Chronic obstructive pulmonary disease (COPD) is a major chronic disease that seriously endangers public health. Some remarkable results have shown that Chinese medicine has an obvious clinical effect in preventing and treating COPD. To further promote the normative use of Chinese medicine to better guide the clinical diagnosis and treatment of COPD, the World Federation of Chinese Medicine Societies developed a panel to establish the guidelines by systematically evaluating, based on the revision and transformation of Guidelines for Chinese Medicine Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease released by the China Association of Chinese Medicine in 2019 (Standard No: T/CACM 1319-2019), the latest clinical research evidence at home and abroad, formatting the International Clinical Practice Guideline of Chinese Medicine—Chronic Obstructive Pulmonary Disease, and publishing in both Chinese and English. The guidelines consist of 12 parts: preface, introduction, scope, normative references, terms and definitions, disease diagnosis and staging, severity assessment, etiology and pathogenesis, syndrome differentiation and treatment, other treatment, prevention and care, and appendix. They also standardize the contents of traditional Chinese medicine (TCM) etiology and pathogenesis, syndrome differentiation and treatment, and prevention and care of COPD. These guidelines are applicable to clinical respiratory physicians of TCM and integrated traditional Chinese and western medicine. The release of these guidelines will help improve the effect and level of Chinese medicine for COPD.

Keywords: Chinese medicine, chronic obstructive pulmonary disease, clinical practice guidelines

INTRODUCTION

Chronic obstructive pulmonary disease (COPD) is a common, preventable, and treatable condition characterized by progressive airflow limitation. Cough, expectoration, dyspnea, and frequent acute exacerbations are the common symptoms of COPD. Due to high prevalence, high mortality, high disability rate, and heavy disease burden, COPD has become a major chronic disease that seriously endangers public health. The global prevalence of COPD is about 11.7%, with about 3.5 million deaths a year. The WHO estimates that more than 4.5 million people worldwide will die each year from COPD and related diseases by 2030. In China, the prevalence of COPD in people aged over 40 years is 13.7%, with nearly 100 million COPD patients. COPD is the third leading cause of death and ranks second in disease burden in terms of disability-adjusted life years in China. Its prevention and treatment conditions are increasingly grim. In recent years, some remarkable results have shown that traditional Chinese medicine (TCM) has an obvious clinical effect in preventing and treating COPD.

To further promote the normative use of Chinese medicine in guiding clinical diagnosis and treatment of COPD in China, The China Association of Chinese Medicine, Henan University of Chinese Medicine, and Lung Disease Branch of China Medical Association of Minorities jointly organized a working group of Guidelines for Chinese Medicine Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease, consisting of multidisciplinary researchers in respiratory diseases (Chinese medicine, western medicine, and integrative Chinese and western medicine), clinical epidemiology, evidence-based medicine, health economics, etc. The release of these guidelines will help improve the effect and level of Chinese medicine for COPD.
and Chinese Materia Medica. Literature document retrieval, Delphi questionnaire surveys, and conference discussions were used to develop the guidelines. First, a search strategy was developed based on the collected clinical problems and outcomes. Then, systematic research and quality evaluation were performed in Chinese literature (including modern literature and ancient books), English literature, and existing relevant international guidelines. Meanwhile, the evidence quality and evidence grading were performed based on the Grading of Recommendations Assessment Development and Evaluation (GRADE) system. The improved Delphi method was also used to conduct questionnaire surveys. After further improving the recommendations, a face-to-face expert consensus meeting was held to develop the guideline recommendations. Finally, the Guidelines for Chinese Medicine Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease was evaluated and released by The China Association of Chinese Medicine (Standard No: T/CACM 1319-2019).

In August 2019, the World Federation of Chinese Medicine Societies, to better apply the Guidelines for Chinese Medicine Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease, developed a panel to systematically evaluate the latest clinical research evidence at home and abroad and revise, transform, and format the International Clinical Practice Guideline of Chinese Medicine—Chronic Obstructive Pulmonary Disease.

Scope

This guideline specifies the contents of TCM etiology and pathogenesis, syndrome differentiation, and the prevention and treatment of COPD. This guideline is applicable to clinical respiratory doctors of TCM and integrated traditional Chinese and western medicine, as well as practitioners of TCM.

Normative References

The following documents are indispensable for the application of this document. For dated references, only the dated version applies to this document. For undated references, the latest edition (including all amendments) applies to this document.

• Global Initiative for Chronic Obstructive Lung Disease (GOLD)
• China’s Expert Consensus on the Diagnosis and Treatment of Acute Exacerbation of Chronic Obstructive Pulmonary Disease (AECOPD) (Updated 2017)
• National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug List (2017 Edition)
• Chinese Medicines Clinical Application Guideline Respiratory Diseases Volume (2016 Edition)
• Pharmacopoeia of the People’s Republic of China (2015 Edition)
• Diagnostic Criteria for Chinese Medicine Syndrome of Chronic Obstructive Pulmonary Disease (2011 Edition)
• Guidelines for Chinese Medicine Diagnosis and Treatment of Chronic Obstructive Pulmonary Disease (2011 Edition)
• International Classification of Diseases Code (ICD-11).

Terms and Definitions

Chronic obstructive pulmonary disease (ICD-11: CA22)

A common disease that can be prevented and treated, characterized by persistent airflow limitation, is referred to as COPD.

Note 1: Airflow limitation is mostly progressive, associated with increased chronic inflammatory response to toxic particles or gases in the airways and lungs.

Disease Diagnosis and Staging

Acute exacerbation stage

AECOPD is an acute exacerbation of respiratory symptoms in patients, leading to additional treatment. Usually, in course of the disease, the patient has an exacerbation in cough, expectoration, and shortness of breath and/or wheezing, has an increased amount of sputum, purulent, or mucopurulent in the short term, and may be associated with fever and other manifestations of inflammation. Different treatment sites and treatment options are selected according to mild, moderate, and severe conditions. COPD is often associated with comorbid conditions; thus, AECOPD needs to be differentiated from acute coronary syndrome, acute congestive heart failure, pulmonary embolism, and pneumonia[1,6].

