DOI: 10.1111/jebm.12460

## GUIDELINE

# Diagnosis and treatment guideline for Chinese medicine on acute trachea-bronchitis

Jiansheng Li<sup>1,2,3</sup> Vaolong Chen<sup>4,5,6</sup> Xueqing Yu<sup>1,2,3</sup> Yang Xie<sup>1,2,3</sup> Xuanlin Li<sup>1</sup> Diagnosis and Treatment Guideline for Chinese Medicine on Acute Trachea-Bronchitis working team, Respiratory Disease Branch of China Association of Chinese Medicine, Respiratory Disease Branch of China Medical Association of Minorities<sup>1</sup>

<sup>1</sup> Co-Construction Collaborative Innovation Center for Chinese Medicine and Respiratory Diseases by Henan & Education Ministry of P.R. China, Henan University of Chinese Medicine, Zhengzhou, Henan Province, P.R. China

<sup>2</sup> Henan Key Laboratory of Chinese Medicine for Respiratory Disease, Henan University of Chinese Medicine, Zhengzhou, Henan Province, P.R. China

<sup>3</sup> Department of respiratory diseases, the First Affiliated Hospital of Henan University of Chinese Medicine, Zhengzhou, P.R. China

<sup>4</sup> Evidence-Based Medicine Centre, School of Basic Medical Sciences, Lanzhou University, Lanzhou, P.R. China

<sup>5</sup> Chinese GRADE Centre, Lanzhou University, Lanzhou, P.R. China

<sup>6</sup> WHO Collaborating Centre for Guideline Implementation and Knowledge Translation, Lanzhou, P.R. China

#### Correspondence

Jiansheng Li, Co-Construction Collaborative Innovation Center for Chinese Medicine and Respiratory Diseases by Henan & Education Ministry of P.R. China, Henan University of Chinese Medicine, Zhengzhou 450046, Henan Province, China.

Email: li\_js8@163.com

## Abstract

Chinese medicine (CM) has significant clinical effects in the treatment of tracheabronchitis. It is of important clinical significance to formulate guidelines for the diagnosis and treatment of tracheal-bronchitis based on the characteristics of TCM syndrome differentiation. The Respiratory Disease Branch of China Association of Chinese Medicine and Respiratory Disease Branch of China Medical Association of Minorities have organized and established a multidisciplinary working group, based on the World Health Organization Handbook for Guideline Development and the Guideline Development Handbook for Diagnosis and Therapy of Integrative Medicine to develop this guideline. It has been developed through technical links such as clinical problem investigation, evidence collection and evaluation, Delphi method, and expert consensus meetings. Based on the current best evidence, CM intervention costs and expert experience, 25 recommendations were established to standardize the etiology and pathogenesis of tracheal-bronchitis, syndrome differentiation and treatment, prevention, and care, etc., which can be used by respiratory physicians at all levels of TCM medical institutions.

#### **KEYWORDS**

guideline, trachea-bronchitis, traditional Chinese medicine

# 1 | INTRODUCTION

Acute trachea-bronchitis (ATB) is an acute inflammation of the tracheabronchial mucosa caused by infection, physical or chemical irritation or allergic factors, often occurring in the cold season or when the

temperature suddenly becomes cold. The clinical presentation is dominated by cough, starting with symptoms of upper respiratory tract infection such as nasal congestion, runny nose, sore throat, hoarseness, and/or accompanied by systemic symptoms such as fever, chills, headache, and generalized aches and pains, which usually last no more

This is an open access article under the terms of the Creative Commons Attribution-NonCommercial-NoDerivs License, which permits use and distribution in any medium, provided the original work is properly cited, the use is non-commercial and no modifications or adaptations are made. © 2021 The Authors. Journal of Evidence-Based Medicine published by Chinese Cochrane Center, West China Hospital of Sichuan University and John Wiley & Sons Australia, Ltd

 $\pm$ WILEY

than 3 weeks.<sup>1-3</sup> ATB belongs to the category of "cough" in Chinese medicine (CM), and CM has good clinical efficacy in the treatment of ATB. In order to further improve the diagnosis and treatment standard, promote the improvement of traditional Chinese medicine (TCM) diagnosis and treatment, and better guide the clinical treatment of ATB in China, the Respiratory Disease Branch of China Association of Chinese Medicine and Respiratory Disease Branch of China Medical Association of Minorities organized a working group for the development of guidelines based on multidisciplinary experts in respiratory medicine (TCM, Western medicine, combined Chinese, and Western medicine), guideline methodology, evidence-based medicine, and clinical pharmacology. Based on the standardized guideline development method, the "Diagnosis and Treatment Guideline for Chinese Medicine on Acute Trachea-Bronchitis" (hereinafter referred to as "this Guideline") was developed based on the best evidence and the characteristics of CM in the treatment of ATB and the current situation of clinical practice in China, and published as a group standard of the Chinese Academy of Traditional Chinese Medicine. In order to better promote the dissemination and implementation of this guideline, the content of this guideline was appropriately adjusted according to the standards of the Journal of Evidence-Based Medicine, and the journal version of the guideline was revised, improved, and published based on the recommendations of the journal editors and external peer reviewers.

## 2 | METHODS

This guideline refers to the standardization steps of the World Health Organization Handbook<sup>4</sup> for Guideline Development and the Guideline Development Handbook for Diagnosis and Therapy of Integrative Medicine,<sup>5</sup> and is based on evidence from existing guidelines, systematic reviews, clinical studies, and ancient classic books, the cost of TCM interventions, and expert experience and is developed using the Grading of Recommendations Assessment Development and Evaluation (GRADE) criteria<sup>6</sup> for development and followed the Reporting Items for Practice Guidelines in Healthcare (RIGHT) statement<sup>7</sup> for reporting.

## 2.1 | Establishment and registration

This guideline was approved as a group standard by the Chinese Academy of Traditional Chinese Medicine on March 28, 2019, and was registered bilingually in Chinese and English (No. IPGRP-2019CN052) on the International Practice Guideline Registration Platform (http://www.guidelines-registry.org), and a guideline development plan was written.

## 2.2 Establishment of working groups

Four major working groups were established for this guideline, including the steering committee, methodology expert group, clinical expert group, and evidence evaluation group, with two chief experts. Members include experts from different disciplines such as CM, combined Chinese and Western medicine respiratory specialties, evidence-based medicine, guideline methodology, clinical pharmacology, and epidemiology.

## 2.3 | Conflict of interest

All members completed a uniformly formatted conflict of interest declaration form before formally participating in work related to the development of this guideline, clearly indicating that there are no commercial, professional, or other conflicts of interest related to the subject matter of this guideline.

# 2.4 | Selection and identification of clinical questions

The clinical questions to be answered in this guideline were selected through a questionnaire format. The first round of questionnaires was conducted through an open-ended questionnaire survey of 36 clinicians at different levels in several provinces, cities, and autonomous regions across China, and 24 clinical questions were initially collected. After deduplication, merging, and screening, 12 clinical questions were compiled. The 2nd round of questionnaire survey invited 64 clinicians (including members of the Respiratory Disease Branch of China Association of Chinese Medicine, Respiratory Disease Branch of China Medical Association of Minorities, and the Central China Regional Respiratory Disease Treatment Center) across China to evaluate the importance of the clinical questions and the technical framework of the guideline, and finally screened out eight clinical questions of concern for this guideline.

