes the final classification of AFP cases; independent of diagnoses made by the clinician, the investigator or the EPI staff. This responsibility may not be delegated to attending physicians.

The national EPI unit is allowed to classify and discard as not polio all fully investigated cases with adequate stool specimens when the virological laboratory results are negative. Should fully investigated cases have other complications, the national EPI office must present such cases to the PEC. See Table 3.4 below on how PEC classifies cases.
PEC also has the responsibility to advise the national EPI unit on polio eradication and certification issues.

Figure 3.3 Virological classification schemes

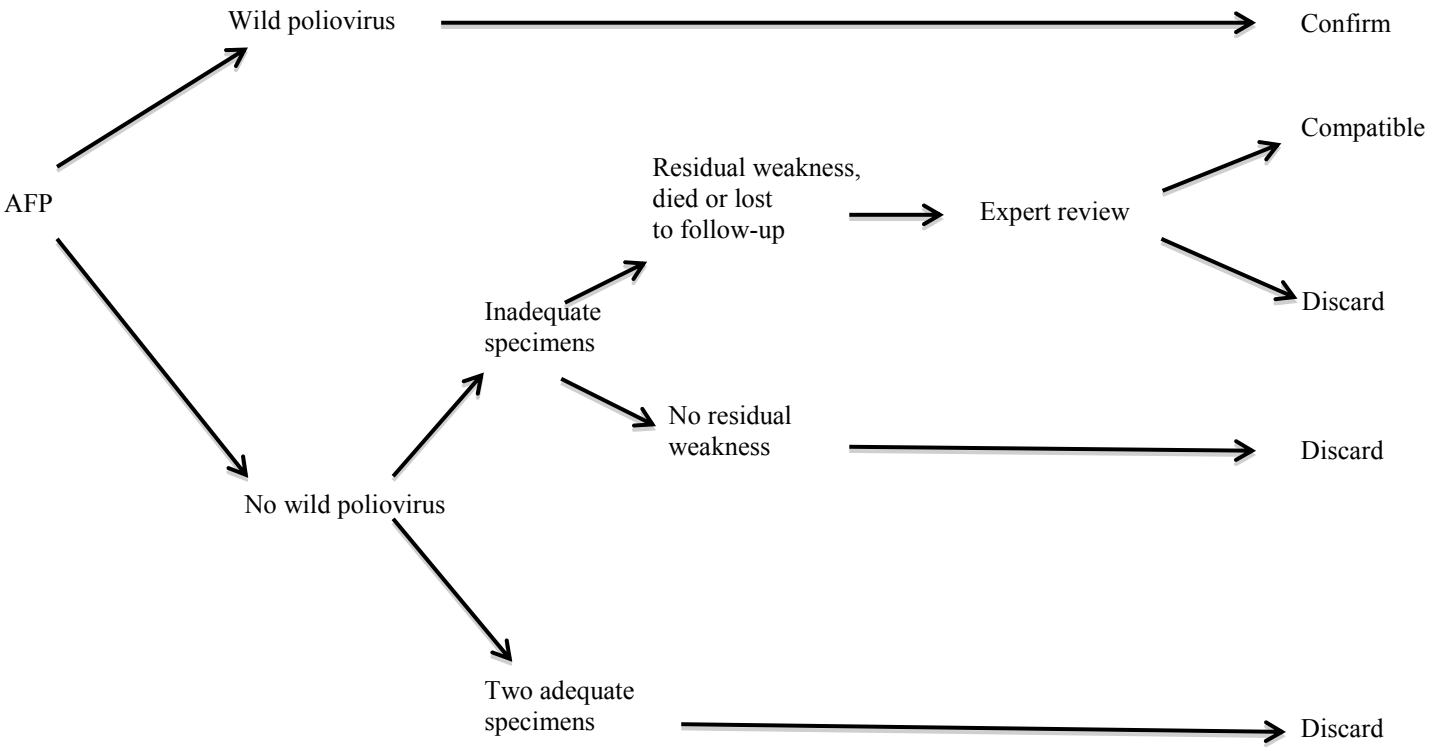


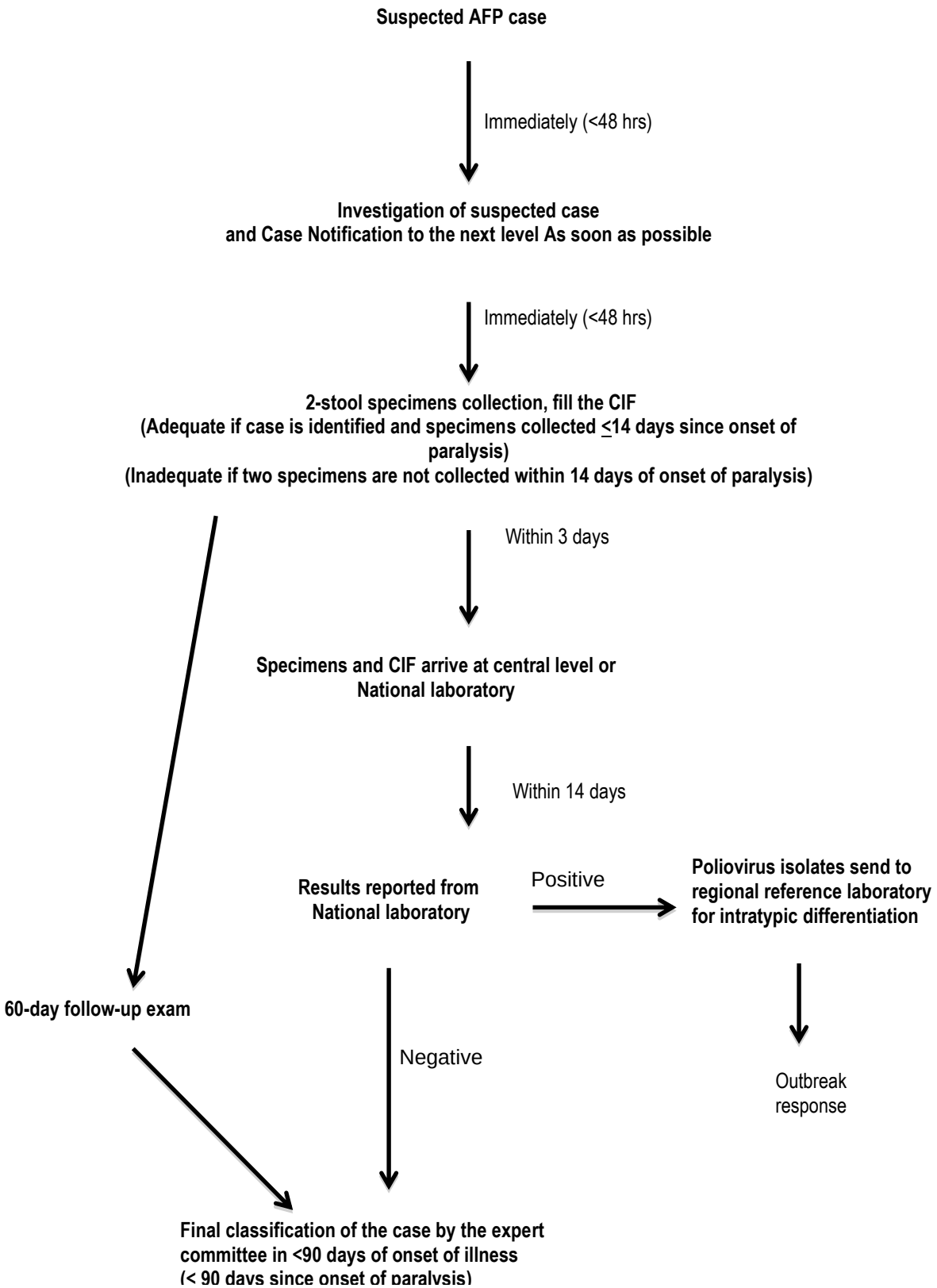
Table 3.4 The classification used by the PEC South Africa

Status	Classification	Code	Reason
Final	Confirmed (Wild type)	A1	Wild type poliovirus found in stool sample of case or one of the contacts.
	Confirmed (Vaccine-associated)	B1	Vaccine-type poliovirus found in stool sample of case, which has residual paralysis at 60-day follow-up; and is confirmed clinically.
	Compatible	C1	AFP case lost to follow-up at 60 days.
		C2	Death related to the illness within 60 days.
		C3	Residual paralysis for which other no medical reason is evident.
	Discarded	D1	No residual paralysis and no wild polio found in stool samples.
		D2	Confirmed alternative diagnosis
		D3	Non-polio enterovirus isolated.
		D4	No virological investigation, and a clinical picture incompatible with polio.
		D5	Two adequate negative stool specimens with 14 days of onset of paralysis
	Denotified	E1	Not an AFP case
Pending	Inadequate Information	F1	PEC is unable to make a decision due to the lack of information. The investigating team is given 30 days from the committee meeting to find further details. The final decision is taken at the next PEC meeting.
	60 day -follow-up not yet done	F2	Final decision is referred to the next PEC meeting for final decision.

AFP Surveillance Milestones, SA

1995: AFP notifiable
1997: Active AFP surveillance implemented
1997: PEC constituted
2001: Switch to virological classification
2003: Reached polio certification surveillance standard
2006: Polio Free Certification status achieved

Figure 3.4 Flow Diagram of Investigating an AFP case



AFP Surveillance monitoring: indicators and targets

EPI-SA monitors AFP surveillance performance based on data reports from facilities and districts. The national office collates and analyses data for all provinces and districts, gives feedback to provinces and WHO regional office. Provinces should collate and analyse AFP surveillance data in their respective districts and provide feedback for prompt actions.

AFP surveillance data is based on:

- Case-based investigation forms, which should be completely filled out and made available at all levels;
- Weekly active AFP surveillance reports from active surveillance sites;
- Monthly routine reports from all surveillance sites.

All data fields in AFP case investigation forms must be filled out with the correct information for meaningful analysis and interpretation. Hence, the value of collecting accurate data cannot be overemphasised, and therefore all officials from facility level to district, province and national level must pay full attention to proper data collection and flow.

All case-based data are recorded at national level for further analysis and shared with WHO on a regular basis.

Annexure 3.3 shows the Standard Operating Procedure (SOPs) for case-based AFP surveillance data in South Africa

The indicators for high quality AFP surveillance are:

The two key indicators

- Detection and investigation of at least 4 non-polio AFP cases per 100 000 children under 15 years of age with a good geographic distribution by province and district. The non-Polio AFP detection rate is calculated as follows:

  $$\text{Non-polio AFP rate} = \frac{\text{number of reported non-polio AFP rates} < 15 \text{ years of age}}{\text{total number of children} < 15 \text{ yrs of age}}$$

- At least 80% of AFP cases should have 2 adequate stool samples collected within 14 days of onset of paralysis

Data must be analysed at all levels. Performance must be monitored more carefully at provincial and district levels since national surveillance indicators may mask wide variation in performance and surveillance gaps at district level.

Note: The targeted detection rate is now 4 cases per 100 000 children below 15 years of age. It is no longer 2 cases per 100 000 children below 15 years of age.

AFP surveillance data is routinely analysed based on the indicators above at national EPI office and feedback is given to provinces. The provinces are expected to do the same and give feedback to districts and sub-districts. The two most commonly reported indicators are the detection rate and stool adequacy. Examples of this analysis at national level for all nine provinces combined, from 2006 to 2011 is given for the two indicators below (*Figure 3.4 & 3.5*).

Figure 3.4: Detection Rate, AFP cases detected per 100 000 population <15 years; 2006 -11

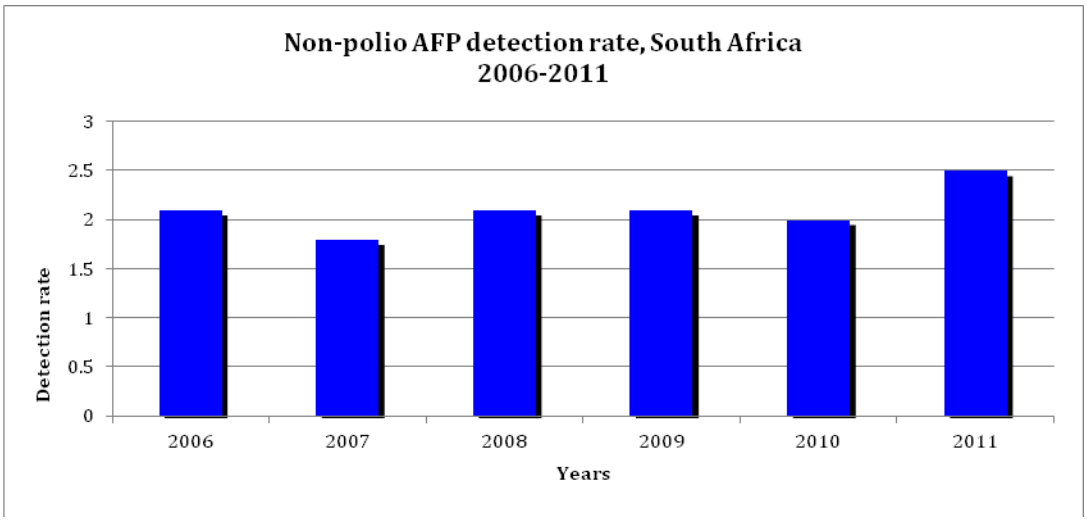
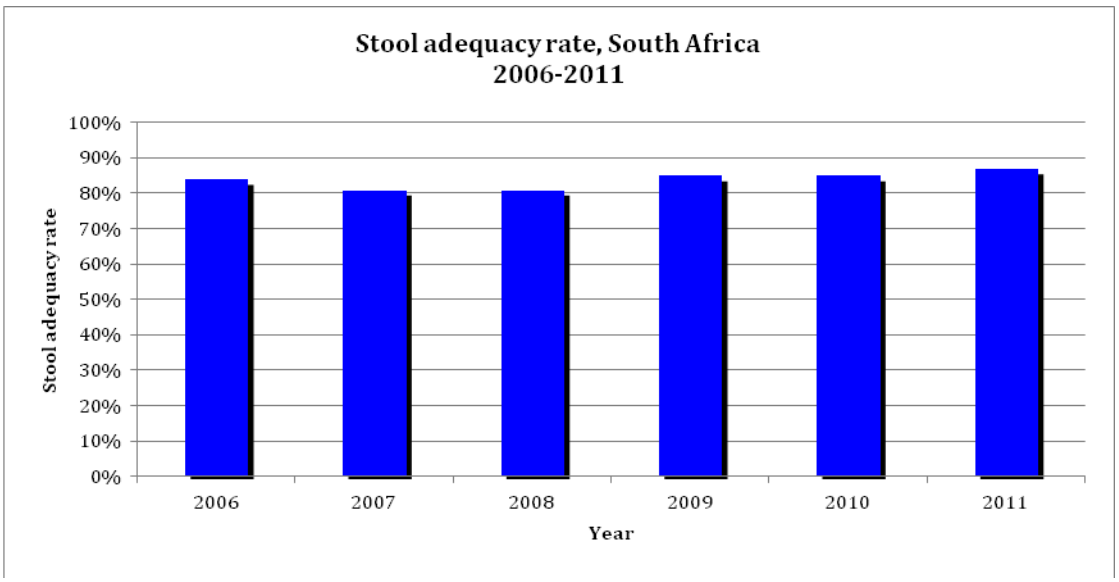


Figure 3.5: Percentage of AFP cases with 2 adequate stools



Other important AFP surveillance indicators:

- At least 80% of AFP cases investigated within 48 hours of being reported;
- At least 90% of all reporting sites submit monthly reports including zero reporting:

$$\text{Completeness} = \frac{\text{number of monthly reports received}}{\text{number of monthly reports expected}} \times 100\%$$

- At least 80% of all data are submitted on time (within 10 days after the last day of the previous month).

$$\text{Timeliness} = \frac{\text{number of reports received before a specified deadline}}{\text{number of monthly reports expected}} \times 100\%$$

- Follow-up exam 60 days after paralysis onset in at least 80% of reported AFP cases to verify the presence of residual paralysis or weakness;
- At least 80% of stool specimen arrive at the laboratory in “good” condition;
- At least 80% of specimen arrive at the National laboratory within 3 days of collection;
- At least 80% of laboratory results are sent back within 28 days of receipt;
- Laboratory isolation of non-polio enterovirus in at least 10% of stool specimens;
- % of reporting sites with active search conducted in the month;
- % of fully completed case investigation forms.

Provincial and National AFP detection targets are calculated by estimating the under 15 years-old population from the census and dividing this by 100 000.

3.5 Key roles of surveillance officers in AFP surveillance

DIFFERENT LEVEL RESPONSIBILITIES ON INVESTIGATION OF AFP CASES			
LEVEL 1 HEALTH WORKER/ REPORTING SITE	**LEVEL 2 DISTRICT/SUB – DISTRICT/LOCAL AUTHORITY**	**LEVEL 3 PROVINCIAL EPI COORDINATOR**	**LEVEL 4 NATIONAL SURVEILLANCE OFFICER**
➡ **Detects an <u>AFP case</u>** ➡ Informs the District EPI coordinator <u>immediately</u> ➡ Conducts the initial case investigation ➡ Collects two stool specimen at least 24 hours apart ➡ Sends samples to National Institute for Communicable Diseases (NICD) Laboratory in cool box (reverse cold chain), with properly filled-in CIF ➡ Completes first section Sends case investigation form to Level 2. **NB:** Check if there are similarly ill children in the neighbourhood of the case ➡ Sends weekly and monthly surveillance reports on time	➡ Receives notification ➡ Assigns the Epid Number ➡ Informs Level 3 ➡ Keeps a line-list of all AFP cases ➡ Cross check the data filled in the AFP case investigation form and conduct additional examination if needed ➡ Sends the case investigation form to District/Province ➡ Does home visit to finds out if there are more similar cases ➡ Does the 60-day follow-up investigation on the case ➡ Sends weekly and monthly surveillance reports on time ➡ Conduct training/supportive supervision to facilities	✯ Keeps a line list of all AFP cases ✯ Ensures that case investigation form is completely filled in and sent to the National office ✯ Make a follow up with the laboratory to find out about the results ✯ Ensures that the address of the child is known for 60-day follow-up ✯ Forwards report to National EPI office weekly ✯ Receives weekly/monthly reports, check for completeness and timeliness and forwards to National EPI office ✯ Conducts training/supportive supervision to Sub-Districts/Districts	○ Ensures completeness of case investigation form ○ Ensures that the laboratory result is out on time and communicated to the case and the surveillance officers ○ Keeps National Data Base on all AFP cases ○ Ensures that all cases are classified by NPEC within 90 days of onset of paralysis. ○ Conducts training/supportive supervision to Sub-Districts/Districts ○ Sends weekly reports to WHO, Health System Research & Epidemiology, Communicable Disease Control Outbreak Response Unit and Provinces

3.6 Outbreak response

A single case of confirmed wild polio infection is considered as a polio outbreak and is an emergency. For every case of paralysis caused by wild poliovirus, 200 to 500 other persons in the community have unapparent infection. Every one of those infected individuals continues to excrete poliovirus for up to a month, spreading the disease everywhere. The objective of polio outbreak response is to place a wall of immune individuals around the poliovirus before it has time to move to the next area. Supplemental immunisation with OPV is the best way to achieve this.

Current recommendations of WHO on response to a polio outbreak include:

- Initiate full epidemiological and social investigation of the outbreak, , activate local responses and notify government officials within 24 hours,
- Requesting international expert risk assessment within 72 hours of confirmation of the index case in order to establish an emergency plan of action;
- Implementing a minimum of three large-scale rounds of immunisation campaigns using a type specific monovalent oral poliomyelitis vaccine, or another appropriate vaccine. The first round to be conducted within four weeks of confirmation of the index case, with an interval of four weeks between subsequent rounds;
- Conduct house-to-house vaccination where applicable;
- Targeting all children aged under five years in the affected and adjacent geographical areas, or a minimum of two to five million children in large population countries, using independent monitoring to determine whether at least 95% immunisation coverage has been reached;
- Ensuring that at least two full rounds of poliomyelitis immunisation are conducted in the targeted area after the most recent detection of poliovirus;
- Enhancing surveillance for acute flaccid paralysis (AFP) to a level of greater than 2 cases per 100 000 children aged under 15 years, for the duration of the outbreak and at least 12 months immediately thereafter;
- Sustaining high coverage of routine polio immunisation coverage of at least 90% and highly sensitive disease surveillance.

Polio outbreak should be considered a national emergency. It calls for an immediate formation of task forces at all levels: national, provincial and district- with representatives of the partners (WHO, UNICEF, Rotary, religious leaders, minority groups and other key partners). These task forces will monitor the general outline of the campaign, work plan, key responsibilities, and progress in the preparations, identification of major obstacles and contingency plans.

At the national level, responsibilities include:

- Drafting national plan, dates, budget, etc.;
- Facilitate the work of lower levels;
- Monitoring at all levels key surveillance data, SIA and EPI routine indicators, itineraries for vaccine distribution, districts with specific risks, places requiring cross border co-ordination;
- Feedback and information to all levels;
- Providing final evaluation.

Provincial and district task forces are responsible for:

- Micro planning;
- Monitoring at district and provincial level key surveillance data, SIA and EPI routine indicators, itineraries for vaccine distribution, areas with specific risks, places requiring cross border co-ordination;
- Feedback and information to national and lower levels.

Timing, target age group and size of a mop up:

A mop up following an importation should take place within 4 weeks of confirmation of a wild polio case.

Unless epidemiological data convincingly shows a high proportion of transmission among older age groups, transmission can generally be interrupted by targeting the under 5 populations, which is the age group affected by the vast majority of polio outbreaks. An increase in the targeted age group has direct consequences in terms of financial, operational and vaccine availability.

Determining the target area for a mop up:

The mop up area should be decided on basis of risk, such as:

- Inadequate surveillance;
- Limited access to health services (hard to reach, displaced, etc.);
- Low routine / NID coverage;
- Densely populated urban areas, which are associated with a given or even higher coverage than rural areas because of the increased risk of importation.

House to house immunisation: may be the preferred strategy for polio eradication and outbreak control in situations where:

- No one is available in the household to take the children to the vaccination post;
- There may be lack of interest or motivation to have children vaccinated;
- The parents may fear or mistrust vaccination;
- Children who need to be carried may not be brought to the vaccination site;
- Migrant populations may not be aware of location of the posts or the need for vaccinating their children;
- Sick children may be missed.

If the house-to-house strategy cannot be applied, the normal strategies of fixed and outreach services as well as mobiles should be used in a well-known location, which is most convenient for the community: a health facility, school, post office, police station, market or petrol station.

The district EPI surveillance team will organise outbreak response teams composed of health workers and trained volunteers. The volunteers involved in outbreak response with OPV immunisation can be local Rotarians, teachers, students, military and police officers as well as other appropriate persons available in the district.

Social Mobilisation, Information, Education and Communication (IEC):

There is a need for high-level advocacy with policy makers to create a sense of urgency to ensure the campaign is of high quality in order to interrupt the transmission of the virus and control its spread within a short space of time. Parents should be informed about the purpose, time and place of supplemental immunisation sessions. Mass media and print material, interpersonal communication (IPC), IEC materials, messages through mosques and churches can be used to ensure maximum participation.

Micro planning

A micro plan is the operational plan describing all aspects of campaign implementation at district and health centre level. It includes details such as how many teams should be deployed and where; how the vaccine should be stored and distributed; how social mobilisation should be conducted, etc. The micro plan operationalizes and adapts the general rules set out in the macro plan. A good micro plan can only be done at district, sub-district or health centre.

A good micro plan will include:

- Number of children / team / day, vehicle allocation, daily mileage for vehicle users, etc. It should serve as a guide and needs to be adapted to local constraints. The adapted plans should be communicated to the higher levels and help with finalisation of the budget;
- Planning meetings should be held with village leaders (councillors in urban areas) and influential members of society to gain insight into what will work best. These meetings will also help identify members of the community who will part of the vaccination teams;
- Plans should be based on local conditions, accessibility, geography, population movements, working hours (to work out when people are at home) culture, etc. in the catchment area.

Micro plans must target all children under the age of 5 years, but special attention has to be paid to the groups such as religious minority groups, communities in difficult-to-reach areas, urban slum dwellers, people living in houses between settlements and persons with high socio-economic status who may disagree with supplemental immunisation.

Budgeting

A detailed budget clearly showing the operational and vaccine costs that is based on the micro plan should be prepared at the lowest level and summarised at district, provincial and national level.

Enhanced AFP Surveillance

District and provincial surveillance staff should immediately intensify active surveillance by visiting all health facilities in the sub-district where the case was reported and the AFP reporting sites within that district to conduct retrospective record reviews and active searches for unreported AFP cases. This exercise should be extended to cover adjoining districts to ensure a thorough search for possibly missed cases.

The frequency of reporting from surveillance sites to districts and from districts to provinces should be increased and maintained until the outbreak is over. Districts surrounding the area where the case was reported should communicate and report daily to the provincial surveillance officer on surveillance findings.

Documentation of the interruption of transmission of wild poliovirus

Detailed and comprehensive documentation is required to describe the epidemiological background, findings of case investigation and surveys including laboratory results, description of immunisation response and results of enhanced surveillance. The report

should be completed in close collaboration of national and international experts involved. In the event of an importation of wild poliovirus, a separate report providing full documentation should be prepared in collaboration with the national and international experts.

3.7 Vaccine Derived Polioviruses (VDPVs)

VDPVs are vaccine viruses related to Oral Polio Vaccine (OPV) that have re-acquired the transmission characteristics of wild polioviruses and thus can cause paralytic poliomyelitis. VDPVs differ from the majority of Sabin vaccine-related poliovirus isolates by having genetic properties (operationally defined as >1% nucleotide divergence from the corresponding OPV strain in the major surface protein, VP1) consistent with prolonged replication or transmission. Some exhibit genetic recombination with other enteroviruses.

The favourable conditions for VDPV circulation are poor hygiene, poor sanitation and areas of low OPV immunisation coverage (both routine and SIAs). Polio outbreaks due to VDPV have been documented in Egypt, Haiti, the Dominican Republic, Philippines, Madagascar and Nigeria in the last decade and recently in Malawi, Madagascar and Mozambique. The Global Polio Eradication Initiative (GPEI) currently divides VDPVs into 3 categories:

1. Circulating VDPVs (cVDPVs): emerge in areas with inadequate OPV coverage where there are enough susceptible children for the excreted vaccine-derived polioviruses to begin circulating in the community. These viruses are called circulating vaccine-derived polioviruses (cVDPV). Due to low population immunity, these viruses survive longer which increases their chance of replication and exchange of genetic material with other enteroviruses, which will eventually lead to change in their characteristics.
2. Primary immunodeficiency associated VDPVs (iVDPVs): occur in a small number of people with rare immune deficiency disorders. Because they are not able to mount an immune response, these people are not able to clear the intestinal vaccine virus infection. Therefore, they excrete immunodeficiency-related vaccine-derived polioviruses (iVDPVs) for prolonged periods. The occurrence of iVDPVs is very rare. Only 42 cases have been documented worldwide.
3. Ambiguous VDPVs (aVDPVs): occur in situations with insufficient clinical, epidemiological and virological data for definitive assignment. They are usually isolated from sewage. Very little is known about them.

It is recommended to conduct mop-up campaigns in response to cVDPV cases. If there is no clustering, the EPI team should assess the immunisation coverage in the area. If there is a gap in immunity, supplementary immunisation campaigns should be conducted to reduce the risk of circulation of the cVDPV.

Vaccine Associated Paralytic Polio (VAPP)

This is a paralytic disease that occurs in a vaccine recipient or close contact. It is **a very r**are event that occurs as 1 case of VAPP in 3-5 million OPV doses or more doses given. VAPP only affects the recipient or the close contact and is not associated with any risk of circulation in a community.

4. MEASLES

4.1 Disease Background: Virus Transmission and Clinical Aspects

Virus and transmission

Measles is an acute illness caused by the measles virus of the genus *Morbillivirus*, a member of the paramyxovirus family. The measles virus is an enveloped, single-stranded RNA virus that has globally retained its monotypic antigenic structure for decades. The genome encodes 8 proteins, including the haemagglutinin (H) against which life-long neutralising antibodies develop following infection. Sequencing of the measles virus genome has so far identified 23 different genotypes that can be used to track transmission.

