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Research Article

The International Application and Standardization of Chinese Medicine for Preventing and Treating COVID-19: An Analysis of International Clinical Guidelines and ISO Standards

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Abstract

Traditional Chinese medicine for the Coronavirus Disease 2019 (COVID-19) prevention and treatment was recommended globally by World Health Organization in 2022. There is an urgent need to develop international standards to ensure the quality and safety of Chinese medicinal materials for this promising global application. Thus, the international application and standardization of Chinese medicine for COVID-19 was explored. Herbal medicine guidelines of COVID-19 in 7 countries (regions and international organizations) were searched and eligible ones were extracted for single herbs. Then the herbs suitable for future standardization in International Organization for Standardization (ISO) were ranked based on a standardization list of single herbal medicines published by ISO. Four guidelines from 2 countries which recorded 62 herbal formulae and manufactured products comprised of 284 single herbs, were included. After merging homogeneous items, 78 eligible herbal medicines were found and 22 of the included herbs were internationally standardized and only 9 of the unstandardized were in the high priority. The results showed narrow scope of international application and low degree of international standardization in using Chinese medicine to prevent and treat COVID-19.

Keywords: COVID-19; Herbal medicine; ISO/TC 249; International Standard

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Introduction

Traditional Chinese Medicine (TCM) has been widely used for preventing and treating the Coronavirus Disease 2019 (COVID-19) in China [1]. In 2022, Chinese experts shared the research data and clinical experience in using TCM for COVID-19 with World Health Organization (WHO) experts and gained recognition. An expert meeting report from WHO found encouraging data to suggest that TCM was beneficial in reducing the risk of progression from mild-to-moderate cases to severe COVID-19 and recommended to Member States to consider the potential use of TCM [2]. In addition to the clinical research, the mechanism studies on TCM preventive and therapeutic effects, such as research on the Huoxiang Zhengqi oral liquid [3], Qingfei Paidu decoction [4-6], Xuebijing injection [7], Lianhua Qingwen capsule [8,9], showed antiviral and anti-inflammatory abilities against the novel coronavirus.

It is necessary and urgently to prompt the development of international standards of Chinese material medica for the treatment of COVID-19 to ensure the quality and safety of herbal medicines for international use. ISO/TC 249, the 249th technical committee of International Organization for Standardization (ISO), is focused on standardization of TCM including single herbal medicine [10]. Thus, this research explored of the international application of herbal medicines through analysis of international clinical guidelines of COVID-19 and found international standardization of commonly used single herbal medicines in ISO/TC 249.

Materials and Methods

Data sources

Traditional Chinese medicine -- Priority list of single herbal medicines for developing standards (ISO/TR 23975:2019) [11] is a consensus and main reference for standardization of Chinese materia medica in ISO/TC 249. This included herbal medicines from pharmacopoeias (or similar official documents) of seven countries (regions and international organizations), China, Hong Kong, Japan, Republic of Korea, European Union, United States and Thailand, in which TCM was widely used and officially regulated. Thus, the official sites of health departments and industrial associations of the seven members of ISO/TC 249 were searched for eligible guidelines.

Inclusion criteria

Clinical Practice Guidelines (CPGs) recommended herbal medicines for preventing, treating and/or recovering from COVID-19, issued by the health department of the government was included. If there were no officially issued guidelines, the documents developed by industrial associations were eligible.

Extraction of herbal medicines with international application

The herbs formulae and manufactured products recommended by CPGs were recorded, and the components of the patent medicines were extracted according to relevant pharmacopoeia or the drug labels of the manufacturers. The single herbs retrieved were computed and analyzed. The herbs used in at least two guidelines from different countries (regions and international organizations) were included and the frequencies were summed.

Exploration of the international standardization of included herbs

The existing ISO standards and standard projects (approved standard proposals) of extracted herbal medicines were searched on the ISO/TC 249 website (till December 31, 2022) and the preliminary working items (PWIs, i.e., unapproved standard proposals) information was obtained from the ISO/TC 249 National Mirror Committee in China. The herbs without standard (project or PWI) were ranked based on ISO/TR 23975:2019.