## 2.5 | Retrieval, evaluation, and grading of evidence

Evidence searches for specific clinical questions were conducted according to the included clinical questions and clinical outcomes, following the PICO (Population, Intervention, Control, Outcome) principles. Databases included MEDLINE, Embase, Cochrane Library, China Biomedical Literature Database (CBM), China Knowledge Network (CNKI), WanFang database, and VIP database. Systematic reviews (meta-analyses), clinical controlled trials, and case series studies were included. The search was conducted until June 16, 2020. Systematic reviews and meta-analyses were first searched and the AMSTAR (A Measurement Tool to Assess Systematic Reviews) tool<sup>8</sup> was used to evaluate the methodological quality of them. When a clinical question lacked a corresponding systematic review, the original study was retrieved and a new systematic review was produced. In the original studies, the risk of bias was assessed using the risk of bias tool<sup>9</sup> for randomized controlled studies; the ROBINS-I (risk of bias in nonrandomized studies of interventions) tool <sup>10</sup> for nonrandomized controlled studies; and the case series studies using the Case Series Methodological Quality Appraisal Tool (a quality appraisal tool for case series TABLE 1 Quality of evidence: The extent to which one can be confident that the predicted value is correct (GRADE methodology)

| Grade    | Implication  |
|----------|--|
| High     | We are very confident that the predicted value is close to the real value.   |
| Moderate | We have medium confidence in the prediction: the prediction may be close to the real value, but it may also be very different. |
| Low      | Our grasp of the predicted value is limited: the predicted value may be very different from the real value.                    |
| Very low | We have little confidence in the forecast: the forecast is likely to be very different from the real one.                      |

TABLE 2 Strength of recommendations (GRADE methodology)

| Grade  | Implication   |
|--------|---|
| Strong | Clearly show that the benefits of intervention outweigh the risks or the risks outweigh the benefits.           |
| Weak   | The pros and cons are uncertain or regardless of the quality of the evidence shows the pros and cons are equal. |

studies)<sup>11</sup> for quality evaluation. The systematic review team graded the quality of evidence and strength of recommendation according to the Grading of Recommendations Assessment Development and Evaluation (GRADE) criteria developed in 2004,<sup>6</sup> resulting in an evidence summary table. The quality of evidence was classified into four grades: high quality, moderate quality, low quality, and very low quality, and the strength of recommendation was classified into strong and weak recommendations. The criteria for grading the quality of evidence and the meaning of recommendation strength are shown in Tables 1 and 2, 3.

## 2.6 | Recommendation formation

A modified Delphi method was used to reach consensus on some recommendations through two rounds of questionnaires. The consensus rule is if the consensus degree of a recommendation is more than 75%, the recommendation is considered to have reached consensus and only minor modifications need to be made according to the experts' opinions; if it is between 60% and 74%, the recommendation does not pass consensus and major modifications need to be made according to the experts' opinions before conducting the second round of research. If the expert opinion consensus is less than 60%, the clinical issue will be given out together with the recommendation after discussion by the guideline working group. The first round of research was conducted on 30 senior-level TCM respiratory specialists in tertiary-level hospitals in 18 provinces in China. Thirty questionnaires were sent out and 30 were returned. Of the 39 recommendations involved, a total of 20 had reached consensus ( $\geq$ 75% expert consensus) and 19 (<75% expert consensus) had not reached consensus. For those recommendations that did not reach consensus, 7 recommendations with an expert consensus of  $\leq 60\%$  were excluded after discussion in the guideline working group, considering the current state of the evidence, clinical usage, and expert opinion. The second round of Delphi survey was conducted on the 12 recommendations that did not reach consensus, and 30 respiratory experts (70% of experts were consistent with the first round) from 19 provinces were surveyed, and 28 valid guestionnaires

were returned. Four of the recommendations reached consensus, four were removed after discussion in the guideline working group, and four needed to be discussed in face-to-face meetings.

## 2.7 Consensus meeting

The chief expert of this guideline convened an expert consensus meeting on recommendation opinions at the 24th Annual Academic Conference of the Respiratory Disease Branch of China Association of Chinese Medicine held in Guiyang City on August 7, 2020, where experts from different regions of China in TCM respiratory disease and guideline methodology were convened to discuss four recommendations face to face. When a recommendation is approved by 75% of the experts participating in the meeting, it is approved as the final recommendation, and 25 final recommendations of this guideline were determined after voting.

## 2.8 | Final draft and publication of the guideline

The working group prepared a first draft of the guideline based on the recommendations, and after internal review, formed an exposure draft. The final draft of this guideline was formed by public consultation through the TCM standardization information platform and refinement based on the feedback. It was also reviewed by relevant experts organized by the Standardization department of the China Association of Chinese Medicine and published on June 18, 2021 after revision and improvement (NO: T/CACM 1359–2021).

## 2.9 Guideline updates

According to the "Management of Group Standards of the Chinese Medicine Society," it is proposed to update this guideline in 3–5 years. At the same time, the evidence from high-quality clinical studies on

| Recommendations  | Quality of<br>evidence | Strength of recommendations |
|--|------------------------|-----------------------------|
| For syndrome differentiation of ATB, it is recommended to refer to the "TCM Syndrome Diagnosis Criteria of Acute<br>Tracheo-Bronchitis (2013 Edition)" issued by the Respiratory Disease Branch of China Association of Chinese<br>Medicine.   | Moderate               | Strong                      |
| For ATB patients with syndrome of wind-cold attacking lung, it is recommended to use Zhisou Powder and Sanao Decoction to shorten the disappearance and relief time of cough, reduce the score of cough symptoms, and the score of TCM syndromes.  | Moderate               | Strong                      |
| For ATB patients with syndrome of wind-cold attacking lung, it is recommended to use Xiaoqinglong Decoction for treatment, which can reduce the recurrence rate of the disease, shorten the disappearance time of cough, fever, and other symptoms, and reduce the TCM symptom score.  | Low                    | Strong                      |
| For ATB patients with cough, consider using Suhuang Zhike Capsule for treatment, which can reduce the scores of<br>coughs, pharyngeal itching, and expectoration symptoms, and shorten the time of symptom relief.   | Low                    | Weak                        |
| For ATB patients with syndrome of wind-cold attacking lung, it is recommended to use Sanao tablets for treatment, which can improve the total clinical effective rate, increase the rate of cough and sputum disappearance, reduce the total score of symptoms after treatment, and shorten the disappearance time of cough, sputum and fever. | Low                    | Weak                        |
| For ATB patients with syndrome of wind-cold attacking lung, consider using Tongxuan Lifei pill (tablet/granule) for treatment.   | Very Low               | Weak                        |
| For ATB patients with syndrome of wind-heat invading lung, it is recommended to use Sangjvyin for treatment, which can improve the recovery rate and reduce adverse reactions.   | Low                    | Strong                      |
| For ATB patients with syndrome of wind-heat invading lung, it is recommended to use Jizhi Tangjiang for treatment, which can increase the clinical recovery rate, with mild adverse reactions and low incidence.   | Very Low               | Strong                      |
| For ATB patients with syndrome of wind-heat invading lung, consider using Shufeng Jiedu capsule treatment, which<br>can shorten the disappearance time of cough and reduce the points of fever, cough, and TCM syndromes.  | Low                    | Weak                        |
| For ATB patients with syndrome of dryness invading lung, it is recommended to use Sangxing Decoction to improve<br>the recovery rate and reduce the symptoms of cough, sputum, and dry nose and mouth.   | Low                    | Strong                      |
| For ATB patients with syndrome of dryness invading lung, Xingsu powder is recommended for treatment, which can<br>improve the clinical cure rate.  | Low                    | Strong                      |
| For ATB patients with syndrome of dryness invading lung, consider using Milian Chuanbei Pipa Gao (ointment).   | Low                    | Weak                        |
| For ATB patients with syndrome of phlegm-heat obstructing lung, it is recommended to use Qingjin Huatan Decoction<br>for treatment.  | Low                    | Strong                      |
|  |                        | (Continues)                 |

**TABLE 3**25 Recommendations of the guidelines for the treatment of ATB in CM

| •                     |   |                        |                                |
|-----------------------|---|------------------------|--------------------------------|
| No                    | Recommendations   | Quality of<br>evidence | Strength of<br>recommendations |
| 14                    | For ATB patients with syndrome of phlegm-heat obstructing lung, it is recommended to use Feilicough Mixture<br>(capsule) for treatment, which can improve the recovery rate, shorten the time of cough disappearance, sputum<br>disappearance time, and systemic symptoms improvement time. | Moderate               | Strong                         |
| 15                    | For ATB patients with syndrome of phlegm-heat obstructing lung, consider using Shema Oral Liquid for treatment,<br>which can improve clinical effectiveness.  | Very Low               | Weak                           |
| 16                    | For ATB patients with syndrome of phlegm-heat obstructing lung, Tanreqing injection can be considered for treatment, which can improve clinical effectiveness, shorten the time of fever, and shorten the time for coughing to disappear.   | Moderate               | Weak                           |
| 17                    | For ATB patients with syndrome of phlegm-dampness obstructing lung, it is recommended to use Erchen Decoction and Sanzi Yangqin Decoction for treatment.  | Low                    | Strong                         |
| 18                    | For ATB patients with syndrome of phlegm-dampness obstructing lung, Erchen pill can be considered for treatment.  | Low                    | Weak                           |
| 19                    | For ATB patients with syndrome of lung qi deficiency, it is recommended to use Bufei Decoction and Yupingfeng San<br>for the treatment.   | Very Low               | Strong                         |
| 20                    | For ATB patients with syndrome of lung qi deficiency, Yupingfeng Keli (granules) are recommended for treatment.   | Low                    | Strong                         |
| 21                    | For ATB patients with syndrome of dual deficiency of qi and yin, it is recommended to use Shengmaisan and Shashen<br>Maidong Decoction for treatment, which can increase the total effective rate and reduce the symptom score.   | Low                    | Strong                         |
| 22                    | For ATB patients with syndrome of dual deficiency of qi and yin, Shengmaiyin Oral Liquid can be considered for<br>treatment.  | Low                    | Weak                           |
| 23                    | For ATB patients with syndrome of dual deficiency of qi and yin, Shengmai Granule can be considered for treatment.  | Low                    | Weak                           |
| 24                    | For ATB patients with syndrome of dual deficiency of qi and yin, Baihe Gujin Pill can be considered for treatment.  | Low                    | Weak                           |
| 25                    | For ATB patients, it is recommended to use acupoint application therapy, which can improve the clinical recovery rate of patients with acute trachea-bronchitis and shorten the duration of fever and cough duration.   | Moderate               | Strong                         |
| Abbreviations: ATB, ¿ | Abbreviations: ATB, acute trachea-bronchitis; CM, Chinese medicine; TCM, traditional Chinese medicine.  |                        |                                |