Acute exacerbation of the dangerous window stage

The acute exacerbation of the dangerous window period means that between the period of AECOPD and the stable period, it is highly likely that an acute exacerbation will occur again, resulting in an increase in hospitalization rate and mortality, mostly within 8 weeks after an acute exacerbation.[7]

Stable stage

This stage refers to patients with cough, expectoration, shortness of breath, and other symptoms that are stable or mild and without acute exacerbation within 6 weeks.[1,8]

Severity Assessment

The assessment of the severity of COPD should be reviewed in the GOLD.[1,9]

Etiology and Pathogenesis

COPD belongs to the category of “dyspnea” and “lung bloating” in Chinese medicine.[8] Root cause deficiency and manifestation excess are the main pathological changes of COPD. Accumulation and damage of healthy qi deficiency are the main pathogeneses of COPD.[10,11] Healthy qi deficiency means the deficiency and damage of the lung, spleen, and kidney, starting with the lung and involving the kidney long term. Healthy qi deficiency is the root cause of COPD, and accumulative damage cannot be recovered. Healthy qi deficiency does not transport generating phlegm and stasis.
which often congeal into accumulation and thus damage the healthy qi. Healthy qi deficiency and accumulation damage are the cause and effect, eventually leading to damage in the shape and qi of the lung. This period is progressive, and recovery is difficult. The acute exacerbation stage is mainly excess syndromes of phlegm (phlegm heat, phlegm turbid) and stasis, combined with healthy qi deficiency. The stable stage is mainly deficiency syndromes of lung qi deficiency, lung spleen qi deficiency, lung kidney qi deficiency, and qi and yin deficiency of the lung and kidney and is commonly combined with blood stasis and phlegm turbidity. In the dangerous window stage, the pathogen excess is gradually removed and the root deficiency shows. Syndromes of phlegm turbidity, phlegm stasis and qi deficiency, and qi and yin deficiency occur. The pathological nature is intermingled deficiency and excess.[12]

**Syndrome Differentiation and Treatment**

In the AECOPD, syndromes of wind cold invading the lung, external cold and internal drink, phlegm turbid obstructing the lung, and phlegm-blinding spiritual orifices are commonly seen.[12-16] In the stable stage, syndromes of lung qi deficiency, lung spleen qi deficiency, lung kidney qi deficiency, and qi and yin deficiency of the lung kidney are commonly seen.[13-16] In acute exacerbation of the dangerous window stage, syndromes of lung kidney qi deficiency combined with phlegm turbid obstructing the lung, lung kidney qi deficiency combined with phlegm turbid obstructing the lung, qi and yin deficiency of lung kidney combined with phlegm turbid obstructing the lung, and qi and yin deficiency of lung kidney combined with phlegm stasis obstructing the lung are commonly seen.[17] Blood stasis is not only the main path of COPD but also a common combining syndrome. For example, blood stasis that combined with phlegm turbid obstructing the lung is the syndrome of phlegm turbid and stasis in the lung, that combined with phlegm heat accumulating the lung is the syndrome of phlegm heat and stasis in the lung, and that combined with lung kidney qi deficiency is the syndrome of lung kidney qi deficiency and blood stasis.[15]

Treatment should be based on the principles of “treating manifestations for acute onset” and “treating the root causes in the stable stage.” In the acute exacerbation stage, the principles are to clear the heat, purify the phlegm, activate the blood, ventilate the lung to descend qi, open the orifice, and consider qi yin. During the stable stage, the treatment is mainly to benefit qi (yang) and nourish yin, combined with expelling phlegm and activating blood circulation.[9,11,16] In the acute exacerbation of dangerous window stage, the syndromes of intermingled deficiency and excess are commonly seen. Treatment involves supplementing the deficiency and strengthening vital qi, resolving the phlegm, and promoting blood circulation.[7,18]

**Acute exacerbation stage**

Research evidence[19,20] shows that Chinese medicine syndrome differentiation and Chinese medicine combined with western medicine for the treatment of AECOPD can significantly improve clinical symptoms, improve lung function, reduce inflammation, etc.

**Wind cold invading lung syndrome**[15]

**Symptoms**

Primary symptoms are cough, wheezing, aversion to cold, white and clear expectoration, thin and white tongue fur, and tight pulse. Secondary symptoms are fever, anhidrosis, nasal obstruction, clear nasal discharge, soreness pain in the body, and floating pulse.

**Diagnosis**

(1) Cough or wheezing, white and clear expectoration; (2) fever, aversion to cold, anhidrosis, or soreness and pain in the body; (3) nasal obstruction, clear nasal discharge; (4) white tongue fur, floating pulse, or floating and tight pulse. Diagnose with 1 and 2 plus one of 3 and 4.

**Therapeutic methods**

Ventilating the lung to dispel cold, relieve cough, and relieve antiasthmatics.

**Formula and herbs**

Modified Sanao decoction (Prescriptions of the Bureau of Taiping People’s Welfare Pharmacy) and Zhisou powder (Medical Revelations) (D, high priority);[15] Zhimahuang (Herba Ephedrae) 9 g, Xingren (Semen Armeniacae Amarum) 9 g, Jingjie (Herba Schizonepetae) 9 g, Zisuzi (Folium Perillae) 9 g, Baiqian (Rhizoma Cynanchi Stauntonii) 9 g, Baibu (Radix Stemonae) 12 g, Jiegeng (Radix Platycodonis) 9 g, Zhiqiao (Fructus Aurantii) 9 g, Shenpi (Pericarpium Citri Reticulatae) 9 g, and Zhigancao (Radix Glycyrrhizae) 6 g.

