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Clinical Practice Guidelines

Shanghai expert consensus on clinical protocol for traditional Chinese medicine treatment of COVID-19 among the elderly population (second edition)



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ABSTRACT

This document is the revised edition of the previously issued *Shanghai Expert Consensus on Clinical Protocol for Traditional Chinese Medicine Treatment of COVID-19 among the Elderly Population*. Based on the clinical experience and the *Protocol for Diagnosis and Treatment of COVID-19 (Trial 9th Edition)*, this revised edition provides treatment approaches and recommendations to proactively cope with Omicron variant and increase the therapeutic efficacy for coronavirus disease 2019 among the elderly population in Shanghai, China.

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1. Introduction

Shanghai is a metropolitan city with a large aging population, where 5.81 million people (23.4% of the overall population) are over 60 years old [1]. Data from China and Italy revealed a case-fatality rate of 2.3% in patients with COVID-19, with more than 50% of the fatalities occurring in patients 50 years of age or older [2]. In the largest reported series from Northern Italy, case-fatality rate in patients 64 years or older was 36%, substantially higher than in younger patients [3]. Under the ongoing epidemic of coronavirus disease 2019 (COVID-19) caused by Omicron variant in Shanghai, traditional Chinese medicine (TCM) treatment is one tool that can be used for critical cases, especially to improve treatment efficacy among COVID-19 cases in the elderly population. This expert consensus is released based on the symptoms of

COVID-19 caused by Omicron variant in conjunction with its etiology and pathogenesis specific to the elderly population, and based on the *Protocol for Diagnosis and Treatment of COVID-19 (Trial 9th Edition)* [4]. The TCM experts searched domestic and foreign studies, consulted with other experts, and discussed their ideas in order to formulate a common understanding of the topic. This consensus is based on existing research to develop a declarative document, focusing on feasible approaches for our current clinical reality.

2. The application principles of TCM in the elderly population with COVID-19

- (1) The goals of TCM treatment are to shorten COVID-19 nucleic acid polymerase chain reaction negativity conversion time, slow disease progression, and reduce mortality.
- (2) For asymptomatic and mild cases, or those without high-risk factors or with well-controlled underlying chronic diseases, disease management follows the “Shanghai Protocol for Adults” [5] based on the *Protocol for Diagnosis and Treatment of COVID-19 (Trial 9th Edition)* [4].

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- (3) For moderate cases with high-risk factors, severe to critical cases, or patients with poorly controlled underlying chronic diseases, clinicians should identify the treatment priorities between COVID-19 and these underlying diseases, and pay close attention to any changes in these underlying conditions. A multidisciplinary team is recommended to establish individualized treatment strategy to address clinical factors associated with disease aggravation, halt or reverse disease progression and thus reduce mortality.
- (4) Elderly patients often have multiple underlying diseases. TCM theory considers decline of healthy qi with age, which results in insidious onset of disease signs and symptoms. In these patients, early identification, diagnosis, and intervention of disease are important. When the patients present with fatigue, drowsiness, loss of appetite or decreased food intake, or constipation, along with decline of oxygen level, dynamic reduction in serum absolute lymphocyte count, dynamic elevation of inflammatory cytokines and blood coagulation indicators such as D-dimer, and notable progression of lung infiltration by chest imaging, initial intensive care is crucial to prevent mild or moderate cases progressing to severe or critical conditions.
- (5) For newly infected moderate cases with a deficiency of healthy qi, the treatment strategy is to replenish qi, clear heat and resolve dampness in order to rapidly halt disease progression. The recommended herbal formula for this strategy is shown in Table 1.
- (6) For severe and critical cases, the treatment strategy is to clear the lung, dredge intestines, remove toxins, and cool blood. The recommended formula for this strategy is shown in Table 2.

