

Terms of Reference for the National GBS Surveillance in the Philippines 2014

A. Background

Acute Flaccid Paralysis (AFP) Surveillance was implemented to detect cases of possible poliovirus transmission. Since 1993, no cases of Polio have been reported; however, there were a few reported vaccine derived polio virus (VDPVs) in 2001 in the country and the subsequent polio outbreak of four cases was successfully controlled with two rounds of national oral polio vaccination. Despite this success, the AFP surveillance system has been struggling to achieve a target of 2/100,000 population of <15 years of age; a significant decline of AFP surveillance core indicators was also observed. Last year, the annual non-polio AFP rate was 0.73; for the past 7 years (2007-2013) the adequate stool collection rate did not reach the 80% benchmark. This trend continues with the current 2014 rate at 60%. In 2013, 2 regions reached the minimum non-polio AFP rate of 1/100,000 compared to 10 regions in 2012. There is also a substantial decrease of the number of cases receiving timely follow-up in 2013. Due to continuous decline of AFP surveillance system, low immunization coverage and threats from nearby countries of wild poliovirus transmission, the country was considered as high-risk for wild poliovirus importation in 2012.

During the 19th meeting of the Regional Commission for the Certification (RCC) of Poliomyelitis Eradication, the country's National Certification Committee (NCC) agreed with DOH concerns on declining surveillance performance and immunization rates and that many factors influencing health service delivery are already beyond the control of technical staff (e.g. the current DOH rationalization plan leading to staff cuts at national and regional level) or even the Department of Health (e.g. LGU support and resource allocation)

The establishment of the AFP surveillance system must be essentially capable of detecting cases to alert the government for outbreak control measures and interrupt possible poliovirus transmission. It is critical for verifying the absence of wild poliovirus circulation in the Philippines to maintain a polio-free certification status.

The AFP detection rate of 2 non-polio AFP cases per 100,000 children below 15 years of age indicates the sensitivity of the surveillance system and it is based on the fact that in the absence of wild poliovirus, cases with acute flaccid paralysis (AFP) continue to occur due to other causes, most specifically Guillain-Barré Syndrome (GBS) and others.

Guillain-Barré Syndrome (GBS) is the most common cause of acute flaccid paralysis in childhood in the post-poliomyelitis eradication era (Sladky, 2004). Reports of FBS incidence in several countries have utilized the AFP surveillance program of the World Health Organization (WHO). Detection and reporting children with AFP, collecting and transporting stool specimen samples for analysis, isolating and identifying poliovirus in the laboratory and mapping the virus to determine the origin of the virus strain are the four steps of the AFP surveillance (WHO, The Polio Eradication Initiative, 2010).

With the realization of the country's declining surveillance system in detecting Polio; through the initiative of the AFP/Polio National Certification Committee and Expert Review Committee chairpersons, a meeting between DOH, RITM and UP Manila National Institutes of Health staff was convened to discuss activities that will help strengthen surveillance. It

was proposed and agreed that a nationwide surveillance of Guillain-Barré Syndrome (GBS) must be done to help increase the case detection rate of AFP in the country and assess its impact on the surveillance system nationwide.

To further strengthen the said initiatives, the Research Institute for Tropical Medicine, National Certification Committee (NCC) for Polio Eradication, Institute of Child Health and Human Development of the UP National Institutes of Health, Philippine Neurological Association and Child Neurology Society of the Philippines will provide technical assistance to ensure that all activities will be implemented to sustain the progress towards the country's commitment for Polio eradication end game strategy.

B. Objectives

General: To conduct a nationwide surveillance of Guillain-Barré Syndrome (GBS) in the Philippines in September 2014 until September 2015 in line with the Polio eradication end game strategy,

Specifically, the objectives of the evaluation are:

1. To increase the case detection rate for AFP among age groups 0-15 years
2. To guide the DOH in enhancing the national plan of action towards polio eradication
3. To establish the incidence of GBS in the Philippines
4. To determine the epidemiological and clinical features of GBS in the Philippines.

