Annex 1

Novel coronavirus pneumonia: case surveillance protocol

This Protocol is formulated to provide guidance on timely detection and reporting of novel coronavirus pneumonia (NCP) cases in local efforts so as to ensure early detection and early reporting and prevent the spread of the epidemic.

1. Purpose

- 1) To timely detect and report the novel coronavirus pneumonia cases, infected persons and clusters of cases;
- 2) To understand the characteristics of the epidemic situation of novel coronavirus infections in the country so as to assess in a timely manner the epidemic trend.

2. Surveillance case definition

A. Suspect cases

Make comprehensive analysis based on following epidemiological history and clinical manifestations:

- 1) Epidemiological history
 - (1) Travel or residence history in Wuhan and its surrounding areas or other communities with reported cases within 14 days before the onset of the disease;
 - (2) History of contact with novel coronavirus infected persons (whose were tested positive for nucleic acid) within 14 days before the onset of the disease;
 - (3) Having contact with patients with fever and respiratory symptoms who are from Wuhan and its surrounding areas or other communities with reported cases within 14 days before the onset of the disease;
 - (4) A cluster of cases: 2 or more cases with fever and / or respiratory symptoms are detected in small areas such as family, office or school class, etc. within two weeks.
- 2) Clinical manifestations:
 - (1) Fever and/or respiratory symptoms;
 - (2) Radiological findings of novel coronavirus pneumonia;
 - (3) Normal or lower WBC count, or lower lymphocyte count in early stage.

Cases that meet any one of the epidemiological history and any two of the clinical manifestations, or have all three clinical manifestations but with no clear epidemiological history, are defined as

suspect cases.

B. Confirmed case

Confirmed case are suspect case with one of the following etiological evidences:

- (1) 2019-nCoV nucleic acid positive using RT-PCR;
- (2) Virus gene sequencing is highly homologous with the known novel coronavirus.

C. Asymptomatic infected persons

Individuals without clinical symptoms but whose respiratory and other specimens are tested positive for the novel coronavirus. They are mainly detected through investigation of clusters of cases and tracking investigation of the infection source, etc.

D. Clusters of cases

Clusters of cases refer to two and more confirmed cases or asymptomatic infected persons detected in a small group such as a family, a construction site or a workplace within 14 days, with the possibility of human to human transmission due to close contacts or common exposure.

3. Work Content

1) Case detection

- (1) Healthcare facilities at all levels should raise their awareness of diagnosis and reporting of novel coronavirus pneumonia cases. Patients with symptoms like fever, dry cough, shortness of breath etc. of unknown causes should be asked about any history of travel to or residence in Wuhan or surrounding areas or other communities with cases reported, whether they have exposure to patients with fever or respiratory symptoms in the above areas or communities, whether they are part of a cluster of cases or have been in contact with any novel coronavirus infected persons within 14 days before onset of the disease.
- (2) Relevant grassroots organizations should screen those at-risk people who have travel or residence history in Wuhan or surrounding areas or communities with cases reported, who have respiratory symptoms, fever, chills, fatigue, diarrhea, conjunctival congestion etc. within the past 14 days as, and have their specimens collected and tested by professional institutions.

2) Case reporting

When healthcare facilities at all levels and of all kinds detect suspect cases, confirmed cases and

asymptomatic infection cases, they should report via the direct online reporting network within 2 hours. The address box in the infectious disease report card should be filled with the place of residence at the time of disease onset, and detailed to the village, residence group, community, household number etc. so that the case can be traced. The CDC should investigate and verify immediately after receiving the report and complete the three-level review and confirmation of the reported information through the network within 2 hours. Healthcare facilities that do not have the capacity of direct online reporting should immediately report to the local county/district CDC and send out the completed infectious disease reporting card within 2 hours. The county/district CDC, upon receiving the report, should immediately make a direct online reporting and any subsequent revision of the information.

When reporting cases online, select "novel coronavirus pneumonia" for the type of disease, and report as a "suspect case", "confirmed case" or "tested positive" for case classification. Suspect cases and confirmed cases should be classified according to and reported as "mild", "moderate", "severe" or "critical" in accordance with *the Diagnosis and Treatment Protocol for Novel Coronavirus Pneumonia* (6th Edition). "tested positive" specifically refers to asymptomatic infected persons, and its clinical severity is "asymptomatic infected person".

The reported "suspect cases" and previously reported "clinical diagnosed cases (in Hubei Province only)", once novel coronavirus nucleic acid tested positive on RT-PCR, should be promptly corrected as "confirmed cases". If the reported "asymptomatic infected persons" have clinical manifestations, they shall be corrected timely as "confirmed cases". "Clinical severity" of all cases shall be timely amended according to the progression of illness condition, with the most severe condition of the case as its final severity.

When reporting asymptomatic infection cases, the "date of onset" should be "collection time of positive specimen", "date of diagnosis" should be "detection time that showed positive". If the reported "asymptomatic infected persons" corrected to "confirmed cases", the "date of onset" should be the time when clinical symptoms appear.

3) Detection and reporting of incidents

According to the requirements of the National Public Health Emergency Response Contingency Plan and the National Public Health Emergency Related Information Reporting and Management Rules (Trial), the index novel coronavirus pneumonia confirmed case or cluster in the county/district should be reported within two hours by the local CDC in the jurisdiction through online direct reporting system for public health emergencies. The incident level can be categorized as "unclassified" for the time being. The health authority shall classify the incident level based on investigation findings, subsequent progress, and results of risk assessment, and adjust it in the system, and submit the initial report, progress report and final report online in a timely manner.

4) Epidemiological investigation

The county/district CDC upon receiving reports of suspect cases, confirmed cases and asymptomatic infected persons, should complete case investigation within 24 hours, and register the close contacts in a timely manner. For details, please refer to the NCP: epidemiological investigation protocol and the NCP: close contact management protocol. After completing the case investigation, the county/district CDC should submit the case investigation information of confirmed cases and asymptomatic infected persons through the online direct reporting system in a timely manner.

5) Specimen collection and laboratory testing

Healthcare facilities that admit and treat suspect cases should collect relevant clinical specimens of the cases and send the specimens to the designated local CDC, healthcare facilities or third-party testing institutions as soon as possible for related pathogenic laboratory testing.

The collected clinical specimens include patients' upper respiratory tract specimens (such as nasopharyngeal swab, throat swabs, etc.), lower respiratory tract specimens (such as deep cough sputum, pulmonary alveoli lavage fluid, bronchial lavage fluid, respiratory tract extracts, etc.), stool/anus specimens, anticoagulant and serum specimens etc. In order to increase the positive rate of nucleic acid tests, efforts should be made to try to collect respiratory tract specimens, take sputum and collect lower respiratory tract specimens during tracheal incubation early in the onset of the disease, send for test as soon as possible after specimen collection. Specific requirements for clinical specimen collection and laboratory testing are described in the *NCP: laboratory testing guideline*.

Specimen collection, transportation, storage and testing are temporarily managed as level 2 highly pathogenic microorganisms, in accordance with the Regulations on Biological Safety Management of Pathogenic Microbial Laboratories, the Regulations on the Management of Transportation of Highly Pathogenic Microorganisms or Samples that Can Infect Humans (Ministry of Health Order No. 45) and other related requirements.

6) Requirements for verification of laboratory test results of clusters of cases

All the original specimens of clusters of five or more novel coronavirus pneumonia cases in each region should be sent to the Chinese Center for Disease Control and Prevention for verification and confirmation.