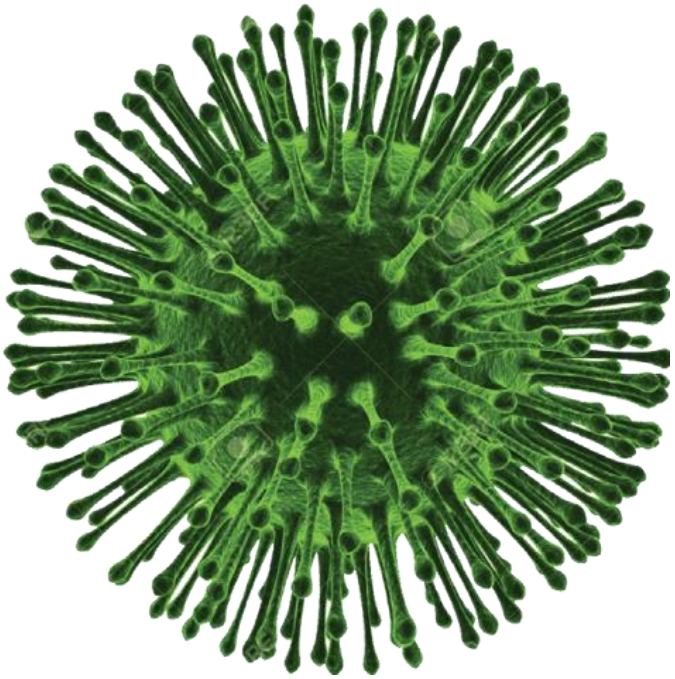


COVID-19 Integrated Influenza Surveillance Guideline

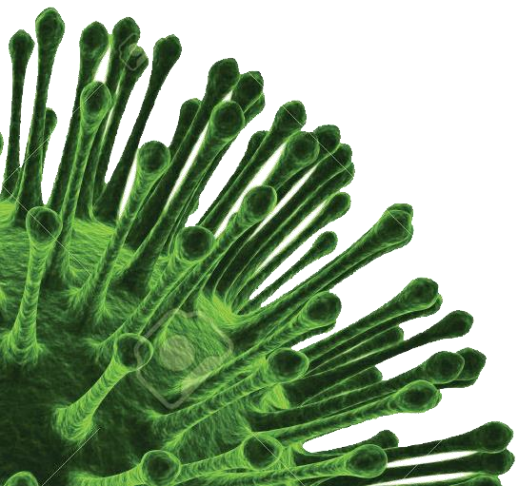
First Edition 2020

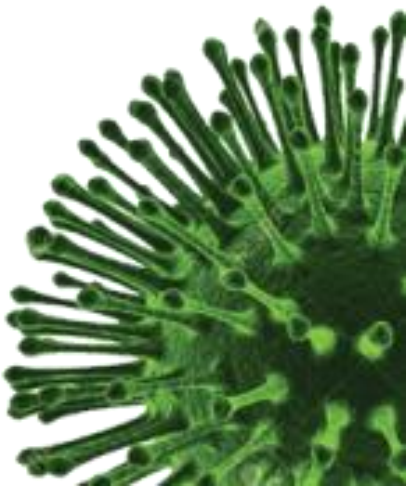
Royal Centre for Disease Control

Department of Public Health

Ministry of Health

Bhutan





COVID-19 Integrated Influenza Surveillance Guideline

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Preface

The COVID-19 pandemic caused by SARS-CoV-2 has demonstrated a need for Bhutan to have a comprehensive national pandemic preparedness and response plan, which can easily be adapted to respond efficiently and effectively any pandemic diseases.

Surveillance is one of the key components of the COVID-19 national pandemic preparedness and response plan and because COVID-19 transmission and manifestation of the disease is similar to influenza, the existing influenza sentinel surveillance system can easily accommodate and integrate a surveillance to monitor and detect COVID-19 transmission and outbreak in the community.

Therefore, there is an urgent need to expand the existing influenza sentinel surveillance system to integrate a national COVID-19 surveillance system. The overall operation of a national COVID-19 with influenza integrated surveillance system remains the same as that of the existing influenza sentinel surveillance system except all hospitals becomes sites for COVID-19 and influenza surveillance case enrollment and sample collection while all primary health care centers become case reporting sites.

The Global Influenza Surveillance and Response System (GISRS) of the World Health Organization (WHO) also recommend adopting the existing influenza surveillance system for COVID-19 surveillance. By and large, the guideline intends to provide guidance to the concerned health care workers involved in the COVID-19 and influenza surveillance on the operational aspects that is adopted from the existing influenza sentinel surveillance system platform.

Background

Coronavirus disease 2019 (COVID-19) is an infectious disease caused by Severe Acute Respiratory Syndrome Coronavirus-2 (SARS-CoV-2). The disease was first identified in December 2019 in Wuhan, the capital of China's Hubei province, and has since spread globally, resulting in the ongoing 2019–2020 coronavirus pandemic.

Common symptoms include fever, cough, and shortness of breath. Other symptoms may include fatigue, muscle pain, diarrhea, sore throat, loss of smell, and abdominal pain. The incubation period is typically around five days but may range from two to fourteen days. While the majority of cases result in mild symptoms, some progress to viral pneumonia and multi-organ failure.

As of 8th May 2020, more than 3.75 million cases have been reported across 212 countries and territories, resulting in more than 259,474 deaths. This exponential increase in cases has been observed around the world despite many countries having adopted unprecedented measures to curb the spread of the virus, such as large-scale use of isolation and quarantine, closing borders, imposing limits on public gatherings, and implementing nationwide lockdown.

In Bhutan, due to timely stringent public health and social measures undertaken such as limitation on international travel, closing borders, closures of schools, public gathering, social distancing, hand hygiene, cough etiquette, mandatory facility quarantine and isolation well ahead of the COVID-19 epidemic, the country has detected only seven cases which are all imported. As of 8th May 2020, Bhutan has tested around 11,568 samples (2427 samples by RT-PCR and 9,141 samples by rapid antibody test). As a result of aggressive implementation of public health interventions and testing, there is no evidence of community transmission till date.