Measles is a highly infectious disease. In the absence of immunisation programmes, it affects nearly every person in a given population by adolescence. Measles occurs only in humans and the virus is transmitted by aerosolised respiratory droplets and by direct contact.

Clinical Aspects

Measles is most infectious during the prodrome, i.e. before the rash appears. Initially, there is localised infection of the respiratory epithelium of the nasopharynx and possibly the conjunctivae, with spread to regional lymph nodes. Primary viraemia (virus circulation in the blood) occurs 2 to 3 days following exposure, and an intense secondary viraemia occurs 3 to 4 days later. The secondary viraemia leads to infection of and further replication in the skin, conjunctivae, respiratory tract and distant organs. The amount of virus in blood and infected tissues peaks 11 to 14 days after exposure and then falls off rapidly over 2 to 3 days.

Prodrome and General Symptoms:

A measles prodrome starts around the end of the incubation period (10-14 days), and presents over 2-3 days with fever, malaise, cough, runny nose (coryza) and conjunctivitis. Although there is no rash at this period, the patient is highly contagious. A harsh, non-productive cough, which starts during the prodrome persists throughout the febrile period, for 1 to 2 weeks in uncomplicated cases, and is often the last symptom to disappear. Generalised lymphadenopathy commonly occurs in young children. Older children usually complain of photophobia and, occasionally of arthralgia.

Koplik’s spots:

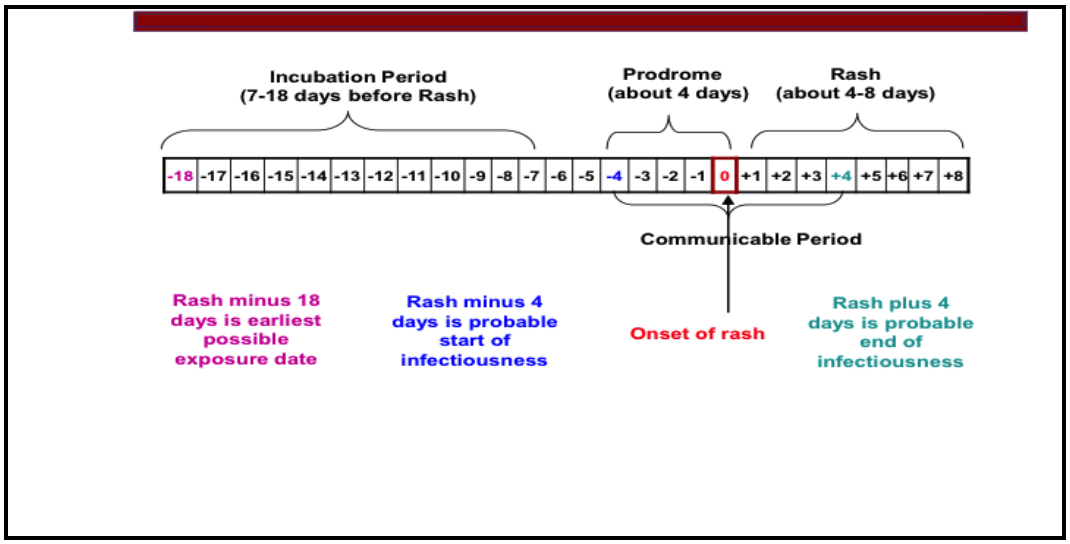
Koplik's spots may be seen on the inside of the cheeks (buccal mucosa) in over 80 percent of cases, if careful daily examinations are performed shortly before rash onset. The spots,

however, may be confused with other lesions. Koplik spots are slightly raised white dots of 2 to 3 mm in diameter on an erythematous base. They have been described as resembling “grains of salt sprinkled on a red background". The lesions persist for only 1 to 3 days, and disappear soon after rash onset.

Rash:

The appearance of a measles rash starts 2 to 4 days after the prodrome symptoms. It is a characteristic rash made up of large blotchy red areas that usually appears first behind the ears and on the face. At the same time, a high fever occurs. In dark skinned children, the rash may not be easily evident, particularly in the early stages. The rash peaks in 2 to 3 days, and becomes most concentrated on the trunk and upper extremities. The rash lasts 3 to 7 days and may be followed by a brawny or fine desquamation. Some children develop severe exfoliation, especially if they are malnourished or have vitamin deficiencies.

Figure 4.1 Illustration of the clinical course of measles

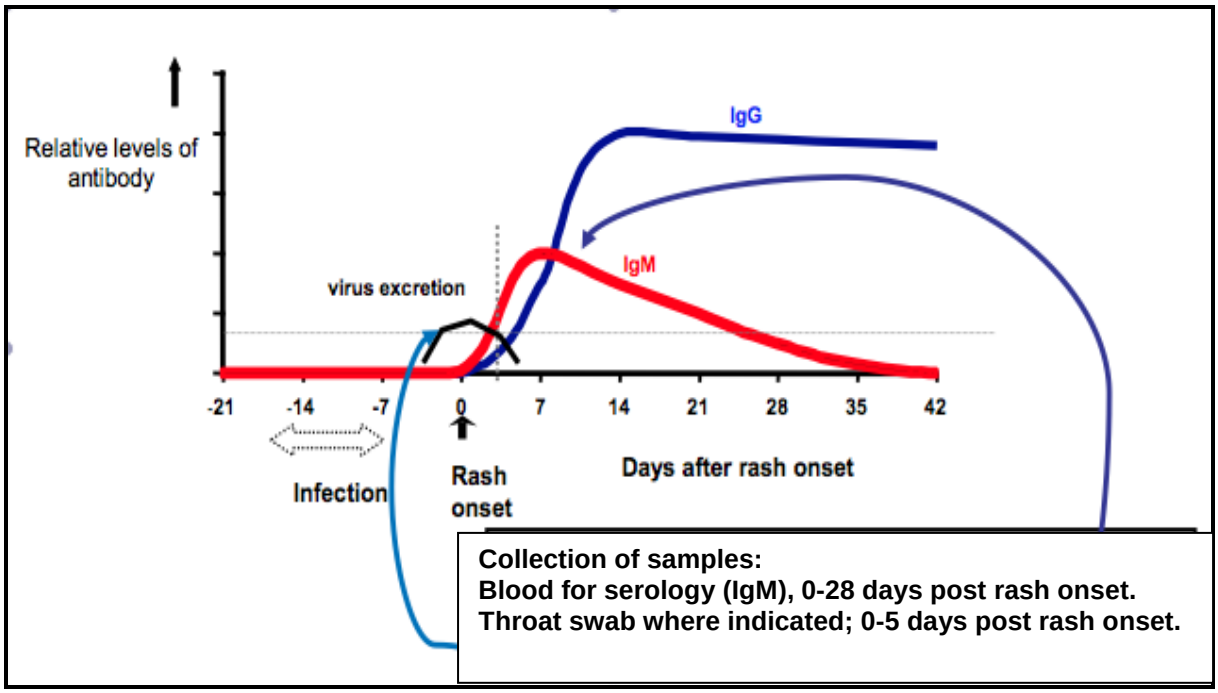


Measles virus infection and antibody response

Similar to other infections, the first antibody to respond to measles infection is IgM. IgM rises rapidly soon after infection and is detectable within a day or two after the onset of rash, but then wanes and is no longer detectable after 30 days. IgG antibody, on the other hand, responds more slowly, it is detectable 4 days after rash onset, but remains positive for life.

Therefore, IgM antibody is used to indicate acute infection, or a simulated infection from vaccination, which mimics natural infection.

Figure 4.2 Human antibody response to measles infection or vaccination



Specimen collection should take the physiological events illustrated in this figure into consideration. Many patients present to a health facility 1 - 2 days after the appearance of the rash. At this time, the majority of these cases will have detectable IgM levels and virus excretion. Therefore, laboratory results from blood and throat swabs will correctly reflect the infection if these specimens are collected at the time when it will most likely indicate the infection and transported appropriately (*refer to specimen collection below*).

Differential Diagnosis:

Development of a rash accompanies many febrile illnesses and a variety of non-specific symptoms as listed in the box below.

Common	Less common
Rubella	Toxic Shock Syndrome
Roseola	Meningococcal septicaemia
Enterovirus infection	Dengue fever
Rickettsial diseases	Scarlet fever
Drug hypersensitivity reactions	Kawasaki's disease
Adenovirus infections	

Complications and permanent sequelae

The severity of measles depends on several factors like age, living in overcrowded conditions, malnutrition (especially with Vitamin A deficiency), and immunological disorders such as advanced HIV infection. In developing countries, case-fatality rates among young children may reach 3-5%, but could be as high as 10% during epidemics.

Complications from measles include otitis media, pneumonia, diarrhoea, blindness and encephalitis. It is estimated that otitis media or pneumonia occurs in 10 to 30% of infants and young children with measles.

Diarrhoeal Diseases: A large number of infants and children in developing countries develop diarrhoeal illness both during and following acute measles illness. Dehydration and the concomitant loss of Vitamin A may have disastrous consequences, raising the probability of dying from measles in these infants.

Respiratory infections: Respiratory infections are the most common cause of significant morbidity and mortality in infants and children with measles. Pneumonia may be due to the measles virus alone or to secondary infection with other viral agents, especially herpes simplex and adenoviruses or bacterial infection.

Malnourished Children: Measles infection is more severe among malnourished children. Diarrhoea is one of the major factors contributing to the adverse impact of measles on the nutritional status. Measles may exacerbate malnutrition because of decreased food intake due to malaise, increased metabolic requirements in the presence of fever, or because parents and health practitioners inappropriately withhold a child's food during an acute illness. Under-nutrition may in turn lead to Vitamin A deficiency and keratitis; this may result in a high incidence of childhood blindness during measles outbreaks.

Neurological complications: These occur in 1 to 4 of every 1 000 infected children. The most common manifestation is febrile convulsions, which are not usually associated with persistent residual sequelae. Encephalitis or post infectious encephalopathy occurs in approximately 1 of every 1 000 infected children. Subacute sclerosing panencephalitis (SSPE) is a rare (incidence of approximately 1 / 100 000 measles cases) chronic degenerative neurological disorder associated with the persistence of the measles virus in the central nervous system. It may develop several years after a measles infection and is usually fatal within 7 years.

Mortality: Case fatality rates vary depending on the age of infection, intensity of exposure, other underlying conditions, nutritional status and availability of treatment. In developed countries, the case-fatality rate for measles tends to be low (between 0.1 and 1.0 per 1 000 cases). In developing countries, the overall case-fatality rate has been estimated at between 3 and 6%. The highest case-fatality rate occurs in infants 6 to 11 months of age.

4.2 Measles Epidemiology

Background:

Prior to the use of measles vaccine, measles infected over 90% of children by the age of 15 years, resulting in over 2 million deaths and 15 000 to 60 000 cases of associated blindness. Since 1989, when the World Health Assembly set a specific goal for measles control to reduce measles incidence by 90% from pre-immunisation levels by 1995; there has intensified efforts directed at the control of measles. In the year 2001, a Measles Initiative was launched to support technically and financially accelerated measles control initiatives.

In the year 2000, the World Health Organisation (WHO) estimated that globally 535 300 children died from measles, the majority from the developing world. Then measles accounted for 5% of all under-5 mortality.

Recognising that measles is a preventable condition (in the year 2000), the World Health Assembly adopted a resolution to halve measles deaths by 2005 compared with 1999. This goal was achieved. Measles deaths dropped from 535 300 in 2000 to 331 400 in 2004. A more ambitious goal was set by the Measles Initiative in 2006 to reduce measles deaths by 90% by 2010 compared to 2000 levels. Although this goal was not achieved, all World Health Organization regions at least achieved a 75% reduction of measles mortality and globally, measles deaths dropped to 139 300 in 2010.

Four strategies are recommended and implemented in WHO regions and countries for reducing mortality attributable to measles and achieving measles elimination:

- Provide every child with a dose of measles vaccine by 12 months of age;
- Give all children from nine months to 15 years of age a second opportunity for measles immunisation;
- Establish effective surveillance;
- Improve clinical management of complicated cases, including Vitamin A supplementation.

Using these strategies, significant progress was made. The African region has achieved 92% reduction in the number of measles deaths from 2000 to 2008. This was a result of increasing routine immunisation and providing a second opportunity of measles immunisation through Supplementary Immunisation Activities (SIAs).

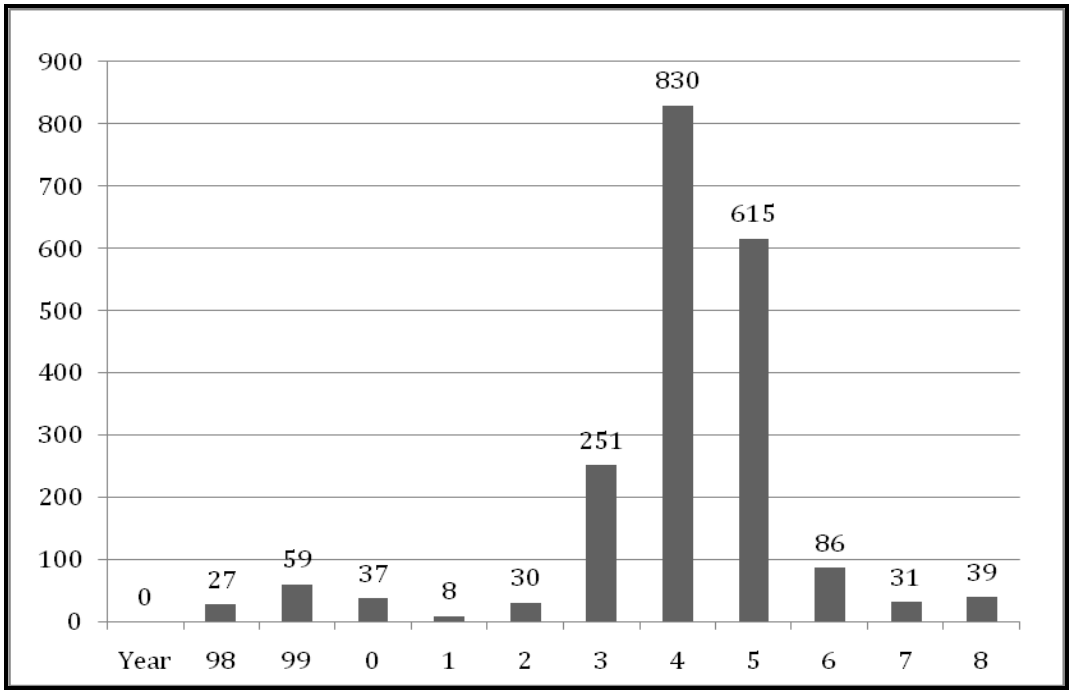
Disease Epidemiology in South Africa

South Africa adopted the measles elimination strategies that have been effective in the control of the disease. Before the introduction of measles elimination strategies, a seasonal pattern was observed; with a primary peak from September to November and a secondary peak in March and April each year. Measles control strategy in South Africa has achieved significant progress. From 1980 to 1997, measles cases ranged from 5 000 to over 20 000 cases a year, but from 1998 to 2002, a significant drop in number of measles cases was observed with a range of 8 to 59 cases. The first measles mass campaign was conducted in 1996 and measles case-based surveillance linked with rubella testing was introduced in 1998 soon after AFP surveillance.

Although the measles control strategies were effective and resulted in significant control of measles, as shown in the figure below, some significant challenges have been faced. There have been outbreaks, the most recent outbreak was in 2009 to 2010 and seriously threatened to undermine the achievements made in the control of measles affecting significant number of susceptible children.

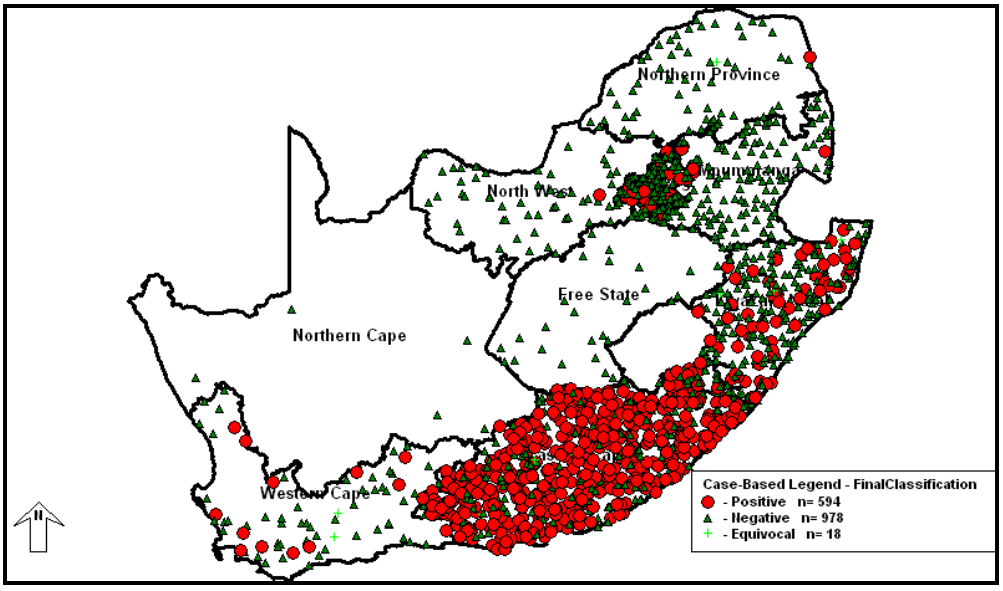
The figure below shows the number of confirmed measles cases from 1998 to 2008 (National DOH – Surveillance Data).

Figure 4.3 Confirmed Measles Cases in South Africa: 1998 - 2008



For the period 1998 to 2002, there was significant progress in the control of measles. In 2003 to 2005, a measles outbreak occurred. The spot map below shows the distribution of the cases in 2005.

Figure 4.4 Spot map of measles cases in 2005



In 2009 / 2010, another outbreak of measles was recorded in South Africa from March 2009. The outbreak spread and at the end of August 2009, a full-blown outbreak was noted in Gauteng. Other provinces were affected later: North West, Western Cape & KwaZulu Natal.

Eventually, by the end of 2010, all 9 provinces were affected. The figure below shows the distribution of cases by province and epidemiologic week (NICD data).

Figure 4.5: Measles IgM positive results by province: January 2009-22 January 2011

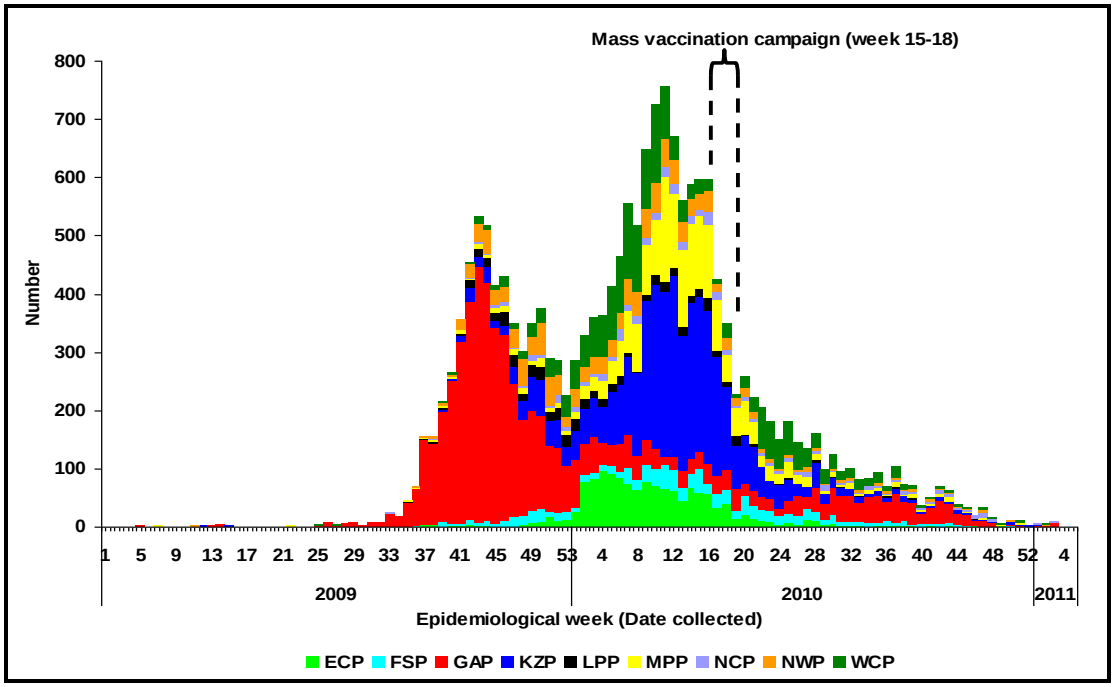
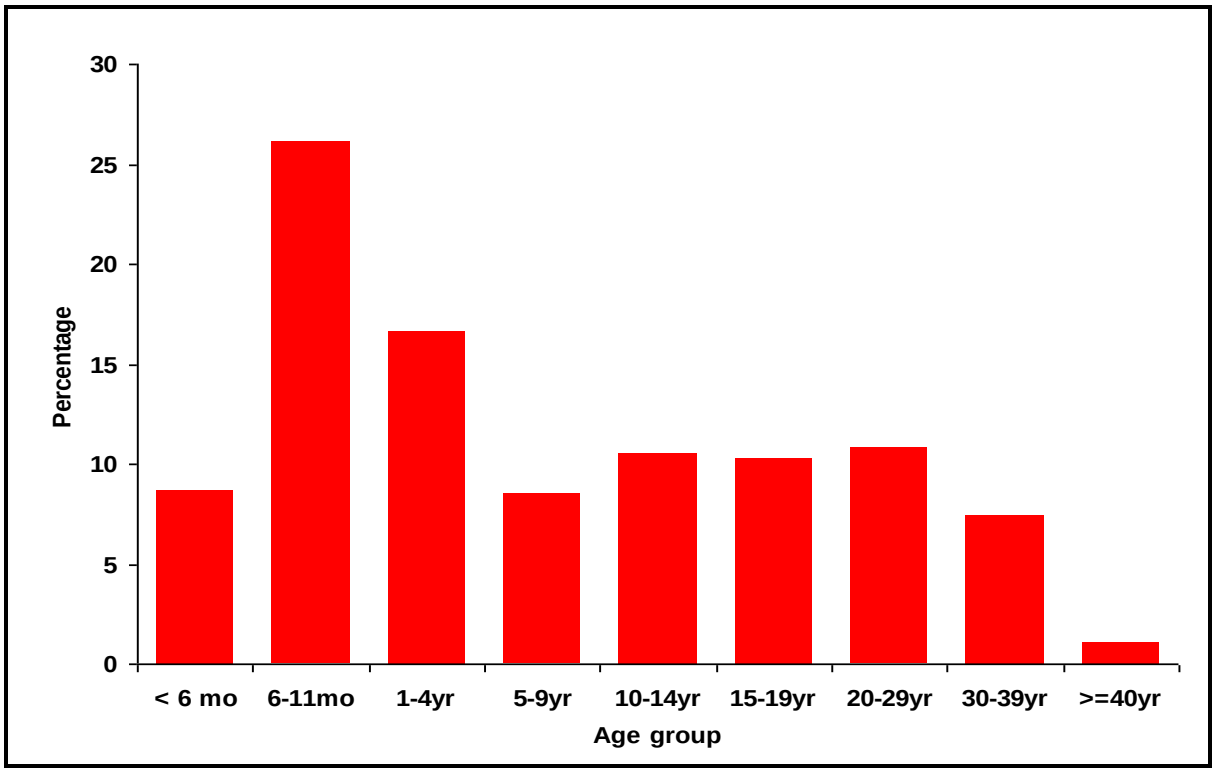


Table 4.1 Positive measles IgM results per province: South Africa, January 2009- 22 December 2010

Province		ECP	FSP	GAP	KZP	LPP	MPP	NCP	NWP	WCP	Total
Measles Cases (IgM positive)		1388	837	5723	4255	510	1974	437	1210	2001	18335

As shown in the figure below, a significant proportion of the cases (~ 35%) were under one year of age. However, it also shows that about half of the affected group was above the age of five years.

Figure 4.6: Age distribution of patients with measles (N=17,452): South Africa, January 2009- 22 December 2010



Measles elimination and control goals

There are continued intense efforts directed at measles control, which have now been expanded to include rubella control and associated congenital rubella syndrome. The current relevant documents are: Measles and Rubella Strategic Plan 2012 -2020 and the Measles Elimination by 2020 – A Strategy for the African Region.

The Global Measles and Rubella Strategic Plan 2012-2020 sets out the following key areas:

Vision:

Achieve and maintain a world without measles, rubella and congenital rubella syndrome (CRS).

Goals:

By end of 2015:

- Reduce global measles mortality by 95% compared to 2000 estimates;
- Achieve regional measles and rubella / CRS elimination goals;
- By end of 2020, achieve measles and rubella elimination in at least 5 WHO regions.

Milestones:

By 2015

- Reduce annual incidence to less than 5 cases per million and maintain that level;
- Achieve at least 90% coverage with the first routine dose of measles containing vaccine or measles / rubella (MR) containing vaccine as appropriate nationally and exceed 80% coverage in every district;
- Achieve 95% coverage with measles or MR during supplementary immunisation activities in every district;
- Establish a target date for global eradication of measles.

By 2020

- Sustain achievements of 2015 goals;
- Achieve at least 95% coverage with the first and second routine doses of measles containing vaccine in each district;
- Establish a target date for the global eradication of rubella and CRS.

These are significant goals with which South Africa aligns its plans.

The Measles Elimination by 2020 Strategy for the African Region, developed in 2011, has similar goals.

It sets out to achieve the following:

Aim:

The aim is to achieve the elimination of measles in all member states in the region by 2020.
Specific Objectives:

- To reduce measles incidence in all countries;
- To increase access to immunisation services;
- Improve coverage during all scheduled measles immunisation campaigns and campaigns in response to outbreaks;
- To improve the quality of measles surveillance as well as the epidemiological and virological investigation of measles outbreaks in all countries.

Targets:

By 2020, all countries in the Africa region will achieve and maintain:

- Measles incidence of less than 1 case per 1 million population at national level;
- At least 95% of measles immunisation coverage at national level and in all districts;

- At least 95% immunisation coverage in all scheduled immunisation campaigns and in response to outbreaks;
- At least 80% of districts investigating one or more measles case within a year and a non-measles febrile rash illness of at least 2 per 100 000 population at national level.

Prior to the development of this African Region Measles Strategy, the African Regional Measles Technical Advisory Group (TAG) had set a **pre-elimination** goal of:

- Reducing measles mortality by 98% by 2012 compared to 2000 estimates;
- Reducing measles incidence to less than 5 confirmed cases per million total population;
- >90% routine measles 1 coverage at national level and > 80% in all districts;
- >95% campaign (supplementary immunisation) coverage in all districts;
- Attaining the targets for main surveillance performance indicators.

The surveillance performance indicators and their targets are in box below.

Surveillance Performance Indicators

- Non-measles febrile rash illness rate of 2 cases / 100 000 total population per year;
- ≥ 1 suspected measles case investigated with blood specimen in at least 80% of districts per year;
- 80% of the suspected cases to be investigated with blood specimen.

South Africa aims to achieve these global and regional measles goals and follows the set global strategies.

Basic strategies for measles elimination

- Increase to >90% the coverage of first-dose measles vaccination provided through routine immunisation services;
- Provide a second opportunity for measles vaccination through campaign or routine strategies;
- Improve surveillance for measles disease (case-based surveillance);
- Monitor measles vaccine coverage (data management and epidemiological analysis);
- Improve case management, including Vitamin A supplementation and treatment of complications.

4.3 Measles Surveillance

Objectives

Objectives of measles surveillance are to:

- Identify high-risk populations to determine where the measles virus is circulating or may circulate;
- Predict when the next outbreak may occur because of a build-up of susceptible persons and embark on intervention measures;
- Assess the performance of the surveillance system (e.g. reaction time for notification, specimen collection) in the detection of virus circulation or potential importation;
- Using performance indicators, identify areas where it is necessary to strengthen surveillance.