**Addition and subtraction**

For patients with white and greasy phlegm or white and greasy tongue fur, add Fabanxia (Rhizoma Pinelliae Preparatum) 9 g, Houpo (Cortex Magnolii Officinalis) 9 g, and Fuling (Poria) 12 g. For patients with soreness and pain in the body, add Qianghuo (Rhizoma et Radix Notopterygii) 9 g and Duhuo (Radix Angelicae Pubescents) 9 g. For patients with headache, add Baizhi (Radix Angelicae Dahuricae) 9 g and Gaoben (Rhizoma Ligustici) 6 g. For patients with obvious wheezing, change Zisuzi (Folium Perillae) into Zisuzi (Fructus Perillae) 9 g and add Houpo (Cortex Magnolii Officinalis) 9 g.

**Chinese patent medicines**

(1) Tongxuan Lifei pills (D, high priority): Oral administration, 7 g/time (water-honeyed pills) or 2 pills/time (large honey bolus), 2–3 times/day. (2) Xingsu Zhike granules (D, low priority): Administration after dissolving, 12 g/time, 3 times/day.

**External cold and internal drink syndrome**[15]

**Symptoms**

Primary symptoms were cough, wheezing, shortness of breath, profuse white and thin foam phlegm, chest tightness, inability to lie down, aversion to cold, white and slippery tongue fur,
stringy, and tight pulse. Secondary symptoms were ease in coughing up, snoring in the throat, anhidrosis, sore limbs, stuffy nose, clear nasal discharge, and floating pulse.

**Diagnosis**

(1) Cough or wheezing; (2) aversion to cold, anhidrosis, or stuffy nose, clear nasal discharge, or sore limbs; (3) white and thin foam phlegm, ease in coughing up; (4) snoring in the throat; (5) chest tightness or even reversed flow of qi leading to an inability to lie down; (6) white and slippery tongue fur, stringy and tight pulse, or floating, stringy, and tight pulse. Diagnose with 1 and 2 and two items of 3, 4, 5, and 6.

**Therapeutic methods**

Expelling wind and cold pathogens and warming the lung to dissolve fluid retention.

**Formula and herbs**

Modified Xiaoqinglong decoction (Treatise on Cold Pathogenic Diseases)\(^{[21-23]}\) (D, high priority): Zhimahuang (Herba Ephedrae) 9 g, Guizhi (Ramulus Cinnamomi) 9 g, Ganjiang (Rhizoma Zingiberis) 6 g, Baishaohu (Radix Paeoniae Alba) 9 g, Xixin (Herba Asari) 3 g, Fabanxia (Rhizoma Pinelliae Preparatum) 9 g, Wuweizi (Fructus Schisandrae Chinensis) 6 g, Xingren (Semen Armeniacae Amarum) 9 g, Zisuzi (Fructus Perillae) 9 g, Houpo (Cortex Magnoliae Officinalis) 9 g, and Zhigancao (Radix Glycyrrhizae) 6 g.

**Addition and subtraction**

For patients with qi ascending while coughing and snoring in the throat, add Shegan (Rhizoma Belamcandae) 9 g and Kuandonghua (Flos Farfarae) 9 g. For patients with water retention depression transforming into heat, irritation and thirst, and bitter mouth, subtract Guizhi (Ramulus Cinnamomi) and add Shengshigao (Gypsum Fibrosum) 30 g ( decocting first), Huangqin (Radix Scutellariae) 9 g, and Sangbaipi (Cortex Mori) 12 g. For patients with sore limbs, add Qianghuo (Rhizoma et Radix Nototerpae) 9 g and Duhuo (Radix Angelicae Pubescentis) 12 g. For patients with headache, add Baizhi (Radix Angelicae Dahuricae) 9 g.

**Chinese patent medicines**

Xiaoqinglong Granules (D, high priority): Administration after dissolving, 13 g/time, 3 times/day.

**Phlegm heat accumulating the lung syndrome**\(^{[25]}\)

**Symptoms**

Primary symptoms were cough, wheezing, chest tightness, profuse yellowish greasy phlegm, difficult expectoration, red tongue, yellowish and greasy tongue fur, slippery, and rapid pulse. Secondary symptoms were chest pain, fever, thirst, preference for cold drinks, dry and hard stool, and thick tongue fur.

**Diagnosis**

(1) Cough or wheezing; (2) profuse yellowish or white greasy phlegm; (3) fever or thirst, preference for cold drinks; (4) constipation; (5) red tongue, yellowish and greasy tongue fur, or rapid or slippery and rapid pulse. Diagnose with 1 and 2 and two items of 3, 4, and 5.

**Therapeutic methods**

Clearing the lung to dissolve the phlegm and descending adverse qi for antiasthmatic.

**Formula and herbs**

Modified Qingqi Huatan Pills (Investigations of Medical Formulas) and Beimu Gualou Powder (Medical Revelations)\(^{[24,25]}\) (D, low priority): Gualou (Fructus Trichosanthis) 15 g, Qingbanxia (Rhizoma Pinelliae Preparata) 9 g, Zhebeimu (Bulbus Fritillariae Thunbergii) 9 g, Zhizi (Fructus Gardeniae) 9 g, Sangbaipi (Cortex Mori) 12 g, Huangqin (Radix Scutellariae) 9 g, Xingren (Semen Armeniacae Amarum) 9 g, Baitouweng (Radix Pulsatillae) 12 g, Yuxingcao (Herba Houttuyniae) 15 g, Maidong (Radix Ophiopogonis) 12 g, and Chenpi (Pericarpium Citri Reticulatae) 9 g.

