A microscopic image of a virus particle, likely an influenza virus, showing its characteristic spherical shape and surface spikes. The image is rendered in shades of green and yellow, with a dark background. The virus particle is the central focus, with several long, thin spikes extending from its surface. The background is a gradient of green, with other smaller virus particles visible in the distance.

Operational Guideline for Influenza-Like Illness and Severe Acute Respiratory Infection

Second Edition 2014

Public Health Laboratory
Department of Public Health
Ministry of Health

ILI & SARI

Surveillance

Second Edition 2014

Public Health Laboratory

ILI & SARI Surveillance

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Preface

The influenza H1N1 pandemic of 2009 has demonstrated a need for Bhutan to have a pandemic preparedness plan in place. The establishment of an influenza surveillance system in the country emerged as one of the major requirements of the preparedness plan. In 2012, Public Health Laboratory (PHL) came up with the first edition of the influenza surveillance guideline (Operational guideline for ARI/ILI/SARI Surveillance). The guideline was operationalized in 2012 and the activities such as selection of surveillance sentinel sites, training and retraining of the relevant stakeholders, reporting of the cases on a timely basis, sample shipment and testing, preparation and dissemination of reports were carried out as required.

This Second Edition of the influenza surveillance guideline is the revised edition of the first influenza surveillance guideline. The revision of the second edition of influenza surveillance guideline was carried out with objective to enhance the efficiency of the existing surveillance system. The changes incorporated in the second edition comprise of refinements of surveillance objectives, segregation of Influenza-Like-Illness (ILI) and Severe Acute Respiratory Infection (SARI) sentinel surveillance sites, removal of Acute Respiratory Infection (ARI) surveillance and redefining the roles and responsibilities of surveillance focal points and Public Health Laboratory.

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Background

Influenza is a respiratory illness caused by influenza virus that can spread very easily from person to person. The virus is spread through the air by the exchange of fluid droplets from the mouth or nose of one person to another person due to sneezing and coughing. The manifestations of illness caused by the influenza virus are usually mild to moderate but for some it could be severe, leading to hospitalization and even death. The influenza virus circulates around the world and undergoes continuous evolution by antigenic drift which causes annual epidemics. In rare instances the virus may change completely called 'antigenic shift', and result in the emergence of novel influenza viruses.

World Health Organization (WHO) estimates 3 - 5 million cases of severe illness and about 250,000 – 500,000 deaths every year around the world due to a seasonal influenza epidemic. Additionally lower respiratory tract infections were found to be the leading cause of death in low income countries and the third leading cause of death globally.

In Bhutan, respiratory illnesses are the major public health concern and affect a majority of the population irrespective of age. The annual Health Bulletin 2013 reports that, for the past many years, acute respiratory infection is rated as the top disease affecting general

population in the country.

The influenza A (H1N1 pdm2009) pandemic in 2009 took many countries by surprise and most developing countries were not prepared for a pandemic of such scale. This pandemic has led to the establishment of influenza surveillance and building of laboratory capacity to diagnose the virus in the country.

The Highly Pathogenic Avian Influenza (HPAI) H5N1 was first detected in Bhutan in poultry in 2011. Since then it has caused periodic outbreaks in the poultry but no human cases have been detected so far. This epizootic incidence poses a serious threat to public health especially because of the severity and high mortality in humans.

In February 2013, another novel influenza virus H7N9 was reported from China in humans. Compared to 2009 H1N1, H7N9 cases have a higher percentage of severe illness and deaths in humans, however its severity and mortality rate is lower than HPAI (H5N1). Like HPAI (H5N1), H7N9 has limited human to human transmission. To date (March 2014), H7N9 has not spread beyond China because of the global concerted public health approach in containing the spread of the virus. However, this virus has the potential to cause another pandemic.

The ILI and SARI surveillance system is aimed to monitor trends in respiratory illnesses and to understand the burden and epidemiology of influenza viruses and other respiratory pathogens. Establishing a good surveillance system will set the foundation to monitor other factors including the social and climatic factors that influence community transmission and help with planning for intervention and preventative measures.

Objectives of ILI & SARI Surveillance

Goal of this Document

This document proposes surveillance objectives and describes standards and a framework adopted from the WHO guidelines for a minimal basic surveillance system for the monitoring of influenza virus. Use of standards will help us to understand the epidemiology, transmission, and impact of influenza in the country and compare with other countries. The existing SARI and ILI surveillance system is sentinel based for efficient data collection, laboratory transport, and other logistics. The data generated and analyzed from the surveillance system can help to make well-informed policy decisions, and also reporting of data back to those who are involved in surveillance will help improve patient care and encourage continued reporting.

Target Audience

This document is intended to be a guidance tool for the medical and health professionals involved in ILI and SARI surveillance.

1. Describe the seasonality of influenza activity.
2. Establish baseline levels of influenza, ILI and severe respiratory disease, which may be related to influenza and other respiratory pathogens.
3. Monitor unusual and unexpected events such as outbreaks of influenza during and outside the typical season.
4. Monitor which seasonal influenza viruses are circulating and detect novel viruses (H5N1, H7N9).
5. Contribute to WHO vaccine strain selection.
6. Identify and monitor groups at high risk of severe disease and mortality, in order to target education and prevention measures.

Roles & Responsibilities

Sentinel Sites

The sentinel sites must have a committed team comprising of: clinicians, laboratory technicians, nurses and the surveillance focal point. Each of these members of the team should be assigned a specific role and responsibilities as follows:

A. Influenza like Illness (ILI) Surveillance Site

Clinicians

1. Identification of patients that meet the ILI case definition in the guideline.
2. Daily recording of ILI cases at their respective sentinel sites.
3. Proper completion of ILI sample collection form for patients to be sent for sample collection (**Annex 4**).
4. Refer the patient to laboratory for collection of respiratory specimens along with the ILI sample collection form.
5. Provide the data collected to SFP on daily basis for compilation.

Surveillance Focal Point (SFP)

Each sentinel site should identify at least two focal points responsible for the routine surveillance operation. Focal person should be appointed in consultation with the hospital administration.

The SFP should:

1. Collect and collate data on total number of patients who meet the ILI case definition from OPD chambers and also count the total number of OPD cases seen every day or on a weekly basis (**Annex 3**).
2. Report all ILI to PHL on weekly basis through online data system or by fax if internet facility is not available.
3. Disseminate the reports and feedbacks received from PHL to the relevant health personnel (Clinicians, laboratory, nurses etc.).