Performance Indicators

The two key indicators for good quality measles surveillance are:

- Non-measles febrile rash illness rate of > 2 cases per 100,000 population per year;
- ≥1 suspected measles case investigated with blood specimens in at least 80% of districts per year.

Other important indicators to monitor the quality of measles surveillance include:

- Completeness of weekly reports on measles ≥ 80%;
- At least 80% of cases investigated within 3 days following notification;
- At least 80% of suspected measles cases investigated with blood specimens (exclude epidemiologically-linked cases from the denominator);
- At least 80% specimens arrived at lab within 3 days of being taken;
- At least 90% of specimens arriving at the laboratory in good condition; (i.e. adequate volume, no leakage, not turbid, not desiccated);
- At least 80% results sent out by the lab to the national level within 7 days of receipt of specimens at the lab.

Case Definition

The use of a sensitive case definition is recommended at every level to identify all probable cases and standardise reporting. The category of Suspected Measles Case (SMC) is a wide catchment that is intended to provide an early alert for health workers at the facility level that measles virus may be circulating in the area.

Suspected Measles Case (SMC) Any person with fever **and** maculopapular rash (i.e. non-vesicular) **and** (any one of the 3 Cs) cough, coryza (i.e. runny nose) or conjunctivitis (i.e. red eyes)' **OR** Any person in whom a clinician suspects measles infection.
Confirmed Measles Case (CMC) A suspected cases with laboratory confirmation (positive IgM antibody) or epidemiological link to confirmed cases in measles outbreak

All such cases should have a single blood specimen for laboratory confirmation of measles virus infection and should be reported immediately to district surveillance authorities. The notification of an SMC should result in the immediate careful investigation of the case, and should stimulate an active search for additional SMCs in the area.

Case Finding and Routine Reporting

Measles surveillance should be integrated with AFP surveillance. Each health facility should identify one individual and one or two others who are responsible for keeping track of suspected measles cases and immediately reporting all new suspected measles cases. Reports should be submitted to district surveillance coordinators by the fastest means possible (telephone, e-mail, fax, etc.,) and be followed up to ensure that the report was indeed received.

All health professionals who are likely to come in contact with or manage suspected measles cases should be provided with written material that describes their responsibilities and duties. Training and close ongoing supervision is important, as staff turnover may be a problem in many areas.

National and provincial staff should ensure at regular intervals that all relevant facility health workers are trained, this includes both clinic and hospital staff who are likely to come into contact with measles cases. Presentations and onsite training on surveillance should be made for doctors, nurses, health promotion officers, allied health personnel and record clerks. Posters and other visual materials that illustrate case definition, investigation and management of suspected and confirmed measles should be designed and used.

Key points to consider:

1. All suspected cases should be investigated by trained health workers, and an appropriate laboratory specimen should be obtained and tested promptly.

2. Each suspected case should be given a unique identification (EPID) number that should be used whenever referring to the case.
3. Regular reports should be made and forwarded to the next level each week, even when no suspected cases of measles have been identified (zero reporting).
4. Repeated visits by surveillance officers from different levels are required to establish and monitor the status at all levels of the reporting system.

In establishing a measles surveillance network, it is important to include the following:

Private Practitioners:

It is important that private medical and nursing practitioners as well as paediatricians are included in the surveillance system. In many areas, it is likely that they will be the first to see suspected cases. The success of the system requires good coordination, training, frequent contact and feedback.

Hospitals:

Case-finding through the emergency department and paediatric wards is critical to the success of a surveillance system. The infection control nurse or a deputy should be assigned at each hospital to check paediatric and infectious disease wards visually and review admission records for suspected measles cases. Reports may be submitted by telephone, e-mail, facsimile, courier service, etc.

Community sources:

In addition to all health facilities, a network of community reporters need to be organised to report suspected cases. These may include pharmacists, private practitioners, private clinics, community health workers, health promoters, village leaders, traditional health practitioners, schools and anyone else likely to come in contact with people who have such an illness.

Since the number of measles cases is now on the decrease, the purpose of measles surveillance is to detect and investigate all suspected measles cases on time and to implement activities that prevent or limit secondary transmission and outbreaks. To accomplish this, healthcare workers should investigate and report all suspected measles cases immediately. Suspected measles cases should be carefully investigated, including the collection of an adequate blood specimen for serologic analysis. Cases are then classified as being either discarded or confirmed after the laboratory result.

In addition to the rapid investigation and reporting of all suspected cases, the recording of vaccination history and history of travel is important as it allows tracking of importations and implementation of a rapid response.

Active surveillance should be conducted in all districts for the timely detection of cases. Active surveillance for measles must be conducted together with AFP surveillance. The system of active visits and reporting should follow that of AFP surveillance. District CDC coordinators should have regular contact with health workers, specifically infection control and operations managers in outpatient departments of high-priority sites (i.e. large hospitals) and conduct active surveillance visits to check records and registers. These activities are especially important in large cities and in cities that have large numbers of international visitors. Active surveillance also may be conducted during outbreaks, when a cluster of suspected cases is reported, and when poor routine surveillance is suspected.

Searching hospital and other records:

Hospital records, emergency department records should be reviewed to identify rash illnesses that may have been unreported cases of measles. This approach may be used to evaluate the sensitivity of the surveillance sensitivity and reporting efficiency.

Monitoring surveillance indicators:

Regular monitoring of surveillance indicators, including completeness of reporting and time intervals between diagnosis and reporting, may identify specific areas of the surveillance and reporting system that need improvement.

Case investigation

Steps in the investigation of a suspected measles case

All suspected cases of measles should be investigated using the case-based measles case investigation form (CIF). Once a case has been identified by a health worker using the case definition for a suspected measles case (SMC), the district EPI or CDC coordinator should be informed immediately by the quickest means possible (phone, SMS, fax or e-mail). The provincial EPI surveillance officer and EPI coordinator should also be informed that a case is under investigation.

At first contact with the suspected measles case, it should be confirmed that the case meets the case definition.

An Epid Number should then be assigned to each case. The Epid Number consists of the country code (SOA), a provincial code (e.g. GAP for Gauteng Province), the district (e.g. WRA for West Rand), the year (e.g. 12) and a sequential number (e.g. 002 for the second case in the district). The full Epid Number, using an example of a second suspected measles case in West Rand district, Gauteng in the year 2012 would read: SOA-GAP-WRA-12-002.

Annex **2.5 Standard Operating Procedure (SOP) on Acute Flaccid Paralysis (AFP) Data Management**

This SOP can be taken as direction to ensure reliability of AFP data. SOPs can be defined as minimum expected standards or detailed guidelines / guidance or basic standards required at any level to facilitate production of clean quality data for decision-making. Furthermore, if this SOP is used and followed strictly, it can ensure that the existing programme personnel are at same level.

Data Management Principle

The main principle of AFP surveillance data management systems is to ensure a better understanding of the epidemiology of AFP cases. Data management processes include identification of data needs, data receipt, data processing (cleaning and harmonisation, analysis, feedback on data quality-surveillance performance-disease epidemiology, and data achieving). Sound data demand that data should be complete, accurate and timely.

Principal uses of AFP data for decision-making

- Track wild and Vaccine Derived Poliovirus (VDPV) circulation in the country;
- Use data to classify cases as: confirmed, compatible or discarded;
- Monitor routine coverage, performance of surveillance in all geographical areas;
- Focus efforts in low performing geographical areas;
- Identify high-risk areas with a view to planning mop-up immunisation campaigns;
- Provide evidence to the Certification Commissions on the interruption of wild poliovirus circulation.

Data Work Flow

A data workflow system provides information on where data is, who handles the data, when is it due at a particular level, etc.

There are two sources of data flow for AFP; case-based data and laboratory-based data.

Harmonised case-based and laboratory-based data should be maintained at district, provincial and national levels. Data quality reflects the completeness and validity of the data

recorded in the public health surveillance system. The importance of clearly identifying the data flow system should be prioritised at all levels.

Roles and responsibilities in data work flow

The provincial surveillance officer will assume responsibility for the AFP line list. It is the duty of the provincial surveillance officer to ensure that an AFP line list is maintained for each district. The provincial surveillance officer must ensure continuity when he/she is not available.

A comprehensive AFP line list must be maintained at district, provincial and national level as well as at the National Institute for Communicable Diseases (NICD). AFP Case Investigation Forms (CIFs) must be maintained at district, provincial and national level as well as at the NICD.

Data Management Activities at Different Levels

Cased-based data

AFP surveillance data flow starts at the health facility after a case has been detected, a case investigation (CIF) and the neurological assessment forms are filled in. The subsequent stages are the sub-district/district, province and national levels. The specimens, together with a CIF and the neurological assessment form, should be taken to the nearby National Health Laboratory Services (NHLS) or directly by courier to the National Institute for Communicable Diseases (NICD).

Health Facility Level

- CIFs should be available at all health facilities;
- Fill in the CIF and the Neurological assessment form for each AFP case;
- Collect first stool specimen, store on ice and send to NICD with CIF as soon as possible
- Collect second stool specimen 24-48 hours after the first specimen and send to NICD on ice with a copy of the CIF.
- Both stools should be collected within 14 days of onset of paralysis. If patient presents later than 14 days but less than 60 days since onset of paralysis two stools must still be collected and sent to NICD on ice.
- If the patient is unable to pass stool, a rectal swab may be taken followed by stools as soon as possible. Rectal swab must be sent with CIF to NICD on ice.
- Inform district of case by e-mail or telephonically and send a copy of CIF to district level;
- File a copy of the CIF in an appropriate file.

District / Sub-district Level

Case-based data

- Acknowledge the receipt of CIF from health facilities;
- Check CIF and Neurological assessment form for completeness upon receipt;
- If CIF and Neurological assessment forms are not completely filled in, contact health facility;
- Record the case and update on a AFP line list prior to sharing with province;
- Assign Epid Number (Unique Number) to CIF and line list;
- Scan/ fax CIF after assigning Epid Number and send CIF to Province;
- File CIFs and Neurological assessment forms according to sub-districts (hard copy or electronic or both);

Lab-based data

- Receive laboratory-based data from NICD weekly on Wednesday;
- Update the district line list with polio isolation results received from NICD;
- Update district line list with any additional cases from NICD not appearing on the district line list (this harmonizes case-based and laboratory-based data);
- Ensure that every case has an assigned Epid Number
- Ensure that each case has a completed CIF
- Send updated line list and completed/updated CIFs to province weekly on Thursday. Conduct 60 day follow-up on inadequately investigated AFP cases (less than two stool specimens, within 14 days of onset, 24-48 hours apart, on ice). Update outcome on CIF and line list (residual paralysis, no residual paralysis, lost to follow-up, death). Send updated information to province and national levels.

Province Level

Acknowledge receipt of weekly line list from districts on Thursday

Case-based data

- Acknowledge the receipt of CIF from districts;
- Check the CIFs for completeness upon receipt;
- If CIFs incompletely filled in, contact district to fill gaps;
- Send copies of all CIFs to national;
- If Epid Number is not assigned at district level, province should assign it and share with the district and NICD;
- Update provincial AFP line list;
- Organise and file CIFs by year and district (hard copy or electronic or both);

- Back up data regularly to prevent unexpected loss;
- Send updated line list weekly to national and NICD on Monday;
- Send weekly summary form for Vaccine-Preventable Diseases (VPD) surveillance to national on Monday.

Laboratory-based data

- Acknowledge receipt of laboratory-based data from NICD weekly on Wednesday;
- Update the provincial line list with AFP results received from NICD
- Update provincial line list with any additional cases from NICD not appearing on the provincial line list (this harmonizes case-based and laboratory-based data);
- Acknowledge receipt of updated district line list weekly on Thursday and update provincial line list
- Ensure that every case has an assigned Epid Number;
- Ensure that each case has a completed CIF;
- Send copies of CIFs of AFP cases to national and NICD
  Send updated line list to NDoH and NICD weekly on Monday.
  Ensure that there has been a 60 day follow up for all inadequately investigated cases (less than two stool specimens, within 14 days of onset, 24-48 hours apart, on ice)

National Level

Case-based data

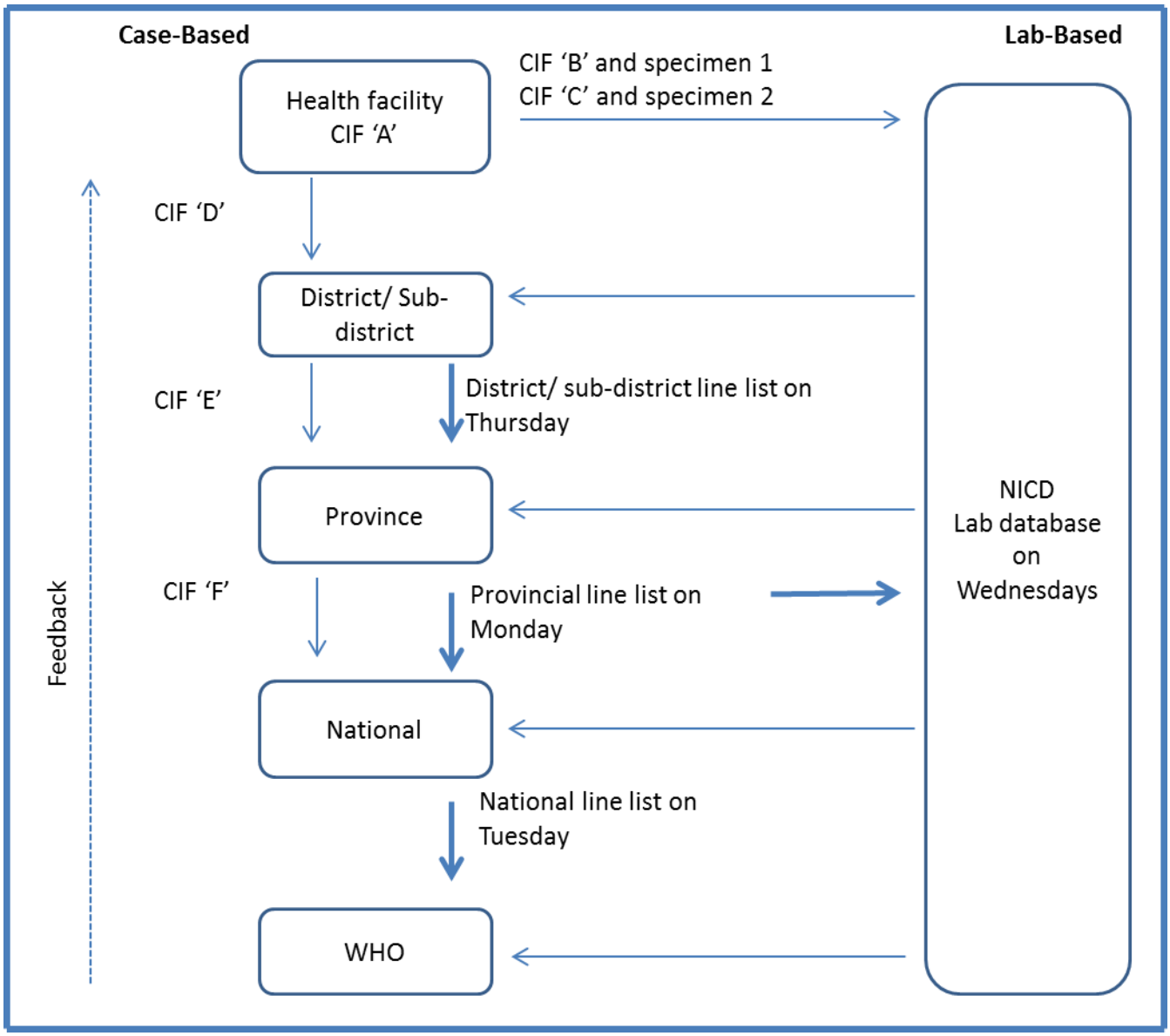
- Acknowledge receipt of weekly provincial line lists on Monday;
- Ensure that all AFP cases have CIFs;
- File CIFs of AFP cases (e.g. file by year, province and district);
- Clean, verify the quality of data and analyse;
- Feedback to provinces monthly ;

Laboratory-based data

- Receive AFP lab database from NICD weekly on Wednesday;
- Harmonise national case-based and lab-based database;
- Provide feedback to NICD and province if there are any discrepancies between the two databases;
- Pre-classify all adequately investigated cases with two negative stool specimen results. Refer list of cases to National Polio Expert Committee (NPEC) for verification
- Refer inadequately investigated cases to NPEC for final classification

- Share the data with WHO-Country office and the WHO-Inter-country Support Team (IST) weekly on Tuesday.
- Get feedback from IST, correct the database accordingly and resend updated database to IST;
- Analyse all performance indicators by district, province and national level and provide feedback via monthly AFP bulletin;

Acute Flaccid Paralysis Data Flow Diagram



* All line lists comprise harmonised lab-based and case-based data

* CIFs B, C, D, E and F represent updated copies of CIF A for the same patient

Checklists for Case-based AFP Data Cleaning /Verification

Verify data whether it is complete and clean:

- Have and check province and district code of currently used;
- Check the date formats;
- Age, sex;
- Check the following dates:
  - Date of onset;
  - Date of specimen collection (1st and 2nd specimen);
  - Date specimen sent to the lab;
  - Date specimen received at lab;
  - Date result sent to national level.
- Epid Number (e.g. CCC-PPP-DDD-YY-000);
- Names of districts (Sometimes the same district is spelt differently. Make sure that district names are spelt the same way at all levels);
- Specimen condition;
- Final cell culture result;
- Final case classification;
- Vaccination status (or number of vaccine doses);
- Outcome;
- Cases with at least one stool collected, but missing Lab result;
- Check for logical flow of date variables, e.g. date of onset should come before dates of collection. This can be evidenced when you get negative answers in analysis;
- Ensure that all cases positive for virus are classified as “1” under final classification;
- Cases missing final classification 90 days after ONSET;
- Check that cases in the current year database match the year entered EPID and Date of Onset, e.g. CCC-PPP-DDD-08-001 and dd/mm/2008.

Data Harmonisation

Please refer to data harmonisation SOP

Annex 3.1 for measles should be used to collect all data in a systematic way. Fill in all required fields legibly. At first contact, all information in the first section needs to be collected and noted on the form. The following fields contain critical information, and should be included in every case:

- All demographic data;
- Date of onset of rash;
- Date of last vaccination;
- Date on which the laboratory specimens were taken.

All suspected measles cases should have a case investigation form (CIF) that confirms the case meets the case definition (rash plus fever with any of the 3 Cs). NICD will not test specimen of cases that do not have CIFs and or do not meet the case definition.
Please Note! Laboratory request slips are not acceptable and do not replace a CIF.

Blood sample should be obtained. This may be collected by venepuncture in regular glass tubes (without any additives) red top. The sample should be sent with the case investigation form (CIF) to the NICD, clearly marked with Epid Number, if it is already allocated.

The District CDC coordinator should enquire and investigate to find out if there are other cases in the area, and if more than 5 cases are found, the instructions on the outbreak investigation should be followed. The District CDC coordinator should also inform other health workers in the vicinity as well as the coordinators in adjacent districts of a suspected measles case or a suspected outbreak, so that they can be on the lookout for additional cases.

Specimen Collection

Blood specimen should always be collected for investigation of all suspected measles cases (SMC).

The collection of throat swabs will be guided by the provincial and district office in collaboration with the national EPI office and NICD. Health workers at health facilities will be guided by the district CDC/EPI coordinator on when to collect the throat swabs. District CDC/ EPI coordinators will provide the viral transport medium (VTM) used for throat swabs and will inform facilities and provide them with VTM when there has been a confirmed case of measles in the area so that all facilities in that area can collect throat swabs.

Throat swabs using the specific viral transport medium (VTM) will only be collected under specific situations in consultation with NICD. The VTM will be supplied by NICD to the district CDC/EPI coordinator, in consultation with the provincial office.

The procedure for collecting a blood specimen for lab confirmation:

Draw 5ml of venous blood into a red top tube labelled with the patient identification (name, age, Epid Number) and the date of the specimen collection. Send the specimen immediately to the local laboratory to be kept under cold chain conditions until it is shipped to NICD.

Facilities that provide direct transportation of specimen to NICD should keep the specimen in a fridge. When ready for transportation, put the specimen with a case investigation form (CIF) wrapped in a protective plastic bag in a cooler box with ice. Ship this through the special courier to NICD. The Epid Number is used as a reference for the courier (Skynet).

Laboratory personnel should do the same; they should keep specimens under cold chain and ship under cold chain to NICD with a CIF. They should ensure that the correct procedures for transport of specimens are followed and ensure that the CIF accompanies the specimen.

Specimen collection for viral isolation

Throat or nasopharyngeal swabs should be collected for isolating a measles virus, to identify the genetic strain of the virus.

The viral isolation from a throat swab will help in tracing the origin of that particular strain of measles virus, which is important information in an outbreak situation. It is no longer

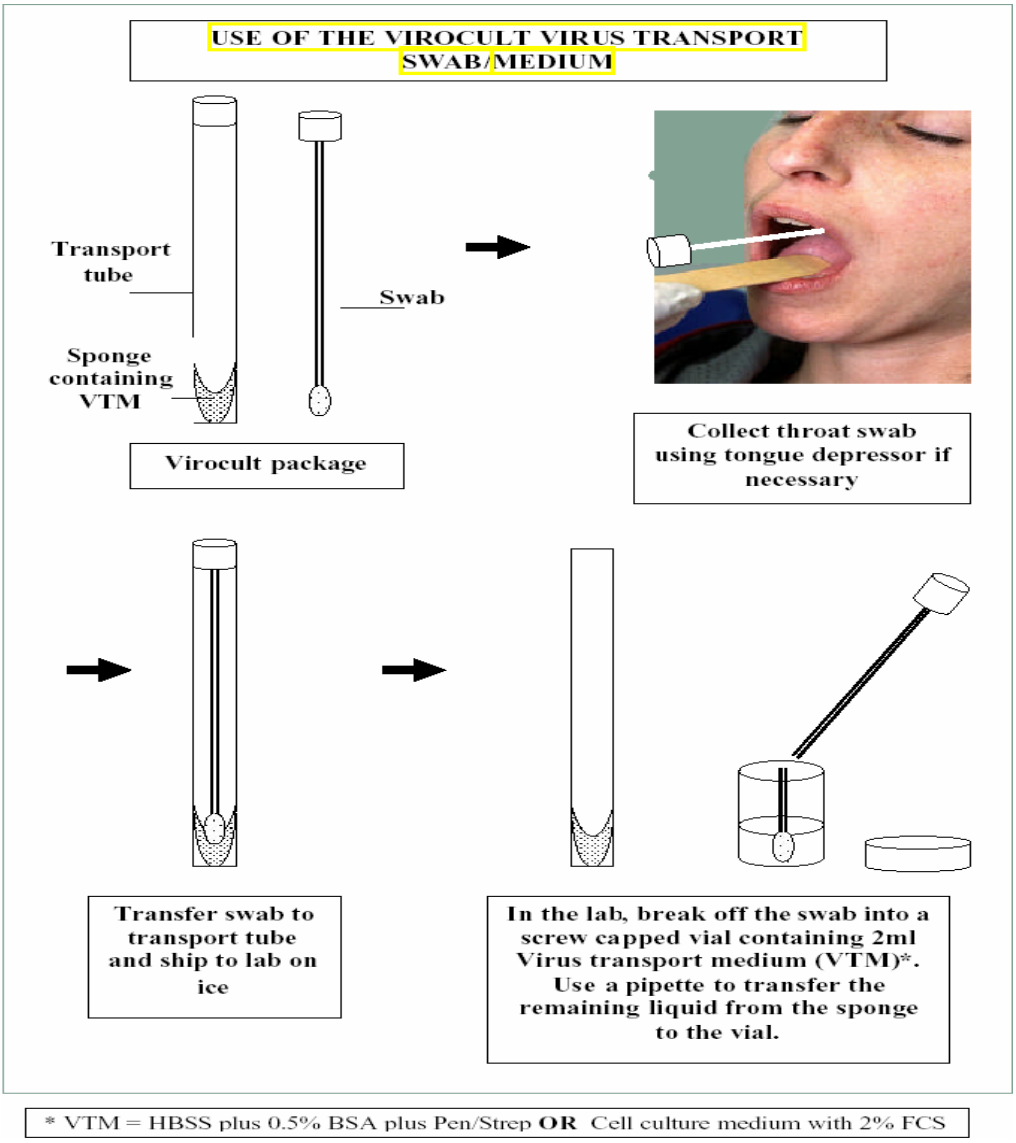
appropriate to collect urine specimen for this purpose. Facilities will be informed as to when throat swabs should be collected and will be supplied with viral transport medium (VTM).

Throat swabs are best collected during the first few days of rash and should be shipped with the serum to the NICD. The virus is more likely to be isolated within 5 days of rash onset, thus specimen collection should not be delayed for more than 7 days after the onset of rash.

Throat Swab Collection

- The patient is asked to open the mouth and say “ah”;
- The tongue should be depressed with a spatula and a nasopharyngeal swab is obtained by firmly rubbing the nasopharyngeal passage and throat with the provided sterile cotton swab to dislodge epithelial cells;
- The swab is then packed in a labelled viral transport tube, ensuring that the swab is immersed in the sponge containing the viral transport medium;
- The swab in the viral transport medium is transported to the NICD laboratory at 4-8^{o}C using frozen ice packs in an appropriate shipping container. See Figure 4.7 below.

Figure 4.7: Throat Swab Collection



Should there be more than 5 cases in a district, District CDC coordinators should communicate with the provincial office and NICD to enquire on the need to collect throat swabs and make necessary arrangements for the supply of VTM to health facilities.

Laboratory Results

Since both measles vaccine and natural measles infection can stimulate an IgM response in the host, a surveillance dilemma occurs when a suspected measles case has a history of measles vaccination within 30 days of rash onset. Measles vaccine can cause fever and rash in about 10% of vaccinees and most are expected to have detectable IgM after vaccination. Moreover, other medical conditions such as rubella, dengue, etc. may cause fever and rash illnesses in persons who have recently received measles vaccine.

Therefore, a suspected measles case with a positive IgM result within 30 days after vaccination is considered to be vaccine-associated measles and is not due to wild measles virus infection.

Serum found to be negative for measles IgM (i.e. no current active measles disease or vaccination) will be tested for rubella, as the public health implications of a proven case of rubella are important.

Data management and a line list

All levels from facility, sub-district, direct, province and national should keep accurate records of all cases that have been detected. This information is mainly kept in a line list. Every district should ensure that they have a Measles Case Line List (*Annex 3.2*) of all measles cases in the district, which should be updated with the information of new cases as they arise.

Line listing should be filled out with particular attention to obtaining basic demographic data, including the age and vaccine history of the patient(s). A line list should be comprehensive and for each case, each line should include: the demographic details; full information about the illness indicating the case definition of fever, rash, and any of the 3 Cs, date of rash onset; vaccination status; date of specimen collection, date results received; IgM results and final classification.

Data collected on measles cases should follow the same procedures of AFP data flow. Standard operating procedure on measles data collection and reporting is attached (*Annex 3.3 Standard* Operating Procedure (SOP) on Measles Data Management).

Final Classification

The final case classification is made by the provincial and national EPI coordinators when the results from the laboratory investigation have been received. By this time, the case investigation form should be complete and all missing information added. Feedback to the district coordinator and to the facility and the health workers who detected the case is the responsibility of the provincial EPI coordinator.

The following WHO-AFRO recommendation is used to classify cases.

Confirmed Measles:

Laboratory confirmed: A suspected measles case that − after investigation − has serological confirmation of recent measles virus infection, is measles IgM positive and had not received measles vaccination in the 45 days preceding the specimen collection.

A confirmed measles case should be treated as a measles outbreak and thus it demands a full epidemiological investigation. The District CDC coordinator should take up this responsibility.

Confirmed by Epidemiological linkage: A suspected measles case that has not had a specimen taken for serologic confirmation and is linked (in place, person and time) to a laboratory confirmed case/s. Such a case may be living in the same or in an adjacent village or neighbourhood with a lab-confirmed case where there is a likelihood of transmission; onset of rash of the two cases being within 30 days of each other. *(NB: Confirmation by epidemiological linkage should only be done in the context of confirmed measles outbreaks.)*

Discarded/ Not Measles: A suspected measles case that has been completely investigated, including the collection of adequate blood specimen, and lacks serologic evidence of recent measles virus infection (IgM negative) or is considered to have IgM positivity due to measles vaccination within the 45 days preceding the collection of a specimen.

