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When to suspect

Any patient with acute respiratory illness with:

- 1. A history of travel to or residence in China in the 14 days prior to symptom onset, or
- 2. Close contact with a confirmed/ suspected case of 2019-nCoV in the 14 days prior to symptom onset, *or*
- 3. Healthcare worker taking care of confirmed/ suspected patients of 2019-nCoV

Case Definition of 2019-nCoV

Suspected case

Patients with acute respiratory infection (sudden onset of at least one of the following: cough, sore throat, shortness of breath) requiring hospitalisation or not

AND

In the 14 days prior to onset of symptoms, met at least one of the following epidemiological criteria:

• Were in close contact with a confirmed or probable case of 2019-nCoV infection;

OR

• Had a history of travel to areas of China with ongoing community transmission of 2019-nCoV;

OR

• Worked in or attended a health care facility where patients with 2019-nCoV infections were being treated.

Close contact

Close contact is defined as:

- Healthcare associated exposure, visiting patients or staying in the same close environment as a nCoV patient.
- Working together in close proximity or living in the same household with a nCoV patient.
- Travelling together with a nCoV patient in any kind of conveyance

The epidemiological link may have occurred within a 14-day period before or after the onset of illness in the case under consideration.

Probable case

A suspected case for whom testing for 2019- nCoV is inconclusive (the result of the test reported by the laboratory) or for whom testing was positive on a pan-coronavirus assay.

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Confirmed case

A person with laboratory confirmation of 2019-nCoV infection, irrespective of clinical signs and symptoms

Clinical Features

The clinical and radiological manifestations of 2019-nCoV include:

- Fever (83%)
- Cough (82%)
- Shortness of breath (31%)
- Sore throat (5%)
- Rhinorrhoea (4%)
- Diarrhea (2%)
- Bilateral pneumonia on imaging (75%)
- ARDS (10-17% of admitted patients)

Laboratory Diagnosis

Whom to test:

- a) For persons with travel history to the Wuhan province in China after 15th January 2020, respiratory samples (nasopharyngeal swab, oropharyngeal swab) and blood samples should be collected for all persons whether symptomatic or asymptomatic
- b) For travel history to rest of China, respiratory and blood samples will be collected only from symptomatic cases

As per directive from MoHFW, Government of India, all suspected cases are to be reported to District & State Surveillance Officers. Their team will arrange for sample collection and transport to the Department of Microbiology at AIIMS and subsequently communicate the reports (to contact helpline number - +91-11-23978046).

*All suspected cases to be mandatorily reported to the District & State Surveillance Officers

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Sample collection

General Guidelines

- Trained health care professionals to wear appropriate personal protective with latex free purple nitrile gloves while collecting the sample from the patient. Maintain proper infection control when collecting specimens.
- Restricted entry to visitors or attenders during sample collection.
- Specimens should be collected as soon as possible once a suspected case is identified regardless of time of symptom onset.
- It is recommended that testing of multiple clinical specimens from different sites, including two specimen types—lower respiratory and upper respiratory must be done.
- Transport immediately to Virology lab 8th floor, convergence block AIIMS, New Delhi <u>through</u> proper channel
- Label each specimen container with the patient's UHID number, name, ward, specimen type and the date the sample was collected. Complete the requisition form for each specimen submitted.
- Proper disposal of all waste generated

Specimen Type and Priority

For initial diagnostic testing for 2019-nCoV by Real Time - PCR, it is recommended to collect and test

• Upper respiratory (nasopharyngeal AND oropharyngeal swabs) and

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- Lower respiratory for patients with productive cough
- Induction of sputum is not indicated.

I. <u>Respiratory Specimen collection</u>

A. Lower respiratory tract

Bronchoalveolar lavage, tracheal aspirate

Collect 2-3 mL into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

Sputum

Rinse the patients mouth with water, expectorate deep cough sputum directly into a sterile, leak-proof, screw-cap sputum collection cup or sterile dry container.

B. Upper respiratory tract

Nasopharyngeal swab <u>AND</u> oropharyngeal swab (NP/OP swab)

Nasopharyngeal swab: Tilt patient's head back 70 degrees. Insert flexible swab through the nares parallel to the palate (not upwards) until resistance is encountered or the distance is equivalent to that from the ear to the nostril of the patient. Gently, rub and roll the swab. Leave the swab in place for several seconds to absorb secretions before removing

Oropharyngeal swab (e.g., throat swab): Tilt patient's head back 70 degrees. Rub swab over both tonsillar pillars and posterior oropharynx and avoid touching the tongue, teeth, and gums.

Use only synthetic fiber swabs with plastic shafts NP and OP specimens should be kept in separate vials.

Do not use calcium alginate swabs or swabs with wooden shafts. Place swabs immediately into sterile tubes containing 2-3 ml of viral transport media.