4. Provide feedbacks from sentinel sites to NAIL, PHL.

Medical Laboratory Technologist/Technician

1. Ensure all 'ILI Sample collection forms' and 'SARI patient sample collection form' are filled out completely and accurately.
2. Ensure all respiratory specimens for ILI and corresponding forms are assigned with unique ID number.
3. Collect respiratory specimens appropriately from patients meeting the case definitions.
4. Properly label, pack, store, and transport specimen to NAIL, PHL according to the (**Annex 6**).
5. Perform rapid flu test for ILI specimen and ensure test results are reported to the treating clinician and simultaneously record on the form (**Annex 4**).
6. Ensure there is adequate stock of test kits, VTM, barcodes and relevant forms in the laboratory.
7. Shipment of specimen along with cases investigation forms to PHL as per the existing shipment schedule.

B. Severe Acute Respiratory Infection (SARI) Surveillance Site

Surveillance Focal Point (SFP)

At least two designate Nurses from sentinel sites (national, regional referral and district hospitals) will be appointed as Surveillance Focal Points for SARI sur-

veillance.

1. Identification of patients that meet the SARI case definition in the guideline.
2. Enrollment of SARI Cases.
3. Daily recording of all SARI cases.
4. Proper filling out of 'SARI Patient Specimen Collection Form' (**Annex 2**).
5. Data collection of the total number of SARI and total number of admitted patients from the wards every week to be sent to PHL on weekly basis (**Annex1**).
6. Collect respiratory specimen and other appropriate specimen for bacteriological investigation and perform rapid test for influenza virus.
7. Ensure all respiratory specimens and corresponding forms are assigned with unique ID number using the label provided by PHL.
8. Liaise with laboratory for specimen pick up from wards, storage and shipment to PHL.

Medical Laboratory Technologist/Technician

1. Pick up sputum specimen from patients enrolled for SARI surveillance and perform bacteriological analysis.
2. Share bacteriological laboratory result for SARI cases with PHL every week using the online system.
3. Shipment of specimen along with cases investigation forms to PHL as per the existing shipment schedule.
4. Support nurse in respective sentinel sites as

and when necessary for collection and rapid testing of SARI specimen.

5. Ensure adequate supply of rapid test kits and VTM in the wards.

C. Public Health Laboratory

National Influenza Laboratory (NAIL)

1. Serve as the technical and scientific focal point for activities pertaining to ILI and SARI surveillance.
2. Perform following activities on specimens received from sentinel sites:
 - a. Enter data from SARI & ILI Specimen collection form.
 - b. Influenza virus typing and subtyping, using molecular methods (Real time RT-PCR / conventional PCR)
 - c. Referral of any untyped specimen to a designated WHO Collaborating Center.
 - d. Receiving, archiving and storing original clinical specimens at -70°C for ILI/ SARI for ten years.
 - e. upload results in the web-based data management system
3. Communicate the results of all individual confirmatory tests for ILI and SARI cases back to the designated SFP weekly (Every Wednesday).
4. Share representative clinical specimen or virus isolates of seasonal influenza specimens with a WHO Collaborating Center (WHO-CC)

- twice a year.
5. Immediate sharing of information on any un-subtypable or suspect novel influenza viruses with a WHO Collaborating Center.
6. Participating in the WHO Global External Quality Assessment Project for the molecular detection of influenza viruses as well as in regional programs.
7. Provide initial and refresher training to sentinel sites on specimen collection, diagnosis, storage and transport.
8. Monitor sentinel sites to maintain quality of data and specimens sent to NAIL, PHL.

National Disease Surveillance & Epidemiology (NADSAE) Unit

1. Managing computer database of ILI/SARI data.
2. Preparing and disseminating the weekly and annual influenza surveillance reports to all stakeholders.
3. Reporting weekly national surveillance data to regional and global influenza surveillance platforms.
4. Reporting to IHR focal point of any influenza novel strains cases as per the IHR requirements.
5. Provide initial and refresher training to sentinel sites on surveillance guidelines.
6. Review and update influenza surveillance guideline as needed.

Selection and location of sentinel sites

The sentinel sites for ILI and SARI are selected based on geographic, climatic and demographic representativeness and also the feasibility such as capacity and accessibility of a hospital. Previously all the sentinel sites (11 sites) were asked to conduct both ILI and SARI surveillance. To improve efficiency of surveillance, existing ILI sites will be down sized to 7. However all the sentinel sites will continue conducting SARI surveillance. ILI and SARI surveillance will now consist of seven ILI sentinel sites and 11 SARI sentinel sites (Table-1 & Figure 1).



Figure-1: SARI Surveillance Sites



Figure-2: ILI Surveillance sites

Table 1: Sentinel Sites

Regions	Code
Western region	
Paro Hospital	BTC
Punakha Hospital	BTD
Phuentsholing Hospital*	BTF
Samtse Hospital	BTK
Central Region	
Trongsa Hospital	BTE
Tsirang Hospital	BTI
Gelephu Regional Referral Hospital*	BTG
JDWNR Hospital*	BTB
Eastern Region	
Trashigang Hospital	BTH
Mongar RR Hospital*	BTA
S/Jongkhar Hospital	BTJ