3. The primary TCM strategies for elderly population with COVID-19

Elderly patients tend to experience a deficiency in healthy qi, weakness of the *zang-fu* organs, and poor circulation of qi and blood. Thus, elderly patients with COVID-19 are at risk of rapid deterioration because of the multiple underlying chronic diseases. When treating elderly patients with TCM, it is important to clear pathogenic factors while simultaneously working to protect and replenish healthy qi through invigorating the spleen and reinforcing the kidney, or activate blood. In choosing clinical treatment strategies, identifying the status or urgency of the disease pattern takes priority. Good clinical judgement takes into consideration how to balance the two treatment aspects between relieving acute symptoms in the short term, and protecting healthy qi for the long run. To help prioritize between removing pathogenic factors and reinforcing healthy qi, appropriate treatment strategies based on core symptoms and pathogenesis may include: (1) removing pathogenic factors being the major goal, supplemented by reinforcing healthy qi; (2) removing pathogenic factors and reinforcing healthy qi; (3) reinforcing healthy qi, securing yang and preventing collapse.

Timely administration of medicine and using accurate treatment strategies (e.g., fine-tuning the proportion of unblocking, clearing, and supporting strategies in a formula) are essential for regulation of the overall state. In addition to oral or intragastric administration, TCM injections are recommended for treating critical cases.

It is worth noting that the two recommended formulas can be modified according to the patient's actual conditions. Detailed modifications are explained as follows.

- (1) For a persistent high fever with an excess pattern, the treatment strategy is to cool blood, remove toxins and dredge intestines. Add the following herbs (Table 3) to the recom-

Table 1

The basic formula for newly infected moderate cases.

Chinese Pinyin name	Latin name	Dose
Sheng Huangqi	Radix Astragali	15 g
Shengshaishen*	Radix et Rhizoma Ginseng Cruda	10 g
Jingjie	Herba Schizonepetae	9 g
Cangzhu	Rhizoma Atractylodis	15 g
Guanghuoxiang	Herba Pogostemonis	9 g
Jinyinhua	Flos Lonicerae Japonicae	15 g
Huzhang	Rhizoma Polygoni Cuspidati	20 g
Lugen	Rhizoma Phragmitis	30 g
Mudanpi	Cortex Moutan	9 g
Sheng Gancao	Radix et Rhizoma Glycyrrhizae	9 g

* 10 g of Xiyangshen (Radix Panacis Quinquefolii) can be used interchangeably.

Table 2

The basic formula for severe and critical cases.

Chinese Pinyin name	Latin name	Dose
Zhi mahuang	Herba Ephedrae Praeparata	10 g
Kuxingren	Semen Armeniacae Amarum	10 g
Sheng Shigao	Gypsum Fibrosum (decoct first)	30–90 g
Jinyinhua	Flos Lonicerae Japonicae	20 g
Zhimu	Rhizoma Anemarrhenae	10 g
Zhebeimu	Bulbus Fritillariae Thunbergii	15 g
Quan Gualou	Fructus Trichosanthis	30 g
Tinglizi	Semen Lepidii	15 g
Chishao	Radix Paeoniae Rubra	15 g
Xuanshen	Radix Scrophulariae	20 g
Sheng Dihuang	Radix Rehmanniae	30 g
Sheng Dahuang	Radix et Rhizoma Rhei (decoct last)	6–9 g

Table 3

Herbs recommended for persistent high fever.

Chinese Pinyin name	Latin name	Dose
Huangqin	Radix Scutellariae	30 g
Huanglian	Rhizoma Coptidis	6 g
Shengma	Rhizoma Cimicifugae	30 g
Qinghao	Herba Artemisiae Annuae	30 g
Shuiniujiao	Cornu Bubali (decoct first)	30 g
Mudanpi*	Cortex Moutan	30 g

* Danshen (Radix et Rhizoma Salviae Miltiorrhizae) can be used interchangeably.

mended formulas. Chinese patent medicines (Table 4) are also recommended. Acupuncture treatment is suggested. Acupuncture points: Dazhui (GV14) and Quchi (LI11).

- (2) For altered state of consciousness, e.g. delirium, deficiency or excess should be distinguished. The treatment strategy for deficiency pattern is to protect fluids, replenish qi and nourish yin. Shengshaishen (Radix et Rhizoma Ginseng Cruda) 10 g or Xiyangshen (Radix Panacis Quinquefolii) 10 g (or their powder) is recommended for the formulas. Also, Shengmai Injection (20–60 mL) is also suggested by intravenous drip, twice a day. The treat-

Table 4

Recommended Chinese patent medicines for persistent high fever.