**Addition and subtraction**

For patients with high fever and irritation and constipation, combine with Modified Xuanbai Chengu decoction (Detailed Analysis of Epidemic Warm Diseases)\(^{[20]}\) (B, high priority). For patients with profuse greasy phlegm and difficult expectoration, combine with Sangbaipi decoction (Medical Complete Book; Ancient and Modern)\(^{[27-31]}\) (C, high priority). For patients with gurgling with sputum, wheezing, and inability to lie down, add Tinglizi (Semen Descursivae) 9 g (wrap decoction), Shegan (Rhizoma Belamcandae) 9 g, and Jiegeng (Radix Platycodonis) 9 g. For patients with fishy phlegm, add Jinqiaomai (Rhizoma Fagopyri Dibotrys) 20 g, Yiyiren (Semen Coicis) 12 g, Taoren (Semen Persicae) 9 g, and Dongguaren (Semen Benincasae) 12 g. For patients with obvious chest tightness and pain, add Yanhusuo (Rhizoma Corydis) 9 g, Chishao (Radix Paeoniae Rubra) 12 g, and Zhiqiao (Fructus Aurantii) 12 g. For patients with little but greasy phlegm, thirst, red tongue, eroded tongue fur, and a fine and rapid pulse, subtract Qingbanxia (Rhizoma Pinelliae Preparata) and add Taizishen (Radix Pseudostellariae) 12 g and Shashen (Radix Glehniae) 12 g. Patients with combined blood stasis syndrome of dark complexion and lips, dark purple or bluish tongue, and ecchymosis can be treated with Tongbai granules formula\(^{[32]}\) (D, low priority): Tinglizi (Semen Descursivae), Dilong (Lumbricus), Zhimahuang (Herba Ephedrae), Zhebeimu (Bulbus Fritillariae Thunbergii), Zhidahuang (Radix et Rhizoma Rhei), Chishao (Radix Paeoniae Rubra), Renshen (Radix Ginseng), Maidong (Radix Ophiopogonis), Shichangpu (Rhizoma Acori Tatarinowii), and Aidicha (Japanese Ardisia Herb).

**Chinese patent medicines**

(1) Tanreqing injection\(^{[33-39]}\) (C, high priority): 20–40 mL, add 5% glucose injection or normal saline 250–500 mL, intravenous drip, once a day. (2) Tingbei capsules (D, high priority): Oral administration, four capsules at a time, 3 times a day. (3) For patients with intermingled phlegm heat and blood stasis, choose Xuebijing injection\(^{[40]}\) (C, high priority): 50 mL, intravenous drip of normal saline 100 mL, 2 times a day.
Phlegm turbid obstructing the lung syndrome[^15]

**Symptoms**
Primary symptoms were cough, wheezing, excessive phlegm, white and greasy phlegm, sticky and greasy mouth, white and greasy tongue fur, and slippery pulse. Secondary symptoms were shortness of breath, foam phlegm, ease in coughing up, chest tightness, fullness in the stomach, indigestion and loss of appetite, less food intake, thin tongue, and taut pulse.

**Diagnosis**
(1) Cough or wheezing, shortness of breath; (2) excessive phlegm, white greasy or in foam shape; (3) fullness in the stomach; (4) sticky and greasy mouth, indigestion and loss of appetite, less food intake; (5) white greasy tongue fur, or slippery pulse or slippery taut pulse. Diagnose with 1 and 2 and two of 3, 4, and 5.

**Therapeutic methods**
Drying dampness to resolve phlegm and ventilating lung to descend qi.

**Formula and herbs**
Banxiao Houpo decoction (Synopsis of Golden Chamber) and Sanzi Jiangqi pills (D, low priority): Oral administration, 6 g; Zizhi (Semen Perillae) 9 g

**Addition and subtraction**
For patients with excessive phlegm and wheezing, chest tightness, and inability to lie down, add Mahuang (Herba Ephedrae) 6 g and Tinglizi (Semen Descurainiae) 9 g (wrap decoction). For patients with epigastric distension and depression, add Muxiang (Radix Aucklandiae) 9 g and Jiaobinglang (Semen Arecae) 9 g. For patients with diarrhea, subtract Zisuzi (Semen Raphani) and add Baizhu (Rhizoma Atractylodis Macrocephalae) 12 g, Zexie (Rhizoma Alismatis) 9 g, and Gegen (Radix Puerariae) 9 g. For patients with constipation, add Jiao binglang (Semen Arecae) 9 g and Zhishi (Fructus Aurantii Immaturus) 9 g.

**Chinese patent medicines**
(1) Suzi Jiangqi pills (D, low priority): Oral administration, 6 g/time, 1–2 times/day; (2) Linggui Kechuanning capsules[^42] (D, low priority): Oral administration, five capsules per time, 3 times/day.

Phlegm-blinding spiritual orifices syndrome[^15]

**Symptoms**
Primary symptoms were wheezing, shortness of breath, absent-mindedness, lethargy, coma, delirium, white, greasy, and yellowish tongue fur. Secondary symptoms were snoring in the throat, convulsions in the limbs, dark red, purple tongue, slippery, and rapid pulse.

**Diagnosis**
(1) Abnormality of mentality (irritation, absent-mindedness, lethargy, delirium, coma); (2) convulsions in the limbs; (3) wheezing, short breath; (4) snoring in the throat; (5) pale or red tongue, white greasy or yellow greasy tongue fur, or slippery or rapid pulse. Diagnose with one of 1 and 2 plus two of 3, 4, and 5.

**Therapeutic methods**
Dissipating phlegm for resuscitation.

**Formula and herbs**
Modified Ditan decoction[^8] (Fine Prescriptions of Wonderful Efficacy) (D, high priority): Qingbanxia (Rhizoma Pinelliae Preparata) 9 g, Tiananxing (Rhiza Arisaematis) 6 g, Tianzhuhuang (Concretio Silicea Bambusae) 6 g, Fuling (Poria) 15 g, Chenpi (Pericarpium Citri Reticulatae) 9 g, Zhishi (Fructus Aurantii Immaturus) 9 g, Danshen (Radix Salviae Miltiorrhizae) 15 g, Renshen (Radix Ginseng) 9 g, Shichangpu (Rhizoma Acori Tatarinowii) 6 g, Xixin (Herba Asari) 3 g, and Shengjiang (Rhizoma Zingiberis Recens) 6 g.