Influenza Like Illness Surveillance

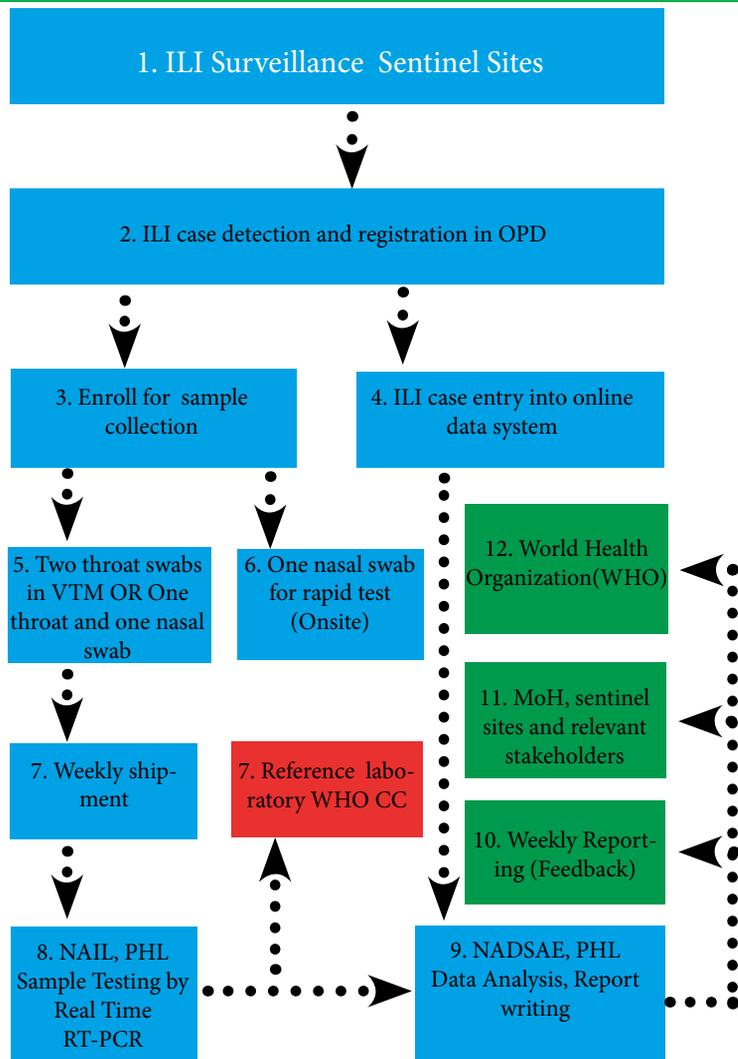


Figure-3: ILI Surveillance Overview

ILI Case Definition

Any person with acute respiratory infection with;

1. Fever $\geq 38^{\circ}\text{C}$; AND
2. Cough or sore throat; AND
3. Onset within the last 10 days.

(Note: Consider sample collection from ILI patients only if onset of fever is within the past 72 hours/3 days)

Case selection and sampling strategy

Case enrollment

All cases in OPD meeting ILI case definition should be enrolled as ILI cases.

ILI cases enrolment for specimen collection

Each identified sentinel site for ILI should enroll at least 6-8 ILI cases every week (i.e. 24-32 specimen per month) for specimen collection. The cases for specimen collection should be equally distributed between children and adult (i.e. 3-4 specimen from children and 3-4 specimen from adult). The ILI specimen collection cases should be done from Monday to Wednesday of the week. Important criteria for sample collection from ILI patients is that the onset of acute fever should be within the past 72 hours or 3 days.

Specimen processing at sentinel sites

Specimen collection

1. The patients meeting the criteria set in case enrolment should be requested to provide clinical information, a nasal swab and a throat swab. Appropriate form should be used to collect clinical and laboratory information required by forms (**Annex 5**)
2. Standard Operating Procedures should be followed to collect nasal swab and throat swab (Annex 6).
3. Collect two throat swabs in VTM for PCR using PPE.
4. Collect one nasal swab for rapid test using PPE.

Patient consent

ILI surveillance is a routine activity for monitoring respiratory illnesses often caused by influenza. Therefore, collection of specimen such as nasal and throat swabs and accompanying information does not require consent. However, if the surveillance specimen is to be used for study purposes, consent is required.

Box 1: Patient Consent

Specimen Labeling

Labeling will be done using barcodes which will be supplied by the National Influenza Laboratory. However if a barcode is not available, sample labeling should be done by sentinel sites laboratory as mentioned in the **Box 2** below.

Specimen Labeling

*The first three letters specify the surveillance type followed (see table 1 for site code) by site code (BTA). The surveillance type and site code is then followed by a last four digits as the case number. The case number should begin at the number 0001 at the start of each year for ILI. An Example: **FLU-BTA-0001** means case is ILI, the sentinel site is Mongar, first ILI case of the year.*

Box 2: Specimen labeling

Onsite testing

PHL will provide all surveillance sites with rapid diagnostic test kits for antigen detection of influenza A and B for onsite testing. Sentinel site should perform rapid diagnostic test using instruction provided in package insert. The results should be provided to the attending clinicians for patient management.

Specimen Storage & Shipment

All collected specimen should be properly sealed and stored in 2-8oC until transportation. Transportation to PHL should be done within 3-4 days from date of sample collection (Annex 7).

Specimen processing at NAIL, PHL

Specimen receipt

Upon receipt of specimen from sentinel sites, NAIL should:

1. Verify the specimen with ID with the 'ILI patient specimen collection form'
2. Check quality of specimen; adequacy, leakage and contamination.
3. Check temperature conditions of the specimen and also check shipment cold chain log for appropriate temperature during shipment.
4. Aliquot specimen for laboratory testing, repository and referral to WHO-CC.

Sample rejection

If the specimen does not meet the required standard, it should be rejected as per the SOP.

Specimen testing

Specimen are used for laboratory analysis to type and

subtype influenza virus. Real-Time PCR will be performed at PHL in accordance with the standard operating procedures (SOPs).

Storage and Shipment

The specimen aliquoted for repository should be stored in freezer at -70oC. Selected positive specimen should be sent to a designated WHO Collaborating Centre (WHO-CC) for further analysis to describe the antigenic characteristics and genetic makeup of circulating viruses at least twice a year (Annex 7).

Disposition of Specimens

Human respiratory specimens at PHL should be kept for at -700C for at least 10 years after which they should be disposed with strict adherence to` SOP. For influenza specimens sent to WHO Collaborating Centers, the clinical specimen should be maintained at -700C for at least 1 year.

Data collection and Reporting

ILI clinical & laboratory data collection

All ILI sentinel sites should provide information of ILI patients selected for the specimen collection as required by form in Annex 4. In the form, the clinical part should be filled out by clinicians and laboratory part should be filled out by laboratory personnel. The original of completed forms should be sent to Public Health Laboratory along with the specimen. The copy of the forms should be retained at the sentinel sites.

Weekly ILI surveillance data reporting.

The designated SFP of sentinel sites should collect the information of total number of ILI patients visiting the Outpatient Department (OPD) using weekly reporting form (Annex 3). The compiled data along with total number of OPD cases should be relayed to Public Health Laboratory through the online ILI & SARI information system (www.phls.gov.bt) no later than Monday of the next week. If reporting cannot be done online due to unforeseen reasons, the report should be sent to NAIL or NADSAE by Fax.

Severe Acute Respiratory
Infection Surveillance

Specimen processing at sentinel sites

Collection of Specimen

1. Patients meeting the criteria set in case enrolment should be requested to provide clinical information, a nasal swab and a throat swab or nasopharyngeal aspirate. In case of intubated patient endotracheal secretion may be collected. Appropriate form should be used to collect clinical and laboratory information required by forms (**Annex 2**)
2. Standard Operating Procedures should be followed to collect nasal swab, throat swab and nasopharyngeal aspirate (**Annex 6**).
3. Collect two throat swabs in VTM to be sent to PHL for PCR.
4. Collect one nasal swab for rapid test for Influenza.
5. Collect sputum, throat swab, nasopharyngeal aspirate or endotracheal secretion for bacteriological investigation at the site.