TABLE 3 (Continued)

338

TCM for ATB will be monitored and tracked, and if the latest evidence changes clinical practice or conflicts with previous recommendations, the working group will update this guideline in a timely manner, considering the needs of clinical practice.

### 2.10 Guideline publication

In order to better promote the promotion and dissemination of this guideline, the content of the group standard version of this guideline has been appropriately adjusted according to the standards of journal criteria, so that it conforms to the standards of journal publication. The Chinese version of this guideline was published in the Chinese Journal of Evidence-based Medicine, and the English version was published in the Journal of Evidence-Based Medicine.

## 3 | RESULTS

## 3.1 | Applicable population

This guideline standardizes the etiology of adult ATB, identification and treatment, and prevention and regulation of care, and is applicable to adult ATB patients. It can be applied by TCM clinical respiratory physicians in tertiary and secondary TCM hospitals, as well as primary TCM medical institutions in the treatment of ATB.

## 3.2 Causes and mechanism of the disease<sup>3,12,13</sup>

ATB can occur in any season, with a higher incidence rate in autumn and winter or alternating seasons, mostly triggered by cold or fatigue and due to the six climatic exopathogens such as wind, cold, heat, humidity, dryness, and fire, as well as dirty air attacking the lung system. Pathogenic factors invade lung either directly from mouth and nose, or from the skin and stay in the lungs. When the pathogenic factors attack lungs, they curb the lung qi from dispersing and descending to induce endogenous phlegm evil (phlegm-heat, phlegm-dampness), and the adverse rising lung qi induces diseases. Since the climate is changeable and human bodies react differently when attacked by exopathogens, common clinical symptoms vary from wind chill, wind heat, and wind dryness. The wind chill turns into heat when entering lungs, and wind heat turns into interior phlegm-heat when invading lungs. Repeated sicknesses hurt the healthy qi, or result in deficiency of healthy qi and lingering pathogenic qi for the old and weak because of their less healthy qi within and weak defensive qi outside. The deficiency of healthy gi normally takes the form of deficiency of lung gi and dual deficiency of gi and yin.

The basic mechanism of ATB is like this: the pathogenic factors attack lungs, causing the lungs' failure of dispersing and descending, and the adverse rising of lung qi. The disease position is mainly in the lungs. The exogenous cases are mainly excess symptoms, and the internal injured cases can be either excess or deficiency symptoms, yet mostly are mixed with both. Cough is the main symptom of ATB. In slight cases it occurs occasionally and can be cured in several days; but in serious cases it can be much more intense and frequent which can transform to other symptoms if not treated in time. The onset of the disease which is light in the lungs can be cured with correct treatment and proper care. But if it is misdiagnosed and improperly treated, the external evil can become internal, the wind chill will transform to heat, and wind heat into dryness, damaging lung yin and causing other pathological transformation from external pathogen to internal injury, and from excess symptoms to deficient symptoms, making the disease lingering and more difficult to heal.

## 3.3 | The methods and principles of treatment<sup>13,14</sup>

In terms of treatment, the first is to disperse and descend lung gi to relieve cough as the general treatment principle, which can disperse wind to dispel cold, clear heat, and moisten dryness accordingly based on the differences between pathogenic factors of wind cold, windy heat and wind dryness. Second, descend lung qi to reduce phlegm to make gi smooth and phlegm eliminated, then cough can be easily cured. The third is to strengthen and protect the healthy qi. The elderly is normally weak with insufficient healthy qi, so dispersion, dispelling, clearing, and relieving should not be over used. It is essential to strengthen and protect healthy qi to remove pathogenic qi without hurting the healthy gi. For those who are with lung gi deficiency or dual deficiency of gi and yin, supporting the healthy gi should be the main method, together with removing the pathogenic qi. The fourth is to pay attention to the long-term adjustment and prevention of diseases. With those who are deficient in healthy gi within and weak in protective gi without, it is liable for them to be attacked by pathogens and recurrent diseases. then tonifying gi or tonifying gi and nourishing yin can be used respectively based on the different natures of healthy gi deficiency.

## 3.4 | Syndrome diagnosis criteria

For TCM syndrome differentiation of ATB, it is recommended to refer to the syndrome classification and judgment criteria of TCM Syndrome Diagnosis Criteria of Acute Trachea-Bronchitis (2013 Edition)<sup>12</sup> issued by Respiratory Disease Branch of China Association of Chinese Medicine. According to the criteria, the common clinical syndromes of ATB are divided into two categories and seven syndromes: category of excess syndromes (syndrome of wind-cold attacking lung, syndrome of wind-heat invading lung, syndrome of dryness invading lung, syndrome of phlegm-heat obstructing lung, syndrome of phlegm-damp obstructing lung), and category of syndromes of deficient healthy qi and lingering pathogenic qi (syndrome of lung qi deficiency and syndrome of dual deficiency of qi and yin). Each syndrome can exist alone as well as coexist with others. Although there are differences between syndromes of deficiency and excess, they can be mixed with each other. Syndromes of deficient healthy qi and lingering pathogenic qi and syndromes of pathogenicity due to weakness are more common in elderly and frail patients (level of evidence: moderate quality; strength of recommendation: strong).

- 1. Main symptoms: cough, white phlegm, clear and watery phlegm, aversion to cold, thin, and white tongue coating, floating, or tight pulse. Secondary symptoms: stuffy nose, runny nose, itching pharynx, fever, no sweat, limb pain.
- 2. Diagnosis: ① cough, white phlegm, clear and watery phlegm, or dry cough; ② stuffy nose and runny nose; ③ aversion to cold, no sweat, or combined fever; ④ limb pain; ⑤ white tongue coating, floating, or tight pulse. With item ①, plus two items in ②, ③, ④, and ⑤.

## 3.4.2 | Syndrome of wind-heat invading lung<sup>12</sup>

- Main symptoms: cough, yellow phlegm, dry throat or even sore throat, fever, aversion to wind, red-tipped tongue, yellow coating of tongue, floating or tight pulse. Secondary symptoms: sticky phlegm, cough with continuous phlegm, stuffy nose, turbid nasal mucus; dry and hot nose, itching pharynx, thirst, thin tongue coating.
- Diagnosis: ① cough, yellow or white sticky phlegm, or less phlegm, cough with continuous phlegm, or dry cough; ② stuffy nose, turbid nasal mucus, or dry and hot nose; ③ aversion to wind or combined with fever; ④ dry throat or even sore throat; ⑤ thirst and dry mouth; ⑥ red-tipped tongue, or the tongue coating is thin and yellow or thin, white and dry, or floating and rapid pulse. With item ①, plus three items in ②, ③, ④, ⑤, and ⑥.

## 3.4.3 Syndrome of dryness invading lung<sup>12</sup>

- Main symptoms: dry cough, cough, dry lips and nose, dry mouth, dry throat or even sore throat, thin tongue coating and floating pulse. Secondary symptoms: sticky phlegm and difficult to cough out, thirst, fever, aversion to wind, red-tipped tongue, thin yellow or thin white coating, rapid pulse.
- Diagnosis: ① dry cough, little or sticky phlegm, and difficult to cough out; ② dry lips and nose; ③ dry mouth or even thirst; ④ dry throat or even sore throat; ③ aversion to wind and fever; ⑥ red-tipped tongue, or the tongue coating is thin yellow or thin white and dry, floating, or rapid pulse. With items of ① and ②, plus two items in③, ④, ⑤, and ⑥.