In order to sustain the current situation/status of COVID-19, the Royal Centre of Disease Control (RCDC) is expanding the existing influenza sentinel surveillance to accommodate and integrate a national COVID-19 surveillance system. The surveillance system primarily aims to early detect COVID-19 cases in order to implement rapid containment measures and understand the trend, burden and epidemiology of SARS-CoV-2 to guide preparedness and response measures. Since influenza surveillance is also a part of COVID-19 surveillance system, the system is also aimed to monitor trend, understand burden and epidemiology of influenza virus and other priority respiratory pathogens.

Acronyms

ILI	Influenza-like illness
SARI	Severe Acute Respiratory Infections
ARI	Acute Respiratory Infections
RCDC	Royal Centre for Disease Control
MoH	Ministry of Health
US CDC	United State, Centers for Disease Control and Prevention
AFRIMS	Armed Force Research Institute of Medical Science
H1N1	Hemagglutinin 1, Neuraminidase 1
WHO	World Health Organization
HPAI	Highly Pathogenic Avian Influenza
CIF	Case Investigation Form
GDMO	General Duty Medical Officer
ACO	Assistant Clinical Officer
HA	Health Assistant
ADENO	Adenovirus
HMPV	Human Metapneumovirus
HPIV	Human Parainfluenza virus
RSV	Respiratory syncytial virus
NAIL	National Influenza Laboratory
RDT	Rapid Diagnostic Test
UTM	Universal Transport Media
VTM	Viral Transport Media
NEWARSIS	National early warning and response surveillance information system
M&E	Monitoring and Evaluation
WHO-CC	WHO Collaborating Centre
NADSAE	National Disease Surveillance and Epidemiology

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The RCDC would like to extend heartfelt gratitude to Hon'ble Sowai Lyonpo (Minister) Dechen Wangmo for providing technical insight in developing this COVID-19 integrated influenza surveillance guideline.

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Purpose of the Document

This document provides an overview of COVID-19 integrated influenza surveillance and reinforces the existing sentinel influenza surveillance. Further, it also describes standards and a framework adopted from the WHO guidelines for a minimal basic surveillance system for the monitoring circulation of SARS-CoV-2 and influenza virus in the Bhutanese Population. Use of standards facilitates understanding the epidemiology, transmission, and impact of COVID-19 and influenza in the country in comparison with other countries.

The surveillance system is a hospital-based one and is designed primarily for efficient data collection, laboratory samples collection and transportation for testing at designated COVID-19 testing laboratory. The surveillance system is also designed to collect ILI and SARI aggregated epi-data from primary health centers across the country. The data generated and analyzed from the surveillance system is aimed to help making well-informed policy decisions, and implementation of timely prevention and containment measures.

Target Audience

This document is intended to guide medical and health professionals involved in COVID-19 integrated influenza surveillance.

Objectives of Surveillance

1. Early detection of COVID-19 cases in the community,
2. Monitor trends of the COVID-19,
3. Provide epidemiological information to conduct risk assessment and to guide preparedness and response measures,
4. Monitor co-circulation of COVID-19 virus, influenza and other respiratory viruses, and to understand the seasonality of influenza activity,
5. Monitor circulating seasonal influenza viruses' subtypes and detect novel viruses,
6. Monitor outbreaks of influenza during and outside the influenza season,
7. Identify and monitor groups at high risk of severe disease and mortality for both COVID-19 and influenza.

Roles and Responsibilities of Hospitals, COVID-19 Testing Laboratory and RCDC

All hospitals must have a team identified comprising of clinicians (GDMO, CO, ACO, HA), laboratory technicians or technologist, nurses and the surveillance focal person (SFP). Each of these members of the team should be assigned a specific role and responsibility as follows:

COVID-19 and Influenza-Like Illness Surveillance Clinicians

The Clinicians should:

1. Identify the patients meeting the suspect COVID-19, ILI and SARI as per the case definition prescribed in the guideline.
2. Daily record suspect COVID-19, ILI and SARI cases at their respective hospitals. If no cases, ensure 'zero reporting' is done (Inform SFP) to verify the surveillance is continuously functioning.
3. Properly fill up clinical and epidemiological part of Case Investigation Form (CIF) for (Annexure 1).
4. Send the patient to the laboratory for collection of respiratory specimens along with CIF.
5. Provide the case data collected to SFP for daily compilation and reporting.

Surveillance Focal Person for COVID-19 and ILI Surveillance

A hospital management should identify a surveillance focal person for OPD. The SFP should:

1. Serve as a point of contact for COVID-19 and ILI surveillance at respective hospital
2. Collect and collate total number of suspect COVID-19 and ILI cases identified by clinicians from Flu clinic/Respiratory Disease Centre/OPD chambers and also count the total number of OPD cases seen every day in the form (Annexure 2).
3. Report all suspect COVID-19 and ILI to the RCDC on a daily basis through a web based or SMS system (Refer Annexure for reporting in the system). If no cases, ensure 'zero reporting' is done to verify the surveillance is continuously functioning.
4. Disseminate the results and feedback received from COVID-19 Testing Laboratory and the RCDC to the relevant health personnel (Clinicians, laboratory personnel, nurses.)
5. Provide feedbacks from hospitals to COVID-19 Testing Labs and the RCDC
6. Coordinate and convene a coordination meeting on a regular basis (at least twice a year).
7. Coordinate and conduct in-house sensitization training on COVID-19 integrated influenza

surveillance.

Surveillance Focal Person for SARI Surveillance

A hospital management should identify a surveillance focal person for OPD. The SFP should:

1. Properly fill up CIF (Annexure 1).
2. Collect respiratory specimens appropriately using PPE (Annexure 4 & 5) set from SARI cases
3. Ensure all respiratory specimens and corresponding CIF are assigned with a unique ID number.
4. Enter CIF data into COVID-19 integrated influenza surveillance systems.
5. Liaise with the laboratory for pick-up of specimens from wards, storage and shipment to designated COVID-19 testing laboratory.
6. Collect and collate total number of SARI cases from IPD (hospital wards) and also count the total number of admission cases every day in the form (Annexure 3). If no cases, ensure 'zero reporting' is done to verify the surveillance is continuously functioning.
7. Report all SARI cases daily through a web based or SMS system (Refer Annexure for reporting in the system).
8. Ensure adequate VTM/ UTM stock in the wards.