C. Scope of Work

A joint surveillance activity will be conducted by staff of surveillance, immunization program and laboratory of DOH, staff of Institutes of Child Health and Human Development of the UP NIH, pediatric and adult neurologist members of the Philippine Neurological Association and Child Neurology Society of the Philippines:

National Epidemiology Center

- Provide data/information and documents that necessitates the conduct of surveillance activity
- Facilitate workshops and advocacy meetings
- Capacitate chosen hospital sites and hired surveillance staff in case detection, reporting investigation and filling out of AFP CIF and GBS report
- Provide technical inputs in the development of the surveillance proposal
- Provide AFP surveillance data analysis
- Assist in the written report on the result, findings, action taken and recommendation of the activity
- Provide inputs in the finalization of technical report
- Provide support (logistics/financial) in the implementation of National GBS surveillance activity

Research Institute for Tropical Medicine

- Participate in workshops, orientation and meetings
- Capacitate chosen hospital sites and hired surveillance staff in the standard specimen collection, handling, storage and transport
- Provide logistics to health facilities, Regional Epidemiology and surveillance staff
- Receive specimen and conducts laboratory testing
- Transmit stool specimen results to NEC, UP NIH and health facilities
- Provide technical support in logistics support for laboratory confirmation
- Provide advocacy materials/videos and laboratory issuances to sites identified
- Assist in the written report on the result, findings, action taken and recommendation
- Provide inputs in the finalization of technical report

Institutes of Child Health and Human Development (ICHHD) – UP Manila NIH

- Draw up methodology preparation, sample selection.
- Supervise data entry for GBS cases
- Provide GBS data encoding and analysis
- Collate AFP surveillance report and GBS surveillance report for the finalization of technical report
- Provide GBS Surveillance Case Investigation tool and form
- Receive and validate reported GBS reports and feedback to NEC

Regional Epidemiology and Surveillance Unit (RESU)

- Provide data/information and documents that necessitates conduct of surveillance activity
- Cooperate in the conduct of the said activity
- Assist the GBS surveillance staff in case investigation and hospital visits in chosen sites
- Carry out usual obligations continuously and efficiently
- Participate in the orientation workshop, meetings and field work

Senior Surveillance Supervisor

- Facilitate overall supervision of GBS surveillance activity
- Facilitate advocacy meetings with partner agencies such as Philippine Neurological Association and Child Neurology Society of the Philippines
- Provide sound technical advice and materials needed to improve conduct of GBS Surveillance activity
- Provide preliminary analysis of findings
- Provide inputs in the finalization of technical report
- Provide final technical report to NEC

Senior GBS Surveillance Coordinator

- Supervision of GBS surveillance assistants
- Participate in workshops, orientation and meetings
- Liaise with the NEC VPD surveillance officer to ensure a two-way flow of information during implementation of activity
- Conduct hospital visits for active surveillance or retrospective records review for AFP and GBS surveillance for NCR and region 4A
- Receive and validate GBS reported cases from other GBS surveillance assistants for Luzon, Visayas and Mindanao cluster
- Submit referred AFP cases referred by Pediatric/Adult neurologists to Regional VPD surveillance coordinator of NCR
- Consolidate all GBS cases reported by GBS surveillance assistants
- Conduct GBS case encoding and data analysis
- Assist the Senior surveillance coordinator with technical preparations and assures that quality surveillance standards are adhered to
- Assist in the written report on the result, findings, action taken and recommendation of the activity

GBS Surveillance assistants (There shall be 1 surveillance assistant each for Luzon, Visayas and Mindanao cluster.

- Receive orientation and training on AFP and GBS surveillance as well as standard specimen collection, handling, storage and transport by NEC and RITM
- (May) conduct hospital visits (sites to be determined based on silent DRUs identified from 2009-2013) for active surveillance or retrospective records review for AFP and GBS surveillance to assigned Regions as necessary
- Coordinate with Regional VPD surveillance officers and disease surveillance coordinators of health facilities for AFP and GBS cases reported from his/her covered Regions
- Refer AFP cases to Regional VPD surveillance officers
- Submit GBS case report forms (electronic and /or hard copy) to Senior GBS surveillance coordinator for encoding and analysis
- Conduct hospital visits for active surveillance or retrospective records review for AFP and GBS surveillance
 - GBS Surveillance Assistant for Luzon Area (Regions 1, 2, 3 4B, 5 and CAR)
 - GBS Surveillance Assistant for Visayas Area (Regions 6, 7 and 8)
 - GBS Surveillance Assistant for Mindanao Area (Regions 9, 10, 11, 12, 13 and ARMM)