**Addition and subtraction**
For patients with cold syndromes of white greasy tongue fur, add Suhexiang pills (D, high priority), taken with ginger decoction or warm water, 1 pill/time, 1–2 times/day. For patients with body heat, delirium, red tongue, and yellowish tongue fur, subtract Xixin (Herba Asari) and Tiannanxing (Rhiza Arisaematis) and add Shuanghuang (Cornu Bubali) 30 g (decocoting first), Shuiniujia (Cornu Bubali) 30 g, Xuanwu (Radix Scrophulariae) 12 g, Lianqiao (Fructus Forsythiae) 12 g, Huanglian (Rhizoma Coptidis) 6 g, Chao Zhizi (Fructus Gardeniae) 9 g, or Angong Niuhuang pills or Zhibao pills (D, low priority). For patients with constipation and obstruction of Fu-qi, add Shengdahuang (Radix et Rhiza Rhei) 6 g (decocoting later) and Mangxiao (Natrium Sulfats) 9 g (administration after dissolving). For patients with obvious convulsion, add Gouteng (Ramulus Uncariae Cum Uncis) 9 g (decocoting later), Quanxie (Scorpio) 6 g, Dilong (Lumbricus) 12 g, and Lingyangjiaofen (Cornu Saigae Tataricae) powder 0.6 g (administration after dissolving).

**Chinese patent medicines**
(1) Xingnaojing injection (D, high priority): 10–20 mL/time, add 5%–10% glucose injection or 250–500 mL normal saline, intravenous drip, 1–2 time/day. (2) Qingkailing injection[^43] (D, low priority): 20–40 mL, add 10% glucose injection 200 mL or normal saline 100 mL, intravenous drip, 2 times a day.

**Acute exacerbation of the dangerous window stage**
The acute exacerbation of the dangerous window stage is a period between the end of the acute exacerbation stage and the stable stage. The pathogenesis is both with deficiency and excess, mainly with qi (yang) deficiency and qi (yin) deficiency, and commonly combined with phlegm and stasis. Therefore, the treatment should eliminate pathogens (resolve phlegm, activate blood) and reinforce healthy qi (tonify and benefit
Lung qi, tonify the lung and invigorate the spleen, and tonify and benefit the lung kidney.\textsuperscript{17,17} A multicenter trial study\textsuperscript{18} showed that the sequential treatment of combined Chinese medicine and western medicine in the acute exacerbation of the dangerous window stage has significant improvements on the curative effect when compared to the western medicine standard alone, by reducing the number of acute exacerbations, improving the clinical symptoms such as dyspnea, and improving the quality of life.

**Stable stage**

Research evidence\textsuperscript{44-49} shows that the efficacy of Chinese medicine syndrome differentiation treatment and Chinese medicine combined with western medicine in the treatment of COPD is more effective than placebo or western medicine alone, mainly in improving symptoms, reducing the number of acute exacerbations, improving exercise capacity, and improving the quality of life. For early COPD patients with pulmonary function Grades 1 and 2 in a stable stage, Chinese medicine syndrome differentiation treatment program (lung qi deficiency syndrome uses Bu fei recipe, lung spleen qi deficiency syndrome uses Bu fei Jian pi recipe, and lung and kidney qi deficiency syndrome uses Bu fei Yishen recipe) can reduce the number of acute exacerbations, improve lung function and dyspnea, improve clinical symptoms, improve exercise endurance and quality of life, and have better long-term effects.\textsuperscript{50} For COPD patients with pulmonary function grades 3 and 4, based on the conventional treatment of western medicine, Chinese medicine syndrome differentiation treatment program (lung spleen qi deficiency syndrome uses Bu fei Jian pi recipe, lung and kidney qi deficiency syndrome uses Bu fei Yishen recipe) can reduce the number and extent of acute exacerbations, improve the quality of life and exercise endurance, and improve clinical symptoms and dyspnea.\textsuperscript{51}

**Lung qi deficiency syndrome\textsuperscript{15}**

**Symptoms**

Primary symptoms were cough, fatigue, ease in catching a cold. Secondary symptoms were wheezing, shortness of breath, aggravation of movement, spiritual tiredness, spontaneous sweating, aversion to wind, pale tongue, white tongue fur, fine, deep, weak pulse.

**Diagnosis**

(1) Cough or wheezing, shortness of breath, aggravation of movement; (2) spiritual tiredness, fatigue, or spontaneous sweating; (3) aversion to wind, ease in catching a cold; (4) pale tongue, white tongue fur, or fine, deep pulse or weak, and fine pulse. Diagnose with three items from 1, 2, 3, and 4.

**Therapeutic methods**

Tonifying lung, benefiting qi, and consolidating defensive qi.

**Formula and herbs**

Modified Renshen Hutao decoction (Jisheng Formula) and Renshen Yangfei pills (Prescriptions of the Bureau of Taiping People’s Welfare Pharmacy)\textsuperscript{15} (D, low priority): Dangshen (Radix Codonopsis) 15 g, Huang qi (Radix Astragali seu Hedysari) 15 g, Baizhu (Rhizoma Atractylodis Macrocephalae) 12 g, Hutaorou (Semen Juglandis) 15 g, Bai bu (Radix Stemonae) 9 g, Chuanbeimu (Bulbus Fritillariae Cirrhosae) 6 g, Xingren (Semen Armeniacae Amarum) 9 g, Houpo (Cortex Magnoliae Officinalis) 9 g, Zisuzi (Radix Glycyrrhizae) 6 g.

**Addition and subtraction**

For patients with excessive spontaneous sweating, add Fu xiaomai (Fructus Trichici Levis) 15 g and Du amnuli (Concha Ostreae) 15 g (decoc ting first). For patients with alternative chills and fever and disharmony between nutrient qi and defensive qi, add Guizhi (Ramulus Cinnamomi) 6 g and Baishao (Radix Paeoniae Alba) 9 g. This syndrome could also use Yi qi Gubiao formula\textsuperscript{52} (B, low priority) (Dangshen [Radix Codonopsis], Fu xiaomai [Fructus Trichi levi Levis], Baizhu [Rhizoma Atractylodis Macrocephalae], Ban xia [Rhizoma Pinelliae], Chen pi [Pericarpium Citri Retieulatae], Zis u [Folium Perillae], Fuling [Poria], Fang feng [Radix Saposhnikoviae], Yi yiren [Semen Coicis], Ku andonghua [Flos Farfarae], Huang qin [Radix Scutellariae], Chuan beimu [Bulbus Fritillariae Cir rhosae], and Pipaye [Folium Eriobotryae]).