Results

Included guidelines

Four treatment guidelines of COVID-19 were explored, 2 from China [12,13] and 2 from Korea [14-16]. Both Chinese CPGs issued by the National Health Commission of China, one was for treatment and the other for rehabilitation. The two Korean guidelines were developed by the Association of Korean Medicine and the Korean Association of Traditional Pulmonary Medicine separately and both referenced the Chinese treatment guideline. Although there was no similar guideline in Japan, the Japanese Association for Infectious Diseases translated the treatment Chinese guideline, Diagnosis and Treatment Protocol for COVID-19 (Trial Version 9) [17, 18].

International application of herbal medicines

Of all the 4 guidelines, there were 62 herbal formulae and manufactured products which comprised of 284 single herbs. In the frequency analysis of these herbs, Glycyrrhizae Radix et Rhizoma (Gan Cao) was found to be the herb with the highest frequency of usage in all the Chinese and Korean guidelines (Table 1).

No.	Title	Herbal formulae and manufactured products	Single herbs	Herb with the highest frequency of usage (frequency)
1	Diagnosis and Treatment Protocol for COVID-19 (Trial Version 9)	27	103	*Glycyrrhizae Radix et Rhizoma* [11]
2	Rehabilitation treatment for discharged COVID-19 patients with major dysfunction	5	35	*Glycyrrhizae Radix et Rhizoma* [5]
3	Korean Medicine Diagnosis and Treatment Recommendation for COVID-19 (Version 2)	17	88	*Glycyrrhizae Radix et Rhizoma* [14]
4	Korean Medicine Diagnosis and Treatment Guideline for COVID-19 (Version 2.1)	13	58	*Glycyrrhizae Radix et Rhizoma* [12]

Table 1: Herbal medicines of the included clinical practice guidelines.

After merging the same herbs, all together 78 herbs were both used in the guidelines from the two countries and the top 5 frequently used medicines were Glycyrrhizae Radix et Rhizoma (Gan Cao), Pinelliae Rhizoma (Ban Xia), Scutellariae Radix (Huang Qin), Armeniacae Semen Amarum (Ku Xing Ren), Citri Reticulatae Pericarpium (Chen Pi) (Table 2).

No.	Single Herb (Pinyin Name)	Single Herb (Latin Name*)	Frequency
1	Gan Cao	*Glycyrrhizae Radix Et Rhizoma*	42
2	Ban Xia	*Pinelliae Rhizoma*	22
3	Huang Qin	*Scutellariae Radix*	20
4	Ku Xing Ren	*Armeniacae Semen Amarum*	20
5	Chen Pi	*Citri Reticulatae Pericarpium*	19
6	Shi Gao	*Gypsum Fibrosum*	18
7	Sheng Jiang	*Zingiberis Rhizoma Recens*	17
8	Bai Zhu	*Atractylodis Macrocephalae Rhizoma*	16
9	Chai Hu	*Bupleuri Radix*	16
10	Fu Ling	*Poria*	16
11	Guang Huo Xiang	*Pogostemonis Herba*	16
12	Ma Huang	*Ephedrae Herba*	15
13	Jie Geng	*Platycodonis Radix*	14
14	Cang Zhu	*Atractylodis Rhizoma*	13
15	Hou Po	*Magnoliae Officinalis Cortex*	13
16	Lian Qiao	*Forsythiae Fructus*	12
17	Ren Shen	*Ginseng Radix Et Rhizoma*	11
18	Chi Shao	*Paeoniae Radix Rubra*	10
19	Mai Dong	*Ophiopogonis Radix*	9
20	Huang Qi	*Astragali Radix*	8
21	Lu Gen	*Phragmitis Rhizoma*	8
22	Qiang Huo	*Notopterygii Rhizoma Et Radix*	8
23	Jin Yin Hua	*Lonicerae Japonicae Flos*	7
24	Ting Li Zi	*Descurainiae Semen Lepidii Semen*	7
25	Bai Zhi	*Angelicae Dahuricae Radix*	6
26	Bo He	*Menthae Haplocalycis Herba*	6
27	Cao Guo	*Tsaoko Fructus*	6
28	Shen Qu	/#	6
29	Wu Wei Zi	*Schisandrae Chinensis Fructus*	6
30	Ze Xie	*Alismatis Rhizoma*	6
31	Zhi Mu	*Anemarrhenae Rhizoma*	6
32	Fang Feng	*Saposhnikoviae Radix*	6