Medical Laboratory Personnel

Medical Laboratory Personnel should;

1. Ensure all suspect COVID-19/ILI sample collection forms are filled out completely and accurately.
2. Ensure all respiratory specimens corresponding forms are assigned with a unique ID number.
3. Collect respiratory specimens appropriately using PPE (Annexure 4 & 5) set from suspect COVID-19/ ILI cases
4. Enter CIF data into COVID-19 integrated influenza surveillance system.
5. Properly label, pack, store, and transport specimens to respective designated COVID-19 testing laboratories (Annexure 7, 8 & 9).
6. Store the specimens in 2-8°C refrigerators not more than three days after sample collection (Annexure 6). If delayed, store in -20 to -40°C (Note: Storage in the freezer compartment of the refrigerator may not provide the desired temperature).
7. Ship samples along with CIF to respective designated COVID-19 Testing Laboratory.
8. Ensure adequate stock of VTM/ UTM, and relevant forms in the laboratory.

COVID-19 Testing Laboratory (Mongar & Phuntsholing)

Serve as regional testing laboratory for SARS-CoV-2 and influenza virus.

1. Receive and verify suspect COVID-19/ILI and SARI samples.
2. Verify CIF data in the COVID-19 integrated influenza surveillance system.
3. Perform molecular detection of SARS-CoV-2 by RT-PCR as per the protocol.
4. A positive COVID-19 case MUST be reported within 24 hours to the RCDC.
5. Perform molecular detection and characterization of Influenza viruses by RT-PCR.
6. Upload results in the web-based data management system.
7. Storing and archiving the original specimens at -40°C.
8. Ship samples to the RCDC weekly using existing shipment mechanism.

Virology and Molecular Laboratory, RCDC

Serve as national testing laboratory for SARS-CoV-2 and influenza virus.

1. Receive and verify suspect COVID-19/ILI and SARI samples.
2. Verify data in the COVID-19 integrated influenza surveillance system.
3. Perform molecular detection of SARS-CoV-2 by RT-PCR as per the protocol.
4. Verify the positive COVID-19 case detected in other two COVID-19 testing centres.
5. Perform molecular detection and characterization of Influenza viruses by RT-PCR.
6. Perform molecular detection and characterization of other non-influenza respiratory viruses by RT-PCR for SARI samples.
7. Perform culture and isolation of influenza viruses.
8. Upload results in the web-based data management system.
9. Storing and archiving the original specimens at -80°C for ten years.
10. Immediate sharing of information on any unsubtypeable or suspect novel influenza viruses to WHO Collaborating Center (WCC).
11. Referral of any unsub-typeable specimen, representative specimens, and culture specimens to a designated WCC.
12. Participating in the international external quality assessment scheme (WHO, RCPA, CDC and AFRIMS External Quality Assessment program for the molecular detection and characterization of SARS-CoV-2 and influenza viruses).
13. Provide training on COVID-19 integrated influenza surveillance guideline.
14. Monitor quality of data and specimens received.

National Disease Surveillance and Epidemiology (NADSAE) Unit, RCDC

1. Manage computer database of COVID-19 integrated influenza surveillance data.
2. Prepare and disseminate the weekly, quarterly and annual surveillance reports to all stakeholders.
3. Reporting to IHR focal point of any influenza novel strains and COVID-19 cases as per the IHR requirements.
4. Provide training on surveillance guideline.
5. Review and update COVID-19 integrated influenza surveillance guideline as needed.

Information Communication and Technology Unit, RCDC

1. Technical review of web-based COVID-19 integrated influenza surveillance system.
2. Monitor and maintain web-based COVID-19 integrated influenza surveillance system.
3. Support NADSAE for data management and analysis.
4. Provide training on surveillance guideline.

COVID-19 Integrated Influenza Surveillance System

In this surveillance system (**Figure 1**), all health centers including community will be involved in COVID-19 integrated influenza surveillance, however, primary health centers (PHC) will not collect samples.

To detect early case of COVID-19 in the village/community, PHC should sensitize all Village Health Workers (VHW) working in their respective village or community under their catchment area to report any cluster of respiratory illness (ILI and SARI) cases to PHC. Whenever respiratory illness cases are reported by VHW, PHC should verify and investigate if necessary and report cases in the system.

PHC should record daily ILI cases in their OPD registry and report cases as per the age group (**Annexure 2**) and report to RCDC website COVID-19 integrated Influenza surveillance system either through web-based or mobile SMS reporting platform. Any SARI and COVID-19 suspect cases should be referred to nearest hospital for sample collection.

Hospitals should record daily COVID-19, ILI and SARI cases in their OPD/Flu Clinic/Respiratory Disease Centre/IPD registry and report collated cases as per the age group (**Annexure 2 & 3**) by SFP and report into the COVID-19 integrated influenza surveillance system available in the RCDC

website through web-based or mobile SMS reporting platform.

Hospitals should mandatory fill up CIF and collect appropriate samples from COVID-19 suspect and SARI cases. The sample should be referred to designated COVID-19 Testing Laboratory within 24 hours for SARS-CoV-2 testing and influenza virus.

Hospitals should randomly enroll only five ILI cases for sample collection and fill up CIF (**Annexure 1**). ILI samples should be shipped weekly to designated COVID-19 Testing Laboratory for SARS-CoV-2 and influenza virus.

Hospitals should enter the CIF data for COVID-19, SARI and ILI cases enrolled for samples collection into the COVID-19 integrated influenza surveillance system available in the RCDC website through web-based or mobile SMS reporting platform.

The COVID-19 Testing Laboratories (Mongar and Phuntsholing) should ship all samples to the RCDC weekly for testing of priority respiratory pathogens.

