新型冠状病毒肺炎诊疗方案

(试行第七版)

Novel Coronavirus Pneumonia Diagnosis and Treatment Plan

(Provisional 7th Edition)

2019年12月以来,湖北省武汉市出现了新型冠状病毒肺炎疫情,随着疫情的蔓延,我国其他地区及境外多个国家也相继发现了此类病例。该病作为急性呼吸道传染病已纳入《中华人民共和国传染病防治法》规定的乙类传染病,按甲类传染病管理。通过采取一系列预防控制和医疗救治措施,我国境内疫情上升的势头得到一定程度的遏制,大多数省份疫情缓解,但境外的发病人数呈上升态势。随着对疾病临床表现、病理认识的深入和诊疗经验的积累,为进一步加强对该病的早诊早治,提高治愈率,降低病亡率,最大可能避免医院感染,同时提醒注意境外输入性病例导致的传播和扩散,我们对《新型冠状病毒肺炎诊疗方案(试行第六版)》进行修订,形成了《新型冠状病毒肺炎诊疗方案(试行第六版)》。

Since December 2019, many cases of novel coronavirus pneumonia have been found in Wuhan City, Hubei Province, and with the spread of the epidemic, such cases have also been found in other regions of China and overseas. As an acute respiratory infectious disease, the disease has been listed as a Class B infectious disease as provided by the "Law of the People's Republic of China on Prevention and Control of Infectious Diseases", and is managed as a Class A infectious disease. By employing a series of measures for prevention, control, and treatment, the upward trend of the epidemic in our nation has been contained to a certain degree, and the epidemic has eased in most provinces, but the number of cases outside China is on the rise. With thorough understanding of the clinical manifestations and pathology of the disease and the accumulation of experience in its diagnosis and treatment, we have revised the "Novel Coronavirus Diagnosis and Treatment Plan (Provisional Version 6)" to form the "New Coronavirus Pneumonia Diagnosis and Treatment Plan (Trial Version 7)", in order to further strengthen the early diagnosis and treatment of the disease, to improve the cure rate, to reduce the mortality rate, and to avoid hospital infection to the greatest extent possible, and at the same time to give a reminder to pay attention to the transmission and spread caused by imported cases.

一、病原学特点

I. Pathogenic Characteristics

新型冠状病毒属于 8 属的冠状病毒,有包膜,颗粒呈圆形或椭圆形,常为多形性,直径 60-140nm。 其基因特征与 SARS-CoV 和 MERS-CoV 有明显区别。目前研究显示与蝙蝠 SARS 样冠状病毒 (bat-SL-CoVZC45) 同源性达 85%以上。体外分离培养时,新型冠状病毒 96 个小时左右即可在人 呼吸道上皮细胞内发现,而在 Vero E6 和 Huh-7 细胞系中分离培养需约 6 天。

The Novel Coronavirus belonging to the genus of betacoronavirus. The enveloped viral particles may appear spherical or oblong, with a diameter of 60-140nm. Its genetic characteristics are significantly different from SARS-CoV and MERS-CoV. Current research shows that it has more than 85% homology with bat SARS-like coronavirus (bat-SL-CoVZC45). When isolated and cultured in vitro, the new coronavirus can be found in human respiratory epithelial cells in about 96 hours, while it takes about 6 days to isolate and culture in Vero E6 and Huh-7 cell lines.

对冠状病毒理化特性的认识多来自对 SARS-CoV 和 MERS-CoV 的研究。病毒对紫外线和热敏感,56°C 30 分钟、乙醒、75%乙醇、含氯消毒剂、过氧乙酸和氯仿等脂溶剂均可有效灭活病毒,氯己定不能有效灭活病毒。

Most of the understanding of the physicochemical properties of coronavirus comes from the research of SARS-CoV and MERS-CoV. The virus is sensitive to ultraviolet rays and heat. Under 56 °C for 30 minutes, ether solvents, 75% ethanol, chlorine-containing disinfectants, peracetic acid, and chloroform can effectively inactivate the virus. Chlorhexidine cannot effectively inactivate the virus.

- 二、流行病学特点
- II. Epidemiological Characteristics
- (一) 传染源。
- (1) Source of infection.

目前所见传染源主要是新型冠状病毒感染的患者。无症状感染者也可能成为传染源。

At present, the source of infection is mainly patients infected by the novel coronavirus. Those who are asymptomatic but infected may also become a source of infection.

- (二) 传播途径。
- (2) Route of transmission.

经呼吸道飞沫和密切接触传播是主要的传播途径。在相对封闭的环境中长时间暴露于高浓度气溶胶情况下存在经气溶胶传播的可能。由于在粪便及尿中可分离到新型冠状病毒,应注意粪便及尿对环境污染造成气溶胶或接触传播。

The main route of transmission is respiratory droplets and close contact. There is the possibility of aerosol transmission when exposed to high concentration aerosol for a long time in a relatively closed environment. As new coronaviruses can be isolated in feces and urine, attention should be paid to aerosol or contact transmission of fecal and urine to environmental pollution.

- (三) 易感人群。
- (3) Susceptible populations.

人群普遍易感。

The population is generally susceptible.

三、病理改变

III. Pathological Changes

根据目前有限的尸检和穿刺组织病理观察结果总结如下。

The pathological observations from autopsies and biopsies are summarized below.

(一) 肺脏。

(1) Lungs

肺脏呈不同程度的实变。

Pulmonary consolidation of varying degrees.