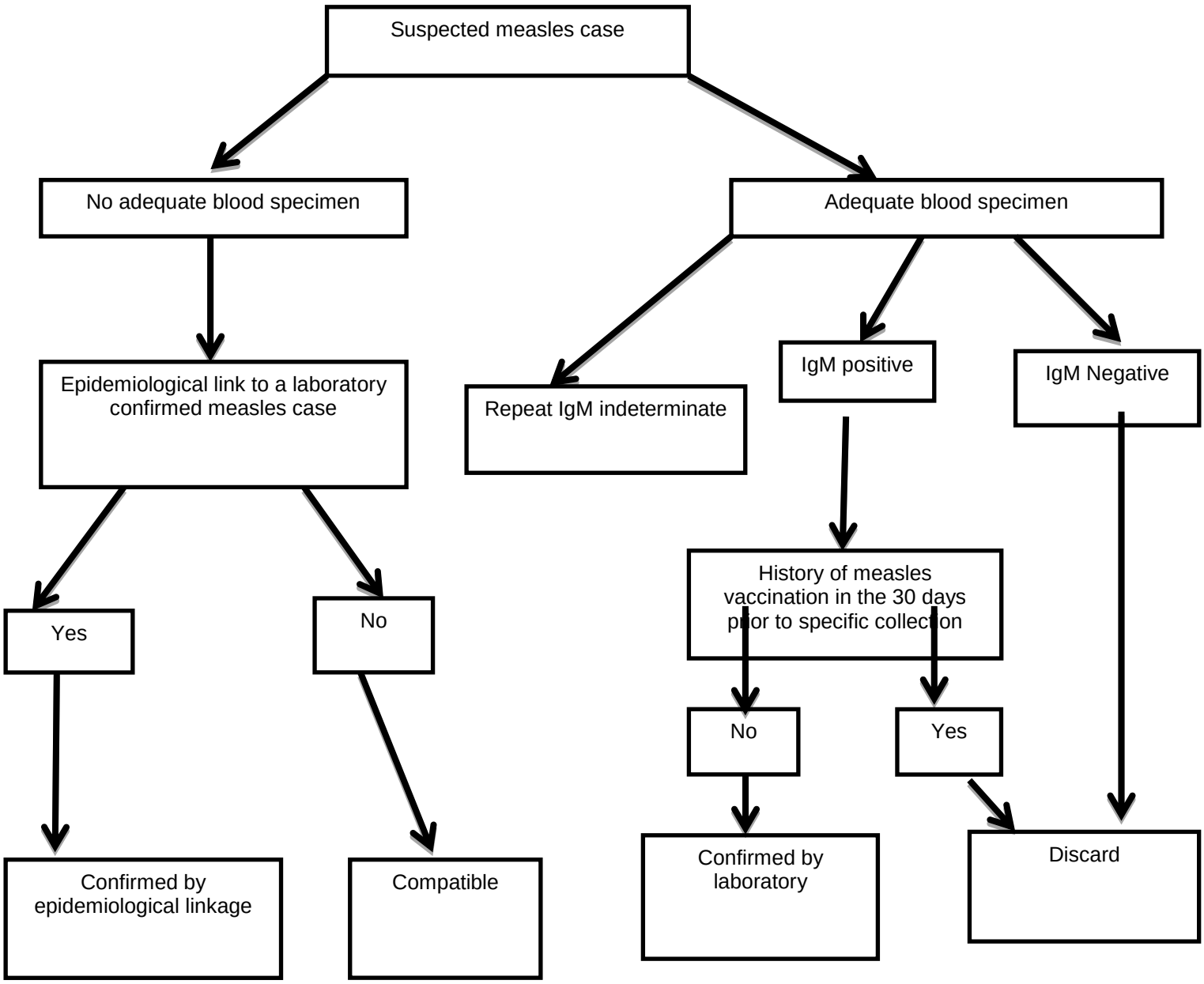
Compatible Measles: A suspected measles case that has not had a blood specimen taken for serologic confirmation and is not linked epidemiologically to any lab confirmed measles case or outbreak of measles.

Possible reasons include:

- Death of the patient before an investigation is complete;
- Patient cannot be located or is lost to follow up;
- Patient receives only a clinical diagnosis from a healthcare worker without laboratory investigation.

Suspected measles cases that have no definite proof of recent infection (measles IgM test indeterminate repeatedly and negative for rubella testing) may also be classified as compatible. All measles IgM negative and indeterminate sera undergo rubella IgM testing and the results are appropriately documented in the database.

Figure 4.8: Classification of suspected Measles Cases



4.4 Measles Outbreak Investigation and Response

Suspected cases of measles should be investigated immediately and the surveillance intensified to detect and respond to a potential outbreak as early as possible. Early detection and appropriate response to reduce morbidity and mortality by providing appropriate case management are essential and vaccinating children who are likely to be exposed to the measles virus. If a potential outbreak is imminent, c*ontrol activities should not be delayed pending the return of laboratory results on suspected or probable cases.*

A *suspected outbreak of measles* is defined as the occurrence of five or more reported suspected cases of measles in one month per 100 000 population living in a specific geographical area (e.g. district/sub-district).

A *confirmed measles outbreak, according to WHO AFRO* is defined as the occurrence of three or more confirmed measles cases (at least two of which should be laboratory-confirmed; IgM positive) in a health facility / district / sub-district (approximate catchment population of 100 000) in a month. However, in South Africa, we treat any confirmed measles case as an outbreak or potential outbreak.

When a suspected measles outbreak occurs in a defined geographic area, the district should rapidly organise outbreak investigation and a report to an Outbreak Response Committee and ensure that the following steps are taken:

Confirm the outbreak

A**ll suspected measles outbreaks should be confirmed through laboratory results of the affected cases.** Blood sample from suspected cases within an affected geographical area should be sent for laboratory confirmation. If there is suspicion that the outbreak has spread to an adjacent area, blood specimens should also be collected from suspected cases in these areas. Once there are two or more IgM positive cases in a facility or sub-district, a measles outbreak is laboratory-confirmed.

In the case of confirmed measles outbreaks, the national, province and district EPI and or epidemiological surveillance units should proactively look at the surveillance data on a regular basis, ensure completeness and full capture of case-based laboratory and line-listed information, and classify epidemiologically-linked measles cases. The analysis and interpretation of the surveillance data relies on accurate and timely classification of cases.

Enhancing surveillance and detection / notification of cases

In order to find additional suspected measles cases, the public should be kept well informed and community leaders should be asked to assist in finding other cases that might be missed. Enhancing surveillance should include conducting epidemiological investigation, which includes the following activities:

- Visiting housing blocks adjacent to the affected households;
- Sending notices to healthcare providers, asking if they have seen or heard of persons with fever and rash illnesses;
- Conducting visits and record reviews in hospitals and clinics in the sub-district and adjacent sub-districts and active case searches at health facilities and at community level (in surrounding villages) to determine the extent of the outbreak;
- Health staff in the affected areas should use every contact with patients as an opportunity to inquire about rash and fever illnesses in the neighbourhood. Efforts to identify additional cases should extend well beyond the specific community in which the suspected case resides;
- Enquiries should also be made to determine whether cases are occurring in places that the case visited within four weeks prior to the onset of the rash, such as a pre-school centres, schools, or another town or village.

The district surveillance team should:

- Create a line list of all cases to record the age, vaccination status, address, date of rash onset, outcome, Epid Number;
- Analyse and interpret surveillance data (date of onset of rash, vaccination status, age, geographic location) to determine the extent of the outbreak and the reason: whether the outbreak was a result of failure to vaccinate or vaccine failure;
- Monitor the evolution of the outbreak by keeping track of the number of cases and dates of onset of rash of reported cases using an epidemic curve;
- Complete and send to the provincial and national level an outbreak investigation report (within 2 weeks of the investigation) summarising the findings, the extent of outbreak, geographic distribution with a spot map, the timelines and epidemic curve, the response, evaluation and feedback processes;
- Complete and send the person analysis, spot map and “epidemic curve” to the provincial and national level within 2 weeks.

Ensuring Adequate Clinical Management of Cases

- Vitamin A is administered to all children with acute measles;
  - One dose (50 000 IU for infants aged under six months, 100 000 IU for infants aged 6-11 months, and 200 000 IU for children aged ≥ 12 months) should be administered on the day of measles diagnosis;
  - and a repeat dose should be administered after 24 hours;
- Supportive treatment should be provided for all cases, including additional fluids (such as oral rehydration solution) and antipyretics;
- Antibiotics should be used for cases complicated by otitis media or pneumonia;
- Nutritional therapy is indicated for children with malnutrition.

Assessing the risk of a larger outbreak, morbidity and mortality

The risk of the outbreak getting bigger and the risk of mortality should be assessed, to be on the guard. The following contributing factors should be checked:

- Immunisation coverage;
- Population characteristics such as size, density, movement, and setting;
- Under-5 mortality rates;
- Nutritional and Vitamin A status;
- HIV prevalence;
- Period of the year: seasonal outbreaks or holidays, festivals and social events that would increase opportunities for spread;
- Cases reported and comparison with previous years;
- Access to health services.

Implementing Control and Preventive Measures

Limit spread by appropriate management of cases and contacts:

- At home, a case should be limited to contact with immediate family members until 5 days after the rash appears. Communicability greatly decreases after the second day of rash. In hospitals, cases should be isolated from the onset of symptoms up to the 5th day of rash;
- All children below 5 years of age (can be up to 15 years) who are hospitalised or attending outpatient clinics, who cannot provide written proof of measles vaccination, should be vaccinated;
- All contacts should be isolated from the case for a period of 14 days from the time the rash appeared on the case, irrespective of whether or not they have been immunised. A

contact is a person living in a household or other close quarters / dwelling with the case during the infectious period (five days before to five days after the onset of the rash).

- During the second week after exposure, at the first sign of possible measles (fever, runny nose, cough, or eyes bothered by light), a contact with these symptoms should stay at home. The child or person, with these symptoms should not attend school, preschool, work, church, clubs, meetings, parties, baby-sitting groups, etc. If the illness is measles, it will become apparent in one or two days by the severity of the illness and the presence of a rash. Parents should be advised to seek healthcare immediately;
- Contacts who were susceptible at the time of a visit should be vaccinated and stay at home and avoid contact with other children until two full weeks after exposure.

Appropriate vaccination activities:

Assessment of the vaccination coverage: Efforts should be made to establish vaccination coverage for the affected community or group. Immunisation coverage of the community area where the case occurred should be reviewed as soon as measles outbreak is suspected.

Selective vaccination activities: If immunisation coverage is not high or if there is not good coverage data, this presents a good opportunity to undertake a rapid vaccination programme and to complete it within 1-2 weeks. Vaccinate all children 6 to 59 months of age presenting to a health facility or an outreach vaccination site where there is no evidence of measles vaccination. The target age group can change if local epidemiology of outbreak dictates.

Children receiving measles vaccine before the age of nine months must be revaccinated after the age of nine months (with at least a one-month interval between the doses). Hospital workers are at risk of exposure and should be vaccinated if their vaccination status is not known. Districts should ensure sufficient supply of vaccine, syringes and other supplies like Vitamin A. Additional required supplies should be requested on time.

Reinforcement of routine vaccination

A measles outbreak provides the opportunity to identify and correct vaccination programme weaknesses, and steps should be taken to:

- Rapidly identify priority areas within the affected district (e.g. communities with low vaccination coverage and at high risk of morbidity and mortality);
- Find out reasons for the low coverage and strengthen the available district immunisation services;
- Take corrective measures such as additional staff or vaccine supplies, more outreach services to communities with a high proportion of unreached children.

Non-selective mass vaccination activity

When an outbreak is confirmed and risk assessment indicates likelihood of spread, control measures should cover a much larger area. If there is sufficient capacity (human and financial resources, vaccine and other supplies) to carry out a safe and timely vaccination campaign, then a mass vaccination campaign should be carried out in the targeted areas (affected and neighbouring areas as determined by the risk assessment).

Infected and neighbouring districts should perform an accelerated micro-planning exercise to determine the amount of vaccine, syringes, logistics, staffing and communication needs for the campaign.

Whom to vaccinate:

The district should perform a susceptibility profile by considering the routine measles coverage, previous measles immunisation campaign coverage, age-specific attack rates and the number of cases affected. If many of the cases are occurring in infants under 9 months of age, vaccinate infants between 6 and 9 months of age (these infants should be revaccinated when they reach one year of age). Vaccination of older age groups should be considered, if high attack rates are observed in children 5 years of age or older, or if the coverage achieved during the “catch-up" or “follow up” vaccination campaign did not reach 90% among the 9-month to 14 year olds. All children without a history of vaccination after their first birthday should be targeted for vaccination.

When to vaccinate:

Start vaccination activities as fast as possible, soon after the decision on the type of vaccination is made.

Where to vaccinate:

In both urban and rural areas, the focus of vaccination efforts should be potential pockets of susceptible children to ensure that high-risk group are prioritised. This includes communities in informal settlements; populations with poor access to health care, like those in remote areas and those who refuse immunisation services; and those known to have low coverage. Specific focus should also be directed to those at high risk of measles-related complications (young children <1 year, malnourished children, HIV infected children, populations with poor access to healthcare, special homes and care centres for children and children attending or visiting hospitals) are reached during the vaccination activities. Supplementary measures such as the provision of Vitamin A should be done.

As much as possible, the largest area possible should be covered. (However, it is to be noted that this is not a preventive campaign and its focus is largely on outbreak-affected and adjacent high-risk areas). Door-to-door vaccination should be used where feasible; it requires greater resources, but is likely to yield better results. Gathering points such as schools, churches, health posts, etc. should be chosen as outreach sites.

If a suspected case has travelled or had close contact with individuals from other areas of the country within 15 days before the onset of the illness, the surveillance coordinator in those areas should be notified immediately. When appropriate, other countries should be notified. The public should also be informed through the media about any outbreak and control efforts that have been implemented.

The information on most recent cases, immunisation activities and villages visited by cases should be monitored continuously during an outbreak. This information should be kept in a form that can be summarised quickly in an Outbreak Summary.

Ensuring effective community involvement and public awareness

During an outbreak, there is a need to engage and inform the public from the outset. Clear messages should reach the community on the outbreak, the benefits of vaccination, the symptoms of the disease and information to bring children to health facilities at the earliest sign of symptoms and for vaccination.

Outbreaks in Special Circumstances

Control of outbreaks in schools and other institutions:

During outbreaks in elementary, junior and senior high school, colleges and other institutions of higher education, as well as other institutions where young adults may have close contact (such as prisons), a programme of revaccination with measles vaccine is recommended in the affected schools or institutions. The National and Provincial Departments of Health will jointly make a decision on how wide the campaign should be and which age groups and institutions to target, based on the epidemiological profile of the outbreak and the population groups considered at risk.

The scope of vaccination effort needed will depend on:

- Age-appropriate measles coverage in the community;
- Population density;
- Patterns of social contacts within the community.

During an outbreak, strong consideration should be given to expanding vaccination efforts to all schools in the community, unless measles coverage is high in those other schools.

All students and their siblings, and all school personnel who cannot provide documentation that they have received two doses of measles containing vaccine or cannot provide other evidence of measles immunity (such as serologic testing), should be vaccinated. Persons who cannot readily provide documentation of measles immunity should be vaccinated or excluded from the school or other institution. Persons revaccinated, as well as previously unvaccinated persons receiving their first dose as part of the outbreak control programme, may be immediately readmitted to school. Persons who continue to be exempted from or who refuse measles vaccination should be excluded from the school, day care or other institution until 21 days after the onset of rash in the last case of measles.

Control of outbreaks in medical settings:

If an outbreak occurs within, or in the areas served by a hospital, clinic or other medical or nursing facility, all personnel (including volunteers, trainees, nurses, physicians, technicians, receptionists and other clerical and support staff) with patient contact should receive a dose of measles vaccine, regardless of their age, unless they have documentation of measles immunity or vaccination. If indicated, healthcare workers who have not been immunised against measles should receive a dose of measles vaccine.

Serologic screening of healthcare workers during an outbreak to determine measles immunity is not recommended, because arresting measles transmission requires the rapid vaccination of susceptible healthcare workers, which can be impeded by the need to screen, wait for results, and then contact and vaccinate the susceptible persons.

Susceptible (unimmunised) health workers who have been exposed to measles should be relieved from all patient contact if possible and should be excluded from the facility from the 5th to the 21st day after exposure. Health workers who become ill should be relieved from all patient contact and excluded from the facility for 7 days after they develop rash.

Minimising measles transmission in hospitals

It is vital to maximise awareness among health workers that a child with measles could present at any health facility at any time. Health workers should be aware of the continual risk of nosocomial spread of measles to non-immune persons. There needs to be a constant state of preparedness to minimise the risk of nosocomial measles transmission.

The following recommendations are made to prevent measles transmission specifically in health facilities. General recommendations, such as maintaining high measles coverage and avoiding missed opportunities, are discussed elsewhere in this document.

Ensure adequate measles immunisation status among hospitalised patients

The immunisation status of all hospitalised children under 15 years of age should be checked rigorously. A dose of measles vaccine must be given to all *unimmunised* infants aged six months to 15 years upon admission to hospital. In order to ensure that no opportunities are missed, the immunisation status of children under 15 years of age should be checked again before discharge. Immunisation of those without documentation of previous measles immunisation will reduce the chances of a child returning home while incubating a nosocomially-acquired measles infection. Failure to do this could result in the infection of children in the community with measles originating in the hospital.

Exposed non-immune contacts of hospitalised measles cases, such as patients sharing the same ward and visitors, aged six months to 15 years, should receive one dose of measles vaccine, where possible, within 72 hours of exposure. Hyper-immune measles gamma globulin is less effective and much more costly than measles vaccine for use with non-immuno-compromised patients.

Isolate fever and rash cases upon arrival

During measles outbreak, patients with fever and rash should be considered as suspected measles cases until proven otherwise. To reduce the chance of exposure, cases of fever and rash presenting at a health facility should ideally not enter the common waiting areas used by all other patients. Where available, such cases should be fitted with a mask and taken directly to a different room reserved for assessment of conditions, which may require respiratory isolation.

Waiting and treatment areas should be well-ventilated, and care should be taken to ensure that sick and well children do not subsequently share the same room or same staff for weighing, clinical examination, immunisation or other consultation, since this would clearly

defeat the purpose of their initial separation by allowing the possibility of measles transmission.

During measles outbreak, specific effort should be made to provide a special waiting area for suspected measles cases. Information should be disseminated that children with a rash illness should not wait in the common waiting area. A sign may be mounted outside the health facility instructing parents / guardians bringing a child with rash to proceed directly to the special waiting room/area.

Inform the Hospital Infection Control Authorities

Measles is a notifiable disease in South Africa. Nosocomially-acquired measles cases should be reported immediately to hospital infection control authorities for immediate investigation and response.

Quarantine:

Quarantine is of limited usefulness in control of measles outbreaks. Imposing quarantine measures for outbreak control is usually both difficult and disruptive to schools and other institutions. Under special circumstances, such as during outbreaks in schools attended by large numbers of persons who refuse vaccination, restriction of an event or other quarantine measures might be warranted. However, such actions are not recommended as a routine measure for control of most outbreaks.

Post-exposure vaccination and use of immunoglobulin to prevent measles in exposed persons

If given within 72 hours of exposure to measles, measles vaccine may provide some protection. In most settings, post-exposure vaccination is preferable to use of immunoglobulin. Immunoglobulin may be preferred for infants <1 year of age who are household contacts of measles patients because it is likely that they will have been exposed more than 72 hours prior to measles diagnosis in the household member, and they are at highest risk of complications from the disease.

Gamma globulin should also be administered to immuno-compromised contacts of measles cases. Due to the risk of overwhelming viraemia, live virus vaccines such as measles vaccine are contra-indicated in individuals with congenital disorders of immune function or those receiving immuno-suppressive therapy. Hence, immuno-compromised contacts of measles cases should receive hyper-immune measles gamma globulin, as soon as possible

after exposure. However, asymptomatic persons who are well, yet infected with human immuno-deficiency virus (HIV) infection, should receive the vaccine.

Measles cases at port of entry

Issues have been raised regarding how to handle international passengers who are suspected of being infected with measles. Below are some guidelines, which may be useful in approaching such situations.

Any traveller who is suspected of having measles should immediately be referred to Port Health Authority at the point of entry or as soon as such, a suspicion is raised. The traveller should be informed of his / her illness and its potential for complications and spread to others.

If hospitalisation is not necessary, the patient with suspected measles infection should be investigated and should remain at a residence, mainly isolated in his / her room with little contact with other residents (hotel or other living quarters) until at least 5 days after rash onset or until negative blood results are received.

A health information card should be given routinely to all travellers visiting from other countries, informing them of the measles eradication programme, and requesting that they assist by seeking immediate medical attention if they experience a rash illness with fever.

Outbreak monitoring

Information on suspected and confirmed measles cases, vaccination activities, and areas visited should be monitored and updated continuously during an outbreak. The line-list should be completed and monitored on a daily basis at the initial phase and weekly when the intensity of transmission decreases. When no new cases are reported during a 3-week period despite the presence of enhanced surveillance, the outbreak may be considered to be over. Cases that occur after or during this period should have specimens collected to establish if they are true measles cases.

Outbreak summary and report

Careful investigations of measles outbreaks can provide useful information regarding factors, which may have facilitated measles virus circulation. The investigation may help to identify risk factors for measles infection and provide information, which may be used to refine and improve the measles elimination strategy.

In order to benefit from the investigation and outbreak control activities, it is necessary to organise and report data related to the outbreak. An outbreak summary report should comprise the following sections:

- Introduction;
- Surveillance methods;
- Description of the outbreak (who, what, where, when?);
- Analysis of the outbreak (why?);
- Control measures and problems encountered;
- Conclusions and recommendations.

End of an Outbreak

An outbreak of measles in a district is said to have come to an end when there has not been any new case of measles for more than 3 weeks (this corresponds to the maximum incubation period of measles), and when all neighbouring districts have not reported any case for a similar period of time.

Table 4.2: Suspected Measles Case (SMC) Reporting and Investigation Procedure

Different Level Responsibilities on Investigation of Measles Cases			
Level 1 **Health Worker**	**Level 2** **District/Sub – District/Local Authority**	**Level 3** **Provincial Epi Coordinator**	**Level 4** **National Surveillance Officer**
➡ **Detects a <u>suspected measles case</u>** ➡ Informs the District CDC coordinator telephonically. ➡ Obtains blood (and throat swab samples when indicated). ➡ Completes first section of case investigation form (CIF). ➡ Sends samples on ice with the filled-in CIF to National Institute for Communicable Diseases (NICD) Laboratory. ➡ Sends a copy of the CIF to Level 2. ➡ Send weekly/monthly reports to district office ➡ Looks out for more suspected measles cases and informs other health workers of the same. ➡ Ensures that children below 15 years are vaccinated against measles on admission. ➡ Ensure appropriate case management.	➡ Receives notification from health facility. ➡ Informs Level 3. ➡ Assigns the EPID no. ➡ Ensures that the CIF is fully filled. ➡ Keeps a lin**e** list of all SMCs. ➡ Compiles weekly/ monthly reports; send to province. ➡ Plans and conducts training & orientation of facility health workers. **NB: <u>If the results are measles positive</u> (IgM +)** ➡ Fills in GW 17/5 form sends to Province. ➡ Supplies facilities in the affected area with VTM for throat swabs. ➡ Does case response. Visits the health facility to obtain more information on the case and check if no other cases. ➡ Does home, neighbourhood and crèche visit to find out if more cases ➡ Does outbreak response with vaccination at crèche, home neighbourhood and to the wider area as necessary.	➡ Allocates the EPID no. if not allocated. ➡ Keeps a line list of all SMCs. ➡ Ensures that case investigation form is fully filled-in and sent to the National office. ➡ Plans and conducts training and orientation of district CDC and EPI coordinators. ➡ Conducts supportive supervision to districts. **NB: If the results are Measles positive** ➡ Ensures and supports the district to conduct an epidemiological investigation: visit the neighbourhood, crèches, schools and other health facilities to check for missed cases ➡ Ensures that all similar cases are investigated ➡ Supports the district to conduct an outbreak response ➡ Compiles outbreak response report and feedback to all levels weekly, until outbreak has subsided ➡ Compile weekly/monthly reports; send to National DoH ➡ Does the case classification	➡ Draw up guidelines and manuals on surveillance. ➡ Develops a policy and SOPs on surveillance including timelines for regular reporting. ➡ Draws up a national plan and strategy for the control and elimination of measles. ➡ Plans and conducts training and orientation of provincial and district CDC and EPI coordinators. ➡ Follows up incompletely investigated cases. **NB: If the results are Measles positive** ➡ Ensures that outbreak response is conducted. ➡ Supports the province if an outbreak is confirmed. ➡ Keeps National Data Base for all SMC, confirmed measles cases and outbreaks. ➡ Sends weekly reports to WHO, Health System Research & Epidemiology, Communicable Disease Control, Outbreak Response Unit and Provinces.

5. NEONATAL TETANUS (NNT)

5.1 Disease Background

Tetanus is an infectious bacterial disease caused by *Clostridium tetani.* The organism is part of the natural environment. It is a normal inhabitant of the intestines of animals and humans. *Clostridium tetani* produces spores, which are ubiquitous in the environment. For this reason, the ultimate eradication of neonatal tetanus is not possible and the tetanus spores remain an endemic environmental hazard. There is a higher incidence of NNT cases in agricultural regions and in underdeveloped areas where contact with animal excreta is more common.

The disease may develop after tetanus spores contaminate wounds, cuts and burns. Under favourable anaerobic conditions, such as in dirty, necrotic wounds, the spores change to toxin-producing vegetative forms and may produce tetanospasmin, an extremely potent neurotoxin. This toxin blocks inhibitory neurotransmitters in the central nervous system and causes the muscular stiffness and spasms typical of generalised tetanus. Tetanus is not a communicable disease and hence does not cause epidemics. It follows the infection of wounds, cuts and burns with tetanus spores.

Maternal and Neonatal tetanus (NNT) are distinctive conditions associated with birth. Neonatal tetanus accounts for the majority of cases. It occurs in new-borns following unsterile methods of cutting the umbilical cord or of dressing the umbilical stump. Maternal tetanus occurs in mothers following unclean deliveries.

Tetanus can occur in any age group as a complication of contaminated injuries or wounds. Tetanus only affects the person who is infected and does not spread from person to person. Thus, it is not a communicable disease and hence does not cause epidemics. The case fatality rate is high even in presence of intensive care. It ranges from 30-90% depending on age, incubation period, the timeliness and quality of treatment received.

Clinical course

The *incubation period* of tetanus ranges from 3-21 days with an average of 6-7 days. Neonatal tetanus is typified by a newborn infant who cries and sucks well for the first few days following birth. As the neurotoxin takes effect, the newborn develops progressive difficulty with inability to feed because of lockjaw, generalised stiffness with spasms and / or convulsions.

Case fatality may exceed 80% among new-borns who develop the disease after a short incubation period and those who do not receive treatment. The diagnosis is based on clinical features and not on laboratory confirmation. Usually, no detectable tetanus antibody response is mounted and tetanus cases require subsequent immunisations.

The vaccine and protection against tetanus

Tetanus toxoid (TT) vaccine and Td (Diftavax), tetanus toxoid plus a lower dose of diphtheria are suitable for vaccination of pregnant women to prevent tetanus in both the mother and the child. Td and TT vaccine are destroyed by freezing and must, therefore, be transported and stored at 2-8^{o}C.

The WHO recommends that, for lifelong protection, the immunisation schedule for women with an appropriate tetanus toxoid containing vaccine (Td or TT) must include five doses with specific minimum intervals between doses: four weeks – between the first and second (1st and 2nd) dose; six months – between the second and third dose (2nd and 3rd); and one year between third and fourth (3rd and 4th) and fourth and fifth (4th and 5th) doses. The first dose serves as a *priming dose* and protection is initiated with the second dose. However, protection wanes within two to three years. The third dose is considered to confer protection for a full five years, the fourth for ten years and the fifth for the entire childbearing period.