33	Bing Lang	*Arecae Semen*	5
34	Chuan Xiong	*Chuanxiong Rhizoma*	5
35	Da Huang	*Rhei Radix Et Rhizoma*	5
36	Gui Zhi	*Cinnamomi Ramulus*	5
37	Qing Hao	*Artemisiae Annuae Herba*	5
38	Shan Yao	*Dioscoreae Rhizoma*	5
39	Zhe Bei Mu	*Fritillariae Thunbergii Bulbus*	5
40	Zhi Shi	*Aurantii Fructus Immaturus*	5
41	Bai Shao	*Paeoniae Radix Alba*	4
42	Mai Ya	*Hordei Fructus Germinatus*	4
43	Ren Gong She Xiang	/#	4
44	Sang Ye	*Mori Folium*	4
45	Sha Ren	*Amomi Fructus*	4
46	Shan Zha	*Crataegi Fructus*	4
47	Sheng Ma	*Cimicifugae Rhizoma*	4
48	Tian Ran Bing Pian	*Borneolum*	4
49	Xi Xin	*Asari Radix Et Rhizoma*	4
50	Yi Yi Ren	*Coicis Semen*	4
51	Zhi Zi	*Gardeniae Fructus*	4
52	Zhu Ling	*Polyporus*	4
53	Zhu Ye	/#	4
54	Dang Gui	*Angelicae Sinensis Radix*	4
55	An Xi Xiang	*Benzoinum*	3
56	Di Huang	*Rehmanniae Radix*	3
57	Fu Zi	*Aconiti Lateralis Radix Praeparaia*	3
58	Niu Bang Zi	*Arctii Fructus*	3
59	She Gan	*Belamcandae Rhizoma*	3
60	Xiang Fu	*Cyperi Rhizoma*	3
61	Xuan Shen	*Scrophulariae Radix*	3
62	Zhu Sha	*Cinnabaris*	3
63	Zi Su Ye	*Perillae Folium*	3
64	Zi Wan	*Asteris Radix Et Rhizoma*	3
65	Bi Bo	*Piperis Longi Fructus*	2
66	Chen Xiang	*Aquilariae Lignum Resinatum*	2
67	Da Fu Pi	*Arecae Pericarpium*	2
68	Da Qing Ye	*Isatidis Folium*	2
69	Ding Xiang	*Caryophylli Flos*	2
70	He Zi	*Chebulae Fructus*	2
71	Kuan Dong Hua	*Farfarae Flos*	2
72	Mu Xiang	*Aucklandiae Radix*	2
73	Ru Xiang	*Olibanum*	2
74	Sang Bai Pi	*Mori Cortex*	2
75	Shan Zhu Yu	*Corni Fructus*	2
76	Su He Xiang	*Styrax*	2
77	Tan Xiang	*Santali Albi Lignum*	2
78	Yu Xing Cao	*Houttuyniae Herba*	2

Table 2: Single herbs used both in the Chinese and Korean guidelines.

*Note: The Latin name of the herbs were based on the 11th edition of the Chinese Pharmacopeia.

#Note: Herbs were not included in the 11th edition of the Chinese Pharmacopeia.

International standardization of herbal medicines

Of the 78 herbs included, 17 were standardized with published standards (under development) and 5 had proposals in ISO/TC 249 work programs (Table 3). Checked in the ISO/TR 23975:2019, 11 of the 56 herbs unstandardized were not recorded and the ranking list of rest herbs was shown in table 4. Nine herbs of the ranking list belonged to the top 100 single herbal medicines and in high priority according to the ISO/TR 23975:2019.

