Interpretation of the diagnosis and treatment protocol for COVID-19 (Trial Version 9)

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Since the outbreak of the COVID-19 pandemic, the National Health Commission of the People's Republic of China (NHC) issued a total of eight editions of the Diagnosis and Treatment Protocol for COVID-19 from January 15, 2020 to August 18, 2020 [1–6]. As the clinical presentation of COVID-19 reported diversifies and the knowledge of its diagnosis and treatment evolves, the Protocol witnesses continuous refinement in the definition of clinical presentation and confirmed cases, solid optimization and streamlining of the diagnosis procedure, and provides additional evidence-based clinical management, serving as a pivotal role to the diagnosis and treatment of COVID-19 in China. With the experience in responding to local epidemics attributed to imported cases, NHC organized experts to study the disease transmission and characteristics of confirmed cases of the Delta and Omicron variants, analyzed domestic and international scientific evidence, and issued the ninth trial version of the Diagnosis and Treatment Protocol for COVID-19 on March 15, 2022 [7].

The new version highlights the improvement in the following respects: (1) Optimization of case identification and reporting; (2) Determination of quarantine and treatment sites based on the disease severity; (3) Further standardization of antiviral therapy; (4) Improvement in Traditional Chinese Medicine treatment; (5) Adjustment of the criteria and precautions regarding release from quarantine and discharge from hospital.

1. OPTIMIZATION OF CASE IDENTIFICATION AND REPORTING

a. Antigen testing is added to the Protocol as a supplement to nucleic acid testing to shorten the testing time and identify cases in a more timely manner. To improve the efficiency of diagnosis or exclusion of suspected cases, suspected cases or those with positive antigen test results must take nucleic acid testing immediately or at a higher level medical institution via closed-loop transfer. Those who tested positive shall be subject to centralized quarantine management or be sent to a designated hospital for treatment. The cases shall be reported through the national direct Internet reporting system in accordance with regulations.

Abbreviations: NHC, National Health Commission of the People's Republic of China; IFN-α, interferon alpha.

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b. The exclusion criterion is changed from “If a person was tested negative for covid-specific IgM and IgG antibodies 7 days after the onset of the disease, they can be excluded from suspected cases” to “If a person tested negative for two consecutive times (sampling time interval of at least 24 h), they can be excluded from suspected cases.”

2 | DETERMINATION OF QUARANTINE AND TREATMENT SITES BASED ON THE DISEASE SEVERITY

a. Mild and asymptomatic cases are subject to centralized quarantine management.

Those who have been vaccinated and infected with the Omicron variant are mainly asymptomatic and mild cases (accounting for up to 95%), and most of them do not require comprehensive treatment. If all these patients are admitted to designated hospitals, a great number of medical resources will be occupied. However, the number of medical staff in centralized quarantine sites is only 20% of that in designated hospitals. The new version of the diagnosis and treatment protocol has adjusted the case classification and admission measures and implemented centralized quarantine management for mild cases. Asymptomatic cases are also subject to centralized quarantine management and do not need to be admitted to designated hospitals. During the centralized quarantine management period, mild and asymptomatic cases should be treated and monitored. If the condition worsens, the patient should be referred to the designated hospitals for treatment. In the meantime, relevant centralized quarantine sites cannot hold inbound personnel, close contacts, and other groups at the same time to avoid cross-infection.

b. Moderate, severe, critical cases, and cases with high-risk factors should be treated in designated hospitals. To improve the treatment of severe, critically ill patients, and patients with high-risk factors and tendencies to become critically ill, the Protocol emphasizes that “severe and critical cases should be admitted to ICU for treatment as soon as possible, and patients with high-risk factors and tendencies to become severely ill should also be admitted to ICU for treatment.”