Young women who received three doses of tetanus toxoid containing vaccines through the national EPI programmes will only require three doses of TT-containing vaccine to complete the full five-dose schedule for life-long protection of their new-borns against NNT. In the near future, when the young girls who have received the benefit of 5 to 6 tetanus toxoid-containing vaccines through the childhood EPI doses and the Td doses at 6 years and 12 years become women of childbearing age, they will have lifelong protection against tetanus for themselves and their new-borns. However, due to the very low uptake of Td at 12 years in South Africa, there is a need to continue to vaccinate all pregnant women with at least 3 doses of tetanus toxoid containing vaccine, unless there is documented proof of full protection and hygiene practices are good.

The highest incidence of NNT occurs in the new-borns of poorly educated, young mothers in their first pregnancy. As healthy teenagers, such mothers will have had little contact with the health system prior to their first pregnancy and are therefore unlikely to have received TT-containing vaccine when they reached childbearing age. Poorly educated women are also less likely to understand the importance of prenatal care and to seek it, and less likely to have the birth of their child attended by a trained attendant. Such women may protect their

second child after receiving a tetanus toxoid containing vaccine at the time of the first child's birth, but the first child may be born unprotected.

A tetanus toxoid containing vaccine like TT or Td should be given to all age groups and to both males and females following any injury.

5.2 Global Goals and Objectives − Neonatal Tetanus Elimination

In 1989, the World Health Assembly committed WHO Member States to achieve the elimination of neonatal tetanus as a public health problem by the year 1995. This target had been redefined and the current goal is to achieve global elimination by the year 2015. Elimination of neonatal tetanus is defined as less than one case of neonatal tetanus for every 1 000 live births in each administrative district throughout the world. Once that target is met, the WHO estimates that fewer than 150 000 cases will occur globally each year.

Elimination is defined as less than one Neonatal Tetanus case per 1000 live births at district level per year.

In some African countries, NNT remained a major problem until recently, accounting for 10-25% of infant mortality and 50% of neonatal deaths. However, the global Neonatal Tetanus Elimination efforts have made an impact resulting in the reduction of this disease. For social and cultural reasons, neonatal deaths are rarely reported (in many countries, less than 10%), so the real burden of NNT may be underestimated. In 2002, the total number of deaths caused by tetanus worldwide was estimated at 213 000, of which neonatal tetanus was estimated to represent about 180 000 and maternal tetanus possibly as many as 15 000 - 30 000 deaths. NNT is also known as the “silent killer” because victims die so quickly that neither their births nor their deaths are reported.

Significant progress has been made in the last decade in the control of NNT. WHO estimates that in 2008 (the latest year for which estimates are available), 59 000 newborns died from NNT, a 92% reduction from the situation in the late 1980s. The same year, 46 countries still had not eliminated MNT in all districts. While progress continues to be made, by February 2012, 34 countries had not reached MNT elimination status. Activities to achieve the goal are ongoing in these countries, with many likely to achieve MNT elimination in the near future.

In South Africa, following the 1994 review of the Expanded Programme on Immunisation, the National and Provincial Health Departments adopted national goals. The NNT elimination

national goal was: *The reduction of neonatal tetanus to less than one case per 1 000 live births in all districts by 1997,* which was revised to “Validate elimination by end of 2002”.

A validation process was conducted in 2002 and confirmed that South Africa has attained the goal of elimination with no district reporting more than 1 case (>1 case) of NNT per 1 000 live births. Hence, the main objective of the country currently is to maintain the status of elimination.

5.3 Neonatal Tetanus Elimination Strategies

The following strategies have been globally successful in eliminating NNT:

- Improve maternity care with emphasis on increasing the proportion of clean deliveries, either attended by health staff in a health facility or by trained attendants at home using hygienic practices;
- Increase the immunisation coverage of pregnant women in high risk areas with a *tetanus toxoid* containing vaccine (TT or Td);
- Establish effective surveillance, with special emphasis on community involvement, aimed at detecting and investigating all neonatal deaths and adequate response if a case of NNT is confirmed.

These strategies are implemented differently depending on whether a country has met the goal or is still working toward it.

The high-risk approach: Focuses on providing tetanus toxoid containing vaccines in districts, or in areas within districts, where women have no (or limited) access to these vaccinations routinely; limited or no antenatal care and where skilled delivery attendants are not available.

- All women of childbearing age are included in the target population (in comparison to routine immunisation that target only pregnant women);
- Three properly spaced rounds of tetanus toxoid vaccination are given as SIAs (with an interval of at least 4 weeks between doses 1 and 2, and of at least 6 months between doses 2 and 3);
    - Clean delivery**:** Midwives must be given professional training and supervision in the methods and equipment for *aseptic childbirth*. Midwives, relatives and the mothers must receive education in the *"three cleans"*: *clean hands*, *clean* instruments *(blade* for cutting the cord), clean environment and discourage harmful traditional practices.

Women who have no access to routine tetanus toxoid vaccinations or antenatal care often have no access to clean deliveries. Therefore, the health workers who are giving vaccinations to these women should also provide information about the components of clean delivery and post-delivery practices, especially umbilical cord care. The application of potentially contaminated substances such as ashes, cow dung, rat droppings and oils to the stump is dangerous and must be avoided.

Post validation, South Africa has maintained elimination status and will continue efforts to maintain elimination.

Strengthening Routine Immunisation

- Maintain high DTaP-IPV//Hib3 coverage at least at 90% in each district;
- Reduce drop-out rates to less than 10 % in each district;
- Increase and maintain high coverage with Td vaccine at 6 and 12 years at 80%, through the School Health Programme;
- High coverage on immunisation in pregnant women with Td or TT.

Strengthen Clean Deliveries

- Skilled delivery practices: 90 % of children delivered by a skilled attendant in each and every district;
- Appropriate cord care and delivery practices.

Strengthen Surveillance Activities

- Incorporate the surveillance for NNT into AFP and Measles surveillance;
- At least 80% of complete monthly reports from all districts;
- 100% of reported cases will be investigated including home and village visits;

The zero report will be included as an indicator in evaluation of district function.

5.4 NNT Surveillance Objectives

Maternal and neonatal tetanus surveillance data is needed to:

- Identify districts and areas where mothers and newborns are at risk of tetanus;
- Measure the quality of immunisation and clean delivery services;
- Monitor a country's elimination status and the sustainability of its achievement.

Types of Surveillance

- **Active surveillance:** Neonatal Tetanus surveillance should be linked to AFP and measles surveillance and major health facilities should be visited regularly (weekly or at least monthly) to identify any NNT case admitted or diagnosed in them. During these visits, hospital inpatient and outpatient registers should be checked and key clinical staff (e.g. in paediatric and emergency wards) should be asked whether any new NNT case has been identified in the hospital since the previous visit;
- **Zero reporting:** Designated reporting sites at all levels should report at a specified frequency (e.g. weekly or monthly) even if there are zero cases (often referred to as "zero reporting");
- **Routine monthly surveillance:** The number of confirmed NNT cases should be included in all routine reports and should be reported separately from other (non-neonatal) tetanus;
- **Retrospective record review:** Hospital records should be reviewed for NNT cases at least once annually in major hospitals to identify previously unreported NNT cases
- **Community sensitisation:** (a) In silent areas where routine reporting is not functional or where health coverage in general is low, the community should be sensitised about NT and be part of reporting suspect cases / deaths to the health authorities. (b) Traditional Birth Attendants (TBAs) should be sensitised with simple messages like: Practice clean delivery by using the "3 cleans" = clean hands, clean surface and clean instruments.

Surveillance targets

The following surveillance indicators for neonatal tetanus have been set as targets:

- At least 80% of reported neonatal tetanus cases are reported within 7 days of the onset of symptoms;
- At least 80% of suspected neonatal tetanus cases are investigated within 48 hours of reporting.

Case definition

Case definitions should be distributed and displayed to draw the attention of health workers and the community. These definitions are used to confirm and classify reported cases.

Confirmed Case
Any neonate with normal ability to suck and cry during the first 2 days of life **and** • who, between 3 and 28 days of age, cannot suck normally **and** • becomes stiff or has spasms (i.e. jerking of the muscles)

Suspected case
• Any neonatal death between 3 and 28 days of age in which the cause of death is unknown; **or** • Any neonate reported as having suffered from neonatal tetanus between 3 and 28 days of age and not investigated.

NNT case investigation and final classification

Within 24 hours of receiving a report of a suspected NNT case, the district CDC coordinator or Public Health Officer in the district where the mother was living during her pregnancy should instruct staff to carry out a case investigation.

The aim of the case investigation is to collect *all the information* required on the NNT Case Investigation Form (*Annex 4.),* as *accurate* and as *complete* as possible. The District CDC coordinator in consultation with the provincial EPI manager should assign a unique Epid Number. This number will include the disease, province, district, year and chronological order of the case, for example: **SOA-ECP-ORT-98-006** is the 6th NNT case reported in 1998 in Oliver Tambo District in Eastern Cape Province. Use the three-letter code for identification of the province and district as indicated in the section for poliomyelitis.

The completion of the form requires the careful compilation of data from different sources. This work should be assigned to a responsible staff member at the district or provincial level.

The subsequent analysis of this information will facilitate the planning of supplemental tetanus toxoid (TT) containing vaccine immunisation among women of childbearing age in

the district, and may identify deficiencies in antenatal care or deficiencies in hygiene practices during delivery, which can then be corrected with training.

If the case was hospitalised, identification and clinical data on the case will be available at the hospital. The person doing the case investigation should interview the examining doctor in order to complete the clinical data. If the doctor is convinced of the NNT diagnosis, the final classification may be entered on the form.

If the case is still hospitalised and the mother is present, epidemiological information can be collected on the spot, such as the conditions under which the infant was born, maternal vaccination status, etc. However, if the case died or has returned home, it is essential to visit the home to complete the epidemiological data. A search for additional NNT cases in the community can be conducted. Information should be compiled for the appropriate response (population size, logistics, etc.). Local authorities and leaders should be informed that supplementary vaccination will be carried out shortly, requesting their assistance and participation.

For epidemiological analysis, the district, province and national Department of Health should all maintain and periodically review a line listing and a spot map of confirmed NNT cases once the case investigation is complete. This line list should be regularly updated.

5.5 Response to a Case of NNT

The surveillance for NNT should be tied to a response system. Under this system, not only is the mother whose newborn has been infected with tetanus immunised with a tetanus toxoid-containing vaccine, but also conduct risk assessment for other new-borns in the area. It is appropriate to establish the risk in the area where the case originated, the high-risk practices, access to healthcare, vaccination during pregnancy and work out if it is necessary, to vaccinate women of childbearing age. The underlying rationale of this activity is that the antenatal services have not been able to prevent a case of neonatal tetanus − therefore, a community-based activity immunising all women of childbearing age is needed to prevent further cases of NNT.

The need for such a response will vary from area to area and it is not easy to generalise. Nevertheless, it is considered that this kind of response is no longer appropriate in many settings because of the level of development reached and efforts made to reach more women during pregnancy and improve maternal safety.

The occurrence of a case of NNT should be used to increase awareness of NNT in health workers and the public. Health workers and teachers in local schools should be encouraged to use NNT as a training topic in health education, emphasising the protection provided by proper antenatal care, vaccination and clean deliveries. This should strengthen the entire primary healthcare system in the district and make a reoccurrence of NNT unlikely.

- *Improve routine vaccine coverage through EPI and maternal immunisation activities;*
- *Educate birth attendants and women of childbearing age on the need for clean cord cutting and hygienic care of the umbilical stump;*
- *Increase the number of trained birth attendants.*

5.6 Maintaining Maternal and Neonatal Tetanus Elimination

Achieving elimination status does not guarantee protection forever because unvaccinated women and children are always at risk. Hence, all effort must continue to maintain the status of elimination through continued immunisation of pregnant women, routine immunisation of children and clean delivery services in all districts.

The following activities should continue to maintain elimination in South Africa.

1. At the national level and provincial level:

- Assessment of performance in providing primary 4 doses of pentavalent or hexavalent and Td at 6 and 12 years;
- Immunisation of pregnant women and status of clean delivery services;
- Identify districts with poor performance and find out the reasons;
- Provide the necessary support and guidance to improve performance.

2. At the district level:

- Prepare a micro plan that addresses reasons for poor immunisation performance and improve performance for immunisation and clean delivery practices;
- Maintain active surveillance for maternal and neonatal tetanus;
- Monitor routine tetanus toxoid immunisation and clean delivery activities;
    - TT2+ coverage in pregnant women or the proportion of neonates “protected at birth” (PAB);
    - DTaP-IPV//Hib1 and DTaP-IPV//Hib3 coverage and drop-out rate;
    - Monitor Td coverage at 6 and 12 years;
    - Antenatal care coverage.

(**PAB = Total number of infants seen for DPT1 or DTaP-IPV//Hib1 vaccination during a defined period who were protected against NT according to their mother’s vaccination history / total number of children assessed at the DPT1 or DTaP-IPV//Hib1 contact during the same period**)

Table 5.1: Recommended immunisation with a tetanus toxoid containing vaccines required to obtain long-term protection against tetanus

	DPT or DTaP	Td	Td	Td		
Recommended schedule	3 doses before age one or as early as possible after age 6 weeks with >=4 weeks intervals	e.g. 4–7 years	e.g. 12– 15 years	Early adulthood		
Adolescents and adults with no previous immunisation		As early as possible	At least 4 weeks later	At least 6 months later	At least 1 year later	At least 1 year later
Pregnant women with no previous immunisation (or unreliable immunisation information)		As early as possible in first pregnancy	At least 4 weeks later	At least 6 months later, or in next pregnancy	At least 1 year later, or in next pregnancy	At least 1 year later, or in next pregnancy
Pregnant women with 3 childhood DTP or DTaP doses		As early as possible in first pregnancy	At least 4 weeks later	At least 1 year later		
Pregnant women with 4 childhood DTP doses		As early as possible in first pregnancy	At least 1 year later			
Supplementary immunisation activities in high-risk areas (women of childbearing age)		During round 1	During round 2, at least 4 weeks after round 1	During round 3, at least 6 months after round 2	At least 1 year later, (e.g. in next pregnancy)	At least 1 year later, or in next pregnancy

6. ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

6.1 Background

Although the goal of immunisation is to protect the individual and the public from vaccine-preventable diseases by providing vaccines proven quite safe, no vaccine is entirely without risk. Very few people may experience events after immunisation, ranging from mild side effects to rare life-threatening illnesses. Unless adverse events, following an immunisation (AEFI), are identified, properly investigated and managed and results made known to the users, rumours may negatively affect the acceptance and public confidence in immunisation programmes. Therefore, the surveillance for AEFI must be an integral part of immunisation programmes to preserve public confidence and improve the quality of immunisation services.

EPI (SA) uses vaccines, which have been proven over many years to be very safe and effective. However, in rare instances, some vaccine recipients experience adverse events after immunisation. The programme has an AEFI reporting system to detect, investigate, take corrective action and report on these cases to maintain public confidence in immunisation. The AEFI surveillance system is an integral part of EPI disease surveillance.

The benefits of vaccinating against diseases far outweigh the risks of a medical incident caused by an immunisation.

The AEFI surveillance system and relations with the Medicines Control Council (MCC)

The MCC has an adverse drug reaction reporting system for all pharmaceuticals. This is not a *duplication* of the EPI (SA) AEFI surveillance system. The AEFI surveillance system conducted by the EPI entails a case investigation aimed at determining the cause of the event, a response that comprises actions to prevent future occurrences due to causes that can be prevented like possible programme errors.

The Medicines Control and Related Substances Control Act, 1965 (Act 101 of 1965) gives the MCC the statutory responsibility to register medicines in the public interest. It deals with issues such as the safety, medical efficiency and quality of all medicines (not only vaccines). Regulation 12(1) stipulates that all medicines should comply with the standards and specifications in the application form, as approved by the MCC. Regulation 12(3) stipulates that the MCC should be informed immediately of any “undesirable” reaction to any medicine.

The MCC system for the reporting of *suspected adverse drug experiences* (GW 12/45) focuses on adverse drug experiences caused by factors inherent to any medicine, not only vaccines.

The system is provided to:

- Enable the MCC to execute the statutory responsibility regarding the safety, medical efficiency and quality of *all* medicines;
- Investigate reported adverse drug experiences in the public interest;
- Establish whether the medicines that caused the adverse drug experience meet the standards and specification as registered.

The MCC needs to know of all suspected drug experiences and their system requires a report only. The district pharmacist responsible for all the drugs / medicine in the district should complete the GW 12/45 form. The form should be sent to the MCC and a copy should be attached to the EPI case investigation form. Provincial Vaccine Coordinators should ensure that this reporting mechanism is in place in all districts.

An arrangement has been made with the unit within the MCC dealing with adverse drug reactions that data would be shared in respect of AEFIs. Data received by EPI (SA) will thus also be forwarded to the MCC and similarly, data received by the MCC on vaccines will be made available to the national EPI unit. A similar arrangement has been made with vaccine supplying companies. It is therefore possible that an investigation into an AEFI will be triggered by a report sent to the national EPI office by either the MCC or a company and reported to the province and district. However, this process is often too slow to be reliable. Proactive reporting of AEFIs at facility level should be maintained.

What are Adverse Events?

An adverse event following immunisation (AEFI) is a medical incident that takes place after an immunisation and is believed to be caused by the immunisation. Immunisation can cause adverse events from the inherent properties of the vaccine (**vaccine reaction**), or some error in the immunisation process (**programme error**). The event may be unrelated to the immunisation, but have a temporal association (**coincidental event**). Anxiety-related reactions can arise from the fear or pain of the **injection** rather than the vaccine. In some cases, the cause of the AEFI remains **unknown.**

Contraindications and vaccine side effects

Vaccinators should be familiar with the *true contraindications and vaccine-specific side effects*. Vaccine-specific side effects are usually mild and self-limiting and in most instances, they can be prevented or minimised. Therefore, parents should be informed of the possibility of symptoms such as mild fever, tenderness or redness at the injection site. Parents also need to be educated to know how to deal with such symptoms appropriately and to return to the health facility when they are concerned. In rare situations where specific vaccines are contraindicated in particular case, vaccinators should avoid administering that vaccine.

Epidemiology of AEFIs

The following table illustrates some serious side effects of immunisation with DTP and measles vaccines and compares them with the serious effects suffered from the disease itself (*Table 6.1*).

Table 6.1: Incidence of complications of pertussis and measles disease compared to the adverse events following their respective vaccinations

Condition	Pertussis		Measles	
	Pertussis disease*	DTP immunisation**	Measles disease*	Measles immunisation**
Encephalopathy / encephalitis	90 - 4 000	0.2	50 - 400	0.1
Convulsions	600 - 8 000	0.3 - 90	500 - 1 000	0.02 - 190
Death	100 - 4 000	0.2	10 - 10 000	0.02 - 0.3

* Per 100,000 cases

** Per 100,000 injections

The incidence of post-pertussis immunisation encephalopathy is variously estimated, ranging from 0.001 to 0.01 per 1 000, i.e. 1 case per 1 million immunisations. A WHO estimation of the frequency of encephalopathy ranges from 0.09 to 4%, including epileptic seizures, local neurological signs and comas, as indicated in the table above.

The incidence of post-immunisation convulsions are estimated at about 1 case per 10 000 doses injected and in most cases, recovery occurs with no sequelae.

6.2 Surveillance for AEFI

Goals and objectives

The following goals are proposed for the measurement of the management of AEFIs in South Africa:

Proposed Goals: South Africa

- To investigate and respond to 80% of reported AEFIs;
- Provincial and district office to respond within 48hrs to severe AEFI that include hospitalisation and death;
- To monitor AEFI surveillance in each district, province and nationally.

To date, the following milestones have been reached:

- Uniform reporting system since 1995;
- Training of health workers / vaccinators; starting with training of trainers in September 1997;
- AEFI surveillance has been incorporated in the EPI disease surveillance field guide since 1998.

Definitions and list of events to be reported

An adverse event following immunisation (AEFI) is any medical incident (trigger event) that follows immunisation and that is believed to be caused by the immunisation.

AEFI cluster: Two or more cases of the same AEFI related in time, geography or the vaccine(s) administered.

As there are occasional side effects of vaccination, which are harmless and well known, these should not be reported as AEFIs. A list of trigger events was, therefore, compiled to provide guidance on which events should always be reported and investigated as AEFIs. In principle, any serious effect perceived to have been caused by an immunisation should be investigated.

The trigger events for AEFI surveillance, i.e. a list of specific, selected medical incidents, perceived to be caused by the immunisation is shown in table 6.2 below. However, any serious effect thought to have been *caused* by an immunisation should be handled in the same way. All the events listed in table 6.2 below should be reported and investigated. Any

case of Vaccine Associated Paralytic Poliomyelitis (VAPP) should be reported as an AFP case and not as an AEFI (see below).

Local reactions

Local reactions that occur following immunisation are common. As a rule, they are *mild*, *not serious* and benign and generally disappear within 24 to 48 hours. Local reactions are characterised by immediate pain at the injection site, usually disappearing after a few minutes and may be replaced by tenderness, lasting several hours, at times an entire day.

The painful local reaction is influenced by the volume of vaccine injected. A nodule frequently develops at the injection site and may last several weeks. These need not to be reported. Nodules may in some rare cases, become inflammatory and turn into an abscess.

The following severe local reactions warrant further investigation:

- **Severe local reactions following immunisation**
  Swelling extending more than 5cm from the injection site or redness and swelling of more than 3 days duration;
- **All cases of BCG Lymphadenitis following immunisation**
  Regional inflammatory adenitis, simple, latent or suppurative. It usually occurs in the territory corresponding to the immunisation point of the vaccine;
- **Injection site abscesses following immunisation**
  This is defined as severe local reactions with the formation of a fluctuating abscess at or near the injection site. As these abscesses can be either suppurative (caused by an unsterile injection) or sterile (caused by a reaction to the vaccine itself), a culture of the abscess fluid should be taken when the abscess is drained.

Systemic reactions

Systemic AEFIs are *rare*. They are more *serious* and occasionally result in hospitalisation. Systemic reactions are in rare instances characterised by severe *anaphylaxis* with major systemic manifestations, hypotension to the point of collapse and oedema of the glottis, which may cause airway obstruction.

Sometimes, a more or less intense feverish syndrome is noted after immunisation, generally including headaches or digestive disorders, lasting 1 or 2 days. This need not be reported as long as the fever remains below 39^{o}C.

The following systemic side effects have to be investigated further:

- **All cases of hospitalisation thought to be related to immunisation**

  A medical condition that requires hospitalised treatment within three days after immunisation and is believed to be associated with immunisation. This can be determined after taking the history of the current illness and the time of onset of symptoms;

- **Encephalopathy within 7 days of immunisation**

  Any diagnosis of encephalopathy made in a child immunised within the last 7 days of the diagnosis should be investigated;

- **Collapse or shock-like state within 48 hours of immunisation**

  This may occur either immediately anaphylaxis) or within 6 to 10 hours after the first injection (delayed reaction), particularly in infants. The onset is sudden, with pallor, occasional cyanosis and a degree of agitation. In most cases, symptoms disappear within minutes, leaving no aftermath. However, depending on the severity of the collapse, it should be treated, using the Essential Drug List (EDL) Guidelines for the management of anaphylaxis (EDL 2014 Section 21.18).

  Although anaphylaxis after immunisation is a very rare event, health workers should be prepared for its possible occurrence. An emergency tray and procedure must be available at each immunisation point, equipped with the prescribed treatment. Health workers who provide immunisations should be trained to provide the appropriate treatment;

- **Fever of 40.5^{o}C or higher within 48 hours of immunisation**

  Fever of this degree may be accompanied by vomiting and restlessness, and may result in febrile convulsions;

- **Seizure within 3 days of immunisation**

  Any seizure (febrile or non-febrile) within 3 days of immunisation should be investigated further;

- **Intussusception**

  Any report of in **Intussusception in a child who had received vaccine 2 weeks prior to symptoms;**

- **All deaths thought to be related to immunisation**

  Fatal events following any immunisation obviously constitute a great problem for a preventative healthcare programme such as EPI. The post-immunisation period is not defined and should be considered as “all deaths thought to be related to immunisation”.

Clearly, a death following immunisation must be fully investigated and the interaction with the parents and other health workers is crucial in ensuring that the relationship of trust between healthcare providers and the community is not harmed. As with all AEFIs, the approach should be open and sympathetic, and not defensive. It is important that in the case of a death that is perceived to be related to immunisation, a post mortem is conducted with other relevant investigations, which are followed in case of a serious AEFI. The decision to conduct a post mortem requires family involvement and their permission. If the family refuses, then a post mortem cannot be conducted.

Table 6.2: List of AEFI trigger events to be reported

LOCAL REACTIONS	SYSTEMIC REACTIONS
• **Severe local reactions** following immunisation (with swelling further than 5cm from injection site, or pain, redness and swelling of more than 3 days duration) • All cases of **BCG lymphadenitis** following immunisation • All **injection site abscesses** following immunisation	• All cases of **hospitalisation** thought to be related to immunisation • **Collapse or shock-like state** within 48 hours of immunisation • **Encephalopathy** within 7 days of immunisation • **Seizures** within 3 days of immunisation • **Disseminated BCG infection**, BCG-osis • **Intussusception** within 2 weeks of immunisation • All **deaths** thought to be related to immunisation

Vaccine Associated Paralytic Poliomyelitis (VAPP)

VAPP is NOT included on the list of trigger events to be reported under AEFI. Suspected cases of VAPP should be reported as suspected acute flaccid paralysis (AFP). The case will be considered by the Polio Expert Committee (PEC) and be classified as a VAPP if appropriate.

Occurrence of one of the listed trigger events after immunisation does not prove that the immunisation caused the symptoms. In most cases, the adverse event is not *caused* by the immunisation, but coincidentally happens to occur shortly after it. Therefore, it is incorrect to talk about an adverse *reaction* following immunisation or a *vaccine reaction* before full investigation.

However, an *association* between a medical incident and an immunisation is suggested in the following instances:

- When there is more than one case (unusual clustering) of a condition in vaccine recipients within a limited interval after immunisation;

OR

- If vaccine recipients experience the event at a rate significantly higher than that in groups of the similar age or background who have not recently received a vaccine.

Detecting and reporting an AEFI

To detect an AEFI is the responsibility of the: -

- Health workers providing clinical treatment and / or immunisation at health centres in the public and private sector;
- Parents and guardians who report AEFIs affecting their children;
- Researchers conducting clinical studies or field trials.

There should be a high *index of suspicion* when a child who has recently been vaccinated becomes ill and presents for treatment at a health facility. District and CDC coordinators should emphasise the importance of detecting an AEFI by increasing the awareness of health workers.

To detect AEFIs, the following steps should be followed:

Always CHECK*:*

- The Road-to-Health card and determine the immunisation status;
- Whether the child was recently vaccinated or previously vaccinated without an incident;
- History of recent illness, time of onset of symptoms to determine whether immunisation / event can be linked to the illness;
- List of EPI (SA) trigger events to determine if current AEFI falls within the list.

ASSESS the situation to:

- Decide whether the child presents with mild side effects of immunisation or with a suspected AEFI;
- Distinguish between mild side effects and trigger events that need to be reported and the management of each.

If this is NOT an AEFI:

- And if the child presents with common *side effects* of immunisation, then proceed with treatment and explain to the parent / guardian what happened and that the benefits of immunisation far outweigh the risks.

If this IS a suspected AEFI:

- Do not hesitate to REPORT the case immediately, as detailed below.

IMPORTANT

If a health worker is unsure about the case, he should report it to the supervisor. The supervisor should assist the health worker and make sure the event is managed in an appropriate manner.

Reporting an AEFI

All cases of suspected AEFIs should be reported to the district health office within 24 hours after detection of the event. The report should come from the health worker at the health facility where the case presented.

The facility health worker who detected the suspected event will report the suspected case to the district coordinator who will inform the provincial coordinator as detailed in the AEFI reporting chain. The provincial coordinator will inform the national office (see Table 6.3 below).

