National Documentation for Certification of Poliomyelitis Eradication

Name of Country: _____

Submitted to WHO/EMRO on: _____

Eastern Mediterranean Region
World Health Organization
Cairo, Egypt

INTRODUCTION

In 1988, the World Health Assembly adopted the goal of poliomyelitis eradication by the year 2000. The maximum benefits of this global disease eradication initiative will only be realized when immunization against polioviruses has stopped sometime after the last wild poliovirus has been detected in the world.

Prior to stopping polio immunization it will be necessary to certify the absence of wild poliovirus circulation from every country of the world. For this reason, the World Health Organization (WHO) established a Global Commission for the Certification of the Eradication of Poliomyelitis which subsequently developed the principles and guidelines for the certification process. As part of the certification process, Regional Certification Commissions have been established in each of the six WHO Regions.

The Regional Certification Commission for the EMR will review reports submitted by the National Certification Committee of each country that has been free of indigenous wild poliovirus for a period of at least three years. Review of documentation from every country of the Region will enable the Regional Commission to verify whether all member countries, and the Region as a whole, are truly polio-free. Following National/Regional certification, it may be necessary to request updated documentation from countries prior to global certification.

The report of the National Committee should include:

1. The composition of the NCC
2. An executive summary describing the method of work/process, main findings, critical discussion points, comments on key data and findings that did or did not convince the committee of the polio free status of the country, any remaining concerns, conclusions and recommendations.
3. National documentation for certification. This is the main component of the report by the National Certification Committee to the Regional Certification Commission

COMPOSITION OF THE NATIONAL CERTIFICATION COMMITTEE:

1. Name:_____Chairperson

Position:_____

2. Name:_____

Position:_____

3. Name:_____

Position:_____

4. Name:_____

Position:_____

5. Name:_____

Position:_____

6. Name:_____

Position:_____

7. Name:_____

Position:_____

Date of Submission of Report:_____

EXECUTIVE SUMMARY

1. The executive summary should include a summary of the method of work of the NCC and its main findings conclusions and recommendations to the Regional Commission. It should also include the key findings which have convinced the NCC of the Polio free status of the country and any remaining concerns about the National Programme or significant gaps in information needed.

NATIONAL DOCUMENTATION FOR CERTIFICATION

The National Documentation for Certification of Poliomyelitis Eradication will consist of three components.

- STANDARD DOCUMENTATION FOR CERTIFICATION OF POLIOMYELITIS ERADICATION: The principal component of the National Documentation will be a set of standard forms which provide information on five sections as defined by the Global Commission.

  The standard information that the Regional Commission for Certification of Poliomyelitis Eradication in the Eastern Mediterranean (RCCPE EMR) will require from each of the Member States of the WHO Eastern Mediterranean Region (EMR) is outlined in details in this document. Since the information from each country will undergo close scrutiny by the Regional Commission, it will be important to prepare the most complete information possible to avoid potential follow-up requests for additional information. It is important that each and every item is answered thoroughly An explanation should be provided for any information that is missing. The original text of the items should not be modified under any circumstances and the answers to questions should be given in a different font or highlighted so that they are clearly distinguishable from the original text of the document.
- SUPPORTING DOCUMENTATION: These documents are needed to clarify or expand upon particular aspects of the Standard Documentation. They will include such things as a graph of national immunization coverage and spot maps of recent polio cases. The Checklist at the end of this manual outlines the main supporting documentation that will be required for certification. Within the manual supporting documentation required is described in the various sections of the standard documentation. Additional supporting documentation may be submitted at the discretion of the National Certification Committee.
- SPECIAL STUDIES AND ADDITIONAL ACTIVITIES: The details of all special studies or additional activities, which may have been conducted to demonstrate the absence of indigenous wild poliovirus circulation from the country or a specific area should be provided.

♦ STANDARD DOCUMENTATION FOR CERTIFICATION OF POLIO ERADICATION

Each National Certification Committee must provide sufficient documentation to demonstrate that the country is polio-free and that indigenous circulation of imported wild polioviruses would be readily detected and effective control measures taken. Although providing documentation for certification to the Regional Commission is expected from the National Certification Committee, it is the responsibility of the national program to provide the needed information in the required format to the National Certification Committee and serve as the secretariat for the Committee activities.

The purpose of the standard documentation is to provide the Regional Commission with a set of internationally consistent data upon which to base its decision whether or not to certify the country as polio-free. The country documentation will be further used by the Global Commission as the basis for endorsing the decision of the Regional Commission.

The National Documentation must cover the following five sections:
SECTION 1: COUNTRY BACKGROUND INFORMATION.
SECTION 2: HISTORY OF CONFIRMED POLIO CASES AND WILD POLIOVIRUSES.
SECTION 3: PERFORMANCE OF SURVEILLANCE ACTIVITIES
SECTION 4: LABORATORY ACTIVITIES FOR POLIO ERADICATION
SECTION 5: IMMUNIZATION ACTIVITIES FOR POLIO ERADICATION.

The information required under each of these sections are available in this document and are summarized in the standard set of forms attached.

Section 1. COUNTRY BACKGROUND INFORMATION

Purpose: to rapidly familiarize regional and Global Commission members with (a) the basic demographics and geography of the country that are relevant to poliomyelitis eradication and its certification and (b) the organization of the poliomyelitis eradication initiative in the country (immunization, surveillance and laboratory).

Data Required: this section should include information on the population of the country, relevant vital statistics and major population centers. Minority populations should be identified along with other groups who may not fully utilize health services or who are known to have low immunization coverage. Geographically remote areas, areas with difficult access, and areas which border recently polio endemic countries should also be specified. A national map should be included which indicates the major population centers, bordering countries/oceans and, if possible, population density.

This part of the documentation should also outline the structure of personnel responsible for poliomyelitis immunization, AFP surveillance, and if applicable, the enterovirus (poliovirus) laboratory. This section should explain the relationship between these units or departments and outline their interaction. It is particularly important to:

- demonstrate how AFP/poliomyelitis notifications are transmitted to those responsible for undertaking the case investigation, stool sample collection and implementation of appropriate control measures, particularly in the event of an imported poliomyelitis case or wild poliovirus detection.

- demonstrate how both positive and negative laboratory results are transmitted to those responsible for initiating a response, whether it be supplementary immunization activities or adjusting of routine immunization strategies.

Section 1. Country Background Information (items 1-14)

Part 1: Demography

(1) Summary of population data, 19___ (please use data from most recent year possible).

	Total Population	Population aged less than 15 years	Population aged less than 5 years	Population aged less than 1 year
Number of persons				
Percentage of total population	100 %	_____%	_____%	_____%

(2) Map of Country

Please attach a map(s) of the country indicating the major population centers, principal geographic features, bordering countries, and, if possible, population density and other relevant features.

(3) Principal administrative units of country:

Number of 1st level administrative units (states, provinces, etc): _____

Number of 2nd level administrative units (districts, municipalities, etc.):_____

(4) Percentage of total population living in 'urban' or 'peri-urban' areas: _____%

(5) Name and population of capital and major cities:

Name of city	Approximate Population
Capital:	

Part 2: Structure/Responsibilities of National Polio Eradication Programme

(6) Division of Responsibilities for Polio Eradication Activities

	Polio Immunization Policies and Activities	Polio Surveillance Policies and Activities	Polio Laboratory Activities*
Responsible Ministry			
Responsible Department Or Institute			
Name and Position of Responsible Person			

* If there is no national poliovirus laboratory please specify where diagnostic specimens are sent for diagnosis.