# 3.4.4 | Syndrome of phlegm-heat obstructing lung<sup>12</sup>

- Main symptoms: cough with thick yellow phlegm, red tongue texture, and greasy and yellow tongue fur, slippery or slippery and rapid pulse. Secondary symptoms: excessive phlegm, cough with continuous phlegm, thirst, oppression in chest, fever, and constipation.
- Diagnosis: ① cough; ② thick and yellow phlegm or cough with continuous phlegm; ③ fever or thirst; ④ constipation; ⑤ red tongue, yellow or slimy yellow tongue fur, slippery or slippery and rapid pulse. With two items of ①, ②, plus two items in ③, ④, and ③.

# 3.4.5 | Syndrome of phlegm-damp obstructing lung<sup>12</sup>

- Main symptoms: cough, copious phlegm, white and thick phlegm or with foam, white or white and thick tongue fur, slippery pulse. Secondary symptoms: easy expectoration of phlegm, thick and greasy mouth, oppression in chest, anorexia, poor appetite, stuffed and full stomach, tooth marks on the margins of the tongue, stringy pulse, or soggy pulse.
- Diagnosis: ① cough; ② copious phlegm, white and thick phlegm or with foam; ③ thick and greasy mouth, anorexia or poor appetite; ④ stuffed and full stomach; ③ tooth marks on the margins of the tongue, white or white and greasy tongue fur, slippery pulse or soggy pulse or stringy and slippery pulse. With two symptoms of ①, ② and two symptoms in ③, ④, and ⑤.

## 3.4.6 | Syndrome of lung qi deficiency<sup>12</sup>

- Main symptoms: cough, shortness of breath, weakness, spontaneous sweating, aggravated with more movement, aversion to wind and cold, light tongue texture, white tongue fur, weak or thready pulse. Secondary symptoms: mental fatigue, easy to catch a cold, thin tongue fur, sinking or slow pulse.
- Diagnosis: ① cough or weak expectoration of phlegm; ② mental fatigue or weakness or shortness of breath, aggravated with more movement; ③ spontaneous sweating, aggravated with more movement; ④ aversion to wind and cold or easy to catch a cold; ⑤ light tongue texture, sink and thready pulse or sinking and moderate pulse or thready and weak pulse. With item ① and two items in ③, ③, ④, and ⑤.

## 3.4.7 Syndrome of dual deficiency of qi and yin<sup>12</sup>

- Main symptoms: cough, less phlegm, dry cough, mental fatigue, weakness, aggravated with more movement, easy to catch a cold, spontaneous sweating, night sweating, red tongue texture, less tongue fur and thready pulse. Secondary symptoms: shortness of breath, aversion to wind, feverishness in palms and soles, dry mouth, thirst, swollen tongue body or even tooth marks on the margins of the tongue or small tongue body, light or red tongue texture, thin or exfoliated tongue fur, sinking or rapid or weak pulse.
- 2. Diagnosis: ① dry cough or cough with less phlegm; ② mental fatigue or weakness or shortness of breath, aggravated with more movement; ③ aversion to wind and cold or easy to catch a cold; ④ spontaneous sweating or night sweating; ③ feverishness in palms and soles; ⑥ dry mouth even thirst; ⑦ swollen tongue body or even tooth marks on the margins of the tongue or small tongue body, light or red tongue texture, thin or exfoliated tongue fur, or sink and thready pulse, or thready and weak pulse, or thready and rapid pulse. With item ① plus two items in ②, ③, ④, and two items in ③, ⑤, ⑦.

WII FV-

# 3.5 | Recommendations for syndrome differentiation treatment

#### 3.5.1 Syndrome of wind-cold attacking lung

Method of treatment: dispersing wind and dissipating cold, ventilating lung, and relieving cough.

Prescription: variations of San'ao decoction from Taiping Huimin Hejiju Fang (formulary of the Bureau of Taiping People's Welfare Pharmacy) and Zhisou Powder (Medical Insights)<sup>3,15–17</sup> (level of evidence: moderate quality; strength of recommendation: strong): 6 g of Zhi Mahuang (honey-fried Herba Ephedrae), 9 g of Ku Xingren (bitter apricot kernel), 9 g of Baiqian (Rhizoma Cynanchi Stauntonii), 9 g of Jingjie (Herba Schizonepetae), 9 g of Fangfeng (Radix Saposhnikoviae), 9 g of Zisuye (Perilla leaf), 9 g of Chenpi (Pericarpium Citri Reticulatae), 6 g of Jugeng (Radix Platycodi), 12 g of Baibu (Radix Stemonae), 12 g of Kuangdonghua (Flos Farfarae), and 3 g of Zhigancao (honey-fried Radix Glycyrrhizae).

Variations: patients suffering from alternating chills and fever should be treated with variations of above prescription and Xiaochaihu decoction; patients suffering from latent cold fluid-retention in the body with syndromes of oppression in the chest, qi counterflow, clear and thin sputum can be modified with Xiaoqinglong decoction<sup>3,18–21</sup> (level of evidence: low quality; strength of recommendation: strong). For patients with profuse phlegm and white, thick and greasy tongue coating, add 9 g of Houpu (Flos Magnoliae Officinalis), 9 g Jiang Banxia (Ginger-processed Pinellia), and 12 g of Fuling (Poria) in the prescription; for those who have heat syndrome caused by wind and cold invading the body or caused by wind-cold fettering exterior, add 20 g of Sheng Shigao (Crude gypsum) (decocted first), 9 g of Huangqin (Radix Scutellariae), and 12 g of Sangbaipi (Cortex Mori) in the prescription; for patients with paroxysmal cough, rapid breathing, wheezing dyspnea and chest tightness, add 9 g of Jiangcao (Bombyx Batryticatus), 12 g of Zhiqiao (Fructus aurantii), and 9 g of Zisuzi (Fructus Perillae) in the prescription; for those suffering from heavy headache, add 6 g of Baizhi (Radix Angelicae Dahuricae) and 9 g of Gaoben (Rhizoma Ligustici) in the prescription; for patients who are sore or even painful all over the body, 9 g of Qianghuo (Rhizoma seu Radix Notopterygii) and 9 g of Duhuo (Radix Angelicae Pubescentis) can be added in the prescription; for patients with gi deficiency, shortness of breath and weakness, add 12 g of Dangshen [Codonopsis pilosula]) and 15 g of Huangqi (Astragalus membranaceus) in the prescription; for those with yang deficiency, aversion to cold and lack of warmth in the limbs, add 2 g of Xixin (Herba Asari) and 9 g Pao Fu tablets (decocted first) in the prescription.

Chinese patent medicine: ① Suhuang Zhike capsule (for suppressing cough)<sup>22,23</sup> (level of evidence: low quality; strength of recommendation: weak): oral administration, 3 capsules at a time, 3 times a day. ② San'ao tablets<sup>22,24-27</sup> (level of evidence: low quality; strength of recommendation: weak): oral administration, 2 tablets at a time, 3 times a day. ③ Tongxuan Lifei Pills<sup>3,22,24,28</sup> (level of evidence: extremely low; strength of recommendation: weak): oral administration. For Da Mi Wan (big candied pills): 2 pills at a time, 2–3 times a day; for tablets: 4 tablets at a time, 2–3 times a day.

#### 3.5.2 | Syndrome of wind-heat invading lung

- 1. Method of treatment: dispersing wind and clearing heat, ventilating lung, and resolving phlegm.
- 2. Prescription: Variations of Sangjv Yin from Wenbing Tiaobian (differentiation of syndromes in epidemic febrile diseases) <sup>3,29–31</sup> (level of evidence: low quality; strength of recommendation: strong): 9 g of Sangye (Mulberry leaf), 6 g of Jvhua (chrysanthemum flower), 9 g of Xingren (almond), 12 g of Lianqiao (*Forsythia suspensa*), 12 g of Niubang Zi (Arctium seed), 12 g of Qianhu (Hogfennel root), 9 g of Huangqin (Baical skullcap root), 6 g of Bohe (Peppermint) (later), 9 g of Jiegeng (Platycodon root), 12 g of Lugen (Reed root), 3 g of Gancao (Liquorice root).

