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ORIGINAL ARTICLE

COVID-19 vaccine guidelines was numerous in quantity but many lack transparent reporting of methodological practices

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Abstract

Objective: To describe the current status of COVID-19 vaccine guidelines.

Study Design and Setting: We searched databases, Google and guideline platforms to retrieve COVID-19 vaccine guidelines published between January 1, 2020 and July 8, 2021. We worked in pairs to identify the eligible guidelines and extract data of whether the methodology, funding, and conflict of interests were assessed/reported, and so on. Results were presented descriptively.

Results: A total of 106 COVID-19 vaccine guidelines were included. In the first half of 2021, on average 15 guidelines were published every month. Fifty (47.2%) guidelines addressed the vaccination of people with specific medical conditions, and 18 (17.0%) guidelines focused on adverse effects after vaccination. Only 28 (26.4%) guidelines reported the methodology they used. Four (3.8%) of guidelines assessed both the quality of evidence and strength of recommendations; 42 (39.6%) and 65 (61.3%) guidelines reported their funding sources and conflict of interest, respectively. Most guidelines were published in English (n = 92, 86.8%).

Conclusion: A high number of guidelines on COVID-19 vaccines have been published in the recent months, but most of them lack clear and transparent reporting of methodology, funding, and conflicts of interest. Rigorous methodological and reporting quality evaluation of these guidelines is needed. © 2021 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>)

Keywords: COVID-19; Vaccine; Guideline; Methodology; Transparency; Conflict of interest

Conflict of interest: None.

Authors' contributions: YC, WZ, XL and YL conceptualized the study. ZW, HL, LW, JZ and SZ searched literatures. ZW, HL, XL, NY, ML, QZ, QL, LW, JZ, SW, YL, RS, XL and QS screened literatures. ZW, HL, XL, NY, ML, QZ, QL, LW, JZ, SW, YL, RS, XL and SZ extracted data. ZW wrote the first version manuscript. HL, XL, NY, ML, QZ, QL,

YL and JE modified manuscript. All authors read and approved the draft for finalization.

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What's new

1. This is the first analysis that provides a full summary and presentation of the current overview of COVID-19 vaccine guidelines, identifies