Combined Nasal & Throat Swab: Tilt patient's head back 70 degrees. While gently rotating the swab, insert swab less than one inch into nostril (until resistance is met at turbinates). Rotate the swab several times against nasal wall and repeat in other nostril using the same swab. Place tip of the swab into sterile viral transport media tube and cut off the applicator stick. For throat swab, take a second dry polyester swab, insert into mouth,

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and swab the posterior pharynx and tonsillar areas. (avoid the tongue) Place tip of swab into the same tube and cut off the applicator tip

In patients with confirmed 2019-nCoV infection, repeat URT and LRT samples should be collected to demonstrate viral clearance. The frequency of specimen collection will be at least every 4 days until there are two consecutive negative results (both URT and LRT samples if both are collected) in a clinically recovered patient at least 24 hours apart.

Infection prevention and control (IPC) measures

IPC is a critical and integral part of clinical management of patients and should be initiated at the point of entry of the patient to hospital. The same should be continued in the designated ward for in-patient care of suspected and confirmed cases. At AIIMS the following areas have been identified for the care of suspected and confirmed patients:

- i. NEW Emergency screening area (both pediatric and adults)
- ii. C6 ward: One cubicle has been identified for the in-patient management of admitted patients

Situation	Measures
At triage	Suspected patients to be triaged at the screening area of the NEW
	Emergency
	• The promotion of hand hygiene and respiratory hygiene are essential
	preventive measures (appropriate signages)
	Give suspected patients a medical mask
	Instruct all patients to cover nose and mouth during coughing or
	sneezing with tissue or flexed elbow
	Perform hand hygiene after contact with respiratory secretions
	• Keep at least 1-2 meters distance between suspected patients

Implementing IPC measures for patients with suspected or confirmed 2019-nCoV infection

•	Adequate supplies including alcohol-based hand rub (ABHR), tissues,
	no touch receptacles for disposal, and facemasks at designated areas
•	Team of dedicated residents manning the area and ensuring minimum
	waiting time before admission
•	Healthcare Worker (HCW) to use a N95 respirator/three-layered
	medical mask during work in designated areas
	incular mask during work in designated areas
•	Use Personal Protective Equipment (PPE) (N95 respirator/medical
	mask, eye protection, gloves and gown) when entering room and
	remove PPE when leaving
•	Use dedicated equipment (e.g. stethoscopes, blood pressure cuffs and
	thermometers)
•	If equipment needs to be shared among patients, clean and disinfect
	between each patient use.
•	Health care workers should refrain from touching their eyes, nose, and
	mouth with potentially contaminated hands.
•	Avoid contaminating environmental surfaces (e.g. door handles and
	light switches).
•	When providing care in close contact, use eye protection (goggles)

Transfer to designated	• Use predetermined transport routes to minimize exposure for staff,
cubicle in C6 ward & Intra-	other patients and visitors
hospital transfer of patients	• Standard, droplet and contact precaution as above
	Restrict visitor access to patients
	Provide dedicated diagnostic and therapeutic devices including
	portable ultrasonography, electrocardiography, mechanical
	ventilation, and cardiorespiratory monitoring equipment within the
	designated patient areas.
	In case of requirement of procedures like computed tomography (CT
	scan) or operative procedures which necessitate shifting, this may be
	scheduled during out-of-routine work hours
	• The hospital personnel involved in shifting and managing the patient
	outside designated areas should follow all standard contact and droplet
	precautions.
	• All specimens collected for laboratory investigations should be
	regarded as potentially infectious; reinforce safe handling practices and
	spill decontamination procedures for staff transporting the samples
Apply airborne precautions	Healthcare workers performing aerosol-generating procedures should
when performing an aerosol	use PPE, including gloves, long-sleeved non-permeable gowns, eye
generating procedure	protection, and N95 respirator
Includes open suctioning of	 Adequately ventilated single rooms should be used performing
respiratory tract, intubation, bronchoscopy,	aerosol-generating procedures. Single isolation room in C6 ward has
Cardiopulmonary resuscitation (CPR)	been identified for this purpose.

* <u>Standard precautions should always be applied.</u> Additional contact and droplet precautions should <u>continue until the patient is asymptomatic.</u>

Standard precautions should always be routinely applied in all areas of health care facilities including OPD. Standard precautions are summarized below:

• Hand hygiene-

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- Healthcare providers (HCP) should perform hand hygiene using alcohol-based hand rub or by washing with soap and water for at least 20 seconds. If hands are visibly soiled, use soap and water before returning to ABHR
- Use of PPE to avoid direct contact with patients' blood, body fluids, secretions (including respiratory secretions) and non-intact skin.
 - An area is designated for donning and doffing PPE in the immediate vicinity of the patient area in C6 ward
 - Gloves- Perform hand hygiene, then put on clean, non-sterile gloves upon entry into the patient room or care area. Change gloves if they become torn or heavily contaminated. Remove and discard gloves when leaving the patient room or care area, and immediately perform hand hygiene
 - Gowns- Put on a clean disposable non-permeable gown prior to entry into the patient room or area. Change the gown if it becomes soiled. Remove and discard the gown before leaving the patient room or care area.
 - Respiratory Protection- Use respiratory protection, i.e as follows:
 - i. Three-layered medical mask to be worn by patients at all times
 - A disposable N95 respirator to be worn by Health Care Providers (HCPs). Disposable respirators should be removed and discarded after exiting the patient's room or care area. Perform hand hygiene after discarding the respirator.