Patient consent

SARI surveillance is a routine activity for monitoring respiratory illnesses caused by influenza and other respiratory pathogens. Therefore, collection of specimen such as nasal, throat swabs, sputum, nasopharyngeal aspirate or endotracheal aspirate and accompanying information does not require consent. However, if the surveillance specimen is to be used for study purposes, consent is required.

Box 3: Patient Consent for SARI Surveillance

Specimen labeling

Labeling will be done using barcodes which will be supplied by the National Influenza Laboratory. However if a barcode is not available, sample labeling should be done by sentinel sites laboratory as mentioned in the Box 4.

Specimen Labeling

The first three letters specify surveillance type followed (see table 1 for site code) by site code (SARI) for SARI. The surveillance type and site code is then followed by a four digits as the case number. The case number should begin at the number 0001 at the start of each year for both ILI and SARI cases (Sentinel Site code/case code)/Year/Case Number). An Example: SARI-BTA-0001 means the sentinel site is Monggar, case is SARI, year of collection is 2014 and first SARI case of the year from Monggar.

Box 4 : Specimen Labeling

Onsite testing

PHL will provide all surveillance sites with rapid diagnostic test kits for antigen detection of influenza A and B for onsite testing. Sentinel site should perform rapid

diagnostic test using instruction provided in package insert. The sites should also perform bacteriological testing. The results should be provided to the attending clinicians for patient management.

Specimen, Storage and Shipment

All collected specimen should be properly sealed and stored in 2-8°C until transportation. Transportation to PHL should be done within 3-4 days from date of sample collection (**Annex 7**). Bacterial isolates should be sent to PHL at 2-8°C for further analysis.

Specimen processing at NAIL, PHL

Specimen receipt

Upon receipt of specimen from sentinel sites, NAIL should:

1. Verify the specimen with ID with the 'SARI patient specimen collection form'
2. Check quality of specimen; adequacy, leakage and contamination.
3. Check temperature conditions of the specimen and also check shipment cold chain log for appropriate temperature during shipment.
4. Aliquot specimen for laboratory testing, repository and referral to WHO-CC.

Sample rejection

If the specimen does not meet the required standard, it will be rejected as per the SOP.

Specimen testing

Specimens should be used for laboratory analysis using Real Time RT PCR to type and subtype influenza virus. Real-Time RT PCR will also be performed to detect other respiratory pathogens at PHL in accordance with the standard operating procedures (SOPs). Bacterial isolates should be used for molecular characterization.

Storage and Shipment

The specimen aliquoted for repository and bacterial isolates should be stored in freezer at -70°C. Selected influenza positive specimen should be sent to a designated WHO Collaborating Centre (WHO-CC) for further analysis to describe the antigenic characteristics and genetic makeup of circulating viruses at least twice a year (**Annex 7**).

Disposition of Specimens

Human respiratory specimens and bacterial isolates at PHL should be kept for at -70°C for at least 10 years after which they should be disposed with strict adherence to SOP. For influenza specimens sent to WHO Collaborating Centers, the clinical specimen should be maintained at -70°C for at least 1 year.

Data collection & Reporting

All SARI sentinel sites should provide clinical and laboratory information of SARI patients using the required form (**Annex 2**). The nurse working in the ward should fill out the clinical information and laboratory personnel should complete the laboratory part of the form. The original of the forms should be sent to Public Health Laboratory along with the specimen and the copy should be retained at the sentinel sites.

Weekly SARI surveillance data reporting.

SFP should collect the total number of SARI cases admitted on weekly basis (**Annex 1**) from ward. The compiled data along with total number of IP cases should be relayed to Public Health Laboratory through the online ILI & SARI information system (www.phls.gov.bt) no later than Monday of the next week. If reporting cannot be done through online system due to unforeseen reasons, it should be sent to by Fax immediately or inform NAIL or NADSAE about the delay.

Data Management,
Analysis & Feedback

Data Management

Both ILI and SARI data from the form (**Annex 2&3**) should be maintained using online surveillance system. NADSAE should manage the data for both the surveillances. NAIL should provide laboratory data to NADSAE.

Data Disposition

Data will be maintained using online database system for at least 10 years after which it will be disposed according to standard procedure.

Analysis

Data obtained from all the sites for ILI and SARI should be analyzed by NADSAE on weekly and annually basis.

For '**Weekly Report**' following parameters should be analyzed:

- a. Trend in both ILI and SARI activity, compared with last weeks, previous seasons, and base-line
- b. Positivity rate of ILI and SARI specimen
- c. Geographical spread
- d, Type and subtype of influenza viruses that have been detected
- e. Affected age groups and deaths due to influ-

enza and pneumonia.

For '**Annual Report**' following parameters should be analyzed:

- a. Description of seasonality
- b. Types and subtypes of circulating influenza viruses during the season.
- c. Comparison of data from the most recent influenza season to previous seasons.
- d. Notable or unusual features of the season when compared to previous seasons should be highlighted.
- e. Proportion of specimen testing positive for influenza by week or month of the year.
- f. Description of laboratory confirmed influenza-associated SARI and ILI cases within each month or week of the year for each age group, by site and aggregate.
- g. The proportions of influenza-positive cases with underlying medical conditions.
- h. Lessons learnt from ongoing surveillance (if any).
- i. Number of sentinel sites reporting weekly to the national level;
- j. Number of sentinel sites regularly submitting specimens for laboratory testing;
- k. Number of specimens sent from the sentinel sites;
- l. Identify high risk groups

Feedback

Weekly Report

NADSAE should prepare a weekly report entitled “Flu-View” and share with relevant stakeholders (MoH, DoPH, national programs, sentinel sites and health workers, Department of Livestock, BAFRA, WHO, CDC).

Annual Report

Each year, additional analyses should be undertaken by NADSAE in collaboration with NAIL to facilitate evidence-based planning and intervention. The Annual Influenza Report which should be disseminated to the sentinel sites, relevant stakeholders and international organization. In the annual report, the findings from monitoring and evaluation (M&E) of the surveillance system should also be incorporated.

Feedback will improve the consistency and encourage reporting from sentinel sites and encourage reporting. Therefore the feedback should provide timely information on influenza and other respiratory pathogen activity and the types of influenza viruses and other respiratory pathogens circulating within the country.