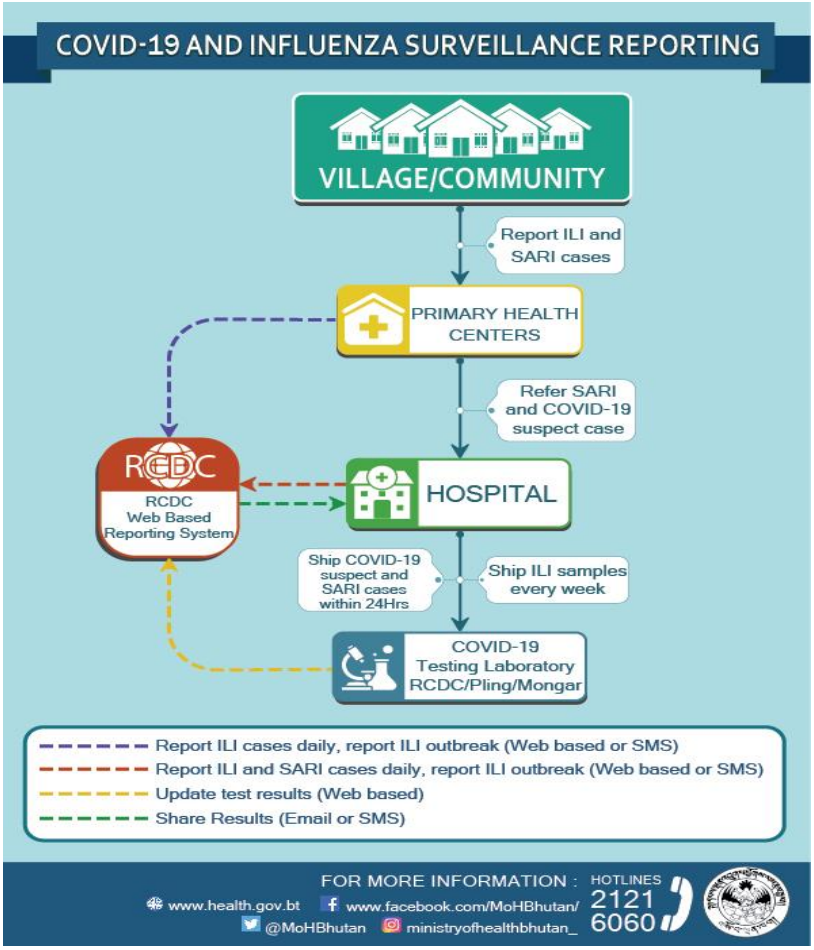

Figure 1: Flow chart for COVID-19 and Influenza Surveillance System

Testing Sites	Dzongkhag	Sl. No	Hospital/BHU-I	Code #
Central & Western region (RCDC)	Bumthang	1	Bumthang Hospital	COVID-BUM-XX
	Paro	2	Paro Hospital	COVID-BTC-XX
	Gasa	3	Gasa Hospital	COVID-GAS-XX
	Haa	4	Haa Hospital	COVID-HAA-XX
	Punakha	5	Punakha Hospital	COVID-BTD-XX
	Thimphu	6	JDWNRH	COVID-BTB-XX
		7	Gidakom Hospital	COVID-GKM-XX
		8	Dechencholing Hosp	COVID-DHN-XX
		9	Lungtenphu Hospital	COVID-LTN-XX
	Trongsa	10	Trongsa Hospital	COVID-BTE-XX
	Tsirang	11	Damphu Hospital	COVID-BTI-XX
	Wangdue	12	Bajo Hospital	COVID-BAJ-XX
		13	Eusa Hospital	COVID-EUS-XX
	Zhemgang	14	Panbang Hospital	COVID-PAN-XX
		15	Yebilaptsa Hospital	COVID-YEB-XX
		16	Zhemgang Hospital	COVID-ZHE-XX
	Sarpang	17	CRRH	COVID-BTG-XX
		18	Sarpang Hospital	COVID-SAR-XX
		19	Chuzergang	COVID-CZG-XX
	Chukha	20	Tsimalakha Hospital	COVID-TSI-XX
		21	Khatoekha Hospital	COVID-KHA-XX
		22	Chukha Hospital	COVID-CHU-XX
	Dagana	23	Dagapela Hospital	COVID-DAGP-XX
		24	Dagana Hospital	COVID-DAG-XX
Southern Region (Phuntsholing hospital)	Dagana	25	Lhamozingkha Hospital	COVID-LMZ-XX
	Chukha	26	Phuntsholing Hospital	COVID-BTF-XX
		27	Gedu Hospital	COVID-GED-XX
	Samtse	28	Sipso Hospital	COVID-SIB-XX
		29	Gomtu Hospital	COVID-GOM-XX
		30	Samtse Hospital	COVID-BTK-XX
		31	Tendu Hospital	COVID-TEN-XX
		32	Dorokha Hospital	COVID-DOR-XX
Eastern Region (Mongar Regional Referral hospital)	Lhuntse	33	Lhuntse Hospital	COVID-LHU-XX
	Mongar	34	ERRH	COVID-BTA-XX
		35	Gyalposhing Hospital	COVID-GPN-XX
	Pemagatsel	36	Pemagatsel Hospital	COVID-PGL-XX
		37	Ngaglam Hospital	COVID-NGA-XX

	Samdrup Jongkhar	38	Samdrupjongkhar Hospital	COVID-BTJ-XX
		39	Jomotshangkha Hospital	COVID-JOM-XX
		40	Samdrupcholing Hospital	COVID-SAM-XX
		41	Deothang Hospital	COVID-DEO-XX
	Tashigang	42	T/gang Hospital	COVID-BTH-XX
		43	Riserbo Hospital	COVID-RIS-XX
		44	Kanglung Hospital	COVID-KAN-XX
		45	Bartsham Hospital	COVID-BAR-XX
		46	Ranjung Hospital	COVID-RAN-XX
		47	Khaling Hospital	COVID-KHL-XX
	Trashiyangtse	49	Trashiyangtse Hospital	COVID-TYG-XX
		50	Khamdang Hospital	COVID-KMG-XX