肺泡腔内见浆液、纤维蛋白性渗出物及透明膜形成;渗出细胞主要为单核和巨噬细胞,易见多核巨细胞。II 型肺泡上皮细胞显著增生,部分细胞脱落。II 型肺泡上皮细胞和巨噬细胞内可见包涵体。肺泡隔血管充血、水肿,可见单核和淋巴细胞浸润及血管内透明血栓形成。肺组织灶性出血、坏死,可出现出血性梗死。部分肺泡腔渗出物机化和肺间质纤维化。

Intra-alveolar serous fluids, fibrinous exude and hyaline-membrane formation are present. Exudate consists mainly of mononuclear macrophages. Multinucleated giant cells are common. Significant hyperplasia of type II pneumocyte. Some desquamation is present. Inclusion bodies can be seen inside type II pneumocyte and macrophages. Alveolar congestion and edema can be seen. Infiltration of monocytes and lymphocytes, as well as the formation of hyaline thrombus in blood vessels, are evident. Focal pulmonary hemorrhage and necrosis. Hemorrhagic infarction can be seen. Exudate organization and pulmonary interstitial fibrosis are present in some alveoli.

肺内支气管黏膜部分上皮脱落,腔内可见黏液及黏液栓形成。少数肺泡过度充气、肺泡隔断裂或囊腔形成。

Desquamation of bronchial mucosal epithelium is present. Intra-cavity mucus and mucus plugs can be seen. Overinflation, alveolar septa fracture and cyst formation are present in some alveoli.

电镜下支气管黏膜上皮和 II 型肺泡上皮细胞胞质内可见冠状病毒颗粒。免疫组化染色显示部分肺泡上皮和巨噬细胞呈新型冠状病毒抗原阳性,RT-PCR 检测新型冠状病毒核酸阳性。

Coronavirus particles can be seen in the cytoplasm of tracheal mucosal epithelial cells and type II pneumocytes under an electron microscope. A portion of the alveolar epithelium and macrophages contain the 2019-nCoV antigen as shown by IHC. Sample tests positive for the nucleic acid of 2019-nCoV with RT-PCR.

(二) 脾脏、肺门淋巴结和骨髓。

(2) Spleen, hilar lymph nodes and bone marrow

脾脏明显缩小。淋巴细胞数量明显减少,灶性出血和坏死,脾脏内巨噬细胞增生并可见吞噬现象;淋巴结淋巴细胞数量较少,可见坏死。免疫组化染色显示脾脏和淋巴结内 CD4+T 和 CD8+T 细胞均减少。骨髓三系细胞数量减少。

The size of the spleen is significantly reduced. Lymphocyte count is significantly reduced. Focal hemorrhage and necrosis are present. Macrophage hyperplasia and phagocytosis can be observed in the spleen. In the lymph nodes, the number of lymphocytes is reduced; some necrosis can be seen. A reduction of CD4+ T cells and CD8+ T cells can be detected in both the spleen and the lymph nodes by IHC. Trilineage hematopoiesis is reduced in the bone marrow.

(三) 心脏和血管。

(3) Heart and blood vessels

心肌细胞可见变性,坏死,间质内可见少数单核细胞、淋巴细胞和(或)中性粒细胞浸润。部分血管内皮脱落、内膜炎症及血栓形成。

Degeneration and necrosis can be seen in cardiomyocytes. Interstitial infiltration of a small number of monocytes, lymphocytes and/or neutrophils can be seen. Desquamation of vascular endothelium, endothelial inflammation and thrombus formation are observed in some vessels.

(四) 肝脏和胆囊。

(4) Liver and gallbladder

体积增大,暗红色。肝细胞变性、灶性坏死伴中性粒细胞浸润;肝血窦充血,汇管区见淋巴细胞和单核细胞细胞浸润,微血栓形成。胆囊高度充盈。

The liver appears enlarged and dark red in colour. Hepatocyte degeneration and focal necrosis are accompanied by neutrophil infiltration; hepatic sinusoidal congestion, infiltration of lymphocytes and monocytes in the hepatic portal area can be seen. Microthrombi are formed. The gallbladder appears highly filled.

(五) 肾脏。

(5) Kidneys

肾小球球囊腔内见蛋白性渗出物,肾小管上皮变性、脱落,可见透明管型。间质充血,可见微血栓和灶性纤维化。

Proteinaceous exudate can be seen inside the glomerular capsule. Degeneration and desquamation of renal tubular epithelium are present. Hyaline casts can be seen. Interstitial congestion, microthrombi and focal fibrosis can be seen.

(六) 其他器官。

(6) Other organs.

脑组织充血、水肿,部分神经元变性。肾上腺见灶性坏死。食管、胃和肠管黏膜上皮不同程度 变性、坏死、脱落。 Cerebral hyperemia, edema, and degeneration of some neurons. Focal necrosis in the adrenal glands. Varying degrees of degeneration, necrosis or desquamation of the esophageal, gastric and intestinal mucosal epithelium.

四、临床特点

IV. Clinical Characteristics

- (一) 临床表现。
- (1) Clinical presentation.

基于目前的流行病学调查,潜伏期 1-14 天,多为 3-7 天。

Based on the current epidemiological investigation, the incubation period is 1-14 days, and most often between 3-7 days.

以发热、干咳、乏力为主要表现。少数患者伴有鼻塞、流涕、咽痛、肌痛和腹泻等症状。重症患者多在发病一周后出现呼吸困难和/或低氧血症,严重者可快速进展为急性呼吸窘迫综合征、脓毒症休克、难以纠正的代谢性酸中毒和出凝血功能障碍及多器官功能衰竭等。值得注意的是重型、危重型患者病程中可为中低热,甚至无明显发热。

The primary presentations are fever, dry cough, and fatigue. A minority of patients have symptoms such as nasal congestion, nasal discharge, sore throat, muscle pain, and diarrhea. Severe patients often suffer from dyspnea and/or hypoxemia one week after symptom onset, and severe patients can rapidly progress to acute respiratory distress syndrome, septic shock, difficult to correct metabolic acidosis, coagulation dysfunction and multiple organ failure. It is worth noting that severe and critical patients may have moderate to low fever or even no obvious fever during the course of the disease.

部分儿童及新生儿病例症状可不典型,表现为呕吐、腹泻等消化道症状或仅表现为精神弱、呼吸急促。

Some children and infants may present with atypical symptoms such as vomiting and diarrhea, or only with malaise and rapid breathing.

轻型患者仅表现为低热、轻微乏力等, 无肺炎表现。

Patients with the mild form of the disease present only as low fever, slight fatigue, and so forth, with no lung inflammation.

从目前收治的病例情况看,多数患者预后良好,少数患者病情危重。老年人和有慢性基础疾病 者预后较差。患有新型冠状病毒肺炎的孕产妇临床过程与同龄患者相近。儿童病例症状相对较轻。

Judging from the current cases, most patients have a good prognosis and a minority are in critical condition. The prognosis of the elderly and those with chronic underlying diseases is more poor. The clinical course of COVID-19 in pregnant patients is similar to that for patients of the same age. The symptoms of children are relatively mild.

- (二) 实验室检查。
- (2) Laboratory examination.
- 1. 一般检查
- 1. General Examination

发病早期外周血白细胞总数正常或减少,可见淋巴细胞计数减少,部分患者可出现肝酶、乳酸脱氢酶(LDH)、肌酶和肌红蛋白增高;部分危重者可见肌钙蛋白增高。多数患者 C 反应蛋白(CRP)和血沉升高,降钙素原正常。严重者 D-二聚体升高,外周血淋巴细胞进行性减少。重型、危重型患者常有炎症因子升高。

In the early stage of the disease, the total number of peripheral blood leukocytes is normal or reduced, and the lymphocyte count is reduced, and some patients may have elevated liver enzyme, lactate dehydrogenase (LDH), myoenzyme and myoglobin; some critically ill patients may have elevated troponin. C-reactive protein (CRP) and erythrocyte sedimentation rate increased in most patients, and procalcitonin

was normal. In severe cases, D- dimer increased and peripheral blood lymphocytes progressively decreased. Inflammatory cytokines often increase in severe and critical patients.

- 2. 病原学及血清学检查
- 2. Etiologic and serologic tests
- (1)病原学检查:采用 RT-PCR 或/和 NGS 方法在鼻咽拭子,痰和其他下呼吸道分泌物、血液、粪便等标本中可检测出新型冠状病毒核酸。检测下呼吸道标本(痰或气道抽取物)更加准确。标本采集后尽快送检。
- (1) Etiologic testing: Use RT-PCR and/or NGS to detect 2019-nCoV nucleic acid in nasopharyngeal swabs, sputum and other lower respiratory tract secretions, blood, and stool samples. Testing done on lower respiratory tract samples (sputum or airway suction) is more accurate. After collection, samples should be sent for testing ASAP.
- (2) 血清学检查:新型冠状病毒特异性 IgM 抗体多在发病 3-5 天后开始出现阳性, IgG 抗体滴度恢复期较急性期有 4 倍及以上增高。
- (2) Serologic testing: nCoV-specific IgM antibodies usually test positive 3-5 days after the onset of symptoms; the titre of IgG antibodies is elevated by 4 times or more in the recovery phase compared with the acute phase.
 - (三)胸部影像学。
 - (3) Chest imaging

早期呈现多发小斑片影及间质改变,以肺外带明显。进而发展为双肺多发磨玻璃影、浸润影,严重者可出现肺实变,胸腔积液少见。

In the early stage, there are multiple small patches and interstitial changes, most notably in the outer lung. It further develops into multiple ground-glass opacity and infiltration shadows in both lungs; and in severe cases, consolidation of the lungs may occur, and pleural effusion is rare.

- 五、诊断标准
- V. Diagnostic Criteria
- (一) 疑似病例。
- (1) Suspected cases.

结合下述流行病学史和临床表现综合分析:

Comprehensively analyze combinations of the following epidemiological history and clinical presentations:

- 1. 流行病学史
- 1. Epidemiological history
- (1) 发病前 14 天内有武汉市及周边地区,或其他有病例报告社区的旅行史或居住史;
- (1) Within 14 days prior to onset, had history of travel or residence in Wuhan or surrounding regions, or other communities reporting cases;
 - (2) 发病前 14 天内与新型冠状病毒感染者(核酸检测阳性者)有接触史;
- (2) Within 14 days prior to symptom onset, having had contact with patients infected with 2019-nCoV (positive nucleic acid test).
- (3) 发病前 14 天内曾接触过来自武汉市及周边地区,或来自有病例报告社区的发热或有呼吸道症状的患者;
- (3) Within 14 days prior to onset, had contact with patients who had a fever or respiratory tract symptoms that had come from Wuhan, its surrounding regions, or other communities reporting cases.
- (4) 聚集性发病(2周内在小范围如家庭、办公室、学校班级等场所,出现2例及以上发热和/或呼吸道症状的病例)。
- (4) Clustered onset (Within a span of 2 weeks, 2 or more cases with fever and/or respiratory symptoms appear in a small area, such as a family, an office, or a school class)

- 2. 临床表现
- 2. Clinical presentations
- (1) 发热和/或呼吸道症状;
- (1) Fever and/or respiratory tract symptoms;
- (2) 具有上述新型冠状病毒肺炎影像学特征;
- (2) Having the imaging features of novel coronavirus pneumonia discussed above;
- (3) 发病早期白细胞总数正常或降低,淋巴细胞计数正常或减少。
- (3) During the early stages of the disease, white blood cell count is normal or reduced, while the lymphocyte count is normal or reduced.

有流行病学史中的任何一条,且符合临床表现中任意 2 条。无明确流行病学史的,符合临床表现中的 3 条。

Where there are any of the epidemiologic history items, and any 2 of the clinical presentions are met. Where there is no clear epidemiological history, and at least 3 of the clinical presentations are met.

- (二) 确诊病例。
- (2) Confirmed cases.

疑似病例同时具备以下病原学或血清学证据之一者:

A 2019-nCoV diagnosis is confirmed if the suspected cases also have one of the following etiological or serological evidence:

- 1. 实时荧光 RT-PCR 检测新型冠状病毒核酸阳性;
- 1. Positive result in real-time fluorescence RT-PCR detection of novel coronavirus nucleic acid;
- 2. 病毒基因测序,与已知的新型冠状病毒高度同源;
- 2. The sequence of the virus is highly homologues to that of 2019-nCoV.
- 3. 血清新型冠状病毒特异性 IgM 抗体和 IgG 抗体阳性; 血清新型冠状病毒特异性 IgG 抗体由 阴性转为阳性或恢复期较急性期 4 倍及以上升高。
- 3. Specific IgM and IgG antibodies against 2019-nCoV test positive in the serum; IgG antibodies specific to 2019-nCoV test positive after previous negative results, or increased by more than 4 times in the recovery phase compared to the acute phase.

六、临床分型

VI. Clinical classifications

(一) 轻型。

(1) Mild form.

临床症状轻微,影像学未见肺炎表现。

Clinical symptoms are minor, imaging does not show signs of lung inflammation.

- (二) 普通型。
- (2) Regular form.

具有发热、呼吸道等症状,影像学可见肺炎表现。

Has fever and respiratory tract symptoms, imaging shows visible lung inflammation.

(三) 重型。

(3) Severe form.

成人符合下列任何一条:

Adults who meet any one of the following:

- 1. 出现气促, RR330 次/分;
- 1. Shortness of breath, RR > 30 breaths/minute;
- 2. 静息状态下,指氧饱和度≤93%;
- 2. Oxygen saturation < 93% at rest
- 3. 动脉血氧分压(PaO2)/吸氧浓度(Fi02)≤300mmHg (1mmHg=O. 133kPa)。

3. Arterial oxygen partial pressure (PaO2)/ fraction of inspired oxygen (FiO2) < 300mmHg (1mmHg=0.133kPa).

高海拔(海拔超过 1000 米) 地区应根据以下公式对 Pa02/Fi02 进行校正: PaO2/FiO2 x [大气压 (mmHg) /760]。

For high altitude (altitude over 1000 meters) regions, (PaO2/FiO2) should be corrected according to the following formula: PaO2/FiO2 x [atmospheric pressure (mmHg)/760]

肺部影像学显示 24-48 小时内病灶明显进展 > 50% 者按重型管理。

The patient should be managed as a severe case if lung imaging shows a substantial progression of lesions (greater than 50%) within 24-48 hours.

儿童符合下列任何一条:

Children who meet any one of the following:

- 1. 出现气促(<2 月龄, RR≥60 次/分; 2?12 月龄, RRN≥50 次/分; 1?5 岁, RRN≥40 次/分; >5 岁, RRN≥30 次/分), 除外发热和哭闹的影响;
- 1. Show shortness of breath (<2 months old, RR>60 times/min; 2 \sim 12 months old, RR>50 times/min; 1 \sim 5 years old, RR>40 times/min; 55 years old, RR>0 times/min), except the effects of fever and crying;
- 2. 静息状态下, 指氧饱和度<92%;
- 2. Oxygen saturation <92% at rest.
- 3. 辅助呼吸(呻吟、鼻翼扇动、三凹征),发绀,间歇性呼吸暂停;
- 3. Laboured breathing (wheezing, flaring of nostrils, three concave sign), cyanosis, intermittent apnea.
 - 4. 出现嗜睡、惊厥;
 - 4. Lethargy, convulsions.
 - 5. 拒食或喂养困难,有脱水征。
 - 5. Refusal to eat or difficulty feeding; signs of dehydration. (四) 危重型。
 - (4) Critical form.

符合以下情况之一者:

Meeting any of the following criteria:

- 1. 出现呼吸衰竭,且需要机械通气;
- 1. Respiratory failure occurs and mechanical ventilation is required;
- 2. 出现休克;
- 2. Shock;
- 3. 合并其他器官功能衰竭需 ICU 监护治疗。
- 3. Combined failure of other organs than require ICU monitoring.
- 七、重型、危重型临床预警指标
- VII. Clinical Warning Signs for Severe and Critical Cases
- (一) 成人。
- (1) Adults.
- 1. 外周血淋巴细胞进行性下降;
- 1. Progressive reduction of peripheral blood lymphocytes
- 2. 外周血炎症因子如"IL-6、C 反应蛋白进行性上升;
- 2. Progressive increase of peripheral inflammatory cytokines such as IL-6 and C-reactive protein.
- 3. 乳酸进行性升高;
- 3. Progressive increase of lactate.
- 4. 肺内病变在短期内迅速进展。

- 4. Rapid progression of lung pathologies in a short period of time.
- (二)儿童。
- (2) Children.
- 1. 呼吸频率增快;
- 1. Rapid breathing
- 2. 精神反应差、嗜睡;
- 2.Lack of mental energy, lethargy
- 3. 乳酸进行性升高;
- 3. Progressive increase of lactate
- 4. 影像学显示双侧或多肺叶浸润、胸腔积液或短期内病变快速进展;
- 4. Imaging shows bilateral or multilobe infiltration, pleural effusion or rapid disease progression within a short period of time.
- 5.3 月龄以下的婴儿或有基础疾病(先天性心脏病、支气管肺发育不良、呼吸道畸形、异常血红蛋白、重度营养不良等),有免疫缺陷或低下(长期使用免疫抑制剂)。
- 5. Infants under 3 months or with underlying disease (congenital heart disease, bronchopulmonary dysplasia, respiratory malformation, hemoglobinopathies, severe malnutrition and so on), immunocompromised or immunosuppressed (long-term usage of immunosuppressants).

八、鉴别诊断

VIII. Differential Diagnosis

- (一) 新型冠状病毒感染轻型表现需与其他病毒引起的上呼吸道感染相鉴别。
- (1) Mild manifestations of 2019-nCoV infection need to be distinguished from other virus-induced upper respiratory tract infections.
- (二)新型冠状病毒肺炎主要与流感病毒、腺病毒、呼吸道合胞病毒等其他已知病毒性肺炎及肺炎支原体感染鉴别,尤其是对疑似病例要尽可能采取包括快速抗原检测和多重 PCR 核酸检测等方法,对常见呼吸道病原体进行检测。
- (2) COVID-19 is to be distinguished from pneumonia caused by known viral agents such as influenza, adenovirus, and respiratory syncytial virus, as well as mycoplasma pneumonia. As much as possible, suspected cases should be tested for common pathogens using methods such as rapid antigen tests and multiplex PCR nucleic acid test.
 - (三)还要与非感染性疾病,如血管炎、皮肌炎和机化性肺炎等鉴别。
- (3) Furthermore, distinguish COVID-19 from non-infectious diseases such as vasculitis, dermatomyositis, and organizing pneumonia.
 - 九、病例的发现与报告

IX. Discovery and Reporting of Cases

各级各类医疗机构的医务人员发现符合病例定义的疑似病例后,应当立即进行单人间隔离治疗,院内专家会诊或主诊医师会诊,仍考虑疑似病例,在 2 小时内进行网络直报,并采集标本进行新型冠状病毒核酸检测,同时在确保转运安全前提下立即将疑似病例转运至定点医院。与新型冠状病毒感染者有密切接触的患者,即便常见呼吸道病原检测阳性,也建议及时进行新型冠状病毒病原学检测。

When a suspected case is discovered by medical workers at the various levels or types of medical institutions, the patient should receive treatment in isolation immediately. Consultations of specialists or attending physicians should consider differential diagnosis and report the case online within 2 hours. Samples should be collected for 2019-nCoV nucleic acid testing. The suspected case should then be transferred to designated hospitals under safe transferring conditions immediately. It's recommended that patients who tested positive for other respiratory antigens be tested also for 2019-nCoV if they have had close contact with 2019-nCoV patients.

疑似病例连续两次新型冠状病毒核酸检测阴性(釆样时间至少间隔 24 小时)且发病 7 天后新型冠状病毒特异性抗体 IgM 和 IgG 仍为阴性可排除疑似病例诊断。

Two consecutive negative nCoV nucleic acid tests (samples taken at least 24 hours apart), and continued negativity for nCoV-specific IgG and IgM antibodies after 7 days of symptom onset can rule out the diagnosis of a suspected case.

十、治疗

X. Treatment

- (一) 根据病情确定治疗场所。
- (1) Determine the place of treatment based on the patients' conditions.
- 1. 疑似及确诊病例应在具备有效隔离条件和防护条件的定点医院隔离治疗, 疑似病例应单人单间隔离治疗, 确诊病例可多人收治在同一病室。
- 1. Suspected and confirmed cases should be treated in quarantine, in designated hospitals with effective isolation and disease control capacity. Suspected cases should be treated in individual isolation. Confirmed cases can be treated with multiple patients in the same isolation room.
 - 2. 危重型病例应当尽早收入 ICU 治疗。
 - 2. Patients who are severely or critically ill should be admitted to ICU as early as possible.

(二)一般治疗。

- (2) General treatment.
- 1. 卧床休息,加强支持治疗,保证充分热量;注意水、电解质平衡,维持内环境稳定;密切监测生命体征、指氧饱和度等。
- 1. Treatment for mild cases includes bed rest, supportive treatments, and maintenance of caloric intake. Pay attention to fluid and electrolyte balance and maintain homeostasis. Closely monitor the patient's vitals and oxygen saturation.
- 2. 根据病情监测血常规、尿常规、CRP、生化指标(肝酶、心肌酶、肾功能等)、凝血功能、动脉血气分析、胸部影像学等。有条件者可行细胞因子检测。
- 2. As indicated by clinical presentations, monitor the hematology panel, routine urinalysis, CRP, biochemistry (liver enzymes, cardiac enzymes, kidney function), coagulation, arterial blood gas analysis, chest radiography, and so on. Cytokines can be tested if possible.
- 3. 及时给予有效氧疗措施,包括鼻导管、面罩给氧和经鼻高流量氧疗。有条件可采用氢氧混合吸入气(H2/O2: 66.6%/33.3%)治疗。
- 3. Administer effective oxygenation measures promptly, including nasal catheter, oxygen mask, and high flow nasal cannula. If conditions allow, a hydrogen-oxygen gas mix (H2/O2: 66.6%/33.3%) may be used for breathing.
- 4. 抗病毒治疗: 可试用α-干扰素 (成人每次 500 万 U 或相当剂量,加入灭菌注射用水 2ml,每日 2 次雾化吸入)、洛匹那韦/利托那韦 (成人 200mg/50mg/粒,每次 2 粒,每日 2 次,疗程不超过 10 天)、利巴韦林(建议与干扰素或洛匹那韦/利托那韦联合应用,成人 500mg/次,每日 2 至 3 次静脉输注,疗程不超过 10 天)、磷酸氯壑(18 岁-65 岁成人。体重大于 50 公斤者,每次 500mg、每日 2 次,疗程 7 天;体重小于 50 公斤者,第一、二天每次 500mg,每日 2 次,第三至第七天每次 500mg、每日 1 次)、阿比多尔(成人 200mg,每日 3 次,疗程不超过 10 天)。要注意上述药物的不良反应、禁忌症(如患有心脏疾病者禁用氯噌)以及与其他药物的相互作用等问题。在临床应用中进一步评价目前所试用药物的疗效。不建议同时应用 3 种及以上抗病毒药物,出现不可耐受的毒副作用时应停止使用相关药物。对孕产妇患者的治疗应考虑妊娠周数,尽可能选择对胎儿影响较小的药物,以及是否终止妊娠后再进行治疗等问题,并知情告知。
- 4. Antiviral therapies: Interferon-alpha (adult: 5 million units or equivalent can be added to 2ml sterile injection water and delivered with a nebulizer twice daily), lopinavir/ritonavir (adult: 200mg/50mg/tablet, 2 tablets twice daily; the length of treatment should not exceed 10 days), ribavirin

(recommended in combination with interferon or lopinavir/ritonavir, adult: 500mg twice or three times daily via IV, the length of treatment should not exceed 10 days), chloroquine phosphate (adult 18-65 years old weighing more than 50kg: 500mg twice daily for 7 days; bodyweight less than 50kg: 500mg twice daily for day 1 and 2, 500mg once daily for day 3 through 7); umifenovir (adult: 200mg three times daily; the length of treatment should not exceed 10 days). Pay attention to issues such as adverse drug reactions, contraindications (for example, chloroquine should not be given to patients with heart diseases), and drug interactions. Further evaluate the efficacy of current treatment regimens in clinical applications. Using 3 or more antiviral drugs is not recommended. Corresponding medication should be discontinued should intolerable side effects appear. Care planning for pregnant patients should consider the stage of pregnancy, the choice of medications that minimize risks to the fetus, and whether the pregnancy should be terminated before the treatment, and inform the patient.

- 5. 抗菌药物治疗:避免盲目或不恰当使用抗菌药物,尤其是联合使用广谱抗菌药物。
- 5. Antibiotic therapies: avoid unjustifiable or inappropriate usage of antibiotics, especially combinatory use of broad-spectrum antibiotics.
 - (三)重型、危重型病例的治疗。
 - (3) Treatment of severe and critical cases.
- 1. 治疗原则: 在对症治疗的基础上,积极防治并发症,治疗基础疾病,预防继发感染,及时进行器官功能支持。
- 1. Treatment principles: on the basis of symptom management, proactively prevent and manage complications, treat underlying diseases, prevent secondary infections, and support organ functions promptly.
 - 2. 呼吸支持:
 - 2. Respiratory support:
- (1) 氧疗: 重型患者应当接受鼻导管或面罩吸氧,并及时评估呼吸窘迫和/或低氧血症是否缓解。
- (1) Oxygen therapy: patients with severe symptoms should be receiving oxygenation through nasal cannulas or oxygen masks. Assess the patient timely to determine whether dyspnea and/or hypoxemia have been alleviated
- (2) 高流量鼻导管氧疗或无创机械通气: 当患者接受标准氧疗后呼吸窘迫和/或低氧血症无法缓解时,可考虑使用高流量鼻导管氧疗或无创通气。若短时间(1-2 小时)内病情无改善甚至恶化,应当及时进行气管插管和有创机械通气。
- (2) High flow nasal cannula or non-invasive ventilation: when patients with dyspnea and/or hypoxemia do not respond to regular oxygen therapy, consider using high flow nasal cannula or non-invasive ventilation. If the symptoms do not improve or worsen within a short period of time (1-2 hours), tracheal intubation and invasive mechanical ventilation should be used.
- (3)有创机械通气:采用肺保护性通气策略,即小潮气量(6-8mL/kg 理想体重)和低水平气道平台压力(≤30mlH2O2)进行机械通气,以减少呼吸机相关肺损伤。在保证气道平台压≤35cmH2O时,可适当采用高 PEEP,保持气道温化湿化,避免长时间镇静,早期唤醒患者并进行肺康复治疗。较多患者存在人机不同步,应当及时使用镇静以及肌松剂。根据气道分泌物情况,选择密闭式吸痰,必要时行支气管镜检查采取相应治疗。
- (3) Invasive mechanical ventilation: using lung-protective ventilation strategy (LPVS), i.e. low tidal volume of 6-8ml/kg ideal body weight, and low inspiratory pressure (plateau pressure <30cm H2O) for mechanical ventilation in order to reduce ventilation-associated lung injury. Higher PEEP may be used appropriately while maintaining airway plateau pressure under 35cm H2O. Maintain airway warming and humidification. Avoid long-term sedation to facilitate early awakening and pulmonary rehabilitation treatment. Patient-ventilator asynchrony is common. Sedation and muscle relaxant should be used

appropriately. Choose airtight suctioning depending on the status of airway secretions. When necessary, conduct a bronchoscopy and give treatment accordingly.

- (4) 挽救治疗:对于严重 ARDS 患者,建议进行肺复张。在人力资源充足的情况下,每天应当进行 12 小时以上的俯卧位通气。俯卧位机械通气效果不佳者,如条件允许,应当尽快考虑体外膜肺氧合(ECMO)。其相关指征:①在 Fi02>90%时,氧合指数小于 80mmHg,持续 3-4 小时以上;②气道平台压≥35cmH20。单纯呼吸衰竭患者,首选 VV-ECMO 模式;若需要循环支持,则选用 VA-ECMO 模式。在基础疾病得以控制,心肺功能有恢复迹象时,可开始撤机试验。
- (4) Salvage therapy: for patients with severe ARDS, a recruitment maneuver is recommended. When human resources allow, prone ventilation should be carried out for 12 hours or more every day. If prone ventilation is ineffective, extracorporeal membrane oxygenation (ECMO) should be considered ASAP if conditions allow. Indications: When FiO2 > 90%, oxygenation index < 80mm Hg and lasting for more than 3-4 hours; airway plateau pressure > 35cm H2O. VV-ECMO is preferred for patients with respiratory failure only. VA-ECMO should be used for patients who also require circulation support. Weaning trials may be considered when the underlying diseases are controlled, and the cardiopulmonary functions of the patient show signs of recovery.
- 3. 循环支持: 在充分液体复苏的基础上,改善微循环,使用血管活性药物,密切监测患者血压、心率和尿量的变化,以及动脉血气分析中乳酸和碱剩余,必要时进行无创或有创血流动力学监测,如超声多普勒法、超声心动图、有创血压或持续心排血量(PiCCO)监测。在救治过程中,注意液体平衡策略,避免过量和不足。
- 3. Circulatory support: on the basis of sufficient fluid resuscitation, improve microcirculation, use vasoactive drugs, closely monitor the changes in the patient's blood pressure, heart rate, urine output, lactate and base excess in arterial-blood gas tests. When necessary, monitor hemodynamics using non-invasive or invasive means, including Doppler ultrasound, echocardiogram, invasive blood pressure or Pulse Contour Cardiac Output (PiCCO) monitoring. During treatment, pay attention to fluid balance strategies to avoid hypervolemia and hypovolemia.

如果发现患者心率突发增加大于基础值的 20%或血压下降大约基础值 20%以上时, 若伴有皮肤灌注不良和尿量减少等表现时, 应密切观察患者是否存在脓毒症休克、消化道出血或心功能衰竭等情况。

If the patient's heart rate suddenly increased by more than 20% of the baseline value, or the blood pressure dropped by more than 20% of the baseline value, closely monitor the patient for septic shock, GI bleeding, or heart failure if symptoms like poor skin perfusion and decreased urine output are also present.

- 4. 肾功能衰竭和肾替代治疗: 危重症患者的肾功能损伤应积极寻找导致肾功能损伤的原因,如低灌注和药物等因素。对于肾功能衰竭患者的治疗应注重体液平衡、酸碱平衡和电解质平衡,在营养支持治疗方面应注意氮平衡、热量和微量元素等补充。重症患者可选择连续性肾替代治疗(continuous renal replacement therapy, CRRT)。其指征包括: ①高钾血症; ②酸中毒; ③肺水肿或水负荷过重; ④多器官功能不全时的液体管理。
- 4. Renal failure and renal replacement therapy: for severely and critically ill patients who have renal damage, actively investigate the causes of renal impairment such as poor perfusion or medication. In patients with renal failure, pay attention to fluid balance, pH balance and electrolyte balance. For nutrition support, pay attention to nitrogen balance and the supplement of calories and trace elements. Continous renal replacement therapy (CRRT) may be used for severely ill patients. Indications include: (1) hyperkalemia; (2) acidosis; (3) pulmonary edema or hypervolemia; (4) fluid management under multiple organ dysfunction
- 5. 康复者血浆治疗:适用于病情进展较快、重型和危重型患者。用法用量参考《新冠肺炎康复者恢复期血浆临床治疗方案(试行第二版)》。

- 5. Use of convalescent plasma collected from recovered patients: indicated for severely or critically ill patients with rapid disease progression. For usage and dosage, see "COVID-19 Clinical Treatment Plan Using Convalescent Plasma Collected from Recovered Patients (Provisional 2nd edition)".
- 6. 血液净化治疗:血液净化系统包括血浆置换、吸附、灌流、血液/血浆滤过等,能清除炎症因子,阻断"细胞因子风暴",从而减轻炎症反应对机体的损伤,可用于重型、危重型患者细胞因子风暴早中期的救治。
- 6. Blood purification treatment: techniques such as plasma exchange, plasma absorption, plasma perfusion, blood/plasma filtration may clear inflammatory cytokines, inhibit "cytokine storm", therefore reduce inflammation-induced damage to the body and can be used in the early/mid-phase treatment of severely and critically ill patients experiencing cytokine storms.
- 7. 免疫治疗:对于双肺广泛病变者及重型患者,且实验室检测IL-6水平升高者,可试用托珠单抗治疗。首次剂量 4-8mg/kg,推荐剂量为 400mg、0.9%生理盐水稀释至 100ml,输注时间大于 1小时;首次用药疗效不佳者,可在 12小时后追加应用一次(剂量同前),累计给药次数最多为 2次,单次最大剂量不超过 800mg。注意过敏反应,有结核等活动性感染者禁用。
- 7. Immune therapy: for patients with extensive and bilateral lung disease and severely ill patients with elevated IL-6 levels, treatment with tocilizumab may be attempted. The initial dose should be 4-8mg/kg, with the recommended dosage being 400mg. Dilute with 0.9% saline to 100ml and infuse over the course of more than 1 hour. Repeat once after 12 hours (same dosage) if the response to the first dose was poor. Maximum two cumulative doses. Single maximum dose is 800mg. Pay attention to allergic reactions. Prohibited in patients with active infections such as tuberculosis.
 - 8. 其他治疗措施:
 - 8. Other treatment measures:

对于氧合指标进行性恶化、影像学进展迅速、机体炎症反应过度激活状态的患者,酌情短期内(3-5 日)使用糖皮质激素,建议剂量不超过相当于甲泼尼龙 1~2mg/kg/日,应当注意较大剂量糖皮质激素由于免疫抑制作用,会延缓对冠状病毒的清除;可静脉给予血必净 100ml/次,每日 2 次治疗;可使用肠道微生态调节剂,维持肠道微生态平衡,预防继发细菌感染。

For patients with progressively deteriorating oxygenation index, rapid imaging progression, and overactive inflammatory responses, short-term (3-5 days) glucocorticoid treatment may be used at the clinician's discretion. It's recommended that the dosage should not exceed the equivalence of methylprednisolone at 1-2mg/kg/day, since the immunosuppressive function of high-dose glucocorticoid may delay the clearance of coronavirus from the system. Xuebijing may be given intravenously at 100ml twice a day. Probiotics can be given to maintain intestinal microbiome balance and to prevent secondary bacterial infection.

儿童重型、危重型病例可酌情考虑给予静脉滴注丙种球蛋白。

IV infusion of gamma immunoglobulin may be considered for severely or critically ill children.

患有重型或危重型新型冠状病毒肺炎的孕妇应积极终止妊娠,剖腹产为首选。

Pregnant patients should be encouraged to terminate pregnancy, preferably with C-section.

患者常存在焦虑恐惧情绪,应当加强心理疏导。

Patients often have anxiety and fear, and psychological counseling should be strengthened.

(四) 中医治疗。

(4) Treatment by Traditional Chinese Medicine

本病属于中医"疫"病范畴,病因为感受"疫戾"之气,各地可根据病情、当地气候特点以及不同体质等情况,参照下列方案进行辨证论治。涉及到超药典剂量,应当在医师指导下使用。

This disease belongs to the category of "epidemic" disease in TCM. The cause of the disease is to invasion the qi of "epidemic evil". All regions can refer to the following regimens for syndrome

differentiation and treatment according to the condition, local climatic characteristics and different physical constitution. In case of overdosage in pharmacopoeia, it should be used under the guidance of a physician.

十一、出院标准和出院后注意事项

XI. Criteria for discharge and notes after discharge

- (一) 出院标准。
- (1) Criteria for discharge
- 1. 体温恢复正常 3 天以上;
- 1. Normal body temperature for 3 days or more
- 2. 呼吸道症状明显好转;
- 2. 2. Significant improvement of respiratory symptoms
- 3. 肺部影像学显示急性渗出性病变明显改善;
- 3. Chest radiology findings show substantial improvement of acute exudative lesions.
- 4. 连续两次痰、鼻咽拭子等呼吸道标本核酸检测阴性(采样时间至少间隔24小时)。
- 4. Two consecutive negative nucleic acid tests using respiratory tract samples (taken at least 24 hours apart).

满足以上条件者可出院。

Those meeting the requirements above may be released from isolation or hospital.

- (二) 出院后注意事项。
- (2) Matters for attention after hospital discharge.
- 1. 定点医院要做好与患者居住地基层医疗机构间的联系,共享病历资料,及时将出院患者信息推送至患者辖区或居住地居委会和基层医疗卫生机构。
- 1. Designated hospitals should communicate with primary care facilities at the patient's place of residence and share medical records. Information on the discharged patients should be forwarded to the relevant neighbourhood committees and primary care facilities in a timely manner.
- 2. 患者出院后,建议应继续进行14天的隔离管理和健康状况监测,佩戴口罩,有条件的居住在通风良好的单人房间,减少与家人的近距离密切接触,分餐饮食,做好手卫生,避免外出活动。
- 2. Discharged patients are at increased risk of acquiring other pathogens due to their reduced immune functions during recovery. It's recommended that the patients: continue to self-monitor for 14 days, wear masks, live in well-ventilated individual suites if possible, reduce close contact with family members, eat separately, practice good hand hygiene, and avoid going outside.
 - 3. 建议在出院后第2周和第4周到医院随访、复诊。
 - 3. Follow-up visits are recommended at 2 and 4 weeks after discharge.
 - 十二、转运原则
 - XII. Transportation principles

按照国家卫生健康委印发的《新型冠状病毒感染的肺炎病例转运工作方案(试行)》执行。

Implement in accordance with the "Novel Coronavirus Pneumonia Case Transfer Program (Provisional)" released by our Commission.

十三、医疗机构内感染预防与控制

XIII. Prevention and Control of Infection in Medical Establishments

严格按照国家卫生健康委《医疗机构内新型冠状病毒感染预防与控制技术指南(第一版)》、《新型冠状病毒感染的肺炎防护中常见医用防护用品使用范围指引(试行)》的要求执行。

Strictly follow the requirements in the "Technical Guidelines for the Prevention and Control of Novel Coronavirus Infection in Medical Establishments (1st Edition)" and "Guidelines on the Usage of Common Medical Protective Equipment in the Management of COVID-19 (Provisional)".

抄送:各省、自治区、直辖市及新疆生产建设兵团应对新型冠状病毒肺炎疫情联防联控机制(领导小组、指挥部)。

Copy sent to: The joint mechanism (leading group, command department) for the prevention and control of the novel coronavirus pneumonia epidemic of each province, autonomous region, and directly governed municipality, as well as for the Xinjiang Construction and Production Corps.

国家卫生健康委办公厅 2020 年 3 月 3 日印发 General Office of the National Health Commission Distributed on March 3rd, 2020