Box 5 : Feedback

Monitoring & Evaluation (M&E)

A surveillance system should undergo regular monitoring to routinely assess whether it is functioning efficiently and providing quality data to meet its stated objectives. Additionally, routine assessments should indicate areas in which personnel at the sentinel sites may need training and logistic support. National Influenza Laboratory of PHL should allocate appropriate budget to enable timely evaluation and monitoring of the surveillance system on yearly basis. During onsite monitoring, checklist (**Annex 11**) should be used.

Indicators to assess the surveillance system

Surveillance data should be monitored at each administrative level, beginning at the sentinel sites where data are collected and entered and continuing at the national levels. Monitoring should be carried out to check the compliance of the indicators shown in Table-2.

Table 2 : Indicators for M&E

Indicators	Frequency	Source	NAIL	NADSAE	Sites
Timeliness	Monthly	Routine data	Yes	Yes	Yes
Completeness	Monthly	Routine data	Yes	Yes	Yes
Consistency	Monthly	Routine data	Yes	Yes	Yes
Number specimen collected	Weekly	Routine data	Yes	No	Yes

Timeliness

Timeliness refers to the speed between steps in a surveillance system. Data must be timely, if it is to be useful to clinicians, public health authorities, and the community. It describes the success of the program in meeting targets for several different time intervals in the surveillance and reporting process.

Table 3: Indicators for Timeliness

SN	Indicator	Administrative level
1	Expected dates of data reporting from sentinel site to NAIL/NADSAE as compared to actual dates of reporting	Sentinel sites
2	Time elapsed from specimen collection at site to arrival at PHL for testing	Sentinel sites
3	Time elapsed from receipt of specimens at PHL to processing, testing and generating results	
	NAIL	
4	Time elapsed from receipt of data from sites to entering data into database by NADSAE.	NADSAE
5	Time elapsed from generation of laboratory results to notification of the clinicians.	NAIL & Sentinel sites
6	Time elapsed from receipt of data from sites and NAIL to providing feedback by NADSAE	NADSAE

Completeness of data collected

Completeness refers to the individual case report forms, weekly aggregate reporting forms and sample collection forms and can be measured by assessing the parameters given in table 3.

Consistency

Should PHL observe sudden or unexpected change in pattern of the data, it must be investigated as these aberrations in data could be caused by changes in the collection system, reporting methods, recent training, etc. The unexpected change in data may also represent an unusual event of public health concern.

Following are some of the possible instances of aberration in data:

1. Unexpected or sudden increase or decrease in number of ILI/SARI cases
2. Unexpected or sudden increase or decrease in number of SARI deaths reported
3. Unexpected or sudden change in the percentage of specimens testing positive for influenza.
4. Unexpected or sudden shift in the type or subtype of virus detected
5. Changes in the distribution of risk factors reported.

Table 4 : Indicators for Completeness

SN	Indicator	Administrative level
1	Percentage of ILI & SARI forms with complete information	Sentinel sites
2	Percentage of sentinel sites reporting	Sentinel sites
3	Percentage of data entered from the forms (annex 1) into the database by the sites and form (Annex 2 &3) by NADSAE.	Sentinel Site & NADSAE
4	Percentage laboratory results generated being entered into database	NAIL

Table 5: Indicators for Consistency

SN	Indicator	Administrative level
1	Number of sites that has aberrations in the data that might be caused by a change in collection or reporting methods	Sentinel site
2	Number of sites that has changes in the data that might indicate an outbreak or a change in disease transmission	Sentinel sites

Number of specimen collected

Number of specimen collected in each site can be used to monitor surveillance.

Table 6 : Indicators for number of specimen collected

SN	Indicator	Administrative level
1	Number of ILI specimen collected as compared to the required number.	Sentinel site
2	Number of SARI specimen collected from total SARI cases registered.	Sentinel sites

Team Composition for M&E

Following team members (Table 7) will conduct M&E annually using standard M&E check list (Annex 10). Additional visit may be made, as and when required, for those sites that have problem.

Table 7 : Team composition for M&E

Team Members	Responsibilities
Chief Laboratory Officer	Overall supervision and guidance during M&E
Epidemiologist/FETP fellow from NADSAE	M&E of Surveillance activity procedures
Medical Technologist from NAIL	M&E of Laboratory procedure
ICT personnel from ICT	Database Management

Outbreak and Rapid Response

ILI outbreak is defined as an “abnormal increase” of cases compared with normal cases or trend in a given period and a change in the type of persons with ILI (say for example, most of the cases are in young adults) or a single detection, by a referral laboratory, of a novel virus, would also trigger a rapid response.

An “abnormal increase” should be understood as an increase above and beyond the normal range of seasonal variation of reported cases or a single case of influenza strain which has a potential to cause epidemic and pandemic. However, abnormal increase will differ from place to place. To confirm the etiology of an outbreak, at least 5-10 specimen from ILI cases should be collected and confirmed at PHL.

The outbreak should be investigated by a Rapid Response Team as per the “**Outbreak Investigation and Rapid Response Manual**” of Bhutan.

Administrative Issues

Data security

The source data sheet (clinical form) and diagnostic test results should be maintained in a safe place with limited access. Computer generated database files should be kept in a password protected computer in a locked room and with a limited access except for authorized personnel only. Users of the data should be provided a personal identifier code (username and password). All specific information pertaining to patients should remain confidential. Data used for analysis or publication shall be based on study subject number and not contain individual identifying information. Both interim and final reports shall be made available to all investigators and collaborating institutions listed on this protocol.

Data Disposition

Source data

Source documents (paper documents) generated from the surveillance should be stored for 5 years. After the term, all the documents should be disposed using paper shredder or incinerator.

Electronic data

The electronic data should be maintained at the data bank (data server) in PHL. The data should be stored in the data bank at all times.

Guideline amendments

Any change or amendment for the guideline shall require a formal clearance from the Ministry of Health. Such amendments should be submitted to the amendment committee for approval and changes if required. The guideline shall then be revised to concur with the amendments.

Training

All clinicians and health personnel working at surveillance sites must have sound knowledge on proper case selection, specimen collection, rapid diagnostic test, storage and transportation of specimen and bio-safety issues to fill their respective roles and responsibilities and should receive training by PHL personnel. Training on the surveillance guidelines must be conducted and the activities documented in PHL and in a related program at Ministry of Health.

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12. Avian Influenza commodities training Guide, USAID, March 2007.