Table 1 : List of hospitals with code numbers

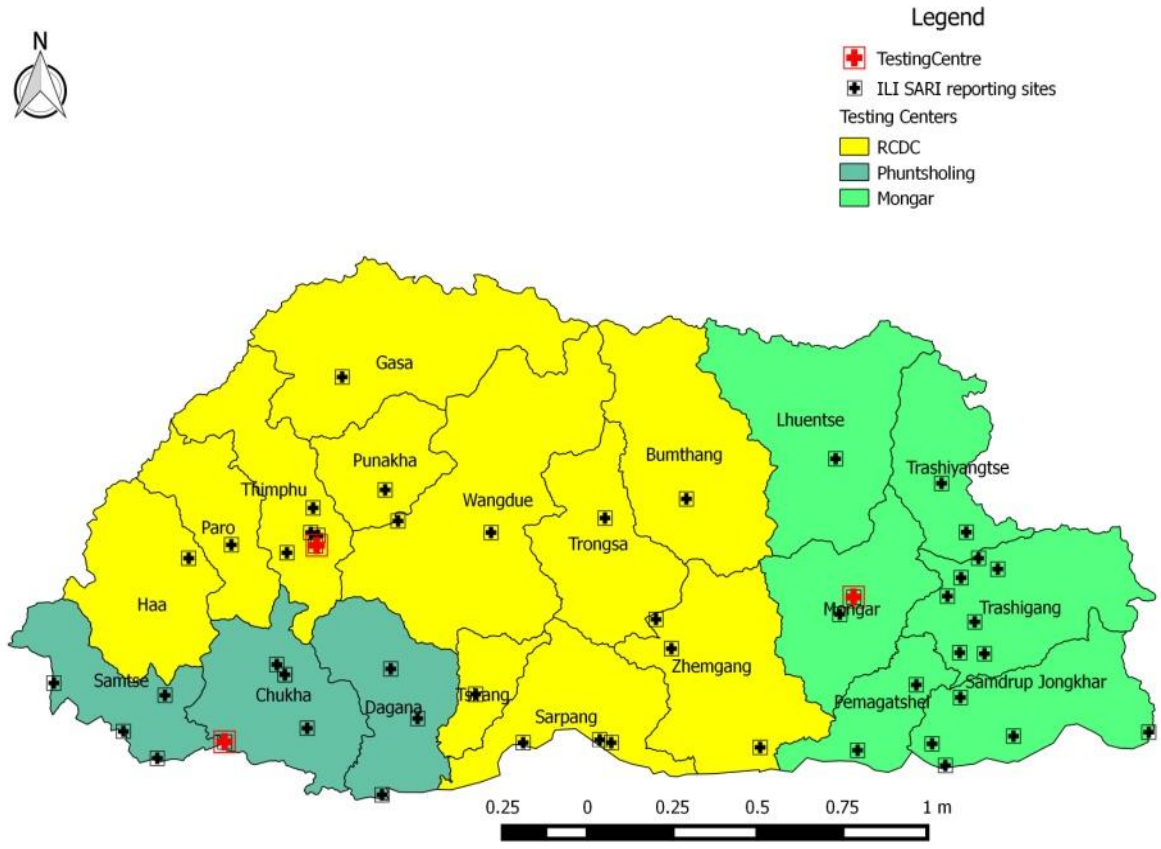

Figure 2 : Distribution of hospitals and their identified COVID-19 testing laboratories

Case Definition of COVID-19, Influenza-Like Illness (ILI), and Severe Acute Respiratory Infection (SARI)

COVID-19 Suspect:

1. Any individual with fever ≥ 38 ºC **OR** signs/symptoms of a lower respiratory illness (cough or shortness of breath) **OR** loss of smell/taste **OR** gastrointestinal symptoms (diarrhea or vomiting) **AND** history of travel to affected places within last 21 days of onset of symptoms.
2. Any individual including health workers with fever ≥ 38 ºC **OR** signs/symptoms of a lower respiratory illness (cough or shortness of breath) **OR** loss of smell/taste **OR** gastrointestinal symptoms (diarrhea or vomiting) **AND** having been in contact (*see definition of contact*) with a confirmed case within last 21 days of onset of symptoms.

Contact: *A contact is a person who experienced any one of the following exposures during the 2 days before and the 14 days after the onset of symptoms of a probable or confirmed case:*

1. *Face-to-face contact with a probable or confirmed case within 1 meter and for more than 15 minutes;*
2. *Direct physical contact with a probable or confirmed case;*
3. *Direct care for a patient with probable or confirmed COVID-19 disease without using proper personal protective equipment; OR*
4. *Other situations as indicated by local risk assessments.*

COVID-19/Severe Acute Respiratory Infection (SARI)

Any individual with fever ≥ 38 ºC **OR** signs/symptoms of a lower respiratory illness (cough or shortness of breath) **AND** requiring hospitalization AND with no other etiology that fully explains the clinical presentation.

Influenza-Like Illness (ILI)

Any individual with fever ≥ 38 ºC **AND** signs/symptoms of a lower respiratory illness (cough or shortness of breath)

*(**Note**: Consider sample collection from ILI patients only if onset of fever is within 5 days)*

Case Enrollment and Sampling Strategy

COVID-19 suspect and SARI case: All COVID-19 suspect cases as per the case definition should be enrolled and sample should be collected mandatory from all cases. Case investigation form (**Annexure 1**) should be filled up mandatory and all information should be filled completely.

ILI case: Each hospital should at least enroll 5 ILI cases every week (i.e. 20 per month/site) for specimen collection. The cases for specimen collection should be equally distributed between different age groups (***one case each for age group: <5 years, 5-14 years, 15-29 years, two cases among age group 30-64 years***) at different days of the week (***cases should represent for entire time of week***). However, mandatory sample should be collected from pre-existing medical condition of all age group and elderly above 65 years. CIF (**Annexure 1**) should be filled up mandatorily and all information should be filled completely for selected ILI enrolled cases.

Specimen Collection, Storage, Packaging and Shipment at Hospitals

1. A patient meeting the criteria for case enrolment should be requested to provide clinical information, nasopharyngeal or nasal and throat swab.
2. Provide labeling to sample and CIF with hospital lab ID number
3. Collect throat swabs in VTM/ UTM
4. Standard Operating Procedures should be followed to collect nasopharyngeal, nasal and throat swab (**Annexure 5**).
5. All collected specimens should be properly sealed and stored in 2-8°C not more than 72 hours after collection. If delay in shipment more than 72 hours is expected, store samples at -20 to -40°C until transportation (**Annexure 6**).
6. Samples should be packed as per the SOP (**Annexure 9**).