(7) Is there a national Polio Eradication Coordinator? : Yes ( ) No ( )

a) Please specify the position and responsibilities of the Polio Eradication Coordinator_____

_____

_____

b) Who has overall responsibility for the national polio eradication programme? (name/position):_____

(8) Are there regular meetings between immunization, surveillance and laboratory personnel to discuss polio eradication activities? : Yes ( ) No ( )

If yes, how often are meetings held:

weekly/monthly/quarterly/other:_____

(9) Who conducts AFP or polio case investigation? (position and level, i.e. district health officer): _____

(10) Who has overall responsibility in the country for co-ordinating the investigation of an AFP case or a suspected or confirmed case of polio (name/position):

_____

(11) AFP or Polio Case Investigation:

a) is there a standard case investigation form & protocol for AFP or polio cases?: yes / no

If yes, please attach copy.

b) does the investigation include collection of stool specimens?: yes / no

i) if yes, please specify the number of specimens which should be collected:_____

ii) when and how should the specimens be collected

_____

_____

(12) National Expert Committee for Classification of AFP (polio) Cases:

a) is there a National Expert Committee for classification of AFP cases?: yes / no

b) how often does the Committee meet?

(circle): weekly/monthly/quarterly/other_____

c) how many people serve on the National Expert Committee?: _____

d) what are the qualifications of each member of the Expert Committee?:

_____

_____

_____

_____

_____

_____

(13) . How would immunization and surveillance personnel be informed of a laboratory isolation of a wild poliovirus?:

_____

(14) . Who has responsibility for co-ordinating the response to a suspected or confirmed case of poliomyelitis?

_____

Comments: Please attach any additional comments on separate sheets

Section 2. HISTORY OF CONFIRMED POLIO CASES AND WILD POLIOVIRUSES

Purpose: to demonstrate the decline and elimination of clinical poliomyelitis and absence of wild poliovirus circulation in the country.

Data Required: the national epidemiology of poliomyelitis should be summarized in this section, including all relevant information on both clinical poliomyelitis cases and the circulation of wild polioviruses.

Definitions: This section should provide the standard criteria or definitions used by the national program for classifying a case of poliomyelitis as indigenous, imported or vaccine-associated paralytic polio (VAPP).

The history of poliomyelitis incidence in the country should be outlined. A graph of polio incidence (possibly bar diagram) for as many years as possible (at least from 1990) should be provided. A detailed history should be provided for the most recent 10-15 cases of poliomyelitis (or all cases with onset since the beginning of 1995 if fewer than 10 cases have occurred within the last 5 years). The documentation should outline the criteria by which these cases were confirmed as poliomyelitis, the laboratory findings, and the probable origin of any viruses that were isolated. There should be documentation of the response to each case. Documentation should be provided on the supplementary investigations that were conducted to rule out indigenous wild poliovirus transmission as the cause of any polio-compatible case (or polio case of 'unknown' origin in non-endemic countries).

The history of wild poliovirus circulation in the country from cases or contacts or other sources (e.g. survey, environment, etc) should be provided, particularly for the previous 5 year period. A detailed summary should be provided for each of the last 10-15 wild polioviruses that were isolated in the country (or all viruses isolated since the beginning of 1995 if less than 10 viruses were detected in the 5-year period). Data on each virus should include the source of the specimen from which the virus was isolated, the geographic location of the source of specimen, the probable origin of the wild poliovirus and the subsequent investigations to demonstrate the elimination of the virus. (NOTE: for the purpose of this information, data on an outbreak caused by a single strain of wild virus will be considered as data on a single virus, regardless of the number of isolates in the outbreak).

Section 2. History of Confirmed Poliomyelitis Cases and Wild Polioviruses (items 15 – 28)

Part 1: Definitions: Please provide the definitions that the national program has used for each of the following:

15. Indigenous case of poliomyelitis:

_____

_____

16. Imported case of poliomyelitis:

_____

_____

17. Vaccine-associated paralytic poliomyelitis (VAPP):

_____

_____

Part 2 : History of Poliomyelitis Cases

18. Graph of Polio Incidence:
Please provide a bar graph showing the number of confirmed polio cases for as many years as possible (at least from 1998). Distinguish between cases due to wild poliovirus and Sabin-like viruses (VAP).

19. Last Confirmed Case of Poliomyelitis due to Wild Poliovirus:

-Date of onset (day / month / year) _____

-Geographic Location _____

-Age _____

-History of vaccination against polio

No. of Routine OPV doses _____
No. of doses received during NIDs: _____
No. of doses received during SNIDs: _____
-Virologic Findings _____

-Travel History _____

-Probable Origin of Virus _____

-Additional Investigations to Rule out Ongoing Indigenous Transmission (attached sheet if needed) _____

-Immunization Response Activities: _____

(20) Summary of Confirmed Polio Cases for the last 5 years:

Confirmed Poliomyelitis Cases (known or probable wild poliovirus, do not include vaccine-associated cases)						
Year	Total Confirmed Polio Cases	Number virologically confirmed	Number clinically confirmed	Number indigenous	Number* imported	Number of 'unknown' origin
2005						
2006						
2007						
2008						
2009						

* Please attach detailed explanation why cases were considered imported

Indicate the year national program shifted to virological case classification:_____

(21) Summary of 'Other Cases' for the last 5 years

	Other Cases	
Year	Vaccine-Associated polio cases	Polio-compatible cases**
2005		
2006		
2007		
2008		
2009		

**Please refer to section 3 part 4 for more details on poliomyelitis compatible case

22. Map of Polio Cases for the last 5 years:
Please provide a map by year showing the location of all polio cases which were either virologically confirmed or probably due to wild poliovirus for the last 5 years. Differentiate the cases by year.

23. Details of Last 10 Confirmed Poliomyelitis Cases, **OR** if fewer than 10 cases occurred during the last five years, then history of All Confirmed Cases Since 1998 (do not include VAPP cases).

For outbreaks please report the index case in the table and attach the full outbreak investigation and response data in the supporting documents.

Date of onset of paralysis	Single case or outbreak	Age of case (Months)	Probable origin of wild poliovirus (Epidemiologic & Virologic data)	Result of full epidemiologic case investigation, active case search and response, if any (Please attach details)

Part3: Wild Polioviruses from Confirmed Polio Cases or Contacts

(24) Summary of Wild Polioviruses Isolated during the last 5 years.

Year	Total number of wild polio-viruses isolated	Wild viruses from polio cases or their contacts			Wild Polioviruses Isolated from Other Sources*, by Type		
		P1	P2	P3	P1	P2	P3
2005							
2006							
2007							
2008							
2009							

* other sources include: specimens from environmental sampling, stool surveys, and additional sources other than polio cases or their contacts.

(25) Last Wild Poliovirus Isolates:

Date of last known indigenous wild poliovirus isolates from cases or contacts:

Wild poliovirus type I: ___ _____ 20__

Wild poliovirus type II: ___ _____ 20__

Wild poliovirus type III: ___ _____ 20__

(26) Details of Last Wild Poliovirus Isolate (only if isolated after the last polio case in 19)

Date of Specimen (day/month/year):_____

Type and Source of Specimen:_____

Geographic Location of Specimen:_____

Virologic Findings:_____

Additional Investigations to Rule out Ongoing Indigenous Transmission:_____

_____

Immunization Response Activities (if any):_____

_____

(27) Summary All Wild Isolates from Other Sources during the last 5 years:

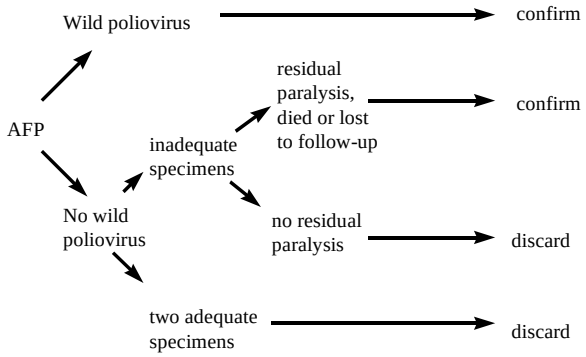
Date specimen collected	Geographic location & type of specimen	TYPE and Probable origin of wild virus (if not indigenous)	Investigations to determine if and when wild poliovirus transmission stopped and final outcome (attach additional sheets, if needed)

28. Map of All Wild Isolates from Other Sources for the last 5 years:
Please provide a map showing the location of each of the wild polioviruses that were isolated in the country for the last 5 years from sources other than a polio case or its contact. Please indicate the date that the last positive sample was collected.