Annex 1

SENTINEL SARI SURVEILLANCE AGGREGATED DATA

SITE NAME	
WEEK NUMBER	
YEAR	

	Age Group					
Aggregated Number of Cases	0-1	2-4	5-14	15-49	50-64	64+
Number of SARI cases during the week						
Number of deaths due to SARI/ Pneumonia during the week						
Total IPD cases during the week						

Reported By: _____ Signature: _____

Mobile Number : _____ Date: _____

Note: Send original of this form to PHL along with the sample. The copy form should be kept at the surveillance site

Annex 2

SARI PATIENT SPECIMEN COLLECTION FORM

Specimen ID	
-------------	--

PATIENT INFORMATION

Patient name		Age/Sex	
Occupation		Address	
Date of onset of symptoms		Date of hospitalization	
Outcome	Discharged /Death	Date of discharged /Death	

CLINICAL INFORMATION

Fever measured >38 degrees?	Yes	No	Unknown
Cough?	Yes	No	Unknown
Sore throat?	Yes	No	Unknown
Shortness of breath or difficulty breathing?	Yes	No	Unknown
Clinical Signs of Pneumonia	Yes	No	Unknown
Others (Specify) :			

Pre-Existing Medical Conditions

Heart Disease	Yes	No	Unknown
Asthma	Yes	No	Unknown
Chronic Lung Disease	Yes	No	Unknown
Liver Disease	Yes	No	Unknown
Pregnant (Trimester _____)	Yes	No	Unknown
Diabetes	Yes	No	Unknown
Neuromuscular Dysfunction	Yes	No	Unknown
Immune compromised	Yes	No	Unknown
Others (Specify) :			

EPIDEMIOLOGICAL INFORMATION

Travel History:

History of Travel within the last 7 days	Yes	No
Area and Location (if yes):		

Exposure History :

Poultry	Yes	No
Swine	Yes	No
Others (specify):		

TYPES OF SPECIMEN COLLECTED

Specimen Collection Date		
Throat Swab	Yes	No
Nasal Swab	Yes	No
Nasopharyngeal Swab	Yes	No
Others:		

RAPID TEST RESULT

(Note: Rapid test to be done by a nurse in wards)

Negative	Flu A Positive	Flu B Positive	Flu A+B Positive	Invalid	Not Done
----------	----------------	----------------	------------------	---------	----------

Reported by : _____ Telephone/Mobile No: _____

Signature: _____ Date: _____

Note: Send original of this form to PHL along with the sample. The copy form should be kept at the surveillance site

Annex 3

SENTINEL ILI SURVEILLANCE AGGREGATED DATA

SITE NAME	
WEEK NUMBER	
YEAR	

Aggregated Number of Cases	Age Group					
	0-1	2-4	5-14	15-49	50-64	64+
Number of ILI cases during the week						
Total IPD cases during the week						

Reported By: _____ Signature: _____

Mobile Number : _____ Date: _____

Note: Send original of this form to PHL along with the sample. The copy form should be kept at the surveillance site

Annex 4

ILI PATIENT SPECIMEN COLLECTION FORM

Specimen ID	
-------------	--

PATIENT INFORMATION

Patient name		Age/Sex	
Occupation		Address	
Date of onset of symptoms			

CLINICAL INFORMATION

Fever measured >38 degrees?	Yes	No	UKN
Cough?	Yes	No	UKN
Sore throat?	Yes	No	UKN
Others (Specify) :			

SPECIMEN COLLECTED

Specimen Collection Date:		
Throat Swab	Yes	No
Nasal Swab	Yes	No
Nasopharyngeal Swab	Yes	No
Others:		

EPIDEMIOLOGICAL INFORMATION RAPID TEST RESULT

Travel History:

History of Travel prior to illness	Yes	No
Place travelled (if yes)		
Duration (In Days)		

Exposure History :

Poultry	Yes	No
Swine	Yes	No
Others (specify):		

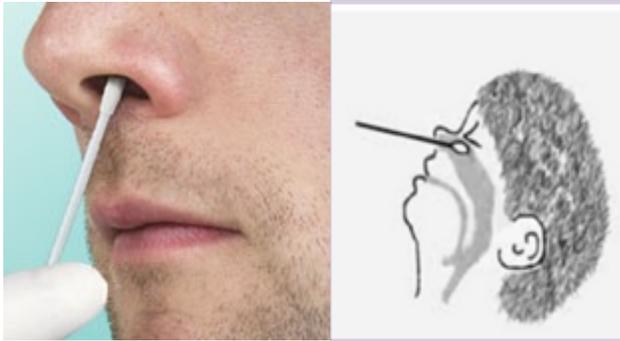
Negative	
Flu A Positive	
Flu B Positive	
Flu A+B Positive	
Invalid	
Not Done	

Reported by : _____ Telephone/Mobile No: _____
Signature: _____ Date: _____

Note: Send original of this form to PHL along with the sample. The copy form should be kept at the surveillance site

B. Nasal swab (for rapid test)

1. Label VTM tube with Lab ID number.
2. Ask patient to sit comfortably on chair
3. Hold patient's head slightly back by one hand
4. Advance the swab tip past the vestibule (anterior nares) to the nasal mucosa (approximately 2-3 cm from the nostrils in adults)
5. Gently rotate to collect nasal secretions from the anterior portions of the turbinate and septal mucosa.
6. Perform the rapid test.



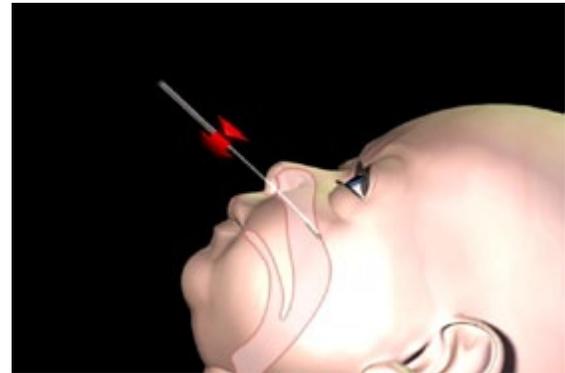
Source : www.webmd.com

C. Nasopharyngeal swab

1. Label VTM tube with Lab ID number.
2. Ask patient (adults) to sit comfortably on chair
3. Hold patient's head slightly back by left hand.
4. Insert a flexible, fine-shafted polyester swab into the nostril and back to the nasopharynx.

The swab is inserted following the base of the nostril towards the auditory pit till resistance is met. (Need to insert at least 5–6 cm in adults to ensure that it reaches the posterior pharynx). (DO NOT use rigid shafted swabs for this sampling method).