Table 6.3 AEFI reporting chain

Health worker/Health facility 
• Health worker becomes aware of an AEFI that fits the list of trigger events or is thought to be caused by the immunisation; • Inform district within 24 hours; • Obtain background information from parents and records; secure vaccine vial if available; • Obtain basic vaccination history from vaccinator; • Talks to parents openly and sympathetically without admitting liability or being defensive.
District CDC 
• Informs provincial EPI coordinator, maintains district AEFI line list; • Constitute case investigation team, initiate case investigation; • Interview vaccinator in a non-threatening and supportive way; initiate secondary response; • Interview parents and be open; discuss concerns and deal with anger.
Provincial EPI coordinator 
• Informs national EPI office; maintains provincial register of AEFIs; • Facilitate case investigation as needed, e.g. vaccine testing, post mortems, etc.; • Assist with secondary response; • Manage political aspects and media.
National EPI 
• Inform MCC and Vaccine supplying company; • Support and facilitate response.

The health worker who detects the case and the district CDC or EPI / MCWH coordinator should gather all the relevant information that is available at this point, by completing the standard AEFI Case Investigation form (Annex 5.1).

This form can only be completed in full after the completion of the AEFI case investigation. However, reports should not be delayed because of other logistic problems and health workers should find the fastest possible means (like telephone, e-mail or fax) to report to next level.

AEFI that lead to hospitalisations and deaths are regarded as “serious” and should be reported immediately. Immediate reporting provides the district coordinator with an

opportunity to assess the validity of data without delay and to monitor and rule out the possibility of widespread occurrence of the event at the same point in time, at the same facility or in the same sub-district or district.

All the listed trigger events should be reported for any vaccine administered, including vaccines that are not included in the routine schedule. All AEFIs should be recorded in the routine monthly surveillance reports.

Immediate Response or Primary Response

Individuals affected by an AEFI should be treated at the health facility where the case presented from, where they can be referred to a hospital for specialist treatment. Mild symptoms such as fever can be treated by parents or health workers and these symptoms eventually go away by themselves. Serious AEFIs should be referred for medical opinion and possible admission to hospital after immediate emergency care.

Immediate care and management to severe vaccine reactions (anaphylactic reaction)

Although anaphylactic reactions are rare after vaccination, their immediate onset and life-threatening nature requires that all personnel and facilities providing vaccinations have procedures in place for anaphylaxis management. All vaccination providers should be familiar with the emergency treatment. Epinephrine and equipment for maintaining an airway should be available for immediate use.

Anaphylaxis usually begins within minutes of vaccine administration. Rapid recognition and initiation of treatment is required to prevent possible progression to cardiovascular collapse. If flushing, facial oedema, urticaria, itching, swelling of the mouth or throat, wheezing, dyspnoea or other signs or symptoms of anaphylaxis occur, the patient should be placed in a recumbent position with the legs elevated if possible. Administration of epinephrine is the management of choice. Additional drugs also might be indicated (*Annex 5.1*). Maintenance of the airway and oxygen administration might be necessary. After the patient is stabilised, arrangements should be made for immediate transfer to an emergency facility for additional evaluation and treatment.

The Clinic Supervisor and the CDC or EPI coordinator should conduct a response as soon as possible after receiving a report of a serious AEFI. The first response – after providing immediate medical needs of the patient − should be to interview and support the parents and the vaccinator immediately, without delay. This response does not depend on the result of

the case investigation and hence, there is no need to wait for completion and results of investigation. A delay in conducting the primary response may result in loss of public confidence in the immunisation programme and in serious cases, may lead to litigation.

The primary response should be conducted as soon as possible and include:

- An interview with the parents of the child with the suspected AEFI;
- An interview with the vaccinator who administered the vaccine that caused the event;
- Collection of samples of the vaccine vial that was used;
- Observation of the immunisation clinical practices in that facility;
- Observation of the adherence to the policies like Multiple Open Vial Policy and cold chain maintenance;
- Observation of related practices and the use of diluents and the condition of the diluents used;
- In rare instances, there may be an urgent need for a media release to deal with rumours that may cause loss of public confidence in the immunisation programme.

The Parents of the Child with the Suspected AEFI

One of the purposes of the investigation into an AEFI is to show the parents that the health authorities are concerned about what happened and are willing to do something to avoid reoccurrence. The parents should know that an investigation will be conducted to determine the cause of the event and that they will be kept fully informed.

Experience has shown that the main concern of the parents and the community is to find out exactly what happened. Parents want to know what caused the event and therefore, it is important to be honest about what happened without attributing the cause of the event to the EPI programme when there is no evidence towards this, as in many incidents the cause may be coincidental or unknown. The public must be assured of the integrity of the immunisation services and therefore, communication with the parents and the community should be honest and clear. A prompt initiative by the health authorities to investigate the event rapidly will increase public confidence in immunisations.

The Vaccinator Involved in a Suspected AEFI

The district investigation team should interview the vaccinator who administered the vaccine that caused the trigger event. It is very important to provide the vaccinator with an opportunity to deal with feelings of stress, fear to administer vaccines in future and possible feelings of guilt about what happened to the child.

Everybody involved in the investigation of an AEFI needs to understand that the investigation is not about apportioning blame, but about supporting the victim of the AEFI being investigated and preventing future occurrences. Occurrence of an AEFI can also affect the morale of other staff members in the health facility.

Members of the AEFI case investigation team should be aware of the underlying feelings. They should conduct interviews with empathy and understanding and maintaining communication in difficult situations.

If it should become clear after the investigation has been completed that remedial action is required involving the vaccinator; this should be done separate from the investigation, during the *secondary response.*

No vaccinator should be blamed for the event; especially not while the AEFI case investigation is in progress.

Case investigation

The purpose of the AEFI case investigation is to:

- Determine the cause of the event;
- Prevent a cluster of events, i.e. further AEFIs of the same cause;
- To prevent loss of the parents' and the public's confidence in the immunisation programme.

The district health office is responsible for the case investigation and response. Within 24 hours of receiving a report of an AEFI, the District Coordinator should conduct the AEFI investigation together with the appropriate team members. At the end of the investigation, the team should be able to:

- Confirm a reported diagnosis or propose another possible diagnosis;
- Determine whether a suspected AEFI was a single case or one of a cluster;
- Clarify the outcome of the medical incident/s and propose a classification category;
- Identify the specifications of the vaccine used to immunise the patient/s;
- Examine the operational aspects of the programme − even if an event may be vaccine-induced, coincidental or − due to programme errors − may have increased the severity of mild side effects.

The Investigation Team

An AEFI case investigation team should be appointed in each district. The appropriate persons should be identified, trained and tasked with the responsibility to investigate suspected cases and/or a cluster of AEFIs. Over and above the district CDC or EPI coordinator, the district AEFI case investigation team should include at least 3-4 persons from the following disciplines, i.e. a pharmacist, professional nurse, medical officer, environmental health officer and an epidemiologist or person from health information. In the case of a *serious* AEFI, i.e. hospitalisation and/or death where the case investigation requires careful compilation of detailed data, the team should consist of at least 4 members.

The person in the district responsible for EPI disease surveillance should be the team coordinator and should facilitate and coordinate AEFI surveillance in the district.

Care should be taken to avoid the appointment of persons as team members when their presence might influence the public's view of objectivity and transparency of the case investigation. Due to the nature of their involvement in the event, it is suggested that the following persons should rather not be included in the case investigation team:

- The vaccinator who administered the vaccine that triggered the suspected AEFI;
- At the health facility level, the direct supervisor of the vaccinator who administered the vaccine that triggered the suspected AEFI;
- Close family members of the vaccinator or the close family members of the child involved in the event.

The case investigation team should involve the direct supervisor of the vaccinator who administered the vaccine that triggered the event to:

- Accompany the case investigation team during their visit to the facility where the suspected vaccines were administered;
- Provide information regarding current immunisation practices and procedures at the facility (like vaccine handling) to the team as needed;
- To ensure that the supervisor and eventually all the health workers at the facility and the public, benefit from the experience. This may be achieved by utilising the opportunity to build capacity at facility level, to make the event a problem solving experience and to ensure correction of possible programme errors without delay to prevent other people from being exposed to the same error.

Data Collection

The Provincial EPI Coordinator should issue each AEFI case with an “Epid Number”, a unique identification number, for example: **SOA-KZP-ILE-08-001** is the first AEFI case reported in 2008 in ILembe District in KwaZulu-Natal Province. The AEFI Epid Number must appear on the AEFI Case Investigation Form (CIF) and should be used in all the AEFI reports and records at the District, Provincial and National Levels and for reporting to the MCC and the WHO.

Annex 5.2 AEFI Event *Description Report* (**EDR**) should be completed in full by the case investigation team. Additional data collected during the case investigation, aimed at determining the cause of the event should be systematically summarised in an Event Description Report (EDR) and should then be attached to the AEFI Case Investigation Form. A framework for data collection in preparation of the EDR is provided in Annex 5.2. Information in the EDR should also include the fields outline in the register of cases as outlined in Annex 5.3.

The following information should also be included in each EDR:

- Indicate whether this is a single event or a cluster, and in the case of a cluster, indicate who reported each AEFI in that cluster and when;
- The names and contact information of the team members who conducted the case investigation;
- The date of the case investigation commenced;
- A short description of how the investigation was conducted.

During data collection, the name of the child with the suspected AEFI and the name of the vaccinator who administered the vaccine that triggered the event, together with the EDR, should be marked and handled as “confidential”.

The aim is to obtain the background information that will assist the investigation team in determining the cause and to plan subsequent actions that need to be taken. The EDR provides a historical record of the AEFI and summarises the findings and conclusions about the event. The final diagnosis and classification of the event will be based on information retrieved from this report. It is therefore important to substantiate findings with examples and to motivate the conclusion and the suggested cause. This should be done in cooperation with the Provincial EPI Coordinator.

Laboratory examination

Laboratory investigations of the individual who presents with an AEFI by itself cannot be used reliably to rule out a diagnosis of an AEFI. Therefore, the testing of blood or urine specimens is seldom done in the event of an AEFI. In the case of an abscess or suppurative lymphadenitis, samples of the abscess fluid should be investigated to determine the causative agent.

Laboratory tests of vaccines should as much as possible be conducted. The vaccine vial that was used in the vaccination or a sample of the same vaccine in the same batch should be sent to the laboratory. Laboratory tests may be of limited value if the vaccine being tested is from a different vial than the one that was used for the recipient who developed an AEFI. If the actual vial of vaccine involved in the AEFI is still available, this vial should be tested as well as an unopened vial of the same batch. A vial from the same batch may be substituted when the original vial is no longer available, but the value of the findings will be weakened.

The vaccine needs to be sent to the laboratory testing the vaccine in the same conditions as the cold chain (the so-called Reverse Cold Chain"). In South Africa, the National Control Laboratory in Bloemfontein is the laboratory responsible for vaccine testing as part of an AEFI case investigation. Contact details for sending this kind of specimen can be obtained from the national EPI office or provincial office.

The laboratory investigation will include tests for toxicity, sterility and to confirm that the contents of the vial are in accordance with the label. The vaccine will also be tested to determine whether it has been frozen and whether it has been contaminated. Vaccine testing should be requested in cooperation with the Provincial EPI Coordinator and a copy of the case investigation report should be sent with the sample vial/s of vaccine/s. In addition, clear instructions should be given what tests should be conducted on the vaccine. For example:

- For an injection site abscess, a test must be done to determine the sterility of the vaccine;
- For a local, long-lasting reaction, a test must be performed to measure how much aluminium was contained in the vaccine;
- For a cluster of AEFIs to a reconstituted vaccine, a test must be done to identify the diluent.

The national EPI office will coordinate requests for vaccine testing and will liaise with manufacturers, the MCC and the National Control Laboratory in Bloemfontein.

6.3 Classification of AEFIs

AEFI may be classified based on the cause of the event or based on the frequency and seriousness of the event. Adverse events may be either systemic or localised.

In 2012, the Council for International Organisation of Medical Sciences (CIOMS) and WHO revised the classification based on the cause one as indicated in the table below.

Table 6.4 Classification of AEFI by the Cause

Cause –Specific type of AEFI	Description
Vaccine Product related reaction	An event that is caused or precipitated by a vaccine due to the inherent properties of the vaccine.
Vaccine Quality Defect related reaction	An event that is caused or precipitated by a vaccine that is due to one or more quality defects of the vaccine product, including its administration devices as provided by the manufacturer.
Immunisation Error related reaction (formerly known as "programme error")	An event that is caused by inappropriate vaccine handling, prescribing or administration and thus by its nature is preventable.
Immunisation Anxiety related reaction	An AEFI arising from anxiety about the immunisation. (such as syncope, that is common with HPV vaccine)
Coincidental	Event that happens after immunisation, but is not caused by the vaccine – a temporal association with immunisation exists.

Table 6.5 Classification by Frequency

Frequency category	Frequency in rate	Frequency in %
Very common	≥ 1/10	≥ 10%
Common (frequent)	≥ 1/100 and < 1/10	≥ 1% and < 10%
Uncommon (infrequent)	≥ 1/1 000 and < 1/100	≥0.1% and < 1%
Rare	≥ 1/10 000 and < 1/1 000	≥ 0.01% and < 0.1%
Very Rare	<1/10 000	<0.01%

Final classification of each AEFI case can only be done once the entire investigation is completed, including the receipt of the results of special investigations such as laboratory tests of the vaccine, post-mortems and clinical opinions. The National EPI office in conjunction with Pharmacovigilance will provide the final classification, after reviewing the report of the investigating team.

Immunisation Error Related Reactions formerly Programme-Related AEFIs

A programme-related AEFI is defined as a medical incident that was caused by some error in the transportation, storage, handling or administration of the vaccine. A case will be classified as a programme-related AEFI when data analysis provides sufficient evidence for

this classification. The following list of possible errors can be considered to assist with identification of the cause and subsequent classification of the event:

- Too much vaccine given in one dose;
- Immunisation injected in wrong place;
- Syringes and needles not sterilised;
- Used needles handled carelessly;
- Vaccine reconstituted with incorrect diluent;
- Wrong amounts of diluent used;
- Vaccine prepared incorrectly;
- Drugs substituted for vaccine or diluent;
- Vaccine or diluent contaminated;
- Vaccine stored incorrectly;
- Contraindications ignored, e.g. when children who have had a severe reaction after a previous dose of DTP is immunised with the same vaccine;
- Failure to follow prescribed policies like the Multidose Opened Vial Policy; a vaccine not discarded at the end of immunisation session and used at a subsequent one.

If there is a cluster of events, possible errors may be:

- When the same health worker vaccinated all of the recipients who developed AEFI, this strongly suggests a programme error but does not rule out any other cause;
- Unimmunised people in the same age group in the same geographical area had the same symptoms − very unlikely that a programme error caused the event;
- Others immunised with the same lot of vaccine in the same facility on the same day did not have the same symptoms − unlikely to be a programme error, but does not rule out the possibility.

If programme error can be ruled out as the cause or one cause of an AEFI or AEFIs under investigation, look for evidence that the events were vaccine-induced or coincidental.

Vaccine Product Related AEFIs

Vaccine product-related AEFIs are caused by the reaction of a specific individual to a specific vaccine. It is most unlikely that more than one person will experience a vaccine-induced reaction to the same vaccine in the same session.

The very rare vaccine-precipitated events are included in this category. They are medical incidents that would have occurred due to an individual's reaction to the inherent properties of vaccine, even when it is handled and prepared correctly.

Most vaccine-induced AEFIs are mild and of short duration. Such AEFIs include mild systemic reactions such as fever and rash or local reactions with redness, tenderness and pain at the injection site.

Coincidental AEFIs

A coincidental AEFI is defined as a medical incident that would have occurred whether the individual had received a vaccination prior to the incident or not, but that coincidentally happened during the same time as the vaccination. This classification can be considered when programme errors and individual reactions to vaccine can be ruled out with sufficient data to support this finding.

Coincidental events are unrelated to immunisations or vaccines in any way except for the time that they occur. The best evidence to support a conclusion that a medical incident is coincidental is that the same event has been diagnosed in people who have not been immunised.

Immunisation Anxiety Related Reaction

This is an AEFI arising from anxiety about the immunisation. Individuals and groups may become stressed and react in anticipation to, and as a result of, any kind of injection. Main presenting feature is fainting (vasovagal syncope), which is a relatively common presenting symptom, particularly in children over five years of age and among adolescents.

Anxiety about the immunisation may cause hyperventilation, which leads to specific symptoms such as light-headedness, dizziness, tingling around the mouth and in the hands. This is also common in mass vaccination campaigns. Younger children tend to react differently, with vomiting a common symptom of anxiety.

Breath holding may occur and can result in a brief period of unconsciousness during which breathing resumes. Young children may also scream or run away to avoid the injection. Anxiety-related reactions are common with HPV vaccine and school vaccination.

Vaccine Product Defect

This classification is rare and has occurred in the past when there is a defect in the manufacture of a vaccine. An example was in 1955, after administration of inactivated polio

vaccine manufactured by Cutter Laboratories in the USA, 40 000 people developed abortive polio, 200 were permanently paralysed and 10 died. In the current era, this kind of AEFI with strict regulatory processes relating to vaccine safety is unlikely to occur.

6.4 Deferred Response to an AEFI or AEFI Cluster (Secondary response)

This response can only be planned when a cause for the AEFI has been determined, as this will determine what action should be taken appropriately to rectify the problem. The actions may include training or replacement of defunct equipment, etc.

This secondary response is important to maintain the credibility of immunisation services and to build capacity at the health facility and district level.

If an AEFI was caused by programme error, the actions to be taken may include:

- Improving logistics will be the appropriate response if programme errors can be traced to the lack of supplies or equipment or to a failure in the cold chain. Managers should investigate suspected breaks in the cold chain to find the cause and act accordingly. These might include training or supervision or the problem might be solved by providing more or better supplies of equipment (needles, syringes, sterilisers, vaccine carriers, cold packs) or by providing more vaccine or diluent;
- Training

  Solving operational problems through training will deal with lack of skills and knowledge and with poor attitude. Training can focus on correcting errors. If the investigator tracks an error to one health worker, that health worker's immunisation activities should be terminated immediately, at least until the person masters the missing skill focus should be on training and providing support for such a health worker.
- Supervision:

  Supervisors should give immediate feedback to health workers on the AEFI activities and on their routine surveillance, case investigation and other reports. When AEFIs are reported, supervision should be intensified. Supervisors should watch out for any problem (e.g. vaccine storage, injection techniques) that has caused a cluster of AEFIs.
- Screening for health status prior to immunisation

  Health workers should screen eligible children prior to immunisation for true contraindications of immunisation.
- Immunisation records

  EPI (SA) policy recommends that the vaccine administered be recorded on the Road-to-Health Card by writing the date of administration and to put a signature next to the vaccine dose listed on the card. In many health facilities, professional nurses developed

a facility-based record for each child where the history of the child's birth and the current health status is recorded. The name of the vaccine, batch / lot number of the vaccine as well as the dose and site of administration is recorded. This information is useful for investigating a suspected AEFI.

The vaccinators should be empowered with the knowledge, supervision and support to feel comfortable with having to make decisions when they consider possible true contraindications prior to immunisation. The correct management of an AEFI will result in increased public confidence in the EPI programme.

The goals of high routine immunisation coverage and of ensuring standardised, safe and effective immunisation practices should be carefully balanced. For example, EPI (SA) vaccinator training focuses on elimination of false contraindications to vaccination. However, to prevent programme-related errors that can cause AEFIs, emphasis should also be placed on screening and recognising true contraindications.

If an AEFI is classified as vaccine induced, the actions to be taken may include:

- Warning the parent of the individual sensitivity to a component of the vaccine and advise to investigate the matter further through specialist investigation;
- Advise the parent on future vaccinations

If an AEFI is classified as coincidental, the actions to be taken may include:

- Informing the parents and, if necessary, the media of the outcome of the case investigation, explaining fully the coincidental nature of the event.

6.5 Communication with the Public and Reporting on the Investigation

In all cases of serious AEFI, the communication with parents, health workers not involved in the investigation, other people in the community and the press must take place regardless of the circumstances of the event. The provincial office should provide leadership to assist districts in responding to public enquiries or rumours. Assistance from the communication office should be obtained and the provincial EPI Coordinator should ensure that any information about vaccines or the immunisation programme is technically correct.

The district supervisor or another knowledgeable person in authority should set up means of direct continuous communication between health workers (investigators, peripheral health workers, supervisors and managers) and the community. The public should be informed frequently about what is being done during the investigation. When the investigation is over,

conclusions and recommendations should be shared and the public informed on the intervention measures taken to address problems found.

The key to maintaining confidence in health services is to be honest. If the cause of the AEFI has not been identified, the public should be informed. If the cause has been programme-related, the actions taken to correct the problem should be explained.

When death occurs because of a programme error, communication should be left to the provincial and national office. Special precautions may have to be taken to protect health workers who are implicated in the error from harm by the community. They may have to be removed from the scene before the findings are communicated.

Communication on AEFIs can be a challenge and needs to be handled in a sensitive manner. The public needs to be assured that severe vaccine-induced events are rare, though this will not comfort the patient's family. Sometimes, managers may find it appropriate to provide technical information on the low incidence of these events. In many situations, however, statistics will be meaningless and the best that can be done is to show sympathy and concern.

A follow-up media release may provide the community with feedback regarding the outcome of the investigation. This should take place AFTER final classification of the case.

The information on the AEFI CIF and the EDR, together with any other relevant information, e.g. laboratory reports, should be used by the district to plan the AEFI response. The District Investigating Team should summarise the findings and conclusions on the EDR. Recommendations should include the actions that need to be taken to correct possible programme errors, the timetable to illustrate, which actions should and can be implemented immediately without additional resources and when they will be implemented.

6.6 Evaluating AEFI surveillance

At the district and provincial level, a register of all AEFIs should be kept using the AEFI Register of cases (

Annex 5.*3*).This should enable the monitoring of the number of cases of each trigger event that has been reported by each district. In South Africa, AEFI reporting is incorporated into the weekly active surveillance report of AFP, Measles and NNT.

Completing the AEFI Line Listing will help identify:

- Whether the same kind of AEFI is occurring in the same health centre every month;
- Whether different health centres are reporting the same kinds of AEFIs;
- How the AEFI incidents reported by different health centres compare.

In this way, supervisors can identify patterns, such as clusters, within or across health centres and take appropriate action.

The provincial and national level should keep information of annual AEFI activity on an AEFI Register. The register should contain the following information:

- Number of AEFI reports received annually;
- Number of AEFIs by type (i.e. each of the trigger events);
- Number of AEFIs by antigen;
- Classification of an event by cause;
- Unusually severe AEFIs.

6.7 Providing Feedback

In addition to the immediate feedback they receive on their case investigation and event description reports, health workers should be given the results of monitoring and evaluation as soon as they are determined. If deficiencies are revealed at a certain level, health workers at that level should be involved in planning for corrective action.

Feedback to local staff is important to communicate any actions needed after the completion of the investigation AND about the occurrence of AEFIs in the facility/district, province and nationally. Information should also be provided to suppliers and manufacturers of vaccines.

7. SELECTED ADDITIONAL READING AND BACKGROUND MATERIALS

General

1. Department of Health, Expanded Programme on Immunisation in South Africa: EPI Diseases Surveillance, Field Guide, 2nd edition, October 1998
2. National Department of Health, Epidemiology and Surveillance Directorate: National Guidelines for reporting notifiable medical conditions, 2005
3. WHO AFRO: Technical Guidelines for Integrated Disease Surveillance and Response in the African Region, 2nd edition, October 2010
4. WHO, Department of Vaccines and Biologicals: WHO-recommended standard for surveillance of selected vaccine preventable diseases, 2003
5. World Health Organization: WHO vaccine-preventable diseases monitoring system 2010 global summary; WHO/IVB/2010
6. World Health Organization, Department of Vaccines and Biologicals; Making surveillance work Module 1: Rapid assessment of surveillance for vaccine-preventable diseases, May 2005
7. World Health Organization, Department of Immunisation, Vaccines and Biologicals; Global Framework for Immunisation Monitoring and Surveillance, November 2007
8. World Health Organization, Department of Vaccines and Biologicals; Making surveillance work Module 2-4
9. World Health Organization Department of Immunisation, Vaccines and Biologicals: Making disease surveillance work, training for mid-level managers module 8; 2008
10. World Health Organization, Global Programme for Vaccines and Immunisation: The Immunological Basis for Immunisation Series, Module 1,3,6 and 7
11. American Public Health Association: Control of Communicable Diseases Manual 19th edition, 2008

Polio

12. WHO AFRO: AFP Surveillance Field Guide – January 2006
13. World Health Organization, Global Programme for Vaccines and Immunisation: Field Guide for Supplementary Activities aimed at achieving polio eradication. 1996 Revision, Geneva, 1997
14. Global Polio Eradication Initiative: Responding to a polio outbreak-Guideline; 7 January 2011
15. Global Polio Eradication Initiative: Guidelines for Investigating a Polio outbreak or AFP case clustering
16. Weekly epidemiological record: Polio vaccines and polio immunisation in the pre-eradication era; WHO position paper 4 June 2010 No. 23, 2010, 85, 213–228
17. Weekly epidemiological record: Laboratory surveillance for wild and vaccine- derived polioviruses, January 2007–June 2008; September 2008 No. 36, 2008, 83, 321–332
18. Weekly epidemiological record: Global update on vaccine- derived polioviruses, January 2006–August 2007; 28 September 2007 No. 39, 2007, 82, 337–344
19. CDC (2006). Update on Vaccine-Derived Polioviruses October 13, 2006 / 55 (40); MMWR 2006; 1093-1097

Measles

20. WHO AFRO: Measles Surveillance Guidelines, April 2011
21. World Health Organization Department of Immunisation, Vaccines and Biologicals: Response to measles outbreaks in measles mortality reduction settings, March 2009
22. Pan American Health Organization: Measles elimination field guide, second edition, 2005
23. World Health Organization Department of Vaccines and Biologicals: Module on best practices for measles surveillance, March 2002 WHO/V&B/01.43
24. WHO/UNICEF Joint Statement Global Plan for Reducing Measles Mortality 2006-2010
25. Weekly epidemiological record: Measles vaccines, WHO position paper; 28 august 2009, No. 35, 2009, 84, 349–360

Neonatal Tetanus

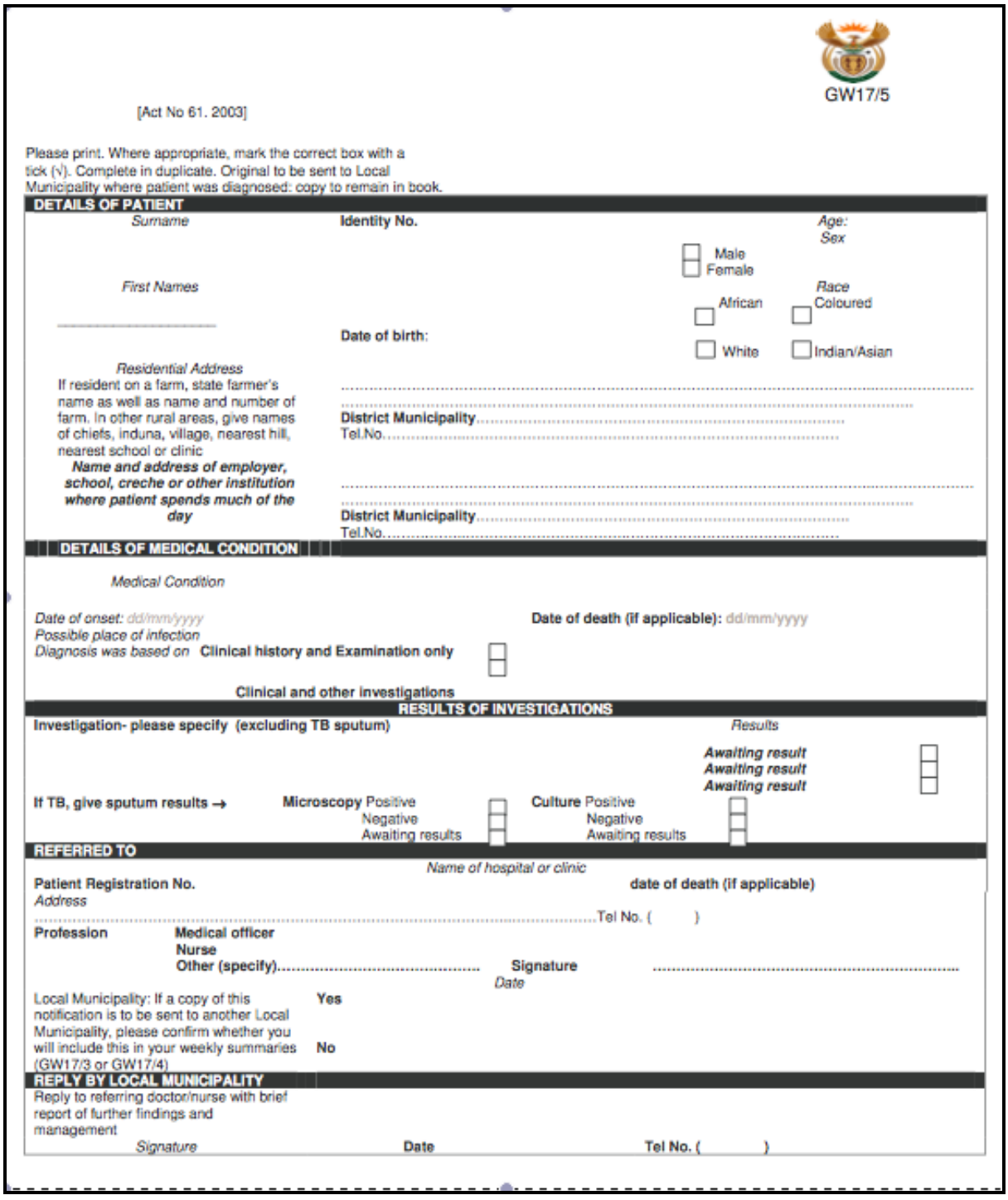
26. World Health Organization Department of Vaccines and Biologicals; Protocol for assessing neonatal tetanus mortality in the community using a combination of cluster and lot quality assurance sampling: Field test version, 2002
27. World Health Organization Department of Vaccines and Biologicals; Maternal and Neonatal Tetanus Elimination by 2005 *Strategies for achieving and maintaining elimination;* WHO/V&B/02.09
28. World Health Organization Department of Vaccines and Biologicals: Maternal and Neonatal Tetanus (MNT) elimination: The initiative and challenges
29. World Health Organization, Department of Making Pregnancy Safer: Maternal immunisation against tetanus; Integrated Management Of Pregnancy and Childbirth (IMPAC); 2002
30. World Health Organization Department of Vaccines and Biologicals: Template of a national plan of action for maternal and neonatal tetanus elimination; May 2001 WHO/V&B/01.18
31. National Department of Health: Report on validation of elimination of maternal and neonatal tetanus in South Africa; 24 January 2003

Adverse Events Following Immmunisation

32. World Health Organization: Aide-Memoire on AEFI investigation – 2005 (http://www.who.int/vaccines-documents/DocsPDF05/792.pdf)
33. World Health Organization: Aide-Mémoire on adverse events following immunization: causality assessment, 2005 (http://www.who.int/vaccines-Documents/DocsPDF05/ 815.pdf)
34. Weekly epidemiological record: Global Advisory Committee on Vaccine Safety, 6–7 June 2006, 14 July 2006
35. Pan American Health Organization, Regional Office of the World Health Organization, Division of Vaccines and Immunisation: How to address events allegedly attributable to vaccination or immunisation, 2002
36. World Health Organization, Western Pacific Regional Office: Guidelines for Managers of Immunisation Programmes on Reporting and Investigating Adverse Events Following Immunisation; 1999
37. World Health Organization, Expanded Programme on Immunisation: Surveillance of adverse events following immunisation, Field guide for managers of immunisation programmes, 1997.