Variations: for those suffering from headache and red eyes, add 12 g of Xiakucao (common selfheal fruit-spike) and 9 g of Zhizi (Cape jasmine) in the prescription; for those suffering from severe cough, add 15 g of Baibu (Radix Stemonae), 9 g of Pipaye (Loquat leaf) and 9 g of Zhebeimu (Thunberbg fritillary bulb) in the prescription; for those with dyspnea, sweating, and thirst, add 6 g of honey-fried Mahuang (Ephedra) and 20 g of gypsum (decocted first) in the prescription; for those with sore body and no sweat, add 9 g of Jingjie (Schizonepetae) and 9 g of Fangfeng (Ledebouriella root) in the prescription; for those with sore throat, add 6 g of Shandou Gen (Vietnamese sophora root), 9 g of Xuanshen (Figwort root), and 6 g of Mabo (Puffball) in the prescription; for thirsty patients, add 12 g of Tianhuafen (Trichosanthes root) and 9 g of Xuanshen (Figwort root) in the prescription; for those with paroxysmal cough, add 12 g of Baijili (Tribulus fruit), 9 g of Jiangcan (Stiff silkworm), 6 g of Chantui (Cicada slough), and 12 g of Baishao (White paeony root) in the prescription; for those with shortness of breath, wheezing, and chest tightness, add 9 g of Jiangcan (Stiff silkworm) and 9 g of Suzi (Perilla) in the prescription; in summer-heat and damp-heat season, for those who are upset, thirsty with a red tongue, subtract Niubang Zi (Arctium seed) and add 9 g of Liuyi powder in the prescription; for those who have yin deficiency, feverishness in palms and soles, dry mouth, night sweat, add 12 g Maidong (Dwarf lilyturf tuber), 9 g Bei Shashen (Coastal glehnia root), and 12 g Digupi (Wofberry bark) in the prescription.

3 Chinese patent medicine: ① Jizhi Tangjiang(acute bronchitis syrup)<sup>3,22,32</sup> (level of evidence: extremely low quality; strength of recommendation: strong): oral administration, 20–30 ml at a time, 3–4 times a day. ② Shufeng Jiedu Capsule<sup>3,22,24,28,33,34</sup> (level of evidence: low quality; strength of recommendation: strong): oral administration, 4 capsules at a time, 3 times a day.

## 3.5.3 | Syndrome of dryness invading lung

Method of treatment: clearing lung-heat and moistening dryness, dispersing wind, and clearing heat.

Prescription: variations of Sangxing decoction (differentiation of syndromes in epidemic febrile diseases)<sup>3,35,36</sup> (level of evidence: low quality; strength of recommendation: strong): 9 g of Sangye (Mulberry

leaf), 12 g of Xingren (*Prunus armeniaca*),12 g of Bei Shashen (Coastal glehnia root), 12 g of Maidong (Dwarf lilyturf tuber), 9 g of Zhebeimu (Thunberbg fritillary bulb), 6 g of Dan Douchi (Semen Sojae Preparatum), 6 g of Zhizi pi (Cape jasmine peel),12 g of Gualou Pi (Snakegourd fruit peel), and 12 g of pear peel.

Variations: for those suffering from obvious dryness and heat, add 12 g of Zhimu (common anemarrhena rhizome) and 20 g of raw gypsum (decocted first) in the prescription; for those suffering from obvious headache and fever, add 6 g of Bohe (Peppermint) (later) and 9 g of Liangiao (weeping forsythia) in the prescription; for those who suffering from obvious pharyngeal pain, add 12 g of Xuanshen (Figwort root) and 6 g of Shandou Gen (Vietnamese sophora root) in the prescription; for those suffering from epistaxis or blood-streaked sputum, 15 g of Baimao Gen (Cogongrass rhizome), 15 g of Sheng Dihuang (dried rehamnnia root), and 15 g of lotus node should be added in the prescription; for those whose mouth and nose are very dry, subtract Dan Douchi (Semen Sojae Preparatum), and add 9 g of Xuanshen (Figwort root) and 15 g of Maidong (Dwarf lilyturf tuber) in the prescription; for those who cough too much resulting in chest pain, add 9 g of Zhike (Fructus Aurantii), 12 g of Yanhusuo (Corydalis tuber), and 19 g of Baishao (Radix Paeoniae Alba) in the prescription; for those with paroxysmal cough, add 12 g of Xuanshen (Figwort root), 15 g of Dilong (Earthworm), 9 g of Chantui (Cicada slough), and 12 g of Baishao (Radix Paeoniae Alba) in the prescription; for those with aversion to cold and no sweat, use variations of Xingsu powder (differentiation of syndromes in epidemic febrile diseases)<sup>3,37,38</sup> (level of evidence: low quality: strength of recommendation: strong).

Chinese patent medicine: Milian Chuanbei Pipa Gao (honey-refined fritillary bulb and loquat concentrated decoction)<sup>3,22</sup> (level of evidence: low quality; strength of recommendation: weak): oral administration, 22 g (about 1 spoonful) at a time, three times a day.

#### 3.5.4 Syndrome of phlegm-heat obstructing lung

Methods of treatment: Clearing heat and resolving phlegm, purifying lung, and relieving cough.

Prescriptions and medicinals: Variations of Qingjin Huatan decoction (synopsis of miscellaneous diseases from Tongzhi Fang)<sup>3</sup> (level of evidence: low quality; strength of recommendation: strong). 9 g of Sangbaipi (Mulberry bark), 9 g of Huangqin (Radix Scutellariae), 9 g of Zhizi (Cape jasmine), 12 g of Quangualou (Fructus Trichosanthis), 9 g of Juhong (Red tangerine reel), 9 g of Zhimu (Common anemarrhena rhizome), 9 g of Zhebeimu (*Fritillaria thunbergii*), 9 g of Xingren (Bitter apricot kernel), and 9 g of Jugeng (Radix Platycodi).

Variations:For patients with severe phlegm-heat, add 15 g of Jinqiaomai (Golden buckwheat) and 9 g of Tianzhuhuang (Concretio silicea bambusae); for those with rapid breathing, wheezing dyspnea, and oppression in chest, subtract Jugeng (Radix Platycodi) and add 9 g of Tinglizi (Lepidium), 9 g of Shegan (Belamcanda Chinesis), and 15 g of Dilong (Earthworm); for those suffering from severe chest pain, add 12 g of Yanhusuo (Corydalis Corydalis), 12 g of Chishao (Red peony), and 9 g of Yujin (Radix curcumae); for those suffering from thirst due to exuberant heat damaging fluids, subtract Jugeng (Radix Platycodi) and Juhong (Red tangerine reel) and add 20 g of Shengshigao (crude gypsum) (decocted first), 12 g of Maidong (Ophiopogon), and 12 g of Xuanshen (Radix Scrophulariae); for those suffering from constipation, add 9 g of Jiudahuang (wine-treated rhubarb) and 9 g of Zhishi (Fructus Aurantii).

Chinese patent medicine: <sup>①</sup> Feilike mixture (capsule)<sup>3,22,28,39,40</sup> (level of evidence: moderate quality; strength of recommendation: strong) is recommended. The mixture is to be taken orally 20 ml per time three times daily while the capsule 3-4 pills per time three times per day. <sup>②</sup> Shema oral liquid<sup>22,41</sup> (level of evidence: extremely low; strength of recommendation: weak) : oral administration, 10 ml per time, three times per day. <sup>③</sup> Tanreqing injections<sup>3,22,42</sup> (level of evidence: moderate quality; strength of recommendation: weak): 20 ml per time, together with 250 ml 5% glucose injection or 0.9% sodium chloride injection. Given by IV, one time a day.

# 3.5.5 Syndrome of phlegm-dampness obstructing lung

Methods of treatment: drying dampness, eliminating phlegm, and relieving cough.

Prescriptions: variations of Erchen decoction from Taiping Huimin Hejiju Fang (formulary of the Bureau of Taiping People's Welfare Pharmacy) combined with Sanzi Yangqin decoction from Jiexiao Fang<sup>3</sup> (level of evidence: low; strength of recommendation: strong) are suggested. 12 g of Fabanxia (*Pinellia ternata*), 15 g of Fulin (*Poria cocos*), 12 g of Chenpi (dried tangerine peel), 12 g of Baizhu (*Atractylodes macrocephala*), 9 g of Houpo (*Magnolia officinalis*), 9 g of Baijiezi (*Semen brassicae*), 9 g of Laifuzi (Semen Raphani), 9 g of Zisuzi (Perilla seed), and 6 g of Zhigancao (honey-fried licorice).