5. Leave the swab in place for a few seconds and withdraw slowly with a rotating motion.
6. Open and put the swab into VTM
7. Immediately close the VTM tube and store in 2-4°C till the sample is processed or transported to PHL.



Source: www.quidel.com

Annex 7

Sample Storage

A. Sample storage procedure (for sentinel sites)

1. Wear an apron and gloves.
2. Seal the VTM tubes with parafilm airtight after collection.
3. Arrange specimens in serial order based on sample ID number in storage rack
4. Label storage racks with detailed information of specimens it contain.
5. Arrange specimens in serial order based on sample ID number in storage rack.
6. Place the specimen racks in a refrigerator at 2-8°C until ready to transport to PHL.
7. Ship the specimens to PHL within 48 hours of collection. Schedule for shipment is given at Annexure-10.

B. Sample Storage Procedure (for PHL)

1. Wear an apron, gloves and other protective barriers Aliquot specimen (140µl of the specimen for PCR and 420µl for stock)
2. Seal the remaining specimen in VTM tubes with parafilm
3. Arrange specimens in serial order based on sample ID number in storage rack.
4. Label storage rack with detailed information of specimens it contain.
5. Store the specimens in -70°C.

Annex 8

Sample Packaging & Transportation

A. Sample packaging and transportation (Sentinel sites to PHL)

1. Prepare the line list of specimen to be shipped in accordance with Annexure-5.
2. Arrange documents for specimen accordingly. Documents to be sent are given in the Box 6 below:

Documents for Influenza Surveillance specimen

- Specimen log form – Annex 5
- Cold-chain Maintenance form – Annex 8
- Copy of ILI sample collection forms with ILI specimen – Annex 4
- Copy SARI sample collection forms with SARI specimen – Annex 2

Box 6: Documents required for shipment of specimen from site to PHL

3. Follow WHO Triple Packaging System: Use 3 packaging layers i.e.
 - Primary receptacle holds respiratory specimens i.e. VTM tube wrapped with parafilm
 - Secondary container Durable, water-tight, leak-proof, Several primary receptacles can go into secondary con-

tainer

- Outer container should be Rigid, durable and insulated e.g. Styrofoam box.

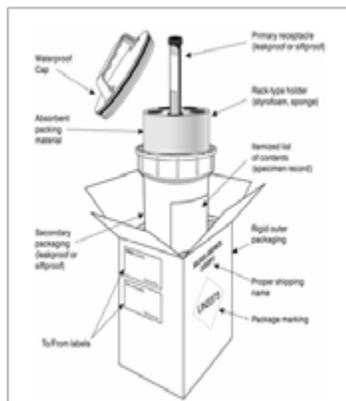


Figure 6: WHO triple packaging container

Steps for packing specimens

- Seal VTM tube with parafilm – this is primary receptacle and wrap with tissue paper to absorb the accidental leakage.
- Place VTM in watertight zip lock bag.
- Place up to 10 single VTM in zip log bag with-in another watertight container depending on size of the container (e.g. sturdy plastic container with lid) – this is secondary container.
- Place absorbent, cushioned material between primary and secondary containers.
- Put secondary container in a “Wizard Box” or

any box provided by PHL for shipment of influenza specimens.

- Place ice/cold packs between secondary and outer containers
- Complete the Cold Chain Maintenance Table forms (**Annex 9**)
- Place all documents between secondary and outer container in a plastic zip lock bag or polythene bag to avoid from getting wet.
- Mark and label the outer container properly, this should include:-

Address of the shipper and the consignee.

Biohazard label

Orientation label

(Note: UN number is not required for in-country shipment.)

- Send the specimens on ice or frozen ice packs to PHL within 48 hours from the date of sample collection.
- Ensure the packing box contains enough ice packs to keep the specimens for few days.
- Transport the specimen to PHL. Ship the specimen from the hospital to your nearest Bhutan Post on scheduled time provided to you by PHL (**Annex 10**)
- Collect the empty box from the same Post Office every week for the next shipment.

B. Sample packaging and transportation (PHL to reference Laboratory)

- Prepare the line list of specimen to be shipped

in accordance with **Annex 5**.

2. Arrange documents for specimen accordingly. Documents to be sent are as follows:

Influenza Surveillance specimen

- Sample log form (**Annex 5**)
- Cold-chain Maintenance form (**Annex 8**)
- Copy of ILI sample collection form with ILI specimen if required (**Annex 4**)
- Copy SARI sample collection form with SARI specimen if required (**Annex 2**)

Ensure that copies are made and retained at PHL for all the forms that are being sent

Box 7: Documents required for shipment of specimen from PHL to Reference Laboratory

3. Follow packaging steps a to e describe under Sample packaging and transportation (Sentinel sites to PHL).
4. Place dry ice between the secondary and transport container to keep the sample at the required temperature during transportation.
5. Place specimen data forms, letters and other relevant documents in a water proof bag (preferably sealed plastic bag) carefully tapped either to the outside of the secondary receptacle or inside of the transportation container. .
6. The outer shipping or transportation container should be labelled with the name of

the receiver, indication of storage conditions required during transport, and bear any additional labels or stickers (biohazard sign) as per the national/international regulations.

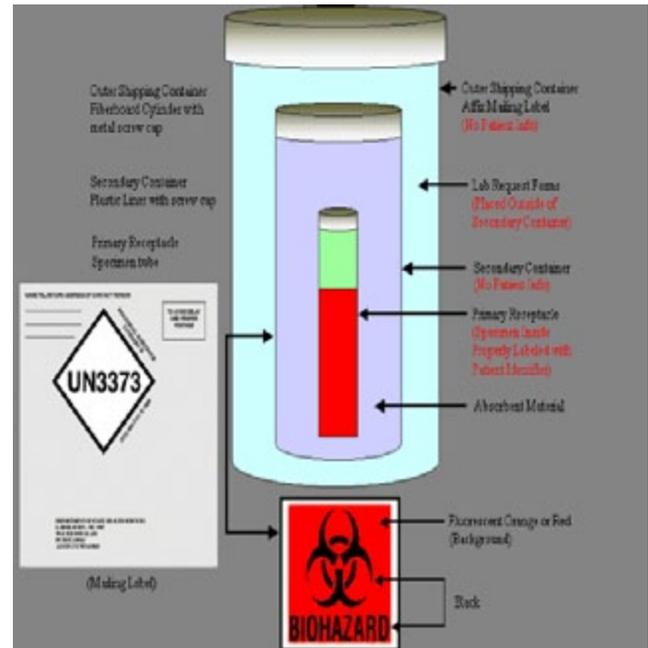


Figure 7 Triple Packaging System with labels.