No.	Single Herb (Pinyin Name)	Single Herb (Latin Name*)	ISO standard (project)	
			Title	Reference number
1	Gan Cao	*Glycyrrhizae Radix Et Rhizoma*	Traditional Chinese medicine -- Glycyrrhiza uralensis, Glycyrrhiza inflata, and Glycyrrhiza glabra roots and rhizome	ISO/TC249 N1596
2	Ban Xia	*Pinelliae Rhizoma*	Traditional Chinese Medicine -- Pinellia ternata tuber	ISO/DIS 7450
3	Huang Qin	*Scutellariae Radix*	Traditional Chinese Medicine -- Scutellaria baicalensis root	ISO/DIS 4564
4	Bai Zhu	*Atractylodis Macrocephalae Rhizoma*	Traditional Chinese Medicine -- Atractylodes macrocephala rhizome	ISO/CD 13615
5	Chai Hu	*Bupleuri Radix*	Traditional Chinese Medicine -- Bupleurum chinense, Bupleurum scorzonerifolium and Bupleurum falcatum root	ISO 23965:2022
6	Fu Ling	*Poria*	Traditional Chinese medicine -- Poria cocos sclerotium	ISO/DIS 9319
7	Ma Huang	*Ephedrae Herba*	Traditional Chinese Medicine -- Ephedra sinica, Ephedra intermedia, and Ephedra equisetina herbaceous stem	ISO/DIS 9306
8	Jie Geng	*Platycodonis Radix*	Traditional Chinese Medicine -- Platycodon grandiflorus root	ISO/TC249 N1600
9	Huang Qi	*Astragali Radix*	Traditional Chinese Medicine -- Astragalus mongholicus root	ISO 22988:2020
10	Jin Yin Hua	*Lonicerae Japonicae Flos*	Traditional Chinese medicine -- Lonicera japonica flower	ISO 21317:2019
11	Bai Zhi	*Angelicae Dahuricae Radix*	Traditional Chinese Medicine --Angelica dahurica root	ISO/CD 5076

12	Zhi Mu	*Anemarrhenae Rhizoma*	Traditional Chinese medicine -- Anemarrhena asphodeloides rhizome	ISO/TC249 N1601
13	Fang Feng	*Saposhnikoviae Radix*	Traditional Chinese medicine -- Saposhnikovia divaricata root and rhizome	ISO 23964:2022
14	Chuan Xiong	*Chuanxiong Rhizoma*	Traditional Chinese Medicine -- Ligusticum chuanxiong rhizome	ISO/CD 8071
15	Da Huang	*Rhei Radix Et Rhizoma*	Traditional Chinese Medicine -- Rheum palmatum, Rheum tanguticum, and Rheum officinale root and rhizome	ISO/DIS 5228
16	Gui Zhi	*Cinnamomi Ramulus*	Traditional Chinese medicine -- Cinnamomum cassia branch	ISO/TC249 N1605
17	Shan Yao	*Dioscoreae Rhizoma*	Traditional Chinese medicine -- Dioscorea opposita rhizome	ISO/TC249 N1604
18	Bai Shao	*Paeoniae Radix Alba*	Traditional Chinese medicine -- Paeonia lactiflora root -- White peony root	ISO 22586:2022
19	Zhi Zi	*Gardeniae Fructus*	Traditional Chinese Medicine -- Gardenia jasminoides fruit	ISO/CD 13619
20	Dang Gui	*Angelicae Sinensis Radix*	Traditional Chinese Medicine -- Angelica sinensis root	ISO 22584:2019
21	Di Huang	*Rehmanniae Radix*	Traditional Chinese medicine -- Rehmannia glutinosa root	ISO/DIS 9109
22	Fu Zi	*Aconiti Lateralis Radix Praeparaia*	Traditional Chinese medicine -- Processed Aconitum carmichaelii lateral root	ISO 23962:2021

Table 3: International standardization of included herbal medicines.

*Note: The Latin name of the herbs were based on the 11th edition of the Chinese Pharmacopeia.