**Chinese patent medicines**

Yupingfeng granules (E lectuary)\textsuperscript{13,44} (B, high priority): Administration after dissolving, 5 g/time, 3 times/day.

**Lung spleen qi deficiency syndrome\textsuperscript{15}**

**Symptoms**

Primary symptoms were cough, wheezing, shortness of breath, aggravation of movement, poor appetite, fatigue, ease in catching a cold, enlarged tongue, tooth marks, pale tongue, and white tongue fur. Secondary symptoms were spiritual tiredness, less food intake, abdominal fullness, loose stools, spontaneous sweating, aversion to wind, deep, fine, slow, and weak pulse.

**Diagnosis**

(1) Cough or wheezing, shortness of breath, aggravation of movement; (2) spiritual tiredness, fatigue or spontaneous sweating, aggravation of movement; (3) an aversion to wind, ease in catching a cold; (4) poor appetite or less food intake; (5) abdominal fullness or loose stools; (6) enlarged tongue or with tooth marks, thin white or white greasy tongue fur, or deep fine pulse or deep slow or fine weak pulse. Diagnose with two items from 1, 2, and 3 and two items from 4, 5, and 6.

**Therapeutic methods**

Tonifying the lung, invigorating the spleen, descending qi, and resolving phlegm.

**Formula and herbs**

Modified Liu junzi decoction (Orthodox Lineage of Medicine) referred to Prescriptions of the Bureau of Taiping People’s
Addition and subtraction

For patients with cough, excessive phlegm, and white greasy tongue fur, subtrah Huangqi (Radix Astragali seu Hedysari) and add Fabanxia (Rhizoma Pinelliae Preparatum) 12 g and Doukou (Fructus Amomi Rotundus) 9 g. For patients with thin phlegm and an aversion to cold, add Ganjiang (Rhizoma Zingiberis) 9 g and Xixin (Herba Asari) 2 g. For patients with a poor appetite and obvious decreased food intake, add Shenqu (Massa Medicata Fermentata) 12 g, Doukou (Fructus Amomi Rotundus) 12 g, and Chaomaiya (Fructus Hordei Germinatus) 12 g. For patients with abdominal fullness, subtrah Huangqi (Radix Astragali seu Hedysari) and add Muxiang (Radix Aucklandiae) 9 g, Laifuzi (Semem Raphani) 9 g, and Doukou (Fructus Amomi Rotundus) 9 g. For patients with loose stools, subtrah Zizan (Radix Asteris) and Xingen (Semem Armeniacae Amaranth) and add Gegen (Radix Puerariae) 9 g, Zexie (Rhizoma Alismatis) 12 g, and Qianshi (Semem Euryales) 15 g. For patients with spontaneous sweating, add Fuxiaomai (Fructus Tritici Leviss) 15 g and Duanmuli (Concha Ostreae) 20 g (decocling first). This syndrome could also use the modified Buzhong Yiqi decoction (Clarifying Doubts about Damage from Internal and External Causes)[55] (B, high priority) or Bufeif Jianpi formula[56,57] (B, low priority): Huangqi (Radix Astragali seu Hedysari), Huangjing (Rhizoma Polygonati), Dansheng (Radix Codonopsis), Baizhu (Rhizoma Atractylodis Macrocephalaes), Fuling (Poria), Zhebeimu (Bulbus Fritillariarum Thunbergii), Dilong (Lumbricus), Houpo (Cortex Magnoliae Officinalis), Chenpi (Pericarpium Citri Reticulatae), Zizan (Radix Asteris), Aidicha (Japanese Ardisia Herb), and Yinyanghuo (Herba Epimedii).

Chinese patent medicines

(1) Yupingfeng granules (Electuary)[53,54] (B, low priority): Administration after dissolving, 5 g/time, 3 times/day;
(2) Liujuunzi pills (D, low priority): Oral administration, 9 g/time, 2 times/day.

Lung kidney qi deficiency syndrome[55]

Symptoms

Primary symptoms were wheezing, shortness of breath, aggravation of movement, spiritual tiredness, fatigue, soreness and weakness of the waist and knees, ease in catching a cold, pale tongue, white tongue fur, fine pulse. Secondary symptoms were aversion to cold, spontaneous sweating, edema of the face, chest tightness, tinnitus, frequent urination at night, cough while enuresis, enlarged tongue, tooth marks, deep and weak pulse.

Diagnosis

(1) Wheezing, shortness of breath, aggravation of movement;
(2) fatigue, spontaneous sweating, aggravation of movement;
(3) easy to catch cold, aversion to cold; (4) soreness and weakness of the waist and knees; (5) tinnitus, dizziness, or edema of the face; (6) frequent urination and that at night; (7) pale tongue, white tongue fur, or deep fine pulse or fine weak pulse. Diagnose with two items from 1, 2, and 3 plus two items from 4, 5, 6, and 7.

Therapeutic methods

Tonifying the kidney, benefiting the lung, inspiration, and relieving asthma.

Formula and herbs

Bufeif Yishen formula[56,57] (B, high priority): Renshen (Radix Ginseng) 6 g, Huangqi (Radix Astragali seu Hedysari) 15 g, Shanzhuyu (Fructus Corni) 9 g, Gouqizi (Fructus Lycii) 12 g, Wuweizi (Fructus Schisandraceae Chinensis) 9 g, Yinyanghuo (Herba Epimedii) 9 g, Zhebeimu (Bulbus Fritillariarum Thunbergii) 9 g, Chishao (Radix Paeoniae Rubra) 12 g, Dilong (Lumbricus) 12 g, Zisuzi (Fructus Perillae) 9 g, Aidicha (Japanese Ardisia Herb) 9 g, and Chenpi (Pericarpium Citri Reticulatae) 9 g.