Specimen processing at COVID-19 Testing Laboratory (RCDC, Mongar and Phuntsholing)

Specimen Receipt: Upon receipt of specimen from hospital, COVID-19 testing lab should:

1. Verify the specimen and CIF ID labeled by hospital.
2. Check the quality of specimen; leakage and contamination.
3. Check temperature conditions of the specimen and also check shipment cold chain log for appropriate temperature during shipment (Annexure 8).

4. Aliquot specimen for laboratory testing, and repository.

Sample Rejection Criteria:

1. Sample leakage
2. Miss-match between sample ID and CIF
3. Sample contamination
4. Sample without corresponding form
5. Form without sample

Specimen Testing: Designated COVID-19 testing laboratories will perform SARS-CoV-2 and influenza virus testing:

1. RT-PCR testing for SARS-CoV-2 according to test kit protocol developed by the concerned manufacturer.
2. RT-PCR testing for influenza virus type and subtype in accordance with the RCDC's SOPs.

Storage and Shipment: The specimen aliquoted for repository should be stored in refrigerator/freezer maximum for a week and ship to the RCDC.

Data Collection and Reporting

Case-Based Data Collection

All hospitals should provide complete information of patients (suspect COVID-19/ILI/SARI) as required by the CIF (**Annexure 1**). The clinicians/nurse should fill up clinical and epidemiology part of CIF and laboratory part by laboratory personnel. The original CIF should be sent to COVID-19 testing laboratory along with the specimen. The copy of the forms should be retained at the hospital for future reference.

Epi-Aggregate Data Collection

All health centers should collect the information of total number of (suspect COVID-19/ILI) visiting the Outpatient Department (OPD)/Flu Clinic/Respiratory Disease Centre in case aggregate reporting form (**Annexure 2**). The denominator for COVID-19/ILI should be a total number of OPD and Flu Clinic/Respiratory Disease Centre.

Similarly, total number of SARI admitted should be collected in case aggregate reporting form

(**Annexure 3**). The denominator for SARI should be a total number of admitted patients (IPD) in the reporting week.

Web based and SMS Reporting

Refer COVID-19 and Influenza Surveillance System User Guide

Data management, Analysis and Feedback

Data Management and Disposition

All data will be maintained in the RCDC centralized web-based data management system. NADSAE will manage database system with support from ICT unit.

Analysis

Data obtained should be analyzed by NADSAE on weekly, quarterly and annual basis.

Weekly Report: Following parameters should be analyzed:

1. Trend in both COVID-19/ILI and SARI activity, compared with last weeks, previous seasons, and baseline,
2. Positivity rate of COVID-19/ILI and SARI specimen,
3. Geographical spread,
4. Type and subtype of influenza viruses
5. Affected age groups and deaths due to COVID-19 and influenza

Annual Report: Following parameters should be analyzed:

1. Description of seasonality
2. Types and subtypes of circulating influenza viruses during the season.
3. Comparison of data from the most recent influenza season to previous seasons.
4. Notable or unusual features of the season when compared to previous seasons should be highlighted.
5. Proportion of specimen testing positive by week or month of the year.
6. Description of laboratory confirmed COVID-19, SARI and ILI cases within each month or week of the year for each age group, by site and aggregate.
7. The proportions of influenza positive cases with underlying medical conditions.

Feedback

1. **Weekly Report**

   NADSAE will prepare a weekly report "FluView" and share with relevant stakeholders (Ministry of Health, WHO, CDC, etc).

2. **Quarterly Report**

   NADSAE will also prepare quarterly report and share with relevant stakeholders (Ministry of Health, WHO, CDC, etc).

3. **Annual Report**

   NADSAE will prepare the Annual Report and share with relevant stakeholders (Ministry of Health, WHO, CDC, etc).

Monitoring and Evaluation (M&E)

A surveillance system should undergo regular evaluation to assess whether it is functioning efficiently and providing quality data to meet its objectives. Additionally, regular onsite assessments should be conducted to find out gaps need in terms of training and logistic support (**Annexure 11**).

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 continue at the national levels. Monitoring should be carried out to check the compliance of the indicators shown in the Table 2.

Table 2 : Indicators for M&E

Indicators	Frequency	Source	NAIL	NADSAE	Sites
Timeliness	Monthly	Routine	Yes	Yes	Yes
Completeness	Monthly	Routine	Yes	Yes	Yes
Consistency	Monthly	Routine	Yes	Yes	Yes
Number of Specimens Collected	Weekly	Routine	Yes	No	Yes

1. **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).

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 RCDC for testing.	Sentinel Sites
3	Time elapsed from receipt of specimens at RCDC 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 and Sentinel Sites
6	Time elapsed from receipt of data from sites and NAIL to providing feedback by NADSAE.	NADSAE

2. Completeness

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 4.

Table 4 : 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 Sites and NADSAE
4	Percentage laboratory results generated being entered into database	NAIL

3. Consistency

Should the RCDC 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 (Table 5).

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

i. Unexpected or sudden increase or decrease in number of ILI/SARI cases
ii. Unexpected or sudden increase or decrease in number of SARI deaths reported
iii. Unexpected or sudden change in the percentage of specimens testing positive for influenza.

iv. Unexpected or sudden shift in the type or subtype of virus detected

v. Changes in the distribution of risk factors reported.

Table 5 : Indicators for Consistency

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

4. Number of Specimens Collected

Number of specimens collected in each site can be used to monitor surveillance (Table 6).

Table 6 : Indicators for Number of Specimens Collected

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

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Annexure 1: Case Investigation and Specimen Collection Form for COVID/ILI/SARI

Case Investigation and Specimen Collection Form for COVID-19/ILI and SARI
(Version-4)

Case type please tick: ☐ **Suspect COVID-19** ☐ **ILI** ☐ **SARI**

Patient Information

Name of Health Centre:			
Patient Name:		Age:	Sex:
Contact Number:		CID #	
Present Address:		Nationality:	
Occupation:		Country of Residence (those residing abroad)	

Clinical Information

Fever or History of fever:	☐ Yes	☐ No	If Yes, Temperature:		
Cough:	☐ Yes	☐ No	Shortness of Breath:	☐ Yes	☐ No
Sore throat:	☐ Yes	☐ No	Diarrhea	☐ Yes	☐ No
Headache	☐ Yes	☐ No	Nausea/Vomiting	☐ Yes	☐ No
Loss of Smell/taste	☐ Yes	☐ No	Abdominal pain/blotting	☐ Yes	☐ No
Musculoskeletal pain	☐ Yes	☐ No	Fatigue	☐ Yes	☐ No
Chills	☐ Yes	☐ No	Others (Specify):		