Variations: for patients suffering from severe cold-phlegm with white sticky foaming sputum and aversion of cold, add 9 g of Ganjiang (dried ginger) and 3 g of Xixin (Asarum); for those with spleen deficiency and dampness, tastelessness in mouth, loose stool, or sticky defecation, add 15 g of Dangshen (*Codonopsis pilosula*), 9 g of Cangzhu (Rhizoma Atractylodis), and 20 g of Yiyiren (Coix seed); for patients suffering from stuffiness and fullness in stomach, add 9 g of Baikouren (white cardamom kernel) and 12 g of Zhiqiao (Fructus Aurantii); for patients suffering from exogenous wind-cold with itchy throat and aversion of cold, add 9 g of Jingjie (Herba schizonepetae), 9 g of Fangfeng (Radix Sileris), and 9 g of Zisugeng (*Perilla frutescens* stem).

Chinese patent medicine: Erchen pill<sup>22,24,28</sup> (level of evidence: low; strength of recommendation: weak) is to be taken orally 9–15 g per time, 2 times a day.

## 3.5.6 | Syndrome of lung qi deficiency

Methods of treatment: tonifying and ventilating lung, replenishing qi and relieving cough.

Prescriptions: variarions of Bufei decoction (lung-tonifying decoction) from Furen Daquan Liangfang (effective prescriptions for women) combined with Yupingfeng San (Jade Screen Powder) from Yifang Leiju (collection of medical prescriptions)<sup>3</sup> (level of evidence: extremely low; strength of recommendation: strong). 15 g of Dangshen (*Codonopsis pilosula*), 15 g of Huangqi (*Astragalus membranaceus*), 9 g of Fangfeng (Radix Sileris), 12 g of Baizhu (*Atractylodes macrocephala*), 12 g of Fulin (*Poria cocos*), 9 g of Wuweizi (*Schisandra chinensis*), 12 g of Ziwan (Aster), 9 g of Xingren (bitter apricot kernel), 9 g of Chenpi (dried tangerine peel), and 6 g of Zhigancao (honey-fried licorice).

Variations: for those suffering from alternative chills and fever, remarkable aversion to wind-cold, add 9 g of Guizhi (Cassia twig) and 12 g of Baishao (Radix Paeoniae Alba); for those suffering from lung deficiency and cold with coughing clear phlegm and occasional coldness, add 6 g of Ganjiang (dried ginger), 9 g of Zisuzi (Perilla seed), and 9 g of Kuandonghua (*Tussilago farfara*). For patients with severe spontaneous sweating, add 15 g of Fuxiaomai (Fructus Tritici Levis) and 20 g of Duanmuli (Calcined oyster); for patients with poor appetite, add 15 g of Chaoshenqu (fried medicated leaven) and 15 g of Chaomaiya (fried malt); for patients with epigastric distention and pain, subtract Huangqi (*Astragalus membranaceus*) and add 9 g of Muxiang (*Aquilaria sinensis*) and 9 g of Laifuzi (Semen Raphani).

Chinese patent medicine: Yupingfeng Keli (Jade Screen Granule)<sup>22,24,28</sup> (level of evidence: low quality; strength of recommendation: strong), administered after dissolved with boiled water, 5 g per time, three times per day.

## 3.5.7 | Syndrome of dual deficiency of qi and yin

Methods of treatment: supplementing qi and nourishing yin, moistening lung, and relieving cough.

Prescriptions: variation of Shengmai powder from Yixue Qiyuan (medicine origin) combined with Shashen Maidong decoction (decoction of Glehnia and Ophiopogon) from Wenbing Tiaobian (differentiation of syndromes in epidemic febrile diseases)<sup>3,43,44</sup> (level of evidence: low quality; strength of recommendation: strong) are recommended. 15 g of Taizishen (Radix Pseudostellariae), 12 g of Beishashen (Radix Glehniae), 12 g of Maidong (*Ophiopogon japonicus*), 9 g of Wuweizi (*Schisandra chinensis*), 9 g of Yuzhu (Radix *Polygonati officinalis*), 9 g of Sangye (Mulberry leaves), 9 g of Zhebeimu (*Fritillaria thunbergii*), 9 g of Kuandonghua (*Tussilago farfara*), and 6 g of Zhigancao (honey-fried licorice).

Variations: for patients with phlegm-heat and cough with yellow phlegm, add 9 g of Huangqin (Baikal Skullcap) and 15 g of Quangualou (Fructus Trichosanthis); for patients with severe thirst, add 15 g of Tianhuafen (Trichosanthin) and 9 g of Xuanshen (Radix Scrophulariae); for patients with persistent low fever, add 9 g of Yinchaihu (Silver Bupleurum) and 12 g of Baiwei (*Cynanchum atratum*); for those with poor appetite and reduced food intake, add 15 g of Chaomaiya (fried malt) and 12 g of Chaoguya (fried rice malt); for those with abdominal distention, add 12 g of Chenpi (dried tangerine peel) and 9 g of Houpo (*Mag*- nolia officinalis); for patients suffering from night sweating, add 15 g of Fuxiaomai (Fructus Tritici Levis) and 12 g of Wumei (Dark Plum).

Chinese Patent Medicine: Shengmaiyin oral liquid<sup>3,22,24,28</sup> (level of evidence: low quality; strength of recommendation: weak) is suggested to be taken orally 10 ml per time, three times daily. Shengmai granule<sup>22,24</sup> (level of evidence: low quality; strength of recommendation: weak) can be taken after dissolved with boiled water 10 g per time three times per day. Baihe Gujin pill<sup>3,22,24,28</sup> (level of evidence: low quality; strength of recommendation; weak), oral administration, water-honeyed pills, 6 g per time; big honeyed pills, one pill per time, two times per day respectively.

## 3.6 Other treatments

Acupuncture, acupoint application, moxibustion, cupping, single prescription and other special treatments have certain clinical effects on acute trachea-bronchitis. According to the existing clinical evidence and consensus among experts, acupoint application therapy is recommended in this guideline (level of evidence: moderate quality; strength of recommendation: strong).

Acupoint application therapy can improve the clinical recovery rate of patients with ATB, shorten the duration of fever and cough, and reduce the incidence of adverse reactions.<sup>3,45–48</sup> The acupoints on the back and the chest can be applied with drug pastes for dispelling wind and dispersing lung, relieving cough, and resolving phlegm. The acupoints of Tiantu (CV 22), Dazhui (GV14), Feishu (BL13, both sides), and Zhongfu (L1) are taken. Change the drug paste once a day for 10 consecutive days.<sup>3</sup>

## 3.7 | Preventive modulation<sup>3,13</sup>

① Prevent cold and keep warm, avoid catching cold, especially for the elderly and those with low immune function. ③ Keep the air fresh, often open windows for ventilation, avoid exposure to inducing factors and inhalation of allergens, avoid going to the air polluted environment, and avoid the inhalation of harmful gases and smoke. Smokers should quit smoking. ③ During the epidemic of respiratory diseases, wear masks properly. ④ Avoid spicy and irritating food. ⑤ Those who cough repeatedly due to qi deficiency can take Yupingfeng San (Jade Screen Powder), etc.

## 4 DISCUSSION

This guideline is based on the standardized guideline development methods at China and abroad, a multidisciplinary team of experts was formed, and through clinical question research, evidence collection and evaluation, Delphi consultation, and expert consensus meetings, 25 recommendations of this guideline were formed based on the current best evidence, cost of TCM interventions, and expert experience in the treatment of ATB in TCM, which are useful for standardizing the clinical practice of ATB in adults. It is a good reference for standardizing the etiology, treatment, prevention, and care of ATB and provides practical and effective guidelines for the clinical practice of TCM treatment of ATB.

This guideline is disseminated and promoted through the following ways: (1) the group standard version is uploaded to the National Group Standard Information Network (http://www.ttbz.org.cn/) for readers' access; (2) after the bilingual publication, it is available on the official website of the journal (http://www.cjebm.com/journal/zgxzyxzz), PubMed, China Knowledge Network, and WANFANG database; (3) relying on the public number of TCM standardization to publish information about this guideline and interpret the relevant recommendations to facilitate public understanding and use; (4) interpreting the guideline at the annual academic meetings of the Respiratory Disease Branch of China Association of Chinese Medicine, Respiratory Disease Branch of China Medical Association of Minorities; (5) relying on the Co-Construction Collaborative Innovation Center for Chinese Medicine and Respiratory Diseases by Henan & Education Ministry of P.R. China and the National Regional TCM (Specialist) Treatment Center (Department of Pulmonary Diseases, The First Affiliated Hospital of Henan University of Traditional Chinese Medicine) to train and promote this guideline to medical institutions at all levels that have established good cooperative relationships.