No.	Single Herbs (Pinyin Name)	Single Herbs (Latin Name*)	ISO/TR 23975:2019
1	Ren Shen	*Ginseng Radix Et Rhizoma*	1
2	Wu Wei Zi	*Schisandrae Chinensis Fructus*	20
3	Bing Lang	*Arecae Semen*	28
4	Bo He	*Menthae Haplocalycis Herba*	45
5	Sheng Ma	*Cimicifugae Rhizoma*	46
6	Kuan Dong Hua	*Farfarae Flos*	76
7	She Gan	*Belamcandae Rhizoma*	81
8	Chi Shao	*Paeoniae Radix Rubra*	91
9	Niu Bang Zi	*Arctii Fructus*	93
10	Xuan Shen	*Scrophulariae Radix*	101
11	Cang Zhu	*Atractylodis Rhizoma*	115.5
12	Zhe Bei Mu	*Fritillariae Thunbergii Bulbus*	119
13	Yi Yi Ren	*Coicis Semen*	128
14	Qiang Huo	*Notopterygii Rhizoma Et Radix*	138
15	Hou Po	*Magnoliae Officinalis Cortex*	165.5
16	Lian Qiao	*Forsythiae Fructus*	165.5
17	Ze Xie	*Alismatis Rhizoma*	165.5
18	Sha Ren	*Amomi Fructus*	165.5
19	An Xi Xiang	*Benzoinum*	165.5
20	Xiang Fu	*Cyperi Rhizoma*	165.5
21	Mu Xiang	*Aucklandiae Radix*	165.5
22	Shan Zhu Yu	*Corni Fructus*	165.5
23	Ku Xing Ren	*Armeniacae Semen Amarum*	184
24	Shan Zha	*Crataegi Fructus*	187
25	Xi Xin	*Asari Radix Et Rhizoma*	191
26	Chen Xiang	*Aquilariae Lignum Resinatum*	192
27	Ru Xiang	*Olibanum*	194
28	Chen Pi	*Citri Reticulatae Pericarpium*	227.5
29	Guang Huo Xiang	*Pogostemonis Herba*	227.5
30	Mai Dong	*Ophiopogonis Radix*	227.5
31	Qing Hao	*Artemisiae Annuae Herba*	227.5
32	Zhi Shi	*Aurantii Fructus Immaturus*	227.5
33	Zhu Ling	*Polyporus*	227.5
34	Zi Wan	*Asteris Radix Et Rhizoma*	227.5
35	Da Fu Pi	*Arecae Pericarpium*	227.5
36	He Zi	*Chebulae Fructus*	227.5
37	Yu Xing Cao	*Houttuyniae Herba*	227.5
38	Ting Li Zi	*Descurainiae Semen Lepidii Semen*	258
39	Zi Su Ye	*Perillae Folium*	260
40	Cao Guo	*Tsaoko Fructus*	318
41	Sang Ye	*Mori Folium*	318
42	Da Qing Ye	*Isatidis Folium*	318
43	Ding Xiang	*Caryophylli Flos*	318
44	Sang Bai Pi	*Mori Cortex*	318
45	Tan Xiang	*Santali Albi Lignum*	318

Table 4: Ranking list of for ISO standardization.

*Note: The Latin name of the herbs were based on the 11th edition of the Chinese Pharmacopeia.

Discussion

Two countries used herbal medicines for preventing and treating COVID-19 and four guidelines were included. 22 of the 78 eligible single herbs were standardized or in work plan of ISO/TC 249 and 45 of the rest herbal medicines were suitable for future international standardization. However, only 9 unstandardized herbs in high priority of the ranking list.

Compared with 194 Member States of WHO, the international application of Chinese medicine for preventing and treating COVID-19 is quite limited. There is still a long way for Chinese medicine to participate in international cooperation on the prevention and treatment of major infectious diseases.

TCM was the first traditional medicine acquired WHO recognition for treating COVID-19 which was a milestone and could not be overstated. The TCM for COVID-19 were used in China and Korea and got support from Japan, the three countries were all important Participating members in ISO/TC 249, which showed great global relevance. The international standardization of herbs treating COVID-19 is in urgent need.

However, the main document for herbal medicine standardized planning in ISO/TC 249, ISO/TR 23975:2019, published before the outbreak of COVID-19, cannot fully adapt to the new international situation. 28% (22/78) of the Republic of Korea and China used herbal medicines for preventing and treating COVID-19 has been standardized. Only 20% (9/45) of unstandardized herbs in high priority of ISO/TR 23975:2019 and 24% (11/45) even did not included. In addition, the pandemic also changed the international trading value of many herbal medicines, which was one of the main developing principles of the ISO/TR 23975:2019. It is time to revise and update ISO/TR 23975:2019.

The international application and standardization of the manufactured products for COVID-19 was even worse. Only the Chinese treatment guideline included applied 16 Chinese patent medicines and no foreign manufacturers of these medicines. Thus the Chinese patent medicines had to be decomposed into single herbs in analysis.

Conclusion

The results showed narrow scope of international application and low degree of international standardization in using Chinese medicine to prevent and treat COVID-19. More efforts are needed from the international colleagues.

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Competing Interests

The authors declare that they have no competing interests.

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