Co morbid conditions (Check all that apply)

☐ None ☐ Diabetes ☐ Cardiac Disease ☐ Hypertension ☐ Cancer (any type)

☐ Pulmonary Disease ☐ Kidney Disease ☐ Liver Disease
☐ Immuno-compromised ☐ Pregnancy ☐ Others specify

Hospitalization: ☐ Yes ☐ No Date of Admission:

Outcome: ☐ Recovered ☐ Referred ☐ Death

Epidemiological Information

Date of notification:: _____ Date of onset: _____

Have you travelled within 21 days before the onset of symptoms: ☐ Yes ☐ No

If yes, place visited and country (in/ex country)

Travel dates: From _____ To _____

Have you worked in high risk area/health centers in last 21 days? ☐ Yes ☐ No if yes nature of work

Any contact with visitor visiting in last 21 days from affected place (in/ex country) ☐ Yes ☐ No
If yes, date of visit and name of place

In past 21 days have you had contact with a person with confirmed COVID-19case
☐ Yes ☐ No (If Yes, date: (/ /)

Advised by : Dr's name and Contact #

Laboratory information

Laboratory Specimen Collected: ☐ Yes ☐ No Sample ID

Type of specimen : ☐ Nasal swab ☐ throat swab ☐ Blood ☐ Sputum Specify if other: _____

☐ 1st Sample ☐ 2nd Sample ☐ 3rd Sample ☐ Specify if other: ___

Collection Site: ☐ Flu clinic ☐ OPD ☐ IPD ☐ Quarantine site

Sample Collected by:Name: _____ **Contact #:**

Annexure 2: COVID-19 and ILI Aggregate Surveillance Data Form

COVID-19 and ILI Surveillance Aggregated Data						
Hospital Name						
Date						
Aggregated number of Cases	Age Group in Years					
	0-1	2-4	5-14	15-29	30-64	65+
Number of ILI cases during the day						
Number of suspected COVID-19 cases during the day						
Total OPD cases during the day						

Reported By_____Signature _____

Mobile # _____Date _____

Annexure 3: SARI Aggregate Surveillance Data Form

SARI Surveillance Aggregated Data						
Hospital Name						
Date						
Aggregated number of cases	Age Group in Years					
	0-1	2-4	5-14	15-29	30-64	65+
Number of SARI cases during the day						
Number of SARI related death during the day						
Total IPD cases during the day						

Reported By_____ Signature _____

Mobile # _____Date _____

Annexure 4: Personal Protective Equipment (PPE)

PPE consists of following items

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/remove 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 for Donning:

1. Before you begin putting on your PPE, check for the correct size of PPE and ensure they are in good working condition.
2. Wash your hands with soap and water before you begin, and remove watches and other non-smooth jewelry like bracelets.
3. Remove inner garments and wear surgical scrub
4. Put on boots if not available, put on shoe cover.
5. Perform hand hygiene
6. Put on inner glove
7. Put on cover all/apron (Make sure it is large and allow free movement). Ensure the cuffs of inner gloves are tucked under sleeves of the cover all.
8. Put on N95 respirator (cup the respirator in your hand with the nosepiece at the fingers). Position 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.
9. Using two hands mold the nosepiece to the shape of your nose by pushing inward while

moving your fingertips down both sides of the nosepiece.

10. Perform seal check (Inhale deeply and feel the respirator slightly being sucked in. Also, exhale sharply and feel the respirator slightly bulge).
11. Put on outer gloves. Pull the edge of the gloves over the cuff of your apron.
12. Put on hair cover
13. Put on goggles

Note: *The health worker should be able to extend his/ her arms, bend at the waist, and do range of motions.*

Procedure for Doffing:

1. Inspect your PPE for any visible contamination or tears
2. Disinfect outer gloves
3. Remove boot covers (touch only the inner surface of the boot cover)
4. Remove outer gloves (Take care not to contaminate the inner gloves)
5. Inspect and disinfect inner gloves (In case your inner gloves are contaminated or torn, disinfect, remove and wear a new pair of gloves
6. Remove goggles/face shield by lifting back of strap over your head, pull out away (Avoid touching the front portion of goggles/face shield).
7. Disinfect the inner gloves
8. Remove coverall/gown (untie the knot first at the back) inside out by pulling the sleeve.
9. Discard the gown in the biohazard bag
10. Disinfect inner gloves and remove it
11. Perform hand hygiene
12. Put on new pair of gloves
13. Remove your N95 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.
14. Disinfect your gloves
15. Remove hair cover
16. Disinfect your gloves
17. Disinfect your washable boots
18. Disinfect and remove gloves
19. Perform hand hygiene
20. 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.
21. Wash your hands and forearms with soap and water.

Annexure 5: Sample Collection

A. Throat Swab

1. Label VTM/ UTM tube with Lab ID number.
2. Ask patient (adults) to sit comfortably on chair or lay down the patient (infants/ young children) in a supine position on bed with extended positioning of the patient's arms above the head (Note: throat swab from infants/ young children should be collected by Pediatrician or trained personnel only)
3. Hold the tongue with a tongue depressor.
4. Use a sweeping motion to swab the posterior pharyngeal wall and tonsilar pillars (Figure 1). Have the subject say "aahh" to elevate the uvula. Avoid swabbing the soft palate and do not touch the tongue with the swab tip. Note: This procedure can induce the gag reflex.
5. Open and put the swab into VTM.
6. Immediately close the VTM tube and store in 2-4°C till the sample is processed or transported to RCDC. If delay in shipment for more than seven days is expected, then place the specimen in preferably in -80°C. (If -80°C deep freezer is not available, -40°C deep freezer should be satisfactory).

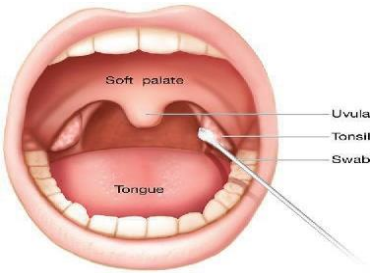

Figure 1: Position of tonsil (Source: www.webmd.com)

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 (Figure 2),
5. Gently rotate to collect nasal secretions from the anterior portions of the turbinate and septal mucosa.
6. Perform the rapid test as per the instructions prescribed in the package insert.