This guideline has the following limitations: (1) the guideline working group did not include patient representatives and did not conduct a comprehensive survey of patient preferences and values, which will be improved when this guideline is updated; (2) the time span of the original studies included was large, and the diagnostic criteria of the original studies were not standardized, so more evidence from studies using the diagnostic criteria recommended in this guideline should be included; (3) some of the recommendations of this guideline are still not supported by high-quality evidence, and it is expected that more high-quality evidence-based support will be obtained in the future; (4) at present, acupuncture, moxibustion, cupping, and other TCM specialties have good clinical efficacy in the treatment of ATB and are widely used in clinical practice, but there is a lack of support from original studies, and the techniques and operational principles of different specialties are not standardized, so this guideline fails to give a clear recommendation.

Based on the above deficiencies, the working group recommends that future research should focus on: (1) continuing to conduct high-quality clinical studies on the treatment of ATB with TCM, especially high-quality clinical studies on TCM characteristic therapies; (2) focusing on the clinical efficacy evaluation of TCM based on the scientific standardization of evidence-based diagnostic criteria; (3) conducting studies on the health and economic comparative effectiveness of TCM interventions in ATB; and (4) conducting research on the comparative economic benefits of TCM interventions for ATB, while focusing on collecting information on patient preferences and values.

## 5 | WORKING TEAM

Steering committee: Yongyan Wang (China Academy of Chinese Medical Sciences), Boli Zhang (Tianjin University of Traditional Chinese Medicine), Enxiang Chao (China-Japan Friendship Hospital), Shuolun Sun (Dongzhimen Hospital Beijing University of Chinese Medicine).

Chair: Jiansheng Li (Henan University of Chinese Medicine).

**Chief methodologist**: Yaolong Chen (Evidence-Based Medicine Centre, Lanzhou University; Chinese GRADE Centre).

Methodology expert group: Yaolong Chen (Evidence-Based Medicine Centre, Lanzhou University; Chinese GRADE Centre), Wei Chen (International Institute of Evidence-Based Chinese Medicine, Beijing University of Chinese Medicine), Yanfang Ma (Evidence-Based Medicine Centre, Lanzhou University; Chinese GRADE Centre).

Clinical expert group (in alphabetical order): Xuefeng Yu (The Second Affiliated Hospital of Liaoning University of Traditional Chinese Medicine), Zhanping Ma (Shanxi Provincial Hospital of Chinese Medicine), Zhen Wang (First Affiliated Hospital of Zhejiang Chinese Medicine University), Qi Wang (Dongfang Hospital Affiliated to Beijing University of Chinese Medicine), Chengxiang Wang (Beijing University of Chinese Medicine Third Affiliated Hospital), Zhiwan Wang (The First Affiliated Hospital of Henan University of Chinese Medicine), Minghang Wang (The First Affiliated Hospital of Henan University of Chinese Medicine), Haifeng Wang (The First Affiliated Hospital of Henan University of Chinese Medicine), Yi Fu (Kunming Municipal Hospital of Traditional Chinese Medicine), Cuiling Feng (Peking University People's Hospital), Nini Qu (The Affiliated Hospital of Liaoning Traditional Chinese Medicine), Jia Zhu (Jiangsu Province Hospital of Chinese Medicine), Liangji Liu (Affiliated Hospital of Jiangxi University of Traditional Chinese Medicine), Jingxia Liu (Yinchuan Yide Hospital of Traditional Chinese Medicine), Zikai Sun (Jiangsu Province Hospital of Chinese Medicine), Fengsen Li (Affiliated Hospital of Traditional Chinese Medicine of Xinjiang Medicine University), Zegeng Li (Anhui University of Chinese Medicine), Suyun Li (The First Affiliated Hospital of Henan University of Chinese Medicine), Junchao Yang (First Affiliated Hospital of Zhejiang Chinese Medicine University), Yuanying Song (Hubei Provincial Hospital of Traditional Chinese Medicine), Wei Zhang (Shandong Provincial Hospital of Traditional Chinese Medicine), Wei Zhang (Shuguang Hospital Affiliated to Shanghai University of Traditional Chinese Medicine), Lishan Zhang (Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine), Mingli Zhang (Henan Academy of Chinese Medicine), Nianzhi Zhang (The First Affiliated Hospital of Anhui University of Chinese Medicine), Hongchun Zhang (China-Japan Friendship Hospital), Huiyong Zhang (Longhua Hospital Shanghai University of Traditional Chinese Medicine), Yanping Zhang (Xiyuan Hospital, China Academy of Chinese Medical Science), Xuechao Lu (Qingdao Hospital of Traditional Chinese Medicine), Sheng Chen (Shenzhen Traditional Chinese Medicine Hospital), Lei Wu (Hebei Hospital of Traditional Chinese Medicine), Lin Lin (Guangdong Province Hospital of Traditional Chinese Medicine), Guangwei Luo (Wuhan Hospital of Traditional Chinese and Western Medicine), Miao Zhou (Third Affiliated

<u><sup>344</sup> |</u> Wile

Hospital of Henan University of Chinese Medicine), Jihong Feng (Second Affiliated Hospital of Tianjin University of Traditional Chinese Medicine), ChengJun Ban (Dongzhimen Hospital Affiliated to Beijing University of Chinese Medicine), Hongsheng Cui (Beijing University of Chinese Medicine Third Affiliated Hospital), Zhenhui Lu (Longhua Hospital Shanghai University of Traditional Chinese Medicine), Zhengxing Ge (The Second Affiliated Hospital of Guizhou University of Traditional Chinese Medicine), Hanrong Xue (Affiliated Hospital of Jiangxi University of Traditional Chinese Medicine).

Members of evidence evaluation group (in alphabetical order): Yanfang Ma (Evidence-Based Medicine Centre, Lanzhou University; Chinese GRADE Centre), Minghang Wang (The First Affiliated Hospital of Henan University of Chinese Medicine), Xuanlin Li (Henan University of Chinese Medicine), Hailong Zhang (The First Affiliated Hospital of Henan University of Chinese Medicine), Hulei Zhao (The First Affiliated Hospital of Henan University of Chinese Medicine), Yang Xie (The First Affiliated Hospital of Henan University of Chinese Medicine).

**Drafter**: Jiansheng Li (Henan University of Chinese Medicine), Xueqing Yu (The First Affiliated Hospital of Henan University of Chinese Medicine), Yang Xie (The First Affiliated Hospital of Henan University of Chinese Medicine).

Secretary: Xuanlin Li (Henan University of Chinese Medicine)

### ACKNOWLEDGMENTS

We express our sincere gratitude to Ms. Sun Junfang of the College of Foreign Languages of Henan University of Traditional Chinese Medicine for her dedication in translating this guideline into the English version.

#### FUNDING

National Special Support Program for High-level Talent ("Ten Thousand Talents Program") Leading Talent (W02060076), Chief Scientist of Qihuang Scholars Award of the State TCM Academic Leader Program and Central Plains Thousand People Program (No. ZYQR202107).

#### ORCID

Jiansheng Li ២ https://orcid.org/0000-0002-6485-2371

#### REFERENCES

- Smith MP, Lown M, Singh S, et al. Acute cough due to acute bronchitis in immunocompetent adult outpatients. CHEST Expert Panel Report. Chest. 2020;157(05):1256-1265.
- Guideline for primary care of acute trachea-bronchitis (2018). Chin J Gen Pract. 2019; 18(04):314–317.
- Li JS, Yu XQ. Diagnosis and treatment guideline for Chinese medicine on acute trachea-bronchitis. J Tradit Chin Med. 2016;57(09): 806-810.
- World Health Organization. WHO Handbook for Guideline Development (2nd ed). Available from: https://apps.who.int/iris/handle/ 10665/145714
- Lu CJ, Yang KH. Manual for Formulating Diagnosis and Treatment Guidelines of Integrated Traditional Chinese and Western Medicine. Beijing: People's Medical Publishing House; 2016.
- Guyatt GH, Oxman AD, Vist GE, et al. GRADE: an emerging consensus on rating quality of evidence and strength of recommendations. *BMJ*. 2008;336(7650), 924-926.