Addition and subtraction

For patients with an obvious cough, add Zhiziyuan (Aster tataricus) 12 g and Xingen (Semem Armeniaca Amaranth) 12 g. For patients with cough, excessive phlegm, and white greasy tongue fur, add Fabanxia (Rhizoma Pinelliae Preparatum) 9 g and Fuling (Poria) 15 g. For patients with wheezing after movement, add Gejiefen (Gecko) 2 g (administration after dissolving). For patients with edema of the face and aversion to wind, add Rougui (Cortex Cinnamomi) 5 g (decocling later), Zexie (Rhizoma Alismatis) 9 g, and Fuling (Poria) 12 g. For patients with soreness and weakness of the waist and knees, add Tuizi (Semem Cuscutae) 12 g and Duzhong (Cortex Eucommiae) 12 g. For patients with obviously frequent urination, add Yizhiren (Fructus Alpiniae Oxyphyllae) 9 g and Jinyingzi (Fructus Rosae Laevigatae) 12 g. For patients with an aversion to cold and insufficient body warmth, add Zhifuzi (Radix Aconiti Lateralis Preparata) 9 g (decocling first) and Ganjiang (Rhizoma Zingiberis) 6 g. This syndrome could also use the modified Renshen Bufeif decoction (Symptoms, Causes, Pulse and Treatment)[58,59] (D, low priority) or modified Renshen Gejie powder[56,60] (C, low priority).

Chinese patent medicines

For patients with lung kidney qi deficiency and blood stasis, choose Bufeif Huxue capsules[53,54] (C, low priority): Oral administration, 4 capsules per time, 3 times/day.

Lung kidney qi yin deficiency syndrome[55]

Symptoms

Primary symptoms were cough, wheezing, shortness of breath, aggravation of movement, fatigue, spontaneous
sweating, night sweating, soreness and weakness of the waist and knees, ease in catching a cold, red tongue, and rapid pulse. Secondary symptoms were dry mouth and throat, dry cough with less phlegm, unwillingness to cough up, feverishness in the palms and soles, tinnitus, dizziness, pale tongue, less and eroded tongue fur, weak, deep, slow and stringy pulse.

Diagnosis

(1) Wheezing, shortness of breath, aggravation of movement;
(2) spontaneous sweating or fatigue, aggravation of movement;
(3) easy to catch cold;
(4) soreness and weakness of the waist and knees;
(5) tinnitus, dizziness;
(6) dry cough with less phlegm, unwillingness to cough up;
(7) night sweating;
(8) feverishness in the palms and soles;
(9) pale or red tongue,
thin, less, or eroded tongue fur, or deep fine pulse, fine weak pulse, or fine rapid pulse. Diagnose with two items from 1, 2, and 3 plus one item from 4 and 5 and two items from 6, 7, 8, and 9.

Therapeutic methods

Tonifying the lung, nourishing the kidney, inspiration, and relieving asthma.

Formula and herbs

Modified Baoyuan decoction (Bo Ai Xin Jian) and Renshen Bufeidecoction\(^{69}\) (D, high priority): Renshen (Radix Ginseng) 6 g, Huangqi (Radix Astragali seu Hedysari) 15 g, Huangjing (Rhizoma Polygonati) 15 g, Shu di huang (Radix Rehmanniae Preparata) 15 g, Gouqizi (Fructus Lycii) 12 g, Maidong (Radix Ophiopogonis) 15 g, Wuweizi (Fructus Schisandrae Chinensis) 9 g, Rou gui (Cortex Cinnamomi) 3 g (decoc ting later), Zizusi (Fructus Perillae) 9 g, Zhe bei mu (Balbus Fritillariae Thunbergii) 12 g, Mudanpi (Cortex Moutan Radicis) 9 g, Dilong (Lumbricus) 12 g, Baibu (Radix Stemonae) 9 g, Chenpi (Pericarpium Citri Reticulatae) 9 g, and Zhigancao (Radix Glycyrrhizae) 6 g.

Addition and subtraction

For patients with severe cough, add Zhipipaye (Angelicae Sinensis) 9 g, Chenpi (Citri Reticulatae) 9 g, and Gancao (Astragali Radices) 9 g. For patients with greasy phlegm that is difficult to expectorate, add Bai bei (Balbus Lilii) 15 g, Yuzhu (Rhizoma Polygonati Odorati) 12 g, and Shashen (Radix Glehniae) 12 g. For patients with feverishness in the palms and soles, add Zhimu (Rhizoma Anemarrhenae) 9 g, Huangbai (Cortex Phellodendri) 9 g, Dugui (Cortex Lycii) 12 g, and Bie jia (Carapax Trionycis) 15 g. For patients with night sweating, add Duan nuli (Concha Ostraeae) 20 g (decoc ting first) and Nuodaogen (Oryza sativa) 15 g. This syndrome could also use Yi qi Zishen Formula (B, low priority): Renshen [Radix Ginseng], Huangjing [Rhizoma Polygonati], Maidong [Radix Ophiopogonis], Wuweizi [Fructus Schisandrae Chinensis], Gouqizi [Fructus Lycii], Shudihuang [Radix Rehmanniae Preparata], Rou gui [Cortex Cinnamomi], Zhe bei mu [Balbus Fritillariae Thunbergii], Dilong [Lumbricus], Danpi [Cortex Moutan Radicis], Zisuzi [Fructus Perillae], Baibu [Radix Stemonae], Chenpi [Pericarpium Citri Reticulatae]; Bufeide Granules\(^{67-69}\) (B, low priority): Dangshen [Radix Codonopsis], Shudihuang [Radix Rehmanniae Preparata], Shanyourou [Fructus Corni], Mimahuang [Herba Ephedrae], Danggui [Radix Angelicae Sinensis], Chishao [Radix Paeoniae Rubra], Huangqin [Radix Scutellariae], Chenpi [Pericarpium Citri Reticulatae], Mizi wan [Radix Asteris], Gancao [Radix Glycyrrhizae].

Chinese patent medicines

(1) Shengmaiyn oral liquid (D, low priority): Oral administration, 10 mL/time, 3 times/day. (2) Yangyin Qingfei pills (for patients with lung yin deficiency and dryness heat) (D, low priority): Oral administration, 6–9 g/time, 2 times/day. (3) Baihe Gujin pills (for patients with lung kidney yin deficiency) (D, low priority): Oral administration, 9 g/time, 2 times/day. (4) Gejie Ding chuan pills (for patients with lung kidney yin deficiency and internal heat cough and wheezing) (D, low priority): Oral administration, 6 g/time (water-honeyed pills), 2 times/day.