Adult and Pediatric Neurologists

- Evaluate referrals for clinical investigation/ neurologic evaluation of AFP and GBS cases
- Acquire consent or help facilitate acquisition of consent from parents/patients with GBS or AFP cases

- Accomplish GBS case record form to be submitted to GBS surveillance assistants either thru e-mail or fax; a complete medical abstract with diagnostic tests results must be attached along with the GBS case record form.
- Notify designated disease surveillance coordinators of the health facility of AFP cases for reporting and stool specimen collection. To facilitate this, for all AFP/ GBS cases, please order in the patient's chart the following: AFP/GBS case: report to Infectious Disease surveillance nurse and collect stool specimens according to AFP protocol.

Consultant(s)

- Provide sound technical advice and materials needed to improve conduct of the National GBS surveillance
- Capacitate members of the team in organizing and preparing necessary data and documents needed during the orientation workshop
- Assist in the interim evaluation/analysis
- Review the results of completed surveillance and assist in report preparation
- Assist in the coordination and execution of the complete evaluation/technical report. This includes a participatory impact assessment with DOH, in which lessons learned are identified for a possible next phase.

D. Methodology

A team composed of DOH surveillance and laboratory staff, GBS surveillance staff from Institute of Child Health and Human Development (ICHHD) will take part of a Nationwide GBS Surveillance activity in the Philippines. All regions will be covered with hospital sites chosen for each region.

All patients presenting with acute flaccid paralysis and GBS who will be initially seen or referred to all participating neurologists nationwide from September 2014 to September 2015 will be screened according to the Acute Flaccid Paralysis Surveillance System. A standard case investigation form for AFP and GBS shall be used for key informant interviews, retrospective records review and data collection.

Participating pediatric and adult neurologists shall cooperate with the disease surveillance coordinators of each health facility chosen and obtain an informed consent and stool specimen collection for laboratory testing. AFP and GBS cases detected shall be referred to the Regional Epidemiology surveillance unit and GBS surveillance assistant.

There shall be one GBS surveillance assistant appointed for Luzon, Visayas and Mindanao cluster and will. Each hired surveillance assistants may conduct hospital visits accompanied by regional epidemiology surveillance staff for active surveillance and retrospective records review. AFP cases detected/referred by the neurologist or disease surveillance coordinator shall be submitted to regional VPD surveillance officer for reporting and encoding. GBS cases detected/referred by the neurologist or disease surveillance coordinator shall be directly submitted to the Senior GBS surveillance coordinator in the ICHHD at the UP National Institutes of Health for analysis.

Components of the above mentioned activity are the following:

a) For Acute Flaccid Paralysis cases

- Case Detection and Notification

The Disease Surveillance Officers (DSOs)/Disease Surveillance Coordinators (DSCs) should conduct daily active case finding in coordination with the participating neurologist in the institution or region. To ensure that all cases are detected, DSOs/DSCs should also review patient's records/logbooks of the health facility based on the following differential diagnoses: Poliomyelitis, Guillain-Barre syndrome, Myelitis (i.e. Transverse myelitis, Pott's disease), traumatic neuritis, and other diseases as long as AFP is manifested. Reporting of all patients that satisfy the standard case definition within 24 hours after detection, regardless of the physician's diagnosis will be done online to the designated project coordinator. Zero reporting of cases will be required from participating neurologists on a weekly basis through email or short message service (SMS). Centralized reporting will be done by each participating neurologist to the designated project coordinator, who will likewise, coordinate with the reference laboratory and NEC designated polio officer for confirmation of receipt of stool specimen and accomplished CRF

- Case Investigation

1. Verify if the case satisfies the case definition for AFP. DSO/DSC will coordinate with the partner neurologist on the neurologic findings of the reported AFP case.
2. Interview and examine the case
3. Collect additional information
4. Collect stool specimen for the AFP age group 0-15.
5. Submit the completed AFP and GBS CIF. GBS CIF will be accomplished by the partner neurologist.
6. Conduct 60-day follow-up examination

- Case confirmation

1. Stool Collection and Storage procedures
2. Specimen transport procedure

- 60-Day Follow-up

A follow-up visit to an AFP case is important to determine the presence of residual paralysis. All AFP cases should be followed up on the 60th day from onset of paralysis. Priority should be given to AFP case that falls in any of the following: without stool samples, stool samples were collected beyond 14 days from paralysis onset, cases classified as polio-compatible, AFP hot case. For cases with inadequate stool specimen or cases classified as polio-compatible, a complete follow-up neurologic evaluation should be conducted by a physician or a trained health worker and coordinated with the designated neurologist in the region to determine if the neurologic deficits are highly suggestive/compatible with polio. The Hughes functional scoring for GBS (see table 2) will be used to assess the neurologic outcome of the patients. This will be done by the designated neurologist.