Environmental Infection Control

- Dedicated medical equipment/single use disposable equipment (eg; Stethoscopes, blood pressure cuff, thermometers etc) should be used for patient care
- All non-dedicated, non-disposable medical equipment used for patient care should be cleaned and disinfected as routine disinfection protocol (70% ethyl alcohol)
- Ensure that environmental cleaning and disinfection procedures are followed consistently and correctly (Sodium Hypochlorite)
- Management of laundry, food service utensils, and medical waste should also be performed in accordance with routine protocol.
- Prevention of needle-stick or sharps injury as universal precautions

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- Safe waste management as routine hospital protocol
- Reinforcing the proper use of PPE by health care workers/ other staff involved in patient care

Case Management

The management will need to be individualized as patient may present with a wide spectrum of illness ranging from uncomplicated illness, mild pneumonia, severe pneumonia, ARDS, sepsis and septic shock.

General supportive measures (as per our existing protocols for SARI)

- Oxygen supplementation
- Conservative fluid management if there is no evidence of shock
- Give empiric antimicrobials to treat all likely pathogens causing SARI. Give antimicrobials within one hour of initial patient assessment for patients with sepsis
- Ventilator management as required
- Systemic corticosteroids are not recommended, unless indicated for other reasons

*Close monitoring for worsening clinical status is of paramount importance (designated team)

Antivirals:

- Lopinavir/Ritonavir to be considered in:
 - Laboratory confirmation of 2019-nCoV infection by RT-PCR from recommended sample
 - o Symptomatic patients with any one of the following:
 - Hypoxia as defined as requirement of supplemental oxygen to maintain oxygen saturation > 90%
 - Hypotension as defined as systolic blood pressure <90 mm Hg or need for vasopressor / inotropic medication
 - New onset organ dysfunction (one or more)
 - Increase in creatinine by 50 % from baseline, GFR reduction by >25 % from baseline or urine output of <0.5 ml/Kg for 6 hours
 - Reduction of GCS by 2 or more
 - Any other organ dysfunction

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- High risk groups
 - Age > 60 years
 - Diabetes mellitus , renal failure , chronic lung disease and immunocompromised persons

NO SPECIFIC ANTIVIRALS are recommended for treatment of SARS-CoV and MERS-CoV due to lack of adequate evidence from literature. The use of lopnavir/ ritonavir in PEP regimens for HIV (4 weeks) is also associated with significant adverse events which many a times leads to discontinuation of therapy. In light of the above, lopnavir/ ritonavir should ONLY be used with proper informed consent on a case-to-case basis within the above framework along with supportive treatment as per need. The current standards of care that are consistent with best clinical practices and WHO guidelines including infection prevention and quarantine as the mainstay of management for the patients should be followed.

Pregnant women with suspected or confirmed 2019-nCoV infection should be treated with supportive therapies and multidisciplinary team.

Dosage:

- Lopinavir/ritonavir (200mg/50 mg) 2 tablets twice daily
- For patients who are unable to take medications by mouth, lopinavir 400 mg/ ritonavir 100 mg
 5-ml suspension twice daily

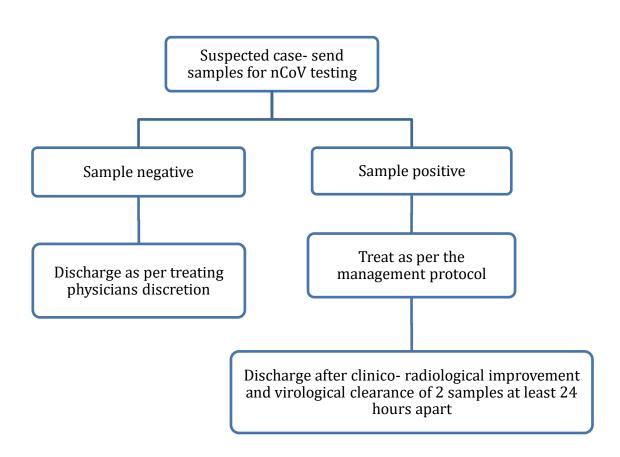
Duration: 14 days or for 7 days after becoming asymptomatic

When to discharge?

- If the laboratory results for 2019-nCoV are negative, discharge is to be decided as per discretion of the treating physician based on his provisional/confirmed diagnosis
- In case of high suspicion of 2019-nCoV repeat samples are to be sent
- Confirmed case- Resolution of symptoms, radiological improvement with a documented virological clearance in 2 samples at least 24 hours apart

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Protocol for Managing a Suspected Case



Note: This document is dynamic and may be modified as per progression of the disease in India and when more data are available regarding epidemiology, transmission, and treatment.