Treatment recommendations for clinical combined syndromes and complex syndromes

Combined syndrome – Blood stasis syndrome\(^{15}\)

Blood stasis often appears in both excess and deficiency syndromes as a combined syndrome. In the treatment, it often uses herbs promoting blood circulation and removing blood stasis based on strengthening healthy qi or replenishing deficiency and removing pathogens. Primary symptoms include cyanosis of the lips, dark redness of the tongue, echymoses, and a hesitant and deep pulse. Secondary symptoms include chest tightness and pain and a dark complexion. Diagnosis requires (1) a purple and dark face; (2) blue and purple lips and nails; (3) dark purple tongue or echymosis or sputum; and (4) distorted and rough sublingual veins. It can be diagnosed with one of 1, 2, 3, and 4. Therapeutic methods include promoting blood circulation and removing blood stasis. According to the different combined syndromes, clinicians can add or subtract herbs that promote blood circulation and resolve blood stasis\(^{6,70}\) (such as Chuan xiong [Rhizoma Ligustici Chuan xiong] 9 g, Chishao [Radix Paeoniae Rubra] 12 g, Taoren [Sem en Persicae] 9 g, Honghua [Flos Carthami] 9 g, and Ezhu [Rhizoma Cursc umae] 9 g).

Complex syndromes

Root excess, manifestation deficiency, and both excess and deficiency are the characteristics of the pathogenesis of COPD. In clinical practice, syndromes often appear with complex syndromes. Even complex syndromes have primary and secondary pathogenesis, such as acute exacerbation stage and stable stage. In the acute exacerbation stage, it is common to see phlegm-heating accumulating the lung or phlegm turbid blocking lung syndrome, among others. This is often combined with spleen qi deficiency or lung and kidney qi deficiency syndrome, etc., or with blood stasis, mainly with excess syndromes of phlegm heat, phlegm dampness, or blood stasis, and followed by lung spleen qi deficiency, lung
and kidney qi deficiency, and other deficiency syndromes. The treatment is to clear the lungs and dissolve phlegm, dry dampness, and dissolve phlegm; promote blood circulation and resolve phlegm; etc., supplemented by tonifying the lung and invigorating the spleen or tonifying the lung and kidney. In the stable stage, it is common to see lung qi deficiency, lung spleen qi deficiency, lung and kidney qi deficiency, and other deficiency syndromes, often combined with phlegm turbid, blood stasis or phlegm stasis mutual resistance, and other excess syndromes, mainly with deficiency syndromes, followed by excess syndromes. The treatment is mainly to tonify and benefit, including tonifying lung qi, tonifying the lung and invigorating the spleen, and tonifying the lung and benefiting the kidney, accompanied by eliminating pathogens, such as resolving phlegm and promoting blood circulation. Due to the complex and variable clinical syndromes of COPD, it is difficult to list all of the complex syndromes in this guideline. It is recommended that in clinical practice, when syndrome differentiation is a complex syndrome, the prescriptions of the syndromes listed in the guideline be used for treatment, considering the primary and secondary and excess and deficiency.\(^{[10,11,14-16]}\)

### Other Treatment Methods

Studies have shown that Taijiquan,\(^{[71]}\) acupuncture,\(^{[72]}\) respiratory guidance,\(^{[73]}\) acupoint application (such as Shufei paste\(^{[74]}\) and Xiaoachuan cream\(^{[75]}\)), Yifei moxibustion,\(^{[76]}\) and other techniques relieve the clinical symptoms of patients with COPD by improving exercise endurance, delaying lung function decline, and improving the quality of life.

### Prevention and Regulation

#### Prevention of exogenous pathogens

Keeping the air moist is conducive to the discharge of respiratory secretions. Encourage patients to cough for sputum excretion, quit smoking, and prevent colds and respiratory infections. Carry out appropriate rehabilitation exercises under strict care to improve the body’s resistance.\(^{[10]}\)

#### Improve nutrition

Malnutrition can make diaphragm fatigue worse. Patients should have more meals a day, but less food at each, with a light, digestible, and nutritious diet that avoids spicy foods to keep the stool smooth.\(^{[10]}\)

#### Mental nursing

Patients with COPD suffer from a long-term disease. The mental burden is very heavy. It is easy to coexist with anxiety and depression. Patients should be helped to establish confidence in fighting the disease.\(^{[10]}\)

### Appendix: Description

The leading drafting organizations of the guideline: Henan University of Chinese Medicine and the First Affiliated Hospital of Henan University of Chinese Medicine. The participating drafting organizations of the guideline: Evidence-based Medicine Center of Beijing University of Chinese Medicine, China-Japan Friendship Hospital, the Second Affiliated Hospital of Liaoning University of Chinese Medicine, Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine, Jiangsu Province Hospital of Chinese Medicine, the First Affiliated Hospital of Anhui University of Chinese Medicine, Affiliated Hospital of Jiangxi University of Chinese Medicine, Shanxi Province Hospital of Chinese Medicine, Xiuyuan Hospital of Chinese Academy of Chinese Medicine Sciences, and Peking University People’s Hospital.

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The doses of Chinese Materia Medica listed in this guideline are reference doses for clinical use.

The Chinese patent medicines listed in this guideline are derived from the Pharmacopoeia of the People’s Republic of China (2015 Edition), the National Basic Medical Insurance, Work Injury Insurance and Maternity Insurance Drug List (2017 Edition), and the Chinese Medicines Clinical Application Guideline • Respiratory Diseases Volume (2016 Edition) and other documents.

This guideline is not a standard or norm for medical conduct, but a declarative document based on the existing research evidence and specific methods. In clinical practice, physicians can refer to this guideline and conduct individualized treatment combining for specific conditions.

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There are no conflicts of interest.

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