Annexes

Annex 1.1 GW17/5 Notification form for cases and deaths



GW17/5

[Act No 61. 2003]

Please print. Where appropriate, mark the correct box with a tick (√). Complete in duplicate. Original to be sent to Local Municipality where patient was diagnosed: copy to remain in book.

DETAILS OF PATIENT

Surname **Identity No.** *Age:* *Sex*

☐ Male ☐ Female

First Names *Race*

☐ African ☐ Coloured ☐ White ☐ Indian/Asian

Date of birth:

Residential Address

If resident on a farm, state farmer's name as well as name and number of farm. In other rural areas, give names of chiefs, induna, village, nearest hill, nearest school or clinic

.....

.....

District Municipality.....

Tel.No.....

Name and address of employer, school, creche or other institution where patient spends much of the day

.....

.....

District Municipality.....

Tel.No.....

DETAILS OF MEDICAL CONDITION

Medical Condition

Date of onset: dd/mm/yyyy **Date of death (if applicable):** dd/mm/yyyy

Possible place of infection

Diagnosis was based on **Clinical history and Examination only** ☐

Clinical and other investigations

RESULTS OF INVESTIGATIONS

Investigation- please specify (excluding TB sputum) *Results*

Awaiting result ☐
Awaiting result ☐
Awaiting result ☐

If TB, give sputum results →

Microscopy Positive ☐
Negative
Awaiting results ☐

Culture Positive ☐
Negative
Awaiting results ☐

REFERRED TO

Name of hospital or clinic

Patient Registration No. **date of death (if applicable)**

Address

.....Tel No. ( )

Profession **Medical officer**
Nurse
Other (specify)..... **Signature** .....

Date

Local Municipality: If a copy of this notification is to be sent to another Local Municipality, please confirm whether you will include this in your weekly summaries (GW17/3 or GW17/4)

Yes

No

REPLY BY LOCAL MUNICIPALITY

Reply to referring doctor/nurse with brief report of further findings and management

Signature **Date** **Tel No. ( )**

Annex 1.2 Supervisory checklist for EPI target disease surveillance

Health Facility _____

District _____

Date _____

1. **Health facility**	**[✓] Tick appropriate box**		**Comments**
	Y	N	
❑ Has any case of SMC, AFP, NNT or AEFI been reported from the health facility?			
❑ Are the health workers fully knowledgeable on the case definitions?			
❑ Do health workers know to whom and how to report when a case is detected?			
❑ Does the relevant personnel (infection control nurse, paediatric nurses and doctors) know what specimen to collect and the procedure of specimen collection from suspected cases?			
❑ Do the health workers know the proper handling and transportation of the specimens?			
❑ Are case investigation forms (CIF) available?			
❑ Are appropriate supplies for collecting laboratory specimens available?			
❑ Have health workers participated in surveillance training in last 12 to 24 months?			
❑ Are there posters on case definitions of EPI target disease surveillance?			
❑ Is the EPI surveillance field guide available in the facility?			
❑ Does health facility keep records of previously sent (weekly, monthly) reports?			

2. **Sub-district/ District health office**	**[✓] Tick appropriate box**		**Comments**
	Y	N	
❑ Is there a designated surveillance focal person			
❑ Does the surveillance focal person know the case definitions for EPI target diseases?			
❑ Does surveillance focal person receive a copy of the CIFs when cases are detected?			
❑ Are CIFs properly filled and updated (lab results, follow up results etc.)			
❑ Is the list of reporting sites for EPI target disease surveillance available? Is it updated yearly?			

❑ Does surveillance focal person receive weekly active surveillance forms on time?			
❑ Are weekly active surveillance data collated and sent to province on time?			
❑ Is there a system to ensure the supply of forms and laboratory specimen collection kits			
❑ In the last one year has there been any refresher training conducted for clinicians or health workers in the district?			
❑ Are surveillance field guides available?			
❑ Is there a supervision plan?			
❑ Are there any written supervisory reports with action points on surveillance in last 6 months?			
❑ Is there a well-kept and organised surveillance data?			
❑ Are surveillance performance indicators regularly monitored? C*heck for maps and graphs)*			
❑ Is there any regular meeting at district level during which surveillance performance is discussed and feedback provided?			

Annex 2.1 Differential Diagnosis of Acute Flaccid Paralysis

	Polio	**Guillain-Barré syndrome**	**Traumatic neuritis**	**Transverse myelitis**
Installation of paralysis	24 to 48 hours onset to full paralysis	From hours to ten days	From hours to four days	From hours to four days
Fever at onset	High, always present at onset of flaccid paralysis, gone the following day	Not common	Commonly present before, during and after flaccid paralysis	Rarely present
Flaccid paralysis	Acute, usually asymmetrical, principally proximal	Generally acute, symmetrical and distal	Asymmetrical, acute and affecting only one limb	Acute, lower limbs, symmetrical
Muscle tone	Reduced or absent in affected limb	Global hypotonia	Reduced or absent in affected limb	Hypotonia in lower limbs
Deep-tendon reflexes	Decreased to absent	Globally absent	Decreased to absent	Absent in lower limbs early (hyper-reflexia late)
Sensation	Severe myalgia, backache, no sensory changes	Cramps, tingling, hypoanaesthesia of palms and soles	Pain in gluteus, hypothermia	Anesthesia of lower limbs with sensory level
Cranial nerve involvement	Only when bulbar involvement is present	Often present, affecting nerves VII, IX, X, XI, XII	Absent	Absent
Respiratory insufficiency	Only when bulbar involvement is present	In severe cases, enhanced by bacterial pneumonia	Absent	Sometimes

Annex 2.2 EPI (SA) Provincial weekly active surveillance report form

EPI (SA) Provincial weekly active surveillance report form					
1. Identification					
Province	**Year**	**Month**	**Week**		**Week No**
2. Timeliness & completeness of reporting					
2.1 Number of districts		2.5 Total number of reports received			
2.2 Number of sub-districts		2.6 Percentage reports received (Completeness = 2.5/2.4)			
2.3 Total number of reporting sites		2.7 Total number of reports received on time			
2.4 Total number of reports expected		2.8 Percentage of reports received on time (Timeliness = 2.7/2.4)			
3. Surveillance data					
	AFP	**Suspected Measles**	**Confirmed Measles**	**Neonatal Tetanus**	**Severe AEFI**
1.1 No of **cases** this week					
3.2 No of **cumulative** cases (since Jan 1st)					
1.2 No of **deaths** this week					
3.4 **Cumulative deaths** *(since Jan 1st)*					
4. Submission *Submit to the NDoH EPI (SA) every Monday of the Week*					
PROVINCIAL SURVEILLANCE TEAM			**NDoH REPRESENTATIVE**		
Date sent _____ Name and signature Surveillance officer:_____ Tel no:			Date of receipt: _____ Name and signature EPI (SA) Representative: _____ Tel no		

Annex 2.3 AFP Case Investigation Form

SA ACUTE FLACCID PARALYSIS (AFP) CASE INVESTIGATION FORM (CIF)

(NB! All Dates dd-mm-yy. Use dark black ink & print legibly please)

Epid number: ___SOA___- LPP -_____-_____-_____ Date Province Received CIF: ____/____/____
(Will be assigned at Provincial Office) — Country — Prov Code — District Code — Year Onset — Case number
EPI (SA) Received CIF: ____/____/____

Surveillance Type (Active, Routine, Retrospective) _____

IDENTIFICATION

Health District: _____ Province: _____ Nearest Health Facility to Patient home: _____

Surname & Name: _____ Father/Mother: _____ Cell No: _____

Address: _____ Town/City: _____

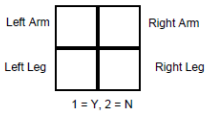
Date of Birth: ____/____/____ Age: years _____ (If DOB unknown / not entered) months_____ (Only if < 1 yr old) Gender ☐ M=Male F=Female

CLINICAL HISTORY

Site of Paralysis

Date Onset of Paralysis ____/____/____

	1=Yes	2=No
Fever at onset of paralysis		
Flaccid & sudden paralysis		
Paralysis progressed <=3 days		
Asymmetrical		



Medical Diagnosis: _____

VACCINATION HISTORY: ☐ (Exclude Birth dose; 99=unknown) OPV/IPV doses Birth____/____/____ 1st ____/____/____

2nd ____/____/____ 3rd ____/____/____ 4th ____/____/____ If >4, last OPV/IV dose ____/____/____

NOTIFICATION/INVESTIGATION

Notified by:_____ Tel _____ Date Notified:____/____/____ Date Case Investigated:____/____/____

HOSPITALIZATION Admitted to hospital: ☐ 1=Yes 2=No Date of Admission: ____/____/____

Medical Record No: _____ Facility Name: _____

STOOL SPECIMENS

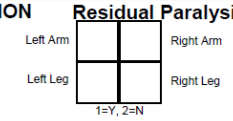
	Date Collected	Days after onset	Date Sent to Lab	Date Received by Lab	Lab Ref No	Stool Condition 1 = Adequate 2 = Not Adeq	P1	P2	P3	NP-Ent	W1	W2	W3	V1	V2	V3	Date Lab result to Prov & EPI (SA)	Date result Received at EPI (SA) or Province
Stool 1																		
Stool 2																		

(Results 1 = Yes = Positive 2 = No = Negative)

60 DAY FOLLOW UP EXAMINATION

Date follow up Examination: ____/____/____

Residual Paralysis?



Findings at follow-up: ☐ 1=Residual paralysis 2=No residual paralysis 3=Lost to follow-up 4=Death before follow-up

Date Died: ____/____/____

INVESTIGATOR

Name: _____ Title:_____ Facility:_____ Phone: _____

PEC - FINAL CLASSIFICATION: [To be completed by EPI (SA)]

EPI (SA) Classification: _____ ☐ 1 = Confirmed 2 = Compatible 3 = Discarded 6 = Not an AFP

True AFP? ☐ 1=Yes, 2=No

PEC Classification: _____ Date PEC: ____/____/____

Remarks: _____

_____

NB: ENSURE THAT THE NEUROLOGICAL ASSESSMENT FORM IS COMPLETED

AFP CASES TO BE NOTIFIED BY PHONE TO DISTRICT / PROVINCIAL CONTACT PERSON

IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT: DISTRICT/PROVINCIAL CONTACT PERSON

Expanded Programme on Immunisation **National Office** 012 395 9453 / 012 395 9530 / 012 395 9458

Annex 2.4 AFP Case Neurological Assessment Form

NEUROLOGICAL ASSESSMENT FORM FOR ALL ACUTE FLACCID PARALYSIS (AFP) CASES

<table>
<tr><td>1</td><td>EPID number</td><td>SOA--_____--_____--_____--_____
Country Province District Year Case number</td></tr>
<tr><td colspan="3">IDENTIFICATION</td></tr>
<tr><td>2</td><td>Province</td><td></td></tr>
<tr><td>3</td><td>District</td><td></td></tr>
<tr><td>4</td><td>Name of AFP case</td><td></td></tr>
<tr><td>5</td><td>Date of Birth</td><td></td></tr>
<tr><td>6</td><td>Onset of paralysis</td><td></td></tr>
<tr><td colspan="3">NEUROLOGICAL EXAMINATION</td></tr>
<tr><td>6</td><td>Glasgow Coma Scale</td><td><table><tr><td>Eye Opening (5)</td><td></td></tr><tr><td>Verbal Response (5)</td><td></td></tr><tr><td>Motor Response (5)</td><td></td></tr><tr><td>SCORE (15)</td><td></td></tr></table></td></tr>
<tr><td>7</td><td>Power (0-5)
0 = No movement
1 = Flicker
2 = Gravity eliminated
3 = Against gravity
4 = Just below normal
5 = Normal for age</td><td><table><tr><td colspan="2">Upper Limb</td><td colspan="2">Lower Limb</td></tr><tr><td>Right</td><td>Left</td><td>Right</td><td>Left</td></tr><tr><td></td><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>8</td><td>Tone
(Normal/Increased/decreased)</td><td><table><tr><td colspan="2">Upper Limb</td><td colspan="2">Lower Limb</td></tr><tr><td>Right</td><td>Left</td><td>Right</td><td>Left</td></tr><tr><td></td><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>9</td><td>Reflexes (0-4)
0 = No reflexes
1 = Decreased
2 = Normal
3 = Brisk
4 = Brisk with clonus</td><td><table><tr><td colspan="2">Upper Limb</td><td colspan="2">Lower Limb</td></tr><tr><td>Right</td><td>Left</td><td>Right</td><td>Left</td></tr><tr><td></td><td></td><td></td><td></td></tr></table></td></tr>
<tr><td>10</td><td>Sensation
(intact/loss distribution/level)</td><td></td></tr>
<tr><td>11</td><td>Bowel control/continence
(normal/abnormal)</td><td></td></tr>
<tr><td>12</td><td>Bladder control/continence
(normal/abnormal)</td><td></td></tr>
<tr><td>13</td><td>Cerebellar signs
(present/none)</td><td></td></tr>
</table>

Name of examining Dr:_____ Date of examination:_____

Contact details of examining Dr:_____Signature of examining Dr:_____

Annex 2.5 Standard Operating Procedure (SOP) on Acute Flaccid Paralysis (AFP) Data Management

This SOP can be taken as direction to ensure reliability of AFP data. SOPs can be defined as minimum expected standards or detailed guidelines / guidance or basic standards required at any level to facilitate production of clean quality data for decision-making. Furthermore, if this SOP is used and followed strictly, it can ensure that the existing programme personnel are at same level.

Data Management Principle

The main principle of AFP surveillance data management systems is to ensure a better understanding of the epidemiology of AFP cases. Data management processes include identification of data needs, data receipt, data processing (cleaning and harmonisation, analysis, feedback on data quality-surveillance performance-disease epidemiology, and data achieving). Sound data demand that data should be complete, accurate and timely.

Principal uses of AFP data for decision-making

- Track wild and Vaccine Derived Poliovirus (VDPV) circulation in the country;
- Use data to classify cases as: confirmed, compatible or discarded;
- Monitor routine coverage, performance of surveillance in all geographical areas;
- Focus efforts in low performing geographical areas;
- Identify high-risk areas with a view to planning mop-up immunisation campaigns;
- Provide evidence to the Certification Commissions on the interruption of wild poliovirus circulation.

Data Work Flow

A data workflow system provides information on where data is, who handles the data, when is it due at a particular level, etc.

There are two sources of data flow for AFP; case-based data and laboratory-based data.

Harmonised case-based and laboratory-based data should be maintained at district, provincial and national levels. Data quality reflects the completeness and validity of the data recorded in the public health surveillance system. The importance of clearly identifying the data flow system should be prioritised at all levels.

Roles and responsibilities in data work flow

The provincial surveillance officer will assume responsibility for the AFP line list. It is the duty of the provincial surveillance officer to ensure that an AFP line list is maintained for each

district. The provincial surveillance officer must ensure continuity when he/she is not available.

A comprehensive AFP line list must be maintained at district, provincial and national level as well as at the National Institute for Communicable Diseases (NICD). AFP Case Investigation Forms (CIFs) must be maintained at district, provincial and national level as well as at the NICD.

Data Management Activities at Different Levels

Cased-based data

AFP surveillance data flow starts at the health facility after a case has been detected, a case investigation (CIF) and the neurological assessment forms are filled in. The subsequent stages are the sub-district/district, province and national levels. The specimens, together with a CIF and the neurological assessment form, should be taken to the nearby National Health Laboratory Services (NHLS) or directly by courier to the National Institute for Communicable Diseases (NICD).

Health Facility Level

- CIFs should be available at all health facilities;
- Fill in the CIF and the Neurological assessment form for each AFP case;
- Collect first stool specimen, store on ice and send to NICD with CIF as soon as possible
- Collect second stool specimen 24-48 hours after the first specimen and send to NICD on ice with a copy of the CIF.
- Both stools should be collected within 14 days of onset of paralysis. If patient presents later than 14 days but less than 60 days since onset of paralysis two stools must still be collected and sent to NICD on ice.
- If the patient is unable to pass stool, a rectal swab may be taken followed by stools as soon as possible. Rectal swab must be sent with CIF to NICD on ice.
- Inform district of case by e-mail or telephonically and send a copy of CIF to district level;
- File a copy of the CIF in an appropriate file.

District / Sub-district Level

Case-based data

- Acknowledge the receipt of CIF from health facilities;
- Check CIF and Neurological assessment form for completeness upon receipt;
- If CIF and Neurological assessment forms are not completely filled in, contact health facility;

- Record the case and update on a AFP line list prior to sharing with province;
- Assign Epid Number (Unique Number) to CIF and line list;
- Scan/ fax CIF after assigning Epid Number and send CIF to Province;
- File CIFs and Neurological assessment forms according to sub-districts (hard copy or electronic or both);

Lab-based data

- Receive laboratory-based data from NICD weekly on Wednesday;
- Update the district line list with polio isolation results received from NICD;
- Update district line list with any additional cases from NICD not appearing on the district line list (this harmonizes case-based and laboratory-based data);
- Ensure that every case has an assigned Epid Number
- Ensure that each case has a completed CIF
- Send updated line list and completed/updated CIFs to province weekly on Thursday. Conduct 60 day follow-up on inadequately investigated AFP cases (less than two stool specimens, within 14 days of onset, 24-48 hours apart, on ice). Update outcome on CIF and line list (residual paralysis, no residual paralysis, lost to follow-up, death). Send updated information to province and national levels.

Province Level

Acknowledge receipt of weekly line list from districts on Thursday

Case-based data

- Acknowledge the receipt of CIF from districts;
- Check the CIFs for completeness upon receipt;
- If CIFs incompletely filled in, contact district to fill gaps;
- Send copies of all CIFs to national;
- If Epid Number is not assigned at district level, province should assign it and share with the district and NICD;
- Update provincial AFP line list;
- Organise and file CIFs by year and district (hard copy or electronic or both);
- Back up data regularly to prevent unexpected loss;
- Send updated line list weekly to national and NICD on Monday;
- Send weekly summary form for Vaccine-Preventable Diseases (VPD) surveillance to national on Monday.

Laboratory-based data

- Acknowledge receipt of laboratory-based data from NICD weekly on Wednesday;
- Update the provincial line list with AFP results received from NICD
- Update provincial line list with any additional cases from NICD not appearing on the provincial line list (this harmonizes case-based and laboratory-based data);
- Acknowledge receipt of updated district line list weekly on Thursday and update provincial line list
- Ensure that every case has an assigned Epid Number;
- Ensure that each case has a completed CIF;
- Send copies of CIFs of AFP cases to national and NICD
  Send updated line list to NDoH and NICD weekly on Monday.
  Ensure that there has been a 60 day follow up for all inadequately investigated cases (less than two stool specimens, within 14 days of onset, 24-48 hours apart, on ice)

National Level

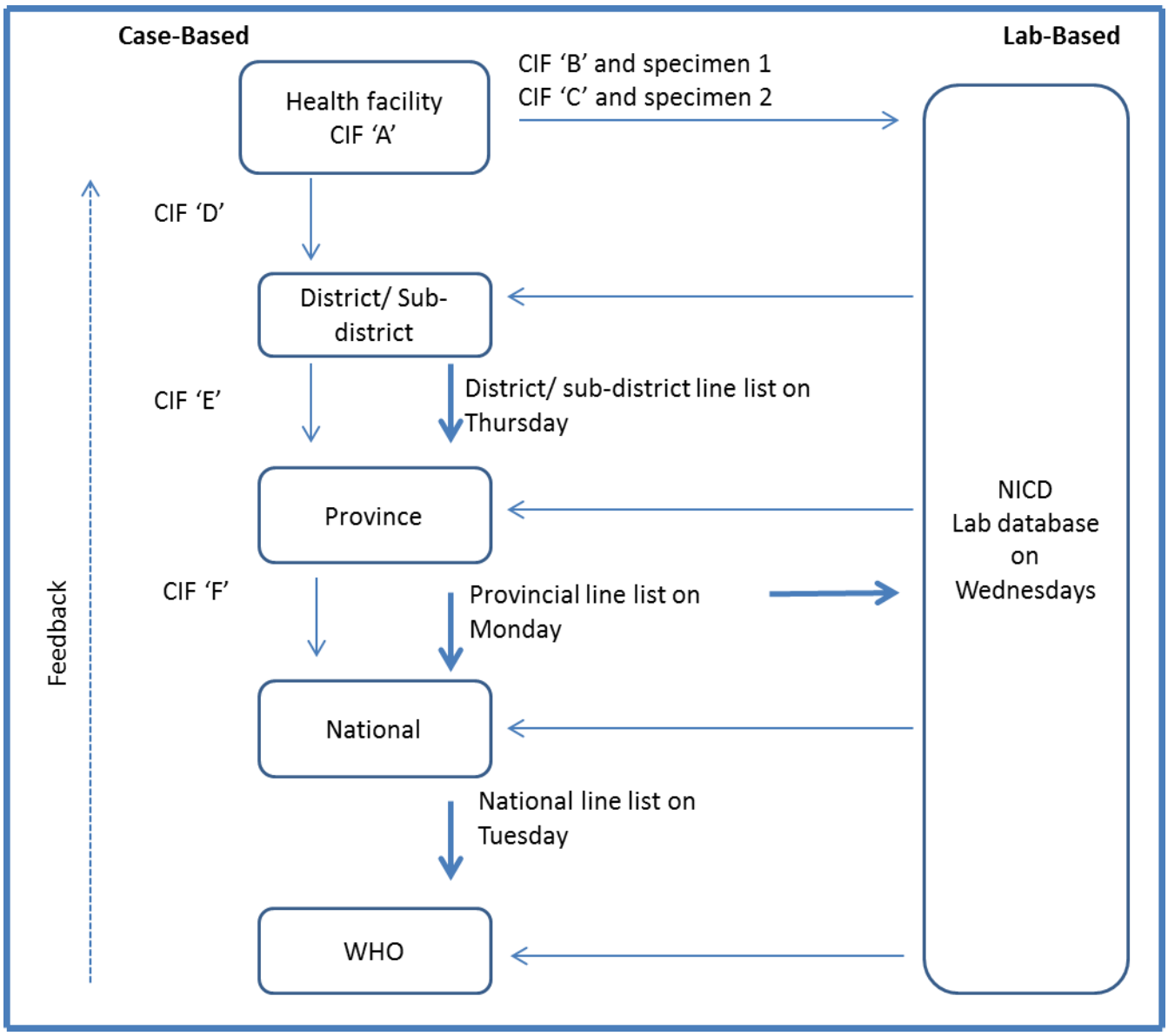
Case-based data

- Acknowledge receipt of weekly provincial line lists on Monday;
- Ensure that all AFP cases have CIFs;
- File CIFs of AFP cases (e.g. file by year, province and district);
- Clean, verify the quality of data and analyse;
- Feedback to provinces monthly ;

Laboratory-based data

- Receive AFP lab database from NICD weekly on Wednesday;
- Harmonise national case-based and lab-based database;
- Provide feedback to NICD and province if there are any discrepancies between the two databases;
- Pre-classify all adequately investigated cases with two negative stool specimen results. Refer list of cases to National Polio Expert Committee (NPEC) for verification
- Refer inadequately investigated cases to NPEC for final classification
- Share the data with WHO-Country office and the WHO-Inter-country Support Team (IST) weekly on Tuesday.
- Get feedback from IST, correct the database accordingly and resend updated database to IST;
- Analyse all performance indicators by district, province and national level and provide feedback via monthly AFP bulletin;

Acute Flaccid Paralysis Data Flow Diagram



* All line lists comprise harmonised lab-based and case-based data

* CIFs B, C, D, E and F represent updated copies of CIF A for the same patient

Checklists for Case-based AFP Data Cleaning /Verification

Verify data whether it is complete and clean:

- Have and check province and district code of currently used;
- Check the date formats;
- Age, sex;
- Check the following dates:
  - Date of onset;

- Date of specimen collection (1st and 2nd specimen);
- Date specimen sent to the lab;
- Date specimen received at lab;
- Date result sent to national level.

- Epid Number (e.g. CCC-PPP-DDD-YY-000);
- Names of districts (Sometimes the same district is spelt differently. Make sure that district names are spelt the same way at all levels);
- Specimen condition;
- Final cell culture result;
- Final case classification;
- Vaccination status (or number of vaccine doses);
- Outcome;
- Cases with at least one stool collected, but missing Lab result;
- Check for logical flow of date variables, e.g. date of onset should come before dates of collection. This can be evidenced when you get negative answers in analysis;
- Ensure that all cases positive for virus are classified as “1” under final classification;
- Cases missing final classification 90 days after ONSET;
- Check that cases in the current year database match the year entered EPID and Date of Onset, e.g. CCC-PPP-DDD-08-001 and dd/mm/2008.

Data Harmonisation

Please refer to data harmonisation SOP

Annex 3.1 Measles Case Investigation Form

MEASLES CASE INVESTIGATION FORM

EPID NUMBER: **SOA** - _____ - _____ - _____ - _____

(Will be assigned at Provincial Office) — Country — Prov Code — District Code — Year Onset — Case number

Name of person completing form: _____ Signature: _____

Sources of Data: Caregiver ☐ Clinician ☐ Medical records ☐ No data obtained ☐

Name of Health Facility attended: _____ Name of attending clinician: _____

Health Facility street address: _____

_____ Contact number: _____

PATIENT DETAILS

Full name: _____ Gender: M ☐ F ☐ Unknown ☐

Date of birth: ____/____/____ If DOB unknown Age: ___ Unit: Days ☐ Wks ☐ Months ☐ Yrs☐; DOB and Age Unk ☐

Street address: _____

Health District _____ Town/ City: _____ Province: _____ Contact Number(s): _____

CURRENT PRESENTATION

Presenting symptoms/signs *(Tick all applicable Boxes):* Rash ☐ Fever ☐ Conjunctivitis ☐ Cough ☐

Coryza/Rhinitis/runny nose ☐ Other *(Specify)* _____

Date of onset of rash: _____/_____/_____	Date of Presentation at the health facility: _____/_____/_____

Clinical Management: Vitamin A given: Y ☐ N ☐ Number of doses ☐

Specimens Collected *(Tick where applicable):* Blood/Serum ☐ Nasopharyngeal/Saliva ☐

Dried Blood Spot ☐ Date of specimen collection: _____/_____/_____

MEDICAL AND CONTACT HISTORY

History of contact with a suspected measles case in the past 7 to 28 days: Y ☐ N ☐ Unknown ☐

History of contact with a laboratory confirmed measles case in the past 7 to 28 days: Y ☐ N ☐ Unknown ☐

History of travel in the past 7 to 28 days: Y ☐ N ☐; if yes, name of place or country travelled to _____

History of previous visit or admission to a healthcare facility in the past 7 to 28 days: Y ☐ N ☐ Unknown ☐

If yes, Name of the Facility: _____ Diagnosis at the Facility: _____

Vaccination Information obtained from: Road to health card ☐ Self reported ☐ Not obtained ☐

Measles vaccination received: Y ☐ N ☐ Unknown ☐	If yes, number of doses: 1 ☐ 2 ☐ >2 ☐ Date of last measles vaccination: _____/_____/_____

RESPONSE TO CASE :

Case Notified: Y ☐ N ☐ Unknown ☐ Date of Notification_____/_____/_____ Date of Investigation_____/_____/_____

Contacts follow-up	Number			Action Taken
	< 5 yrs	5-14 yrs	>=15 yrs	
Household				
School/Crèche				
Other (Specify)_____				
Active Case Finding: Y ☐ N ☐	Number of suspected measles cases found: None ☐ or specify number_____			

30 DAY FOLLOW-UP OF ALL IgM POSITIVE CASES

Complications *(Tick where applicable):* None ☐ Pneumonia ☐ Otitis Media ☐ Diarrhoea ☐ Febrile seizures ☐ Laryngotracheobronchitis (Croup) ☐ Corneal Ulceration ☐ Blindness ☐Encephalitis ☐

Final outcome *(Tick where applicable):* Patient admitted to Hospital: Y ☐ N ☐ Patient Died: Y ☐ N ☐

NB: Complete a separate case investigation form for each suspected measles case identified

MEASLES CASES TO BE NOTIFIED TO THE PROVINCIAL CONTACT PERSON:

IMMEDIATELY SEND A COPY OF THIS COMPLETED FORM TO: *: District & Provincial EPI coordinators*

IF YOU HAVE ANY QUESTIONS, PLEASE CONTACT: *: District & Provincial EPI coordinators*

Expanded Programme on Immunisation National Office : 012 395 9453 / 012 395 9530 / 012 395 9458

Annex 3.2 Line-listing for Measles Cases

District _____ Person responsible_____

Province _____

Codes

1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26

1 **Epid Number**
2 **Name of Patient**
3 **Sex**
4 **Date of Birth**
5 **Age in years**
6 **Age in months**
7 **Reporting Health facility**
8 **Province of Residence**
9 **District of Residence**
10 **Town / city**
11 **Village**
12 **Date of onset**
13 **Fever**
14 **Rash**
15 **Cough / Coryza / Conjunctivitis**
16 **Date Seen Health Facility**
17 **Number of Measles Vaccine Doses**
18 **Date of Last vaccination**
19 **Date Specimen collected**
20 **Specimen Type**
21 **Date Specimen Sent to lab**
22 **Date Lab Received Specimen**
23 **Measles IgM**
24 **Rubella IgM**
25 **Date Lab Sent Result to district**
26 **Outcome**

(This line list format is available in soft copy and was shared with all provinces. It is important that provinces share the line list data every week with national EPI).

Annex 3.3 Standard Operating Procedure (SOP) on Measles Data Management

This SOP can be taken as direction to ensure reliability of measles data. SOPs can be defined as minimum expected standards or detailed guidelines / guidance or basic standards required at any level to facilitate production of clean quality data for decision-making. Furthermore, if this SOP is used and followed strictly, it can ensure that the existing programme personnel are at same level.

Data Management Principle

The main principle of measles surveillance data management systems is to ensure a better understanding of the epidemiology of measles. Data management processes include identification of data needs, data receipt, data processing (cleaning and harmonisation, analysis, feedback on data quality-surveillance performance-disease epidemiology, and data achieving). Sound data management principles demand that data should be complete, accurate and timely.

Principal Uses of Measles Data for Decision-making

- Track measles virus circulation in the country;
- Classify measles cases as Lab-confirmed, epidemiologically confirmed, clinically confirmed or discarded;
- Monitor measles routine coverage with measles incidence , as well as performance of surveillance in all geographical areas and focus efforts in low-performing geographical areas;
- Monitor seasonality to determine low season of measles virus transmission in the interest of planning national immunisation days (NIDs);
- Identify high-measles risk areas with a view to planning mop-up immunisation campaigns.

Data Work Flow

A data workflow system provides information on where data is, who handles the data, when is it due at a particular level, etc.

There are two sources of data flow for measles; case-based data and laboratory-based data.

Harmonised case-based and laboratory-based data should be maintained at district, provincial and national levels. Data quality reflects the completeness and validity of the data recorded in the public health surveillance system. The importance of clearly identifying the data flow system should be prioritised at all levels.

Roles and responsibilities in data work flow

The provincial surveillance officer will assume responsibility for the measles line list. It is the duty of the provincial surveillance officer to ensure that each district maintains a measles line list. The provincial surveillance officer must ensure continuity when not available.

A comprehensive measles line list must be maintained at district, provincial and national level as well as at the National Institute for Communicable Diseases (NICD). Measles Case Investigation Forms (CIFs) must be maintained at district and provincial level as well as at the NICD.

Data Management Activities at Different Levels

Cased-based data

Measles surveillance data flow starts at the health facility after a case has been detected and a case investigation forms (CIF) is filled in. The subsequent stages are the sub-district, district, province and national levels. The specimen, together with a CIF, should be taken to the nearby National Health Laboratory Services (NHLS) or directly by courier to the National Institute for Communicable Diseases (NICD).

Health Facility Level

- CIFs should be available at all health facilities;
- Fill in a CIF for each suspected measles case;
- Collect a specimen of blood;
- Under certain circumstances (under guidance from the laboratory/NDoH), an oro-pharyngeal swab in viral transport media should be sent;
- Put a copy of the CIF in Zip-lock plastic bag together with sample;
- Inform district of case by e-mail or telephonically and send a copy of CIF to district level;
- Send specimens to NICD or to nearby NHLS lab for referral to NICD;

- File a copy of the CIF in an appropriate file.

District Level/ Sub-district Level

Case-based data

- Acknowledge the receipt of CIF from health facilities;
- Check CIF for its completeness upon receipt;
- If CIF is not fully filled in, contact health facility;
- Record the case and update on a measles line list prior to sharing with province;
- Assign Epid Number (Unique Number) to CIF and line list;
- Scan/ fax CIF after assigning Epid Number and send CIF to Province;
- File CIFs according to sub-districts (hard copy or electronic or both);
- Observe and make simple data analysis to look for clusters and trend of measles cases.

Lab-based data

- Receive laboratory-based data from NICD weekly on Friday;
- Update the district line list with IgM results received from NICD;
- Update district line list with any additional cases from NICD not appearing on the district line list (this harmonizes case-based and laboratory-based data);
- Ensure that every case has an assigned Epid Number
- Ensure that each case has a completed CIF

Send updated line list and completed/updated CIFs to province weekly on Thursday. Conduct telephonic 30 day follow-up on measles IgM positive cases and update outcome on CIF and line list (e.g. pneumonia, blindness, encephalopathy, death or recovered). Send updated information to province and national levels.

Provincial Level

Acknowledge receipt of weekly line list from districts on Thursday

Case-based data

- Acknowledge the receipt of CIF from districts;
- Check the CIFs for completeness upon receipt;

- If CIFs incompletely filled in, contact district to fill gaps;
- Send copies of CIFs of IgM positive cases to national;
- If Epid Number is not assigned at district level, province should assign it and share with the district;
- Update provincial measles line list;
- Organise and file CIFs by year and district (hard copy or electronic or both);
- Back up data regularly to prevent unexpected loss;
- Send updated line list weekly to national and NICD on Monday;
- Send weekly summary form for Vaccine-Preventable Diseases (VPD) surveillance to national on Monday.

Laboratory-based data

- Acknowledge receipt of updated district line list weekly on Thursday;
- Acknowledge receipt of laboratory-based data from NICD weekly on Friday;
- Update the provincial line list with IgM results received from NICD;
- Update provincial line list with any additional cases from NICD not appearing on the provincial line list (this harmonizes case-based and laboratory-based data);
- Ensure that every case has an assigned Epid Number;
- Ensure that each case has a completed CIF;
- Send copies of CIFs of IgM positive cases to national and NICD

Send updated line list to NDoH and NICD weekly on Monday.

Ensure that there has been a 30 day telephonic follow-up on all IgM positive measles cases.

National Level

Case-based data

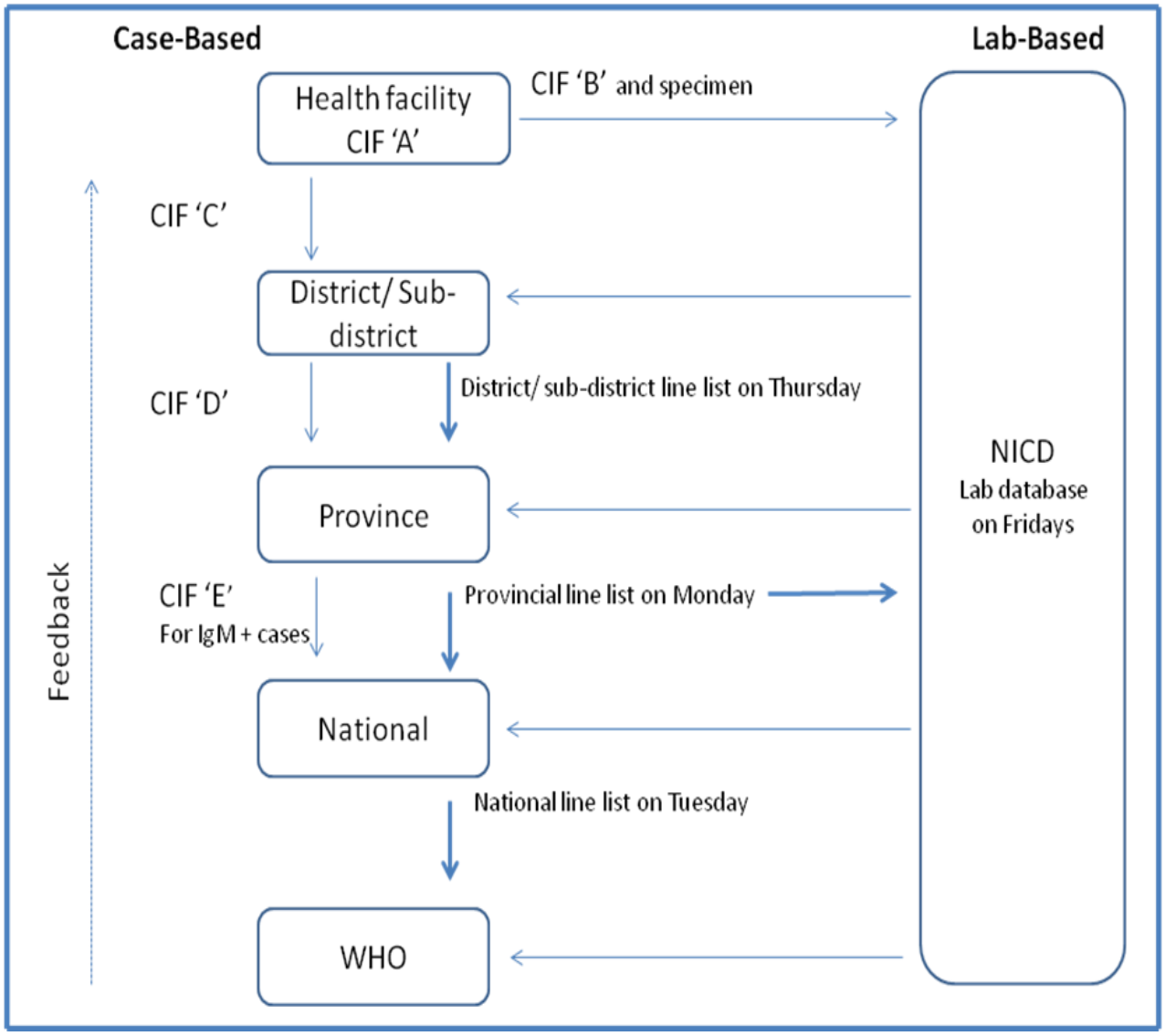
- Acknowledge receipt of weekly provincial line lists on Monday;
- Ensure that all measles IgM positive cases have a CIF;
- File CIFs of IgM positive cases (e.g. file by year, province and district);
- Clean, verify the quality of data and make analysis;
- Feedback to provinces monthly ;

Laboratory-based data

- Receive measles lab database from NICD weekly on Friday;
- Harmonise national case-based and lab-based database;
- Provide feedback to NICD and province if there are any discrepancies between the two databases;

- Assign a final classification for all cases.
- Share the data with WHO-Country office and the WHO-Inter-country Support Team (IST) weekly on Tuesday.
- Get feedback from IST, correct the database accordingly and resend updated database to IST;
- Analyse all performance indicators by district, province and national level and provide feedback via monthly measles bulletin;

Measles Data Management Flow Diagram



* All line lists comprise harmonised lab-based and case-based data

* CIFs B, C, D and E represent updated copies of CIF A for the same patient

Checklists for measles data cleaning / verification at all levels

Verify if data is complete and clean:

- Check for duplicate entries;
- Update and check province and district codes currently used;
- Check the date formats;
- Age, sex;
- Check the following dates:
    - Date of rash onset;
    - Date of specimen collection;
    - Date specimen sent to the lab;
    - Date specimen received at lab;
    - Date result sent to national level.
- Epid Number (e.g. CCC-PPP-DDD-YY-000) and check if correctly labelled;
- Check that cases in the current year database match the year entered EPID and DATE ONSET, e.g. CCC-PPP-DDD-08-001 and dd/mm/2008;
- Names of districts (Sometimes the same district name is spelt differently). Please make sure that district names are spelt the same way at all levels;
- Specimen condition;
- Final result: IgM Negative; IgM Positive;
- Final case classification: Lab confirmed; epidemiologically confirmed; clinically confirmed; discarded;
- Vaccination status (or number of vaccine doses);
- Outcome: Patient admitted to hospital or died;
- Check for logical flow of date variables, e.g. Date of rash onset < Date of collection, etc. This can be evidenced when you get negative answers during analysis;
- Check if correct specimens were collected.

Recommended Measles Data Analysis at NDoH

- **Review sources of surveillance data**
    - Measles line-lists and case investigation forms;
    - Key surveillance indicators;
    - Timeliness and completeness of reporting;

- **Visualise: map the area**
    - Location of measles outbreak; Confirmed (Lab, Epid, clinical) measles cases;
    - Variance in surveillance indicators.

- **General data analysis**
  - Measles confirmed cases by age group, sex, immunisation status, geographical area, month and year;
  - Measles confirmed cases from which outbreak was identified by geographical area, sex, month and year;
  - Compatible cases by geographical area and month;
  - All measles suspect cases by final classification;
  - Annualised non-measles febrile rash illness rate.

Data Harmonisation

Please refer to data harmonisation SOP

Annex 3.4 Outbreak Investigation Report Format (Generic)

Title/Description (include disease/condition investigated)

Period

Place (Villages, Neighbourhoods, District, Province)

Executive summary:

_____

_____

_____

Introduction:

Background:

- Reasons for investigation: (public health significance, threshold met, etc.);
- Investigation and outbreak preparedness:

Methods:

- Date/s of investigation:
- Site(s) of investigation (healthcare facilities, villages, other):
- Case finding (indicate what was done regarding case finding, e.g., register review, contact investigation, alerting other health facilities, other):
- Laboratory specimens collected:
- Describe response and intervention (include dates):

Results:

- Date and location of first known (index) case:
- Results of additional case finding:
- Laboratory analysis and results:
- With text, describe key features of results of time, place and person analysis, i.e. description of the outbreak (who, what, where, when?):
- For detailed results by time use EPI curve; by place use map, and by person use characteristics table and line lists:
- Analysis of the outbreak (why?):
- Control methods used:
- Results of response and evidence of impact:
- Date and health facility seen by the healthcare:
- Problems encountered:
- Conclusions and recommendations:

Annex 4.1 Neonatal Tetanus Case Investigation Form

Case Investigation Form: NEONATAL TETANUS (NNT)

INSTRUCTIONS: This form should be completed in full for each suspected NNT case. The case definition for NNT is: History of normal sucking and crying for the first two days of life, AND history of onset of illness between 3 and 28 days of age, AND inability to suck followed by stiffness and/or convulsions and often death.

Official use only: EPID NUMBER: (Will be assigned at Provincial Office) SOA (Country) - LPP (Prov Code) - ____ (District Code) - ____ (Year Onset) - ____ (Case number) Received on ___/___/____

IDENTIFICATION OF MOTHER

Surname of mother: _____

First names of mother: _____

Date of birth (mother) ___/___/___ Age (mother) ____ yrs.

Res. address / Contact information: _____ Clinic/Hospital name: _____

_____ Town: _____

_____ District: _____

_____ Province: _____

NOTIFICATION / INVESTIGATION / RESPONSE

Notified by: _____ Tel no.: _____

Date district notified: ___/___/___ Date case investigation ___/___/___ Date of response ___/___/___

Detail of response: _____

MOTHER'S IMMUNISATION HISTORY

Number of documented doses of TT vaccine_____ Date of last dose: ____/____/____

INFANT DETAILS & PERINATAL CLINICAL INFORMATION

Name of infant: _____ Date of birth: ____/____/____ Sex: M ☐ F ☐

Mother received antenatal care? Yes No Unk No of visits: _____ Place: _____

Where was baby born? At home Clinic Hospital Name:

Attended by: Nurse Doctor Traditional BA Name:

Cord cut with sterile blade? Yes No Unk

Any substance placed on cord? Yes No Unk Describe:

Describe any post-natal care given: _____

_____

Baby normal at birth?	Yes	No	Unk	Stiffness?	Yes	No	Unk
Normal suck/cry in first 2 days?	Yes	No	Unk	Spasms or convulsions?	Yes	No	Unk
Then stopped sucking?	Yes	No	Unk	Arched back?	Yes	No	Unk
Date when sucking stopped:	____/____/____			Umbilicus swollen / red?	Yes	No	Unk
Baby died?	Yes	No	Unk	Other symptoms?	Yes	No	Unk

Date of death: ____/____/____ Describe: _____

DETAILS OF HOSPITAL ADMISSION AND TREATMENT

Admitted to hospital? Yes No Date of admission; ___/___/___ Hosp No._____

Patient on ventilator? Yes No Unk

Complications? Yes No Unk Describe: _____

Comments on examination:

FINAL DIAGNOSIS (MADE BY CLINICIAN AND PROVINCIAL EPI COORDINATOR)

Confirmed NNT Yes No Other diagnosis: _____ Date: ___/___/___

INVESTIGATOR: Name _____ Tel: _____

Position and facility/district _____ Fax:

Annex 5.1 AEFI Case Investigation Form

Case Investigation Form:
ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

INSTRUCTIONS: This form should be completed in full for each AEFI case.

Official use only: **EPID NUMBER:** _____ Received on ____/____/20____

IDENTIFICATION OF PATIENT

Surname of patient: _____

First names of patient: _____

Names of father/mother: _____

Sex: Male Female
Date of birth ____/____/____ Age____ months ____ yrs
Res. address / Contact information:
Clinic/Hospital name: _____ Town: _____

District: _____ Province: _____

REPORT / INVESTIGATION

Reported by: _____ Tel no: _____

Date district notified: ___/___/20___ Date case investigation ___/___/20___

HISTORY OF IMMUNISATION

Date of immunisation: ___/___/20___ Date of onset of event: ___/___/20

Place of immunisation: _____ Name of vaccinator:

VACCINES GIVEN TO PATIENT				Manufacturer	BATCH No./ LOT No.	DOSE No.
BCG	Yes	No	Unk			
OPV	Yes	No	Unk			
RV	Yes	No	Unk			
DTaP-IPV-HB-Hib	Yes	No	Unk			
Hep B	Yes	No	Unk			
PCV	Yes	No	Unk			
Measles	Yes	No	Unk			
DT	Yes	No	Unk			
TT	Yes	No	Unk			
Other	Yes	No	Unk			
Specify vaccine:						

TRIGGER EVENT Mark the trigger event with an X in front of it!

	Local reactions		**Systemic reactions**
	Severe local reaction (swelling extended more than 5cm from the injection Site or redness and swelling for more than 3 days)		All cases of hospitalisation (thought to be related to immunisation)
	Lymphadenitis		Encephalopathy within 7 days
	Injection site abscess		Collapse / shock-like state within 48 hours
			Seizures within 3 days
			All deaths (thought to be related to immunisations)

DETAILS OF EVENT (Symptoms at time of onset)

Case Investigation Form:
ADVERSE EVENTS FOLLOWING IMMUNISATION (AEFI)

Official use only: **EPID NUMBER:**

RESPONSE TO THIS EVENT

Treated at OPD	Yes	No	Unk	Admission Date: _____/_____/20
Admitted to hospital for treatment	Yes	No	Unk	Hosp. No. _____

Name of hospital: _____

Event explained to parent/guardian?	Yes	No	Unk	Interview Date: ____/____/20
Vaccinator guidance / retraining given?	Yes	No	Unk	Interview Date: ____/____/20

HISTORY OF PREVIOUS REACTIONS TO IMMUNISATION AND/OR TREATMENT

Has this child had any previous reaction after immunisation?	Yes	No	Unk
Was a history of any allergies in this child obtained?	Yes	No	Unk
Was any information given prior to immunisation?	Yes	No	Unk
Was the health status of the child assessed before immunisation?	Yes	No	Unk
Were any other AEFIs reported from this clinic in the last 30 days?	Yes	No	Unk

FINAL CLASSIFICATION
(By provincial EPI coordinator in cooperation with national office)

Programme Error		Coincidental	
Faulty vaccine		Unknown	

Give a brief reason for the classification:

Date of final classification: _____/_____/20

INVESTIGATOR: Name Tel:

Position and facility/district Fax:

An AEFI should be reported within 24 hours of the event and the case investigation done within 36 hours. Please keep the district and provincial EPI coordinators informed about your progress and any problems. Send a copy of this form to the Provincial EPI Coordinator.
In addition, please complete an EVENT DESCRIPTION REPORT (EDR) on a separate page where you describe step by step the development of the adverse event and its consequences and the actions taken in the treatment and investigation.
THANK YOU FOR YOUR RAPID RESPONSE!

Annex 5.2 AEFI Event Description Report (EDR)

Framework for data collection during the case investigation

A.	**DATA ON EACH PATIENT**
i.	Demographic data about the patient
ii.	History of present illness, e.g. date of immunisation related to date of onset of symptoms, duration, treatment, outcome and medical diagnosis
iii.	History of previous illness, e.g. previous reactions to immunisation, known drug allergies, pre-existing neurological disorders and current medications
iv.	Data about the suspected immunisation, e.g. screening for contraindications and health status, information given to parents/guardians, vaccine type, batch/lot no, dose no, preparation of site, sterility procedures and recording procedures.
v.	Results of laboratory examinations performed, e.g. on the patient wound swabs in the case of an abscess, throat swabs of health workers, results of vaccine tests for sterility, toxicity and confirmation of the contents of the vial, autopsy results in the case of death after immunisation
B.	**DATA ABOUT THE VACCINE/S ADMINISTERED**
i.	In the event of a cluster, whether the vaccine/s are from the same batch/lot
ii.	In the event of a cluster, whether the vaccine/s are from the same manufacturer
iii.	Vaccine distribution, e.g. from where were vaccines sent, when were they received and opened/reconstituted
C.	**PROGRAMME-RELATED DATA**
i.	Storing of vaccines, e.g. whether vaccine could have been frozen, whether the measles diluent is kept cold.
ii.	Stock control procedures to use vaccines before the expiry date, e.g. if the principles of first expiry out (EFO) and first-in first-out (FIFO) are adhered to, etc.
iii.	Handling of vaccines during and after immunisation sessions, e.g. whether DPT and TT are properly shaken before use, whether vaccines are kept cold during immunisation sessions, whether a needle is left in the vial and whether opened vial policies are practiced according to EPI(SA) policy
iv.	During reconstitution and administration of vaccines, e.g. whether the correct, sterile diluents are used, whether the correct dosage are administered, using the recommended route and site for administration, whether a 23-gauge needle is used and whether one sterile needle and one sterile syringe are used for each injection
D.	**DATA ON OTHER PEOPLE IN THE AREA**
i.	Number of people who received immunisations with vaccine from the same batch/lot
ii.	Number of people who received immunisation during the same immunisation session
iii.	Number of people from the above categories (I and ii), who became ill and their symptoms
iv.	Number of people in the same geographical area who were not immunised during the suspected event/s who became ill and their symptoms
v.	Number of people immunised during the same period with vaccines from a different lot/batch who became ill and their symptoms
vi.	Name of the health worker who administered the vaccine that caused the suspected AEFI/'S
vii.	Whether people not immunised at the time, experienced the same medical incidents.
E.	**SOURCES FOR DATA COLLECTION**
i.	*Examination,* e.g. patient/s involved in the AEFI
ii.	*Interview,* e.g. supervisor/s about immunisation practises, other health workers in the facility, the treating physician, parents and the vaccinator and community members.
iii.	*Observation,* e.g. immunisation sessions in the same facility with the same health workers, it might reveal the cause, since the practice may be repeated.
iv.	*Records,* e.g. review health facility records where vaccine was given, patient registers, temperature records for the vaccine fridge, stock control records, laboratory reports about the patient and any related records.

*A*DVERSE EVENTS FOLLOWING IMMUNISATION (AEFI'S)

*E*VENT DESCRIPTION REPORT (EDR) *[detail information]*

Name of Child: _____ **EPID NO:** _____

Date case investigation: ___ / ___ / ____ **Date report:** ___ / ___ / ____ **District:** _____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

_____

___ / ___ / ____ _____ _____

Date **Signature (District Team Coordinator)** **Name, surname, title (Print)**

Tel No: _____ **Fax No:** _____

Annex 5.3 AEFI Register of Cases

District _____

Reporting period from _____to _____

Province _____

EPID No.	Name	Address	Sex	Date of immunisation	Date of onset of event	Place of immunisation	Suspect Vaccine	Vaccine batch/lot number & manufacturer	Trigger event	Classification (P C V U)*
TOTAL NUMBER OF AEFI REPORTED										
Key: P = Programme related V= Vaccine related C= Coincidental U= Unknown										