The patient may be declared “lost to follow-up” after three failed attempts to locate him or her within 90 days after paralysis onset. Death of the patient before the 60-day follow-up should be reported immediately to RESU and NEC.

- Case classification

Expert Panel Classification: the main responsibility of the AFP/Polio Expert Review Committee is to review and classify all the AFP cases reported and entered into the surveillance system. Complete medical records with relevant information and laboratory results should be provided especially for cases with inadequate stool specimen to facilitate case classification.

For cases diagnosed with GBS with electrophysiologic studies, the following case classification will be used: AIDP, AMAN, AMSAN and MFS.

b) GBS Surveillance

- Data collection

Data collection will be done using a standardized GBS case record form with the following details: demographic characteristics, antecedent events, vaccination records, treatment given, available laboratory tests (i.e. electrophysiologic tests, CSF studies and neuro-imaging) and outcome. The participating neurologist will be required to obtain informed consent forms and to accomplish the GBS case record form. Inter-site standardization process will be maintained on each site through quality control procedures on data entry and data processing. Each site will use the same set of forms. Epi-Info Version will be utilized as data entry program. Batch forms will be submitted to the data manager responsible for range checks and other basic data- cleaning procedures.

- Clinical Investigation for GBS cases

Weakness severity will be estimated by calculating the Medical Research Council (MRC) sum score, which is defined as the sum of MRC grades (ranging from 0-5) of six bilateral muscle groups/ pairs: upper arm abductors, elbow flexors, wrist extensors, hip flexors, knee extensors, and foot dorsiflexors. The range of MRC sum scores is from 0 (tetraplegia) to 60 (no paralysis) (Verma, 2013). MRC scale for muscle strength is graded on the following (see table 2): Grade 5 (Muscle contracts normally against full resistance), Grade 4 (Muscle strength is reduced but muscle contraction can still move joint against resistance), Grade 3 (Muscle strength is further reduced such that the joint can be moved only against gravity with the examiner’s resistance completely removed), Grade 2 (Muscle can move only if the resistance of gravity is removed), Grade 1 (Only a trace or flicker of movement is seen or felt in the muscle or fasciculation are observed in the muscle), and Grade 0 (No movement is observed) (MRC, 1981).

Presence of autonomic dysfunction characterized with either one of the following: cardiac arrhythmias, fluctuations in rate and blood pressure, sweating abnormalities, pupillary abnormalities, gastrointestinal dysfunction and urinary retention will be recorded. Likewise, the presence of respiratory impairment and need for ventilatory support will be noted.

Functional outcome of enrolled patients will be graded according to Hughes functional grading scale on three settings: on admission, upon discharge and on follow-up check-up.

For cases diagnosed with GBS with electrophysiologic studies, the following case classification will be used: AIDP, AMAN, AMSAN and MFS.

E. Estimated duration of engagement: 12 months (September 2014 to September 2015)

Time Frame	Activity
January-July 2014	<ul style="list-style-type: none"> • Protocol Development • Statistician consultation • Presentation of research protocol to CNSP meeting and PNA board of members
July–1 st week August 2014	<ul style="list-style-type: none"> • Institutional Review Board Approval • Budget Proposal Approval c/o DOH
August 1-15 2014	<ul style="list-style-type: none"> • MOA signing with PNA and CNSP • Hiring of GBS surveillance staff
August 21,2014	<ul style="list-style-type: none"> • Pre-orientation/Briefing of Regions
September 2014-2015	<ul style="list-style-type: none"> • Data collection
November 2014	<ul style="list-style-type: none"> • Interim analysis
September 2015	<ul style="list-style-type: none"> • Preliminary report
October 2015	<ul style="list-style-type: none"> • Final report