Annex 9

Cold Chain Maintenance Table

SN	Specimen ID	Collection Date	Temperature History				Transferred to AFRIMS in			
			2-8 °C Duration hours *	-70°C freezer	LN	DI	WI	LN	DI	

*specimens can be kept in a refrigerator (between 2-8 oC) for not more than 72 hours. Demographic /clinical form should accompany this form. LN = liquid nitrogen, DI = dry ice, WI = ice or frozen ice pack

Shipment prepared at site by: Date:.....(dd/mmm/yy).

Shipment received at AFRIMS by: Date (dd/mmm/yy)

Shipment inventory: Date:..... (dd/mmm/yy)

Annex 10

Sample shipment schedule by Bhutan Post

SN	Sentinel Sites	Schedule time
1	Paro District Hospital	Wednesday evening
2	Punakha District Hospital	
3	Trongsa District Hospital	
4	Tsirang District Hospital	
5	Samtse District Hospital	
6	Gelephu Central Regional Referral Hospital	
7	Phuntsholing General Hospital	
8	Trashigang District Hospital	
9	Samdrupjongkhar District Hospital	
10	Mongar Eastern Regional Referral Hospital	

Annex 11

Monitoring and Evaluation Form

Name of the Sentinel site: _____ Date of evaluation: _____

1. Timeliness

SN	Attributes	Target	Time elapsed in days
1	Time taken for weekly data form to reach PHL	Report reaches by fax or mail ????or is /entered into online system latest by Monday of every next week	
2	Time taken for specimen from sentinel site to arrive at PHL	Within 3-4 days of sample collection	
3	Time taken to process, test and generate results by PHL	Within 1 week of sample receipt	
4	Time taken to notify SFP after result generation	within 1 day of report	
5	Time taken to generate report by PHL	Every Tuesday of next week	
6	Time taken to disseminate report to the sentinel sites by PHL	Every Tuesday of next week	

2. Completeness

SN	Attributes	Target	Percentage
1	Percentage of forms received with complete information from sites	At least 80% of the reports have all data fields completed	
2	Percentage of sentinel sites reporting regularly?	At least 80% of all sentinel sites deliver every reporting interval	
3	Percentage of data forms entered from the forms into the database.	At least 80% of cases from which specimens are collected have data collected	

3. Consistency in data or Aberrations

SN	Attributes	Target	Number
1	Unexpected or sudden increase or decrease in number of SARI, ILI, or SARI deaths reported	--	
2	Unexpected or sudden change in the specimens testing positive for influenza	--	
3	Unexpected or sudden shift in the type or subtype of virus detected	--	
4	Changes in the distribution of risk factors reported	--	
5	Change in the age distribution of cases reported	--	

Additional Observation

Evaluator _____ Initial/Date _____

4. Specimen Collected

SN	Attributes	Target	Numbers
1	Numbers of ILI specimen collected and sent	6-8specimen per week	
2	Numbers of SARI specimen collected and sent	Samples from all registered cases	

5. Outbreaks

SN	Attributes	Target	Numbers
1	Number of outbreaks reported as compared to that of the previous year	--	
2	Number of outbreaks investigated and confirmed by laboratory	--	
3	Number of outbreaks that have been intervened and controlled	--	

Annex 12

Personal Protective Equipment (PPE)

PPE consists of following items

1. Aprons
2. Shoe cover
3. Respirators / face masks
4. Hood/cap/hair cover
5. Gloves
6. Disposable bag
7. Hand wipe/alcohol mop

Area Designation for donning gown

A designated area for putting on PPEs and removal should be identified and all personnel should use this area to put on their PPEs. This should ideally be in a clean area away from any potentially contaminated area.

Note: requirement of PPE will differ between sentinel sites and national levels.

Procedure:

1. Before you begin putting on your PPE, go to a designated clean room to put on the equipment, preferably away from anything that could be contaminated with infectious materials.
2. Wash your hands with soap and water before you begin, and remove watches and other non-smooth jewelry like bracelets.
3. Put on apron first.

4. Put on shoe covers.
5. Put the respirator under your chin with the nosepiece up. Pull the bottom strap over your head, and place it around your neck below the ears. Then pull the top strap over your head and rest it high at the top back of your head. Place your fingertips from both hands at the top of the metal nosepiece.
6. Using two hands mold the nose area to the shape of your nose by pushing inward while moving your fingertips down both sides of the nosepiece.
7. Put on gloves. Pull the edge of the gloves over the cuff of your apron.

Procedure for Removing and disposing off PPE

1. Open the germicidal wipe/alcohol mop and use it first on your gloves and then on your shoe cover.
2. Place it in the biohazard bag when done.
3. Remove your respirator by grabbing the top and then the bottom elastic bands and pulling them up over your head. Place the respirator in the biohazard bag.
4. Remove and dispose of your apron in the biohazard bag.
5. Remove and dispose of your outer shoe covers in the biohazard bag.
6. Close the biohazard bag by tying a knot at the top or otherwise tying it shut. The biohazard bag should be placed at a designated location so that it can be collected and burned or

buried.

7. Wash your hands and forearms with soap and water.

How to Wash Your Hands Correctly

1. Wet your hands with water and apply soap. Use clean, running water.
2. Rub hands together to make lather and scrub all surfaces.
3. Continue rubbing hands for 20 seconds.
4. Rinse hands well under running water
5. Air dry your hands, or use towel.

When to Wash Your Hands While Using PPE

1. Before putting on your PPE
2. Before putting on your gloves or respirator again after taking a work break
3. Before and after changing your respirator
4. After taking off your gloves and the rest of your PPE, and placing them in the waste bag
5. Any other time your ungloved hands have come into contact with potentially infected equipment or surfaces.

This guideline is the Second Edition with several changes incorporated. This edition comprise of refinements of surveillance objectives, segregation of Influenza-Like-Illness (ILI) and Severe Acute Respiratory Infection (SARI) sentinel surveillance sites, removal of Acute Respiratory Infection (ARI) surveillance and redefining the roles and responsibilities of surveillance focal points and Public Health Laboratory and all others involved.

This document describes surveillance objectives, standards and a framework adopted from the WHO guidelines for a minimal basic surveillance system for the monitoring of influenza virus. This standard will help us to understand the epidemiology, transmission, and impact of influenza in the country and compare with other countries. The data generated and analyzed from the surveillance system can help to make well-informed policy decisions, and also providing feedbacks to those who are involved in surveillance will help improve patient care.

For information visit our website www.phls.gov.bt

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