3 | ADJUSTMENTS TO THE ANTIVIRAL DRUGS

Based on the clinical practice and scientific research results over the past 2 years, the previously used antiviral drugs, such as “interferon-alpha (IFN-α), ribavirin, chloroquine phosphate, and Arbidol” were deleted from the Protocol. Two antiviral drugs were added: one is an oral drug, PAXLOVID (nirmatrelvir/ritonavir), and the other is monoclonal antibodies, Amubarvimab/Romlusevimab (BRII-196/BRII-198). Research showed that both drugs can reduce the risk of hospitalization or death in treated patients by 89% and 78%, respectively, and that no patients in the trial group died [8, 9]. At the same time, “intravenous injection of COVID-19 human immunoglobulin and convalescent plasma of recovered patients” is also included in the antiviral treatment, with the usage and dosage specified.

4 | IMPROVEMENT IN TRADITIONAL CHINESE MEDICINE TREATMENT

Based on the clinical treatment experience in various places, the application of nondrug therapy in traditional Chinese medicine was strengthened, and the option of acupuncture treatment was added; catering to the characteristics of children, the content of traditional Chinese medicine treatment for children was added.

5 | ADJUSTMENT OF THE CRITERIA AND PRECAUTIONS REGARDING RELEASE FROM QUARANTINE AND DISCHARGE FROM HOSPITAL

Relevant domestic studies have shown that when the \( Ct \) value of a SARS-CoV-2 patient is \( \geq 35 \), no viable virus could be isolated from the sample, and no close contacts were found to be infected. Accordingly, the new version of the treatment protocol amended the criteria for release from quarantine and discharge from the hospital from “two consecutive negative nucleic acid test results of respiratory specimens (sampling time interval of at least 24 h)” to “the \( Ct \) values of ORF1ab and N gene are greater than or equal to 35 (Fluorescent RT-PCR Kit, \( Ct < 35 \), and sampling time interval of at least 24 h) or two consecutive negative results for nucleic acid tests (Fluorescent RT-PCR Kit, \( Ct \) at 40, and sampling time interval of at least 24 h).” To enable the infected convalescents to return to normal work or life as soon as possible, “14-day quarantine management and health monitoring after discharge” is replaced by “7-day home quarantine and health monitoring after release from quarantine management or discharge from hospital.”
“Follow-up visit 2 weeks after discharge” is deleted in the new version of the Protocol.

6 | MISCELLANEOUS

a. In terms of etiological characteristics, the description of variant strains, especially the biological and clinical characteristics of the prevalent Omicron has been added to the Protocol. For instance, the Omicron strain is more transmissible than the Delta strain, and its pathogenicity is weaker. The diagnostic accuracy of PCR detection is not affected, but the neutralization effect of some monoclonal antibody drugs on the Omicron strain may be reduced.

b. There are three ways of transmission, namely,

(1) Transmission by respiratory droplets and close contact is the main route of transmission.

(2) Transmission by aerosol in a relatively closed environment.

(3) Contact with objects contaminated with the virus can also cause infection.

c. “Glucocorticoid therapy and interleukin 6 (IL-6) inhibitor (tocilizumab)” are included in the section “Immunotherapy.” The indications for glucocorticoid therapy are “severe and critically ill patients with progressive deterioration of oxygenation indicators, rapid imaging progress, and over-activation of the inflammatory response of the organism,” and dexamethasone 5 mg/day or methylprednisolone 40 mg/day is recommended for a course of up to 10 days.

d. For patients with COVID-19 infection who are prone to thrombosis, “anticoagulation” is stated separately, and the indication is “for moderate, severe and critical patients with severe risk factors and rapid disease progression.” Therapeutic doses of low molecular weight heparin or unfractionated heparin can be given in the absence of contraindications.

e. As “prone position treatment is effective for COVID-19,” “prone position treatment” is stated separately in the Protocol. “Standard prone position treatment of no less than 12 h a day” is recommended for “moderate, severe and critical cases with high-risk factors for severe disease and rapid disease progression.”

AUTHOR CONTRIBUTION

Jiang Rongmeng: Conceptualization; writing—original draft.

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None.

CONFLICT OF INTEREST

The author declares no conflict of interest.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are available on request from the corresponding author. The data are not publicly available due to privacy or ethical restrictions.

ETHICS STATEMENT

None.

INFORMED CONSENT

None.

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