Name	Dosage
Zixue Powder	1.5–3 g for each dose (oral route), 2 doses a day
Angong Niu Huang Pill	1–3 pills (oral route after dissolving in warm water), 2–3 doses a day
Antelope horn Power	0.6 g for each dose, 2–3 doses a day
Tanreqing Injection	Intravenous drip, 40 mL for each dose, 2 doses a day

ment strategy for excess phlegm heat includes adding the following herbs (Table 5) to the recommended formulas. The recommended Chinese patent medicines are listed in Table 6. Acupuncture treatment is suggested. Acupuncture points: Renzhong (GV26), Laogong (PC8) and Zhongchong (PC9). Method: Shallow puncture or prick for mild bloodletting.

- (3) For constipation, the treatment strategy is to move the bowels and benefit the lung. For deficiency patterns, Quanguai (Fructus Trichosanthis) 30 g, Huomaren (Fructus Cannabis) 30 g and Houpo (Cortex Magnoliae Officinalis) 20 g are recommended additions to the formulas; the decoction can be taken orally or intragastrically. For excess patterns, add the following herbs (Table 7) to the recommended formulas and take the decoction orally or intragastrically. Acupuncture treatment is suggested. Acupuncture points: Zhigou (SJ6), Zhaohai (KI6) and Tianshu (ST25).
- (4) For sticky sputum that is difficult to expectorate, the treatment strategy is to clear heat, resolve phlegm, regulate qi and disperse stagnation. Add the following herbs (Table 8) to the recommended formulas. Recommended Chinese patent medicine: Tanreqing Injection: 40 mL, twice a day, intravenous drip. Acupuncture treatment is suggested. Acupuncture points: Tiantu (CV22), Fenglong (ST40) and Chize (LU5).

Table 5
Recommended herbs for excess phlegm heat syndrome.

Chinese Pinyin name	Latin name	Dose
Shichangpu	Rhizoma Acori Tatarinowii	12 g
Yuanzhi	Radix Polygalae	9 g
Yujin	Radix Curcumae	15 g
Dannanxing	Arisaema cum Bile	15 g
Tianzhuhuang	Concretio Silicea Bambusae	15 g

Table 6
Recommended Chinese patent medicines for excess phlegm heat syndrome.

Chinese Pinyin name	Dosage	Actions/indications
Shengmai Injection	20–60 mL for each dose, 2 doses a day, per oral	Deficiency pattern
Xingnaojing Injection	20 mL for each dose, 2 doses a day, per oral	Excess pattern
Suhexiang Pill	1–2 pills for each dose, 2–3 doses a day, per oral	Loss of consciousness
Angong Niu Huang Pill	1–3 pills for each dose, 2–3 doses a day, per oral	Clears heat and refreshes the mind
Zhibao Pill	1 pill for each dose, 2–3 doses a day, per oral (oral or nasal route after dissolved in warm water)	Refreshes the mind and calms the mind

Table 7
Recommended herbs for excess patterns of constipation.

Chinese Pinyin name	Latin name	Dose
Sheng Dahuang	Radix et Rhizoma Rhei	10–30 g
Houpo	Cortex Magnoliae Officinalis	20 g
Zhishi	Fructus Aurantii Immaturus	20 g
Mangxiao	Natrii Sulfas (dissolved)	10 g

These herbs are also recommended for use in enema format, in which case the dose of Mangxiao can be increased up to 30 g. Alternatively, 10–30 g of Sheng Dahuang (Radix et Rhizoma Rhei) powder mixed in water can also be taken orally.

Table 8
Recommended herbs for difficult expectoration of sticky sputum.

Chinese Pinyin name	Latin name	Dose
Pugongying	Herba Taraxaci	30 g
Maidong	Radix Ophiopogonis	30 g
Yiyiren	Semen Coicis	30 g
Dongguazi	Semen Benincasae	30 g
Jiegeng	Radix Platycodonis	9 g
Zhuli Shui	Succus Bambusae water	30 mL
Zaojiaoci	Spina Gleditsiae*	15 g
Dannanxing	Arisaema cum Bile*	6 g

* Used for intractable sputum retention.