- Chen Y, Yang K, Marušic A, et al. A reporting tool for practice guidelines in health care: the right statement. *Ann Intern Med.* 2017;166(2):128-132.
- Xiong J, Chen RX. An introduction to a measurement tool to assess the methodological quality of systematic reviews/meta-analysis: AMSTAR. J Evid Based Med. 2011;11(9):1084-1089.
- Higgins JP, Altman DG, Gøtzsche PC, et al. The Cochrane Collaboration's tool for assessing risk of bias in randomised trials. *BMJ*. 2011;343:d5928.
- Sterne JA, Hernán MA, Reeves BC, et al. ROBINS-I: a tool for assessing risk of bias in non-randomised studies of interventions. *BMJ*. 2016;355:i4919.
- Wang XQ, Chen YL, Qu QY, et al. Interpretation of methodological quality evaluation tools for case series study. *Chin J Evid Based Pediatr*. 2015;10(5):381-385.
- Li JS, Wang ZW, Li SY. The diagnostic criteria of traditional Chinese medicine syndrome for acute trachea-bronchitis (2013). J Tradit Chin Med. 2014;55(3):59-261.
- Li JS. Clinical Lung Disease of Traditional Chinese Medicine. Beijing: People's medical publishing house; 2015.
- Li JS. Summary of syndrome differentiation and treatment of acute trachea-bronchitis. *Henan Traditl Chin Med.* 2009;29(10):984-985.
- Lang YY. Clinical observation on Zhisou powder and Sanao decoction in the treatment of acute tracheal-bronchitis with syndrome of windcold invading lung. *Guang J Chin Med*. 2019;34(24):3756-3758.
- Cai SQ. Clinical study on modified Zhike powder combined with San'ao tang for acute tracheobronchitis with wind-cold invading the lung syndrome. J N Chin Med. 2019;51(2):87-89.
- Ou JZ. Clinical observation of Sanao decoction combined with Zhisou powder in the treatment of acute bronchitis caused by mycoplasma infection. J North Pharm. 2016;13(02):52-53.
- Zhu HD. Clinical value of Xiaoqinglong decoction in the treatment of acute asthmatic bronchitis. *Capital Food Med*. 2020;27(03):191.
- Lai CS, Li XL. Clinical observation of Xiaoqinglong decoction in the treatment of acute asthmatic bronchitis. *Guang J Chin Med.* 2018;33(23):3530–3532
- Chu WM, Fang R. Investigate the clinical significance of Xiao Qinglong decoction in the treatment of acute bronchitis. *Chin J Med Guide*. 2015;17(12):1245-1246.
- Wu XQ. Clinical effect of Xiaoqinglong decoction on acute trachea bronchitis. World Clin Med. 2016;10(22):158-159.
- 22. Ministry of Human Resources and Social Security of the People's Republic of China. Medicine List for National Basic Medical Insurance, Employment Injury Insurance and Maternity Insurance. Beijing: China Human Resources & Social Security Publishing Group; 2019.
- Gu YJ. Clinical study of Suhuang Zhike capsule in the treatment of cough caused by acute bronchitis. Asia-Pacific Tradit Med. 2015;11(18):110-111.
- 24. Chinese Pharmacopoeia Commission. *Chinese Pharmacopeia Guidelines* for *Clinical Drug Use*. Beijing: China Medical Science Press; 2015.
- Ma LG. Efficacy and safety of Sanao tablet in the treatment of acute bronchitis. J North Pharm. 2018;15(06):159-160.
- Li CD, Sun SY. Clinical observation of San'ao tablets combined with eucalyptol limonene pinene enteric soft capsule in treatment of acute bronchitis. *Drugs Clin.* 2015;30(09):1124-1127.
- Fan MR, Wang B, Gao JZ, et al. Sanao tablet in treating acute bronchitis (syndrome of wind-cold attacking the lung): a randomized controlled trial. Chin J Clin Pharmacol Therapeut. 2014;19(1):44-48.
- Wang YY, Chao EX, Wang GQ. Clinical Practice Guideline of Chinese Patent Medicine • Respiratory Disease. Beijing: China Press of Traditional Chinese Medicine; 2016.
- Luo P. Clinical efficacy analysis of Sangju decoction in the treatment of acute bronchitis. Modern Med Health Res Electr J. 2018;2(04):174.
- Rong SF. Clinical analysis of Sangju decoction in the treatment of acute bronchitis. Inner Mongol J Tradit Chin Med. 2016;35(10):19.

- Shen JZ, Piao RF. Observation on Sangju yin decoction treating 36 cases of bronchitis. J Pract Tradit Chin Inter Med. 2015;29(10):105-106.
- Chen YJ, Hao DW, Yang LB. A random controlled clinical study of Jizhi syrup or antibiotic in treating acute trachea-bronchitis. *Pharmacol Clin Chin Materia Medica*. 2015;31(01):262-264.
- 33. Tan XC, He N. Clinical observation of Shufeng Jiedu capsule in the treatment of acute trachea bronchitis (wind heat invading the lung syndrome). *J Emerg Tradit Chin Med*. 2017;26(08):1467-1469.
- Xie J. Clinical observation of Shufeng Jiedu capsule in the treatment of acute trachea bronchitis (wind heat invading the lung syndrome). J Emerg Tradit Chin Med. 2016;25(10):1929-1931.
- 35. Zhou FL. Treatment of 125 cases of exogenous intractable cough with Sangxing decoction. *J Snake*. 2005;4: 273-274.
- Wang W, Zhang YP & Miao Q et al. Curative effect of modified Sangxing decoction on 60 cases of acute bronchitis. Shanghai China: 2004:204-205.
- 37. Chen QT. Treatment of 183 cases of acute bronchitis with modified Xingsu decoction. *J Emerg Tradit Chin Med.* 2006;1:95.
- Li SZ. Observation on 106 cases of bronchitis treated with modified Xingsu powder. Yunnan J Tradit Chin Med Materia Medica. 2005;2: 31-32.
- Liu YS, Yan HJ, Li CY. Clinical study of Feilike capsules combined with amoxicillin in treatment of acute tracheal-bronchitis. *Drugs Clin.* 2020;35(4):735-738.
- 40. Li J. Clinical observation of Feilike mixture combined with western medicine in the treatment of acute bronchitis. *Inner Mongol J Tradit Chin Med*. 2016;35(16):25.
- 41. Wang HR, Jin GZ, Yang JQ, et al. Clinical observation of Shema oral liquid. *Chin Tradit Patent Med*. 1997;3:22-23.
- 42. Wang P, Liao X, Xie YM, et al. Tanreqing injection for acute bronchitis disease: a systematic review and meta-analysis of randomized controlled trials. *Complement Ther Med.* 2016;25:143-158.

- Zhang QB. Effectiveness observation of Shashen Maidong decoction of TCM in acute tracheobronchitis. *Chin J Ethnomed Ethnopharm*. 2018;27(15):88-89.
- Wang PR, Wang YH, Liu M, et al. Observation on therapeutic effect of modified Shashen Maidong decoction on acute tracheobronchial. *Mod*ern J Integr Tradit Chin West Med. 2006(10):1303-1304.
- 45. Ma SR. Shansan Decoction acupoint application combined with traditional Chinese medicine in the treatment of acute bronchitis. *Inner Mongol J Tradit Chin Med*. 2017;36(16):85-86.
- Lin QQ, Liu FY, Kuang QX. Clinical observation of acupoint application plus TDP in the adjuvant treatment of acute bronchitis. *Int Med Health Guid News*. 2014;20(17):2664-2665.
- 47. Huang F. Influence of pulmonary function and blood gas analysis index for treating acute bronchitis elderly patients with Yiqi Xuanfei powder and point application therapy. *Liaon J Tradit Chin Med*. 2016;43(08):1645-1648.
- Yu JH, Hu J, Ma DJ. Clinical observation of point application of far infrared Zhike plaster in the treatment of adult acute bronchitis cough. *Inner Mongol J Tradit Chin Med.* 2017;36(13):97.

How to cite this article: Li J, Chen Y, Yu X, Xie Y, Li X. Diagnosis, Treatment Guideline for Chinese Medicine on Acute Trachea-Bronchitis working team, Respiratory Disease Branch of China Association of Chinese Medicine, Respiratory Disease Branch of China Medical Association of Minorities. Diagnosis and Treatment Guideline for Chinese Medicine on Acute Trachea-Bronchitis. *J Evid Based Med*. 2021;14:333–345. https://doi.org/10.1111/jebm.12460