F. Implementing arrangements

- a. The NEC will provide sub allotment to the RITM for the conduct of the National GBS Surveillance in the Philippines
- b. The NEC together with RITM and ICHHD of the UP Manila National Institutes of Health will provide support staff during implementation of the activity
- c. NEC, RITM and ICHHD will work closely with Regional health offices, Pediatric and Adult Neurologists and selected health facilities in the implementation of the activity
- d. 3 GBS surveillance assistants will be hired and appointed for Luzon, Visayas and Mindanao cluster. Each assistant will be based at the Regional Health Office and will also travel to field sites with RESU surveillance officer as required.
- e. The 3 GBS surveillance assistants appointed for each cluster shall conduct hospital visits for active surveillance/retrospective records review for hospitals Pediatric/ Adult neurologists who will be working as site coordinators will provide referrals of AFP cases to the disease surveillance coordinator of the health facilities for case investigation and stool specimen collection; for GBS cases, the GBS surveillance assistant shall be notified.
- f. A senior surveillance supervisor from the ICHHD will supervise all the work that has to be done for the project when force majeure, the consultant cannot assume his/her responsibility

G. Expected outputs and deliverables

Documentation of the proceeding on meetings, results, findings, recommendations and impact assessment of the surveillance activity on the AFP surveillance system.

H. Qualifications

Consultant

- A holder of MPH post graduate studies with expertise on vaccine preventable disease surveillance from academic and practical perspectives
- Familiar on new methodologies and approaches with regard to vaccine preventable disease surveillance and response system
- Having at least 5 years of experience working on public health, preferably in the field of Epidemiology and Disease Surveillance
- A graduate of medicine or other allied health professional
- Proven experience in information analysis and report writing

Senior GBS Surveillance Coordinator

- A graduate of nursing or other allied health professional
- Analytical thinker with good reporting and writing skills
- Leadership qualities and personnel and team management skills
- Having at least 2 years of experience working on research studies, analysis and report writing

GBS Surveillance assistant

- A graduate of nursing or other allied health professional
- Having at least 1 year of experience working on public health preferably in the field of epidemiology and disease surveillance
- Analytical thinker with good reporting and writing skills
- Demonstrated ability to work harmoniously with other staff
- Good contextual knowledge of local issues, community priorities, organizational relationships, social and cultural constraints and realities, and environmental conditions.
- Language skills (including knowledge/fluency in local dialects)
- Resourcefulness to work under frequently trying and isolated field circumstances.

I. Proposed terms of payment

Consultants and surveillance staff will be hired and paid by RITM

J. Budget source and coverage

ITEM DESCRIPTION	QTY	UNIT	RATE/UNIT/ PRICE	AMOUNT
Personnel				
Senior Surveillance Supervisor	1	14 mo	10,200.00	142,800.00
Co-supervisor	5	12 mo	6,000.00	360,000.00
Senior GBS Surveillance coordinator	1	12 mo	32,254.00	387,048.00
GBS Surveillance assistants	3	12 mo	18,543.00	667,548.00
Honoraria				
Neurologists (site coordinators; 2/region)	34	one shot	5,000.00	170,000.00
Consultants	5	one shot	5,000.00	25,000.00
Encoder	1	6 mo	5,000.00	30,000.00
Subtotal	50			1,752,396.00
MOOE				
Per Diem	3	12 mo	800.00	28,800.00
Incidentals		12 mo	6276.00	75,312.00
Transportation Expenses				
Surveillance personnel Transportation allowance				
By land and water	17	12 mo	1,500.00	306,000.00
Airfare	3	6 mo	18,000.00	324,000.00
Communication Expenses				
- Load and internet allowance	3	6 mo	315.00	5,670.00
- Internet/DSL	2	6 mo	450.00	5,400.00
Supplies and Materials		6 mo	1,000.00	6,000.00
Printing expenses		3 mo	1,000.00	3,000.00
Representation expenses (meeting and coordination expenses)		12 mo	2,500.00	30,000.00
Other				
Technical review fee			5,000.00	5,000.00
Insurance	4		600	2,400.00
Laboratory Budget for 750 cases (see breakdown below)				1,333,000.00
REB Fee				30,000.00
Subtotal				2,154,582.00
Total Cost				
				3,906,978.00
Administrative Overhead Cost (7.5%)				293,023.00
GRAND TOTAL				4,200,001.00