- (5) For progressing infiltration of lung lesions seen on chest imaging, the treatment strategy is to clear heat and activate blood circulation. Add the following herbs (Table 9) to the recommended formula for severe or critical cases. The recommended Chinese patent medicines are shown in Table 10.
- (6) For persistent turbid greasy tongue coating, chest tightness, nausea, vomiting, headache, and restlessness due to qi stagnation and pathogenic factors hidden in the pleuro-diaphragmatic interspace (known as *Mo Yuan* in Chinese medicine), the treatment strategy is to remove pathogenic factors out of the pleuro-diaphragmatic interspace and facilitate functional activities of qi. The following herbs (Table 11) are recommended additions to the formulas.
- (7) For qi deficiency, it is important to invigorate qi as early as possible to help remove pathogenic factors. Chinese herbal formula modifications include adding Huangqi (Radix Astragali) up to 30–60 g and Dangshen (Radix Codonopsis) 15 g or Taizishen (Radix Pseudostellariae) 30 g to the recommended

Table 9
Recommended herbs for aggravated infiltration lung lesions on chest imaging.

Chinese Pinyin name	Latin name	Dose
Jinqiaomai	Rhizoma Fagopyri Dibotryis	30 g
Yuxingcao	Herba Houttuyniae	30 g
Huangqin	Radix Scutellariae	15 g
Sangbaipi	Cortex Mori	15 g
Zhi Zisuzi	Fructus Perillae Praeparata	15 g
Mabiancao	Herba Verbenae	30 g
Guijianyu	Ramulus Euonymi	15 g
Dilong	Pheretima	15 g

Table 10
Recommended Chinese patent medicines for progressing infiltration of lung lesions on chest imaging.

Name	Dosage (intravenous drip)
Xuebijing Injection	100 mL for each dose, 2 doses a day
Tanreqing Injection	40 mL for each dose, 2 doses a day

Table 11
Recommended herbs for persistent turbid greasy tongue coating.

Chinese Pinyin name	Latin name	Dose
Binglang	Semen Arecae	12 g
Houpo	Cortex Magnoliae Officinalis	12 g
Caoguo	Fructus Tsao	9 g
Shaoyao	Radix Paeoniae	15 g
Huangqin	Radix Scutellariae	15 g
Yiyiren	Semen Coicis	30 g
Sharen	Fructus Amomi (decoct last)	6 g
Roudoukou	Semen Myristicae (decoct last)	6 g

formulas. For severe qi deficiency, use Dushen Tang (namely Sole Ginseng Decoction), and the type of ginseng can be used interchangeably from Xiyangshen 15–60 g, Shengshaishen 15–60 g, Hongshen (Radix et Rhizoma Ginseng Rubra) 15–60 g, to Wild Ginseng 4–6 g when necessary. Alternatively, ginseng can be taken by cooked decoction or ground powder with water. For severe kidney deficiency, add Jingui Shenqi Pill (Golden Cabinet's Kidney Qi Pill) or the following herbs (Table 12) into the recommended formulas. For severe Yang deficiency, add principal herbs of Shenfu Tang (Ginseng and Aconite Decoction), Shenfu Longmu Tang (Ginseng and Aconite Decoction plus Os Draconis and Oyster) or Sini Tang (Frigid Extremities Decoction) to the recommended formulas. The Chinese patent medicines in Table 13 are also recommended. Acupuncture treatment is suggested. Acupuncture points: Zusanli (ST36), Qihai (CV6) and Zhongwan (CV12).

- (8) For deficiency of the spleen and stomach, bitter and cold medicines should be used with caution; sweet and cold medicines can be used if necessary. Healthy diet needs to be taken into account. Drugs for activating and invigorating spleen are recommended, including the core herbs in Xiangsha Liujun Wan (Six Gentlemen Pill plus Costusroot and Amomum), Jianpi Wan (Spleen-Fortifying Pill) and Buzhong Yiqi Wan (Middle Energizer-Supplementing and Qi-Boosting Pill). Alternatively, the patients can take the pills orally with warm water. Acupuncture treatment is suggested. Acupuncture points: Zusanli (ST36) and Neiguan (PC6).