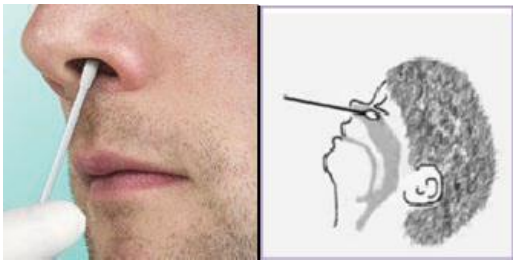

Figure 2 :Position of nasal mucosa (Source: www.webmd.com)

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 (Figure 3). 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 RCDC.

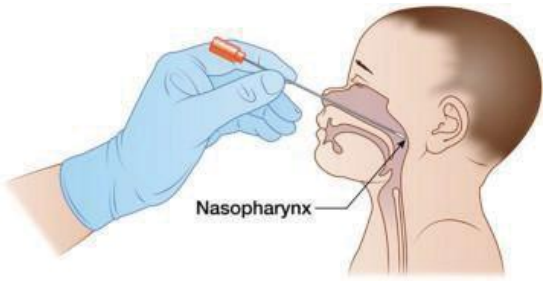

Figure 3 : Position of nasopharynx (Source: www.quidel.com)

Annexure 6: Sample Storage

A. Sample Storage Procedure (Hospitals)

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 contains.
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 RCDC.
7. Ship the specimens to RCDC within 48 hours of collection. Schedule for shipment is given at **Annexure-10**.

B. Sample Storage Procedure (RCDC)

1. Wear an apron, gloves and other protective barriers Aliquot specimen (140µl of the specimen for PCR and 420 µl 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 contains.
5. Store the specimens in -70°C.

Annexure 7: Sample Packaging and Transportation

A. Sample Packaging and Transportation (Sentinel Sites to RCDC)

1. Prepare the line list of specimens to be shipped in accordance with **Annexure-5**.
2. Arrange documents for specimen accordingly. Documents to be sent are as follows:
    - ✓ Specimen log form
    - ✓ Cold- chain maintenance form
    - ✓ Copy of CIF
3. Follow WHO Triple Packaging System (Figure 6): Use 3 packaging layers i.e.
    - ✓ Primary receptacle holds respiratory specimens i.e. VTM tube wrapped with parafilm
    - ✓ Secondary container durable, watertight, leak- proof, several primary receptacles can go into secondary container
    - ✓ An outer container should be rigid, durable and insulated e.g. Styrofoam box

Figure 4 : Triple Packaging System

Steps for Packing Specimens

1. Seal VTM tube with parafilm –this is primary receptacle and wrap with tissue paper to absorb the accidental leakage.
2. Place VTM in a watertight zip-lock bag.
3. Place up to 10 single VTM in a zip-log bag within another watertight container depending on size of the container (e.g. Sturdy plastic container with lid) – this is a secondary container.
4. Place absorbent, cushioned material between primary and secondary containers.
5. Put the secondary container in a “Wizard Box” or any other shipment box provided by the RCDC for shipment of influenza specimens.
6. Place ice/cold packs between secondary and outer containers.
7. Complete the Cold Chain Maintenance Table forms (Annexure 9)
8. Place all documents between the secondary and outer container in a plastic zip-lock bag or polythene bag to avoid from getting wet.
9. Mark and label the outer container properly, this should include:
10. Address of the shipper and the consignee.
11. Biohazard label Orientation label (Note: UN number is not necessary for in-country shipment.)
12. Send the specimens on ice or frozen ice packs to RCDC within 48 hours from the date of sample collection.
13. Ensure the packing box contains enough ice packs to keep the specimens for few days.

14. Transport the specimen to RCDC. Ship the specimen from the hospital to your nearest Bhutan Post on scheduled time provided to you by RCDC (**Annexure 10**)
15. Collect the empty box from the same Post Office every week for the next shipment.

B. Sample packaging and transportation (RCDC to Reference Laboratory)

1. Prepare the line list of specimens to be shipped in accordance with **Annexure 5**.
2. Arrange documents for specimen accordingly.
3. Documents to be sent are as follows;
4. Follow packaging steps to describe under Sample packaging and transportation (Sentinel sites to RCDC).
5. Place dry ice between the secondary and transport container to keep the sample at the required temperature during transportation.
6. Place specimen data forms, letters and other relevant documents in a waterproof bag (preferably sealed plastic bag) carefully tapped either to the outside of the secondary receptacle or inside of the transportation container.
7. The outer shipping or transportation container should be labeled 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. (Ensure that copies are made and retained at RCDC for all the forms that are being sent).
8. The following documents are required while shipping samples to reference laboratories outside the country:
    - ✓ Specimen log form
    - ✓ Cold- chain maintenance form
    - ✓ Copy of CIF
    - ✓ Airway bill
    - ✓ Shipment invoice

Annexure 8: Cold Chain Maintenance Form

SN	Specimen ID	Collection Date	Temperature History				Transferred		
			2-8°C Duration	-70°C freeze	LN	DI	WI	LN	DI

Note:

Specimens can be kept in a refrigerator (between 2- 8°C) 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:_____

Shipment Received at RCDC By:_____ Date:_____

Shipment Inventory :_____ Date:_____

Annexure 9: Specimen Log Form

Specimen Log Form			
SN	**Specimen ID**	**Comments**	**Log Date**

Annexure 10: Monitoring and Evaluation Form

Name of the Hospital:_____Date of Evaluation:_____

1. Timeliness

SN	Attributes	Target	Time Elapsed in Days
1	Time taken for weekly data form to reach RCDC	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 RCDC	Within 3-4 days of sample collection	
3	Time taken to process, test and generate results by RCDC	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 RCDC	Every Tuesday of next week	
6	Time taken to disseminate report to the sentinel sites by RCDC	Every Tuesday of next week	

2. Completeness

SN	Attributes	Target	Percent
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		

4. Specimen Collected

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

Annexure 11: Hand Washing Steps