Section 3. PERFORMANCE OF SURVEILLANCE ACTIVITIES

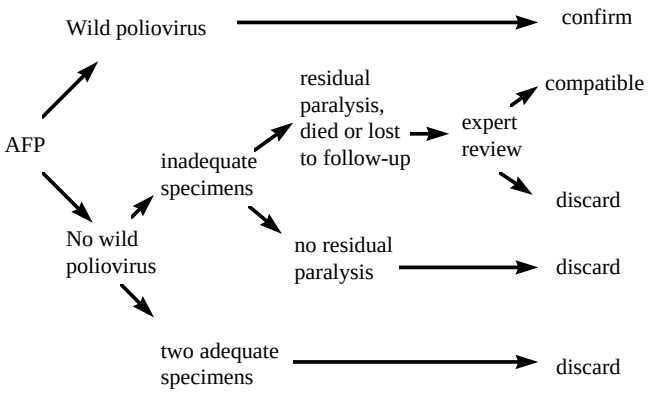
AFP Surveillance: For the purpose of polio eradication, the WHO recommends the reporting and investigation of all cases of Acute Flaccid Paralysis (AFP) among children aged less than 15 years and all cases of suspected poliomyelitis in individuals of any age (AFP includes illnesses such as Guillain-Barré Syndrome and transverse myelitis). The Global Certification Commission has stated that high quality AFP surveillance should be the basis for demonstrating the absence of wild poliovirus in a country. All AFP cases should have a full clinical, epidemiological and virological investigation, including the collection and analysis of 2 adequate* stool samples and a clinical follow-up examination at 60 days after the onset of paralysis. The final classification of AFP cases should be on the basis of the following scheme:

Clinical classification of AFP cases



When AFP rate = 1/100,000, and
Adequate Samples = 60% or more and
All specimens tested in a WHO-accredited laboratory

Virologic classification of AFP cases



Purpose: to demonstrate to the Regional Commission that disease surveillance is of a sufficient standard to detect cases of paralysis due to indigenous wild polioviruses. This section should also show that the re-establishment of wild poliovirus circulation due to importations would be rapidly detected.

* See definition page (52)

Data required

These fall in six parts: The first part should include information on the national surveillance policies and systems relevant to polio eradication, case reporting and viruses reporting.

The second part should outline the completeness of routine and active surveillance systems for Acute Flaccid Paralysis (AFP) or poliomyelitis. This section should include data on the number of routine reporting sites in the country, the geographical representativeness of the reporting sites and completeness of routine reporting as well as active surveillance systems.

The third part should describe the performance of the national AFP surveillance system and case investigation. The quality of surveillance and case investigation should be demonstrated with data on standard surveillance performance indicators. Particular attention should be given to demonstrating that the non-polio AFP rates and stool specimen collection rates have reached the standards set by the Global Commission (i.e. at least 1 case of non-polio AFP per 100,000 population aged less than 15 years and 2 'adequate'[*] stool samples in 80% of cases). The quality of AFP surveillance at the sub-national level (i.e. province or state level) should be thoroughly investigated. This section also deals with actions taken to improve performance in areas with low AFP and specimen collection rates.

The fourth part deals with poliomyelitis compatible cases. It should provide details on all AFP cases which were reviewed by an Expert Committee. Spot maps will be required for all polio-compatible cases. It will be particularly important to document the supplementary investigations that were conducted to demonstrate that compatible cases or clusters of polio compatible cases were not due to wild polioviruses. The reasons for classification of AFP cases as polio-compatible must be explained.

The fifth part should be used to summarize the performance and results of supplementary surveillance activities, which have been conducted to demonstrate both the absence of wild poliovirus and the sensitivity of existing surveillance systems to detect both paralytic poliomyelitis cases and wild poliovirus.

[*] See definition on page 52

NOTE: the Global Certification Commission has recognized that additional surveillance activities will be required in *countries with sparse populations which have been polio-free for many years* and where the number of expected reported AFP cases would be low despite active surveillance. The suggested activities include:

i) Extending the Target Age Group for Routine AFP Surveillance: extending the target age group for AFP surveillance from all individuals aged less than 15 years to an older age group (i.e. aged less than 30 or 45 years of age) will provide further information that wild poliovirus is not endemic in countries with total populations of less than 1-2 million people. Such a strategy may also be epidemiologically appropriate if the country has been polio-free for more than 10 or 15 years.

ii) Zero reporting: all countries should be able to demonstrate that reporting units are reporting weekly, even when no AFP cases have been identified, "zero" reporting. Data should be included which quantifies the completeness and timeliness of weekly zero reporting.

iii) Retrospective Record Review: in countries which rely on reporting of suspected poliomyelitis cases, a retrospective record review can be conducted as a method of verifying the sensitivity of the polio reporting system. Such a search should use ICD codes to search for poliomyelitis cases or VAPP, ideally through a national hospital discharge database system. If such a system is not available, a targeted search could be conducted through the principal sites that would be expected to see poliomyelitis cases such as major pediatric hospitals, neurology wards and/or rehabilitation centers.

iv) Incentives – All countries should consider the introduction of incentive programs whenever appropriate, particularly as polio-zero approaches. Especially, in sparsely populated countries this may be another factor, which could contribute to maintaining the accuracy of zero reporting.

v) Rumor registry: in all countries which are close to polio zero, but particularly in sparsely populated or long established polio-free countries, a rumor registry will help prevent health authorities from "dropping their guard".

Section 3. Performance of Surveillance Activities (items 29-61)

Part 1: National Surveillance Policies

(29) Case Reporting Policy:

Is there a policy of routine reporting of all AFP cases?: yes / no

If yes, specify the year it began: yes / no 20_____

(30) What is the national case definition or reportable condition for AFP (your case definition) : _____

(31) Is reporting of an AFP or suspected polio done immediately (as and when discovered) or on a routine basis with regular interval of time?:_____

(32) Please circle the appropriate response for each of the following:

	Mandatory immediate notification	Mandatory routine* reporting
a) acute flaccid paralysis (AFP) cases:	yes / no	yes / no
b) suspected polio cases:	yes / no	yes / no
c) clinically confirmed polio cases:	yes / no	yes / no
d) virologically confirmed polio cases:	yes / no	yes / no

(33) How often are routine* AFP or polio surveillance reports required? (circle correct answers): weekly / monthly / bimonthly / other (specify):_____

(34) Which facilities are required to send routine* reports of AFP or polio? (circle)

hospitals / rehab centers / laboratories / private doctors / health clinics

other:_____

(35) Is there a national 'zero' reporting policy? (i.e. all reporting sites must file a regular report stating '0' cases of AFP or polio when no such cases are detected):

yes ( ) / no ( )

(*routine reporting refers to either weekly or monthly reporting from health facilities)

(36) Who is required to immediately report AFP (acute flaccid paralysis) or polio cases? (circle 'yes' for all that apply):

a) Health care worker who first sees the case: yes/no

b) Doctor or physician who makes the diagnosis: yes/no

c) Other:_____

(37) To whom should an AFP or polio case be reported immediately?:_____

(38) Virus Reporting Policy

Please circle the appropriate response for each of the following:

	Mandatory immediate notification	Mandatory routine* reporting
a) all poliovirus isolates:	yes / no	yes / no
b) wild poliovirus isolates:	yes / no	yes / no

Part 2: Completeness of Routine and Active Surveillance Systems

(39) Is there at least 1 designated routine reporting site, such as a health clinic, in every 2nd administrative unit (i.e. district, municipality, etc.): yes / no

If no, what areas of the country are without any routine reporting system?:

_____

(40) Completeness of routine reporting from health facilities in the last 3 years:

Year	Number of reporting sites	Completeness of Routine Reporting			Comment (i.e. areas with poor reporting)
		# reports expected*	# reports received	% reports received	

* number of routine reporting sites x number of reporting periods in 1 year
(i.e. if monthly reporting, periods = 12; if weekly reporting, periods = 52).

(41) Additional comments on completeness of routine reporting:

_____

_____

_____

(42) Is 'active surveillance'* conducted for AFP cases?: (circle) yes/no

a) if yes, specify the types of facilities that are targeted for active surveillance:

_____

b) are all pediatric/neurological hospitals included in active surveillance? yes/no

c) what is the total number of active surveillance sites in the country?:_____

d) is there an active surveillance site in at least every 2nd administrative unit (i.e. district, municipality): yes/no

e) how often are active surveillance visits conducted?:

weekly / biweekly / monthly / other (specify) _____

f) who conducts the active surveillance visits?:_____

g) is the completeness of active surveillance visits monitored?: yes/no

* See definition on page 52

(43) Summary of the completeness of active surveillance visits for AFP in the last 3 years:

* Number of active surveillance sites x number of visits in 1 year (i.e. if weekly, periods =52).

Year	No of active Surveillance sites	Completeness of Active Surveillance Visits			Comment (i.e. areas with poor active surveillance)
		No of visits expected*	No of visits conducted	% of visits conducted	

(44) Comments on AFP active surveillance (active case finding in health care facilities on a regular basis):

_____

_____

_____

_____

Part 3: Performance of AFP Surveillance and Case Investigation

(45) Quality of AFP or poliomyelitis case investigation:

a) is there a line list summarizing AFP case investigations for the last 3 years: yes / no

b) are all AFP/polio investigation forms for the last 3 years available?: yes / no

if no, approximately what percentage of forms are missing and why:

_____

c) are all investigation forms completed? (i.e. no missing information?): yes / no

If no, please identify information routinely missing from the investigation forms?:

_____

(46) Performance of AFP Surveillance for the last 5 years:

Year	Total AFP cases (<15 yrs)	Total 'non-polio' AFP cases	Population aged <15 yrs	Non-polio AFP rate*	Total AFP cases with 2 adequate stool samples	% AFP cases with adequate stool samples
2005						%
2006						%
2007						%
2008						%
2009						%

* per 100,000 population aged less than 15 years

(47) AFP Performance by 1st Administrative Level (e.g. state, governorate or province): please attach the following

a) a table with the population under 15, non-polio AFP rate and % of AFP cases with adequate stool specimens by 1st administrative level (i.e. province, state, oblast, etc.) for each of the last 3 years.

b) a map showing the *AFP rate by 1st administrative level* for the last year with an explanation of any 'blind areas' (i.e. geographic areas with a low rate).

c) a spot map showing the expected annual geographic distribution of AFP cases and specimens by 1st administrative level for the last year (reflecting the population density).

d) spot maps showing the distribution of *AFP cases with stool specimens* for each of the last 3 years with an explanation of any 'blind areas' where very few or no stool specimens have been collected.

(48) Areas With Low AFP and Specimen Collection Rates:

a) does the distribution of specimens match the expected distribution?: yes / no

(i.e. are there 'blind areas' where specimens should have been collected?)

b) summarize the reasons for each 'blind area' on the AFP specimen maps (please provide details on a separate sheet):

_____

_____

_____

c) summarize the special surveillance activities that have been conducted in areas with low AFP or stool specimen collection rates or areas considered 'high risk' for undetected virus transmission (please give details on a separate sheet):

Weekly Active Surveillance**:**

_____

_____

Stool specimen collection from Contacts*:*

_____

_____

Stool Surveys:

_____

_____

Other Surveillance Activities:

_____

Part 4: Polio Compatible Cases*

(49) Is the final classification of AFP cases based on the WHO-recommended

classification scheme (as per introduction to section 3)?: yes / no

If yes, what year was the WHO-virologic classification scheme introduced?: 20_____

(50) Summary of AFP Case Classification for the last 5 years:

Year	Total number of AFP cases	No. AFP cases confirmed as Poliomyelitis	No. AFP cases discarded as non-polio AFP	AFP cases reviewed by the Expert Committee		
				Total	Compatible[4]	Discarded
2005						
2006						
2007						
2008						
2009						

(51) AFP Cases Reviewed by the Expert Committee: For each of the previous 3 years, please attach a line listing of the AFP cases reviewed and classified by the expert committee (see attached form, Annex 1).

* See definition in glossary

Country: _____ line list of cases reviewed and classified by the National Committee in the previous 3 years. Annex 1
Year:_____ (Item 51)

AFP Case Findings										**Stool Specimens**			**Probable**	**Exp Comm**	**Cluster of Compatibles**	
#	ID Number	Age	Onset Date	OPV Doses	Reason Reviewed*	Fever at Onset	Asym Paral.	Max Para <4 days	Other Investigs	#	# ad.	NPEV (y/n) & typing	Clinical Diagnosis	(compatible or discard)	Onset Location	Cluster (y/n) & result of epidemiologic investigation
1																
2																
3																
4																
5																
6																
7																
8																
9																
10																
11																
12																
13																
14																
15																
16																
17																
18																
19																
20																

* In contries where every AFP case is reviewed by the National Expert Committee, this line list should include only those cases that had inadequate specimens and residence paralysis, lost to follow-up or died; for which VAPP is a possible diagnosis; or when the final diagnosis is not clear.

Note:AFP Case Finding:

Reas Rev = reason AFP case was reviewed by National Expert Committee (i.e. inadequate stool and residual paralysis, lost to follow-up or died).
Asym. Para = asymmetrical paralysis; Max Para. <4 days = maximum paralysis within 4 days onset.
Other Investigations = additional follow-up, case research in area, EMG results, etc.
Cluster of compatibles: Example = 2 or more compatibles in either 1 district or 2 bordering districts within a 2-month period.
Cluster investigation = case search in area, routine PV3 coverage, date last wild virus isolated in area, etc.
Stool specimens: # as. = number of adequate specimens, NPEV & typing = nonpolio enterovirus isolated and typing result.

(52) Summary of AFP cases discarded as non-polio by National Expert Committee for the last 5 years.

Year	GBS** (No. and %)	Transverse Myelitis	Trauma	Other (please specify)	Unknown	Total AFP cases discarded as non-polio
2005						
2006						
2007						
2008						
2009						

(53) Spot map of Polio Compatible Cases:
Please attach a spot map showing the geographical location of all polio compatible cases during the last 3 years (NOTE: a single map can be used if different symbols are used to differentiate the polio compatible cases from each year).

(54) Summary of the supplementary investigations and any immunization activities conducted in response to each polio compatible case detected in the last 3 years.

Date of Onset	Location	Summary of Additional Investigations, immunization activities and Conclusion (please attach additional details, if needed)

(55) Is a file maintained in the country with the details of all polio-compatible cases and their investigations? yes / no

** Guillain-Barre Sydrome

Part 5: Supplementary Surveillance Activities for Certification of Poliomyelitis Eradication

(56) The details of all supplementary surveillance activities should be provided as attachments to the documentation submitted for national certification. The following section should summarize these activities.

(57) Extension of Target Age Group for AFP Surveillance:

Specify to which age group:

(58) Zero Reporting:
Include data, which quantifies completeness and timeliness of weekly zero reporting when no AFP cases have been identified.

(59) Retrospective Record Review:

a) was a retrospective record review conducted?: yes / no

b) what was the period covered by the review?: from ___ _____ ___ to ___ _____

c) how was the review conducted?:

i) national discharge diagnosis database?: yes / no

if yes, please provide summary of discharge database (eg. facilities included, etc):

_____

_____

ii) facility-based review?: yes / no

if yes, what type of facilities were included?:

i) neurology wards: yes / no if yes, number of sites:_____

ii) pediatric hospitals: yes / no if yes, number of sites:_____

iii) rehabilitation centers: yes / no if yes, number of sites:_____

iv) other (please specify type of sites and number):

_____

d) what diagnoses were searched during the review? (please specify diagnosis & ICD code): _____

_____

e) Summary of results of retrospective review (e.g. comparison of reported vs. detected cases, etc.) _____

(60) Incentive system: introduce yes ( ) no ( )

If yes, please clarify to whom the incentive was given and how was the system managed.

(61) Rumour Registry:

Has this been established: yes ( ) no ( )

If yes how many rumours investigated last year

Section 4. LABORATORY ACTIVITIES FOR POLIO ERADICATION

Purpose: to demonstrate to the Regional Commission that laboratory facilities could isolate and identify wild poliovirus. The second purpose is to provide an inventory of laboratories which continue to store wild polio viruses and potentially infected materials.

Data required: only results from laboratories which are accredited members of the Global Polio Laboratory Network, or results which have been confirmed by an accredited network laboratory, can be considered in the certification process.

The first part of this section deals with laboratory accreditation. The national laboratory responsible for polio eradication is identified and its accreditation in the Global Polio Laboratory Network (including proficiency test results, enterovirus isolation rates, etc.) is documented. The reference laboratory that is used for intratypic differentiation of polioviruses should also be identified.

The second part deals with the laboratory process. The sources of stool or other specimens which have been submitted for poliovirus studies should be clearly stated (i.e. AFP cases, contacts of AFP cases, suspected polio cases only, environmental samples, etc.).

The following documentation will be required from each national laboratory for a minimum of a 3 year period:

- the total number of stool specimens received, from AFP cases, from contacts with AFP cases and from other sources, and the total number of clinical specimens and environmental specimens that were submitted for poliomyelitis virus studies.
- the reasons for each failure to process a specimen which was received in the laboratory,
- the total number of polioviruses that were isolated and the total number of isolates that were sent for intratypic differentiation (i.e. determination of wild vs. vaccine virus), particularly among isolates from AFP cases,
- the reasons for each failure to send a poliovirus isolate for intratypic differentiation,
- the reasons for each missing intratypic differentiation result.

While summary data will be needed for the Regional Commission, the National Committees should review and comment on the data management system in the national laboratory and ensure that all specimens can be tracked, if necessary.

The third part deals with Coordination Between Surveillance and Laboratory Activities: a separate section should provide details on how the surveillance and laboratory activities are [5]coordinated in the country. Particular attention should be given to determining whether there are regular (i.e. at least monthly) meetings or communications between national surveillance and laboratory personnel to ensure that the line listings of both the surveillance unit and laboratory are complete and up-to-date.

The fourth part deals with the inventory of laboratories which continue to store wild polioviruses and potentially infectious material*. An inventory should be provided of all laboratories in the country which continue to store polioviruses or potentially infectious materials. To be certified as polio-free, National Authorities will have to provide details to demonstrate that polioviruses and infectious material** are held under secure, properly controlled conditions and demonstrate a clear commitment from all levels that all polioviruses and infected material will be disposed of according to the recommendations of the Global Certification Commission. The Global Technical Consultative Group for the Eradication of Poliomyelitis is in the process of developing explicit guidelines on proper containment of wild polioviruses and potentially infected material as well as appropriate bio-safety procedures for laboratories. This section of the manual will be amended according to the guidelines once they are finalized.

* See definition in glossary
** See definition in glossary

Section 4. Laboratory Activities for Polio Eradication (items 62 - 72)

Part 1: Laboratory Accreditation

(62) National Polio Laboratory:

i) is there a National Poliovirus Laboratory in the country?: (circle) yes/no

Specify:_____

ii) is the laboratory accredited as part of the Global Polio Lab Network?: yes/no

iii) if there is no National Polio Laboratory in the country, which laboratory serves as the national laboratory for enterovirus isolation and identification?:_____

iv) are all polio isolates, regardless as to source, sent to a WHO accredited laboratory for intratypic differentiation?: yes/no

if no, please explain which isolates are not sent and why:

_____

(63) Summary of National Laboratory Accreditation Results for the last 5 years*.

Year	Score of onsite review	Proficiency test score (%)	NPEV** isolation rate (%)	Annual # of specimens processed	Correct polio typing result (%)	Results reported on time (%)	Fully accredited (yes / no)
2005							
2006							
2007							
2008							
2009							

*Countries with national laboratories.

** NPEV = non-polio enterovirus

Part 2: Laboratory Process

(64) Sources of stool specimens for poliovirus isolation and identification:

a) Acute flaccid paralysis (AFP) cases: yes / no

b) Contacts of AFP cases: yes / no

c) Healthy Children yes / no

d) Suspected polio cases*: yes / no

(*person >15 years with suspected poliomyelitis diagnosis):

e) Aseptic meningitis cases: yes / no

f) Other clinical specimens: yes / no

if yes, please specify types and sources: _____

g) Environmental specimens: yes / no

if yes, please specify sources:_____

(65) Summary of specimens submitted for poliovirus studies for the last 5 years:

Year	specimens from AFP case	Specimens from AFP contacts	Other stool specimens*	Other clinical specimens**	Environment specimens	Total
2005						
2006						
2007						
2008						
2009						

other stool specimens such as stool from surveys or from cases other than AFP cases and their contacts (e.g. Aseptic meningitis)

**other specimens: samples and clinical specimens other than stools.

(66) Stool and other specimens received or sent (if no lab in the country) and processed for polioviruses for the last five years.

Year	Total AFP or AFP contact stools Received	Other stools received	Completeness of stool Specimen analysis Processed	Not Proc'd	Total other specimens received	Completeness of other specimen analysis Processed	Not Proc'd
2005							
2006							
2007							
2008							
2009							

(67) Completeness of specimen analysis:

a) were all stool samples from AFP cases processed?: yes ( ) / no( )

b) summary of reasons for any unprocessed specimens in the last 3 years:

_____

_____

(68) Summary of polioviruses isolated and processed for intratypic differentiation for the last 5 years:

(Please include data for the country only)

Year	Total polioviruses isolated	Source of Poliovirus isolates AFP cases	Other	No. of isolates sent for Intratypic Differentiation	Intratypic differentiation (I.D.) results Sabin like	Wild	Mixed W+SL
2005							
2006							
2007							
2008							
2009							

Please attach specimen line list including Province, District, Source, P1, P2 and P3 results.

(69) Were all intratypic differentiation studies done in one accredited Regional Lab?:

yes/no

If no, which laboratories were used?: _____

(70) Summary of poliovirus isolates without intratypic differentiation in last 3 years.
Every effort must be made to ensure that all poliovirus isolates, particularly from the last 3 years, have been subjected to intratypic differentiation. If it is possible to locate the original isolates, these should be sent for intratypic differentiation before submitting the certification documentation. Information should be provided in the following table on poliovirus isolates from the last 3 years for which intratypic differentiation results are not available.

Date of Specimen	Type of Specimen	Type of poliovirus	Reason for missing results of intratypic differentiation	Additional actions taken to assess probability of the isolates to be wild poliovirus

Comments: Please attach any additional comments on separate sheets.

Part 3: Coordination with Surveillance

(71) Are poliovirus isolates immediately reported to immunization/surveillance staff?:

yes/no

a) specify person/position notified:

_____

_____

b) are isolates reported only after intratypic differentiation?: yes/no

c) are all wild poliovirus isolates reported within 24 hours?: _____days

d) what are the reasons for delays in reporting isolates?:

_____

Attach a sheet describing the coordination activities between the poliovirus laboratory and the national program, with particular attention to communications between national surveillance and laboratory personnel to ensure that the line listings of both the surveillance unit and laboratory are complete, up-to-date and without discrepancies.

Part 4: Inventory of all laboratories which continue to store or maintain polioviruses and/or potentially infectious material (See table 72)

(72): National Inventory of laboratories with wild poliovirus infectious or potential infectious materials

Government Department	Name of Institution	Address	Number of laboratories with wild poliovirus materials				
			only WPV infectious materials	only WPV potential infectious materials	Both WPV infectious & potential infectious materials	TOTAL Number of laboratories	Biosafety level of laboratories with polio materials

Section 5. IMMUNIZATION ACTIVITIES FOR POLIO ERADICATION

Purpose: to demonstrate to the Regional Commission that high routine polio immunization coverage has been maintained and, where appropriate, that supplementary immunization activities have been implemented to interrupt wild poliovirus circulation. These data should also demonstrate that the indigenous spread of imported wild polioviruses would be limited by high levels of population immunity.

Data Required: this section should contain full information on both the routine and supplementary polio immunization activities that have been conducted in the country. The first part deals with the history of polio immunization, the current routine immunization schedule and the polio vaccines that have been and are being used.

The second part deals with routine polio immunization coverage and methods of its estimation. National poliomyelitis vaccine immunization figures should be provided for as many years as possible (at least for the last 5 years). Routine immunization coverage should be provided by first and second administrative level (i.e. highest sub-national level of governments: e.g. state, province or region and second level such as district or part of district etc.) for the previous three-year period to demonstrate homogeneously high coverage.

The third part deals with immunization in high risk areas and among high risk populations i.e. those geographic areas or population subgroups with low routine immunization rates , there should be evidence of targeted measures taken to improve coverage.

The fourth part deals with data on supplementary polio immunization. It should include:

- all National and Sub-National OPV Immunization Days,
- all 'Mopping-up' activities [*]

The fifth part covers immunization response to outbreaks and importations.

[*] See definition in glossary

Section 5. Polio Immunization Activities (items 73 - 97):

Part 1: Routine Polio Immunization Policy

(73) Is polio immunization mandatory in the country (circle): yes / no

If yes,

- specify year it became mandatory …….……20__ .
- how immunization receipt is monitored _____

_____

(74) Type of polio vaccines used routinely in the country (circle):

a) oral poliovirus vaccine (OPV): yes / no Years used: from 20__ to _____

b) inactivated poliovirus vaccine (IPV): yes / no Years used: from 20__ to _____

c) mixed schedule: yes / no Years used: from 20__ to _____

(75) Outline of major changes in polio immunization policy since introduction of polio vaccines (i.e. change in vaccine used, immunization strategy, number of doses, etc.)

Year Change in Polio Immunization Policy

20__

_____

20__

_____

20__

_____

20__

_____

(76) Current routine polio immunization schedule:

Vaccine Dose No.	**Age (months)**	**Vaccine Used** (circle type of vaccine used)
0	Birth	OPV / IPV
1		OPV / IPV
2		OPV / IPV
3		OPV / IPV
4		OPV / IPV
5		OPV / IPV
6		OPV / IPV

Part 2: Routine Polio Immunization Coverage

(77) How is routine immunization coverage estimated? (administrative method, survey, etc.):

_____

_____

(78) Are additional methods/activities used to validate coverage estimates? (circle): yes / no

Specify methods (please provide details on a separate sheet):

_____

(79) What age group is used for calculating routine immunization coverage?

_____

(80) National Polio Immunization Coverage:
Please attach a graph showing the national polio immunization coverage that has been achieved since the introduction of routine polio vaccination in the country or for as many years back as available.

(81) Summary of national polio immunization coverage with at least 3 doses for the last 5 years:

Year	Vaccine (OPV vs. IPV)	Total OPV3 Doses used /year	Immunization Coverage (%)	Method used to determine coverage

(82) Annual Immunization Coverage by 1st Administrative Level: i.e. state, province, or Governorate for the last 3 year.

Immunization Coverage (%)				
Admin. Level	Year:	Year:	Year:	**Remarks**

83) Please attach a map showing the districts which had less than 80% OPV3 coverage during any one of the last 3 years.

Part 3: Immunization In High Risk Areas and Among High Risk Populations

(84) List the geographic areas (districts or parts of districts) where routine polio coverage is < 80% in any of the last 3 years:

Area (District or part of district)	**OPV3 coverage** Year:	Year:	Year:	**Population characteristics**	**Other reasons for being 'High Risk'**

(85) Please specify the actions that have been taken to raise polio immunization coverage in these low-coverage areas or districts:

_____

_____

_____

_____

(86) List the population sub-groups at high risk of poliomyelitis due to low immunization coverage (i.e. refusal of immunization services, lack of access to services, migrant or refugee population, etc.) or regular contact with recently endemic countries or populations (please provide geographic location of these groups and their estimated immunization coverage):

a)

_____

b)

_____

c)

_____

d)

_____

(87) Please specify the actions that have been taken to raise polio immunization coverage among these high risk groups (attach additional information if necessary):

_____

_____

_____

_____

_____

Part 4: Supplementary Immunization Activities for Polio Eradication

(88) Specify supplementary immunization activities conducted for polio eradication:

a) National OPV Immunization Days (NIDs): yes / no

b) Sub-national OPV Immunization Days (SNIDs): yes / no

c) 'Mopping-up'[5]activities with OPV: yes / no

d) Other (specify):_____

(89) Summary of National and Sub-national OPV Immunization Days (NIDs and SNIDs) in the last 5 years:

Year	NIDs/SNIDs (specify)	Target age group	No. of Children Targeted	Date of 1st round	Date of 2nd round	1st round coverage (%)	2nd round coverage (%)

(90) NIDs Coverage :

a) please attach a table with the NIDs coverage by 1st administrative level (i.e. province, state, etc.) for each NID.

b) please attach a map showing the districts which had less than 80% NID coverage during any one of the NIDs.

(91) Please state the criteria used for deciding the areas to be included in 'Mopping-up' [*]activities:

a) _____

b) _____

c) _____

d) _____

e) _____

[*] See definition page 52

(92) Summary of 'Mopping-up' activities in the last 5 years:

Year	Reason for 'Mopping-up'	Geographic Area Included	Age Group	Date 1st round	Date 2nd round	number immunized 1st round	Number immunized 2nd round

(93) Detailed description of 'Mopping-up' activities:

On a separate sheet, please provide details of 'mopping-up' activities, (the number of households visited, the average number of children immunized per household visited). If active case search was conducted, please provide details.

Part 5: Immunization Response to Polio Outbreaks and Importations

(94) How is a polio outbreak defined in the country?:_____

_____

(95) Outbreak Response Immunization:

a) is there a national policy for polio outbreak response immunization': yes / no

If yes, please specify:

b) how many rounds of immunization are conducted per outbreak?: _____

c) what is the usual age group targeted for outbreak immunization?: _____

d) how is the target age group for outbreak immunization determined: _____

_____

e) Please specify the minimum no. of children to be immunized:_____

(96) Polio importations:

a) are there special activities to detect importations? yes / no

b) if yes, please describe:

_____

_____

c) Please attach a copy of the national plan of action for the control of polio importation been prepared.

(97) Summary of the last 3 immunization responses to a polio outbreak or importation.

Year	Location of outbreak or importation	Geographic area included in response	Target age group	Date 1st round	Date 2nd round	Number immunized 1st round	Number immunized 2nd round

Comments: Please attach any additional comments on separate sheets.

(98) Immunity profile for the last 5 years.

Please attach the profile as obtained from the number of OPV doses received by the non polio AFP cases 6-59 months.

The Number of doses may be divided to the following categories 0 doses, 1-3 doses, 4-6 doses and 7 doses and over. Please make two profiles one for cases aged 6-24 months and the other for cases 6-59 months.

Supporting Documentation for Certification of Polio Eradication

Additional supporting documents may be submitted at the discretion of the National Certification Committee. The Regional Certification Commission for EMR may also request other information upon review of the documentation for certification of a country.

Checklist: Supporting Documentation for Certification of Polio Eradication

Standard Documentation Forms Completed:	yes / no / NA
Country Background Information	
Item 2 National map including major population centres, etc.	yes / no / NA
History of Poliomyelitis Cases and Wild Polioviruses,	
Item 18 Graph of polio incidence	yes / no / NA
Item 22 Map of confirmed poliomyelitis cases since 1995:	yes / no / NA
Item 28 Map of wild polioviruses since 1995:	yes / no / NA
AFP and Polio Surveillance	
Item 47 a) table of AFP performance by 1st administrative level:	yes / no / NA
Item 47 b) map of AFP rate for the previous year	yes / no / NA
Item 47 c) spot map showing 'expected' distribution of AFP cases:	yes / no / NA
Item 47 d) AFP stool specimen spot maps for previous 3 years:	yes / no / NA
Item 51 Summary of AFP cases reviewed by Expert Committee	yes / no / NA
Item 53 Spot maps of polio compatible cases:	yes / no / NA
Item 56 Supplementary surveillance activities: detailed reports	yes / no / NA
Polio Immunization	
Item 80 Graph of National Polio Immunization Coverage:	yes / no / NA
Item 83 b) Map showing districts with routine coverage <80%:	yes / no / NA
Item 90 a) Table of NIDs coverage by 1st administrative level:	yes / no / NA
Item 90 b) Map showing districts with NIDs coverage <80%:	yes / no / NA
Item 93 Detailed description of " Mopping-up" activities:	yes / no / NA

NOTE: NA: not applicable

Any other relevant documents included by NCC

Special Studies and Additional Activities

The details of all special studies or additional activities which may have been conducted to demonstrate the absence of indigenous wild poliovirus circulation from the country or a specific area should be provided.

Annex 2

Summary of biosafety level requirements

	Biosafety level			
	1	**2**	**3**	**4**
Isolation of laboratory	No	No	Desirable	Yes
Room sealable for decontamination	No	No	Yes	Yes
Ventilation:				
Inward air flow	No	Desirable	Yes	Yes
Mechanical via building system	No	Desirable	Desirable	No
Mechanical independent	No	No	Desirable	Yes
Filtered air exhaust	No	No	Yes	Yes
Double-door entry	No	No	Yes	Yes
Airlock	No	No	No	Yes
Airlock with shower	No	No	No	Yes
Effluent treatment	No	No	No	Yes
Autoclave:				
on site	Yes	Yes	Yes	Yes
in laboratory room	No	No	Yes	Yes
double-ended	No	No	Desirable	Yes
Biological safety cabinets				
Class I or II	No	Yes	Yes	Desirable
Class III	No	No	Desirable	Yes

Note: For more details, please refer to *Laboratory Biosafety Manual*, WHO, Geneva, 1993

Glossary:

Active Surveillance: defined as regular visits (i.e. weekly or biweekly) to principal health care facilities to search for and investigate unreported AFP cases through admission records, physician interviews, pediatric and neurological ward visits, etc.

Acute Flaccid Paralysis (AFP): Acute Flaccid Paralysis in a child aged less than 15 years including Guillain-Barre syndrome; or any paralytic illness in a person of any age when polio is suspected .

Adequate Stool Specimen: 2 stool specimens collected at least 24 hours apart, within 14 days of the onset of paralysis, and arriving in the laboratory with proper documentation, ice or cold ice packs present, sufficient quantity for laboratory analysis without drying or leakage.

Blind Area: geographic areas with lower than expected or no reporting disease rate.

Case-based Surveillance: The surveillance of a disease by collecting specific data on each case (e.g. reporting of details on each case of AFP).

Clinical Specimens: biological samples intended for analysis.

Clinically Confirmed Poliomyelitis Case: A case that meets the clinical classification scheme for AFP cases (see figure page 19).

Cluster: The occurrence of an unusual number of diseased individuals limited in person, place and time.

Compatible Case (Poliomyelitis Compatible Case): A case of AFP in which a diagnosis of poliomyelitis cannot be excluded with confidence based on all available information. Compatible cases represent a surveillance failure and should be scrutinized for clustering in space and time. (see figure, page 19).

Confirmed Poliomyelitis Case: A case that meets the WHO clinical or virologic classification scheme for AFP cases (see figure page.19)

Endemic: The constant presence of a disease or infectious agent within a given geographic area or population group.

Environmental Specimens: Samples collected external to a case for virologic analysis; e.g. sewage, soil, dirt, or water samples that might be contaminated with virus.

Facility-based Review: Inspection of a health facility such as neurology wards, pediatric hospitals, or rehabilitation centers as part of a retrospective record review for AFP surveillance.

Feedback: The regular process of sending results of data analysis and surveillance reports through all levels of the surveillance system so that all participants can be informed of trends and performance.

Immediately Notifiable Disease: Those health events that should be reported immediately or within hours of detection. Usually these are public health emergencies and require immediate action.

Imported Case of Poliomyelitis: Exposure to wild virus outside and onset of paralysis outside or inside the country which reports.

Indigenous Case of Poliomyelitis: Exposure and onset of paralysis within the country, even if virus was recently imported.

Infectious clinical laboratory materials : all clinical and investigative materials from confirmed or suspected cases of poliomyelitis.

Intratypic Differentiation: Characterization of a Poliovirus strain as wild type or vaccine type Poliovirus using appropriate laboratory methods.

Line Listing: Inventory of cases organized so that each row contains all the appropriate clinical and viral data on one case.

Mopping-up: Refers specifically to 2 rounds, 4 – 6 weeks apart of house-to-house immunization with oral polio vaccine (OPV) targeting all children in a specified age group, regardless of prior immunization status. 'Mopping-up' activities are usually conducted after NIDs, over a wide geographic areas (at least multiple districts) to interrupt the last foci of wild poliovirus transmission.

National Discharge Diagnosis: Database of final diagnosis of patients when released from health facilities.

NID: National Immunization Days. A Mass Campaign conducted over a short period (days) in which two doses of OPV are administered to all children in the target age group (usually less than 5 years) regardless of previous vaccination history, with an interval of 4-6 weeks between the 2 doses.

Outbreak: Unusual occurrence of disease in person, place, and time.

Potentially Infectious Material: clinical materials such as feces, intestinal contents, CNS, and respiratory secretions collected for other purposes, such as clinical trials, epidemiological studies, and diagnoses of other diseases. Each of these collections must be assessed separately to determine the likelihood of the presence of wild or vaccine polioviruses.
Consideration must be given to the country, the year, the last wild indigenous poliovirus isolates in the country, type of specimen (whether feces, respiratory secretions, or cell cultured fluid or animal tissues) and laboratory of origin. Stool samples would likely contain the highest levels of infectious polioviruses.

Potentially infectious experimental animals: any experimental animal infected with a strain containing capsid sequences derived from a wild poliovirus, especially CD 155 transgenic mice infected with wild poliovirus.

Reporting Completeness: Is usually calculated as a proportion of all expected reports that were actually received (usually stated as "% completeness of a certain date").

Reporting Timeliness: Proportion of all expected reports that were received by a certain due date.

Routine Disease Surveillance: The ongoing collection of information on health events and usually includes number of health events by district by months. It sometimes also includes health events by age group and/or immunization status.

Rumour Registry: Particularly in sparcely populated or long established polio-free countries, a system to investigate rumors suggesting occurrence of polio cases.

Sensitivity of Surveillance: The ability of the system to detect a disease, an epidemic or other changes in disease occurrence.

Sentinel Surveillance: The ongoing collection of information on health events from a limited number of reporting sites. Although these data are not representative of the entire country, they indicate trends and facilitate monitoring of severe diseases. More detailed data is often collected from sentinel surveillance sites than is possible form routine surveillance sites.

Spot Map: A map that indicates the location of each case of a disease by showing places that are potentially relevant to the health event being investigated, such as where the case lived, worked, or became ill.

Supplementary Surveillance Activities for Poliomyelitis: Ongoing collection of information to demonstrate both the absence of wild poliovirus and the sensitivity of existing surveillance systems to detect both paralytic poliomyelitis cases and wild poliovirus

Vaccine-associated Paralytic Poliomyelitis: see attached Regional Guidelines on VAPP.

Virologically Confirmed Poliomyelitis Case: A case of Poliomyelitis confirmed by isolation of wild poliovirus from stool specimen of the case or from a close contact

Zero Reporting: Reporting that no cases are detected. A report of zero cases is to be submitted by each reporting unit. Zero reporting is often required for diseases in the weekly and monthly reporting system.

Regional Guidelines for Diagnosis and Reporting of Vaccine Associated Paralytic Poliomyelitis (VAPP) Cases

Background

Countries in the EMR have relied primarily on OPV for control and eradication of poliomyelitis through routine and supplementary immunization. However, one disadvantage associated with OPV is the rare occurrence of VAPP. The overall risk of VAPP has been estimated at 1 case per 2.5 million doses of OPV distributed in the U.S.A and 1 case per 1.4 million doses administered in England and Wales.

In countries of Central and South America that have conducted mass immunization campaigns with OPV, the estimated overall risk for VAPP was not different from that reported from U.S.A and England and Wales, and ranged from 1 case per 1.5-2.2 million doses of OPV administered.

The best strategy to prevent VAPP is to eradicate wild poliovirus globally and eventually stop immunization against polio. However, until we reach that goal, cases of VAPP are expected to occur in some countries of the Region. The purpose of this document is to:

- Provide a case definition for VAPP with minimum criteria that must be fulfilled for establishing diagnosis
- Describe issues related to the process of establishing diagnosis and reporting of VAPP cases in EMR.
- Provide background information about VAPP.

Case Definition and Criteria for Diagnosis of VAPP

Recipient VAPP: Any case of AFP with onset of paralysis 4-30 days following receipt of OPV and the presence of neurological sequelae compatible with poliomyelitis 60 days following paralysis onset, isolation of vaccine-derived poliovirus from the stools and negative for wild poliovirus

The following criteria must be fulfilled before a diagnosis of VAPP is established:

1. The paralytic illness should be clinically compatible with poliomyelitis with residual paralysis at 60 days after paralysis onset and there should be no epidemiological links with wild virus confirmed or outbreak associated cases of poliomyelitis.
2. Adequate[6] stool specimens test negative for wild poliovirus in a WHO-accredited laboratory but positive for vaccine-related virus.
3. Other illnesses, which can cause flaccid paralysis, such as Guillain-Barre syndrome (GBS), transverse myelitis, neuritis, tumor, and trauma, have been ruled out.
4. The patient is evaluated by an expert committee, which considers additional information, including exposure history, clinical and virological data, and potential epidemiological links to confirmed poliomyelitis cases. The diagnosis must be established or endorsed by the National Expert Committee for Final Classification of AFP cases.

[6] adequate specimens: 2 stool specimens collected at least 24 hours apart, within 14 days of the onset of paralysis and arriving at the laboratory with adequate volume and in good condition. Good condition = no dessication, adequate documentation and evidence that the cold chain was maintained.

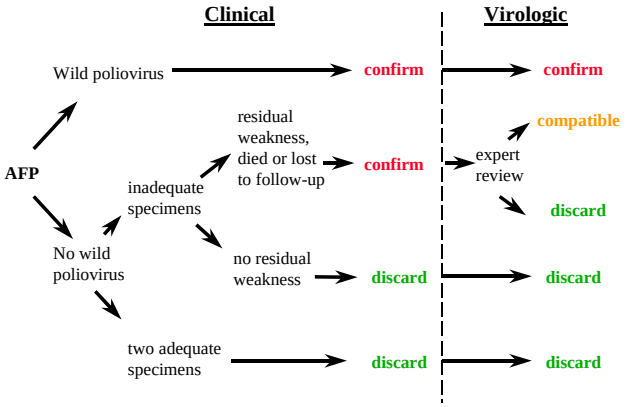
Process of establishing diagnosis of VAPP and reporting cases in EMR

The diagnosis of VAPP must be endorsed by the National Expert Committee for Final Classification of AFP cases. Optimally, the expert committee should include among its members a pediatrician, a neurologist, a virologist, and an epidemiologist or public health professional.

Detailed information related to the case should be made available to the expert committee. This should include an adequate history of exposure to OPV before paralysis onset, clinical findings and course of illness, neurological sequelae, investigations undertaken to rule out other diagnoses, virological findings, and findings of epidemiological investigations.

Reporting a case of VAPP: Since the objective of the polio eradication initiative is to eradicate wild poliovirus, under the WHO AFP Classification System (see Figure), VAPP cases should not be counted as 'confirmed due to wild poliovirus'. For the purpose of standardizing data management and reporting, cases diagnosed as VAPP should be included under the category of 'Discarded Cases'. VAPP should be reported under the final diagnosis of the AFP case.

Classification of AFP Cases



Background information on VAPP

Wild poliovirus and VAPP: Clinically VAPP is indistinguishable from wild virus confirmed poliomyelitis. The priority during evaluation of cases suspected of VAPP is to rule out wild poliovirus as the possible etiologic agent. This is best achieved by testing of adequate stool specimens in WHO accredited laboratories. Moreover, the possibility of an epidemiological link with wild virus confirmed or outbreak-associated cases of polio should be thoroughly investigated.

Incidence of VAPP: A number of studies have described the risk of VAPP in a variety of epidemiological settings. When adjusted for study methodology and system of disease reporting, the estimated risk is remarkably constant in all settings. The table below shows the risk of VAPP reported in various studies.
Reported risk of VAPP.

Study	1st dose	Recipient	Contact	Overall
Canada	--	1:9.5	1:3.2	--
England	1:0.7	1:2.0	1.4.5	1:1.4
Germany	--	1:4.4	1:15.5	1:3.4
Italy	--	1:8.1	1:4.1	1:2.7
Latin Am	1:1.2	1:3.6	1:5.6	1:2.2
U.S.	1:0.7	1:6.8	1:4.1	1:2.5
WHO		1:5.9	1:6.7	1:3.2

Risk of VAPP by OPV dose number: The risk of VAPP is highest following the first OPV dose and declines sharply with each subsequent dose. The risk following the first dose was estimated at 1 case per 700,000 doses of OPV administered in U.S.A and England and 1 case per 1.2 million doses administered in Central and South America. The risk following subsequent doses declined to 1:6.8 million doses administered in the U.S.A and to 1:3.2 million doses administered in Central and South America.

Contact VAPP and AFP surveillance: Approximately half the cases of VAPP reported from Americas are among contacts of vaccinated children. However, data collected in the AFP surveillance system in the region do not permit an adequate assessment of contact history between a case of AFP and an OPV recipient. Since cases of VAPP among contacts of OPV recipients are likely to be detected as AFP in the surveillance system, the minimum criteria for diagnosis of recipient VAPP also apply to the diagnosis of contact VAPP. However, a case of contact VAPP should have had a known contact with a vaccinee that received OPV 7-70 days before onset of paralysis of the patient and the contact between the patient and the vaccinee should have occurred 4-30 days before paralysis onset.

Poliovirus Serotypes and VAPP: Serotype 3 is the most frequently isolated poliovirus from patients with VAPP (60%-90% of cases), whereas serotype 1 poliovirus is rarely isolated from VAPP cases.

Other epidemiological features of VAPP: There are no secondary cases of VAPP and thus there is no clustering of VAPP cases. There is generally no seasonality to the occurrence of cases. The age distribution varies, but recipient VAPP occurs most frequently among infants and young children receiving their first dose of OPV.

VAPP in immuno-deficient persons: The risk of VAPP is greatly increased among persons with conditions associated with immuno-deficiency. However, not all immuno-deficient states appear to be associated with increased risk. For example there is no increased risk among persons with HIV infection whereas the risk appears to be highest in patients with agammaglobulinemia.

Risk of VAPP following NIDs: The risk is mainly determined by the number of children receiving their first OPV dose during the campaign. Since most children have usually already received OPV doses through the routine program and other supplementary mass campaigns, the risk of VAPP from during NIDs is much lower.