4. The primary TCM strategies for COVID-19 in the elderly population with chronic underlying diseases

Since chronic underlying diseases have a critical role for increasing morbidity and mortality in elderly patients with COVID-19, it is important to determine the treatment priorities and place more emphasis on the chronic underlying diseases in order to halt disease progression and protect the Zang-fu organs in this population. Other measures include general medical care, sufficient management of the chronic underlying diseases, proper daily nutrition, supporting normal bowel movements and preventing aspiration pneumonitis. The recommended formulas or treatment strategies for three underlying diseases are listed as follows.

Table 12
Recommended herbs for severe kidney deficiency.

Chinese Pinyin name	Latin name	Dose
Shanzhuyu	Fructus Corni	15–30 g
Shudihuang	Radix Rehmanniae Praeparata	15–30 g
Bajitian	Radix Morindae Officinalis	15 g
Roucongrong	Herba Cistanches	15 g
Zhi Wumei	Fructus Mume Praeparata cum Melle	6–9 g

Table 13
Recommended Chinese patent medicines for severe Yang deficiency.

Name	Dosage (intravenous)	Indications
Shengmai Injection	20–60 mL for each dose, 2 doses a day	Qi deficiency
Shenfu Injection	20–60 mL for each dose, 2 doses a day	Unstable blood pressure
Xuebijing Injection	100 mL for each dose, 2 doses a day	Qi deficiency coupled with blood stasis

- (1) For cases with chronic renal disease, the treatment strategy is to replenish qi, warm yang, activate blood and dredge intestines. The Chinese herbal formula should include an increased dose of Huangqi (Radix Astragali) to 30–90 g and the following additions (Table 14) to the recommended formulas.
- (2) For cases with chronic cardiac disease, the treatment strategy is to replenish qi, warm yang, activate blood and promote urination. Add the following herbs (Table 15) to the recommended formulas.
- (3) For cases with deficits caused by cerebrovascular disease, the treatment strategy is to replenish qi, warm yang, activate blood and dredge collaterals. The core herbs from Buyang Huanwu Tang (Yang-Supplementing and Five-Returning Decoction), Xuefu Zhuyu Tang (Blood Stasis-Expelling Decoction), Tongqiao Huoxue Tang (Orifice-Unblocking and Blood-Invigorating Decoction), and Dahulu Dan (Major Collateral-Activating Elixir) can be added to the recommended formulas.

This expert consensus was given only as a reference for clinical decision making. While treating individualized patients, doctors need to take all causative factors into consideration, identify the etiology, pathogenesis and symptoms, make treatment strategy based on pattern identification, and modify the herbal dosage regimen according to the patient's volume of fluid intake and output. Acupuncture treatment is suggested for once a day: use disposable filiform needles with a plastic guide tube, conduct even reinforcing-reducing manipulation, and retain the needles for 30 minutes for each treatment.

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Table 14
Recommended herbs for cases with chronic renal disease.

Chinese Pinyin name	Latin name	Dose
Pao Fuzi	Radix Aconiti Lateralis Praeparata	12 g
Chaihu	Radix Bupleuri	12 g
Gegen	Radix Puerariae Lobatae	15 g
Chuanxiong	Rhizoma Chuanxiong	12 g
Jiangcan	Bombyx Batryticatus	12 g
Yimucao	Herba Leonuri	30 g
Danshen	Radix et Rhizoma Salviae Miltiorrhizae	30 g
Zhi Dahuang	Radix et Rhizoma Rhei Praeparata (decoct last)	9 g

Table 15
Recommended herbs for cases with chronic cardiac disease.

Chinese Pinyin name	Latin name	Dose
Renshen	Radix et Rhizoma Ginseng	15 g
Zhi Fuzi	Radix Aconiti Lateralis Praeparata	15 g
Guizhi	Ramulus Cinnamomi	12 g
Fuling	Poria	30 g
Zhuling	Polyporus	30 g
Zexie	Rhizoma Alismatis	15 g
Yimucao	Herba Leonuri	30 g
Danshen	Radix et Rhizoma Salviae Miltiorrhizae	30 g

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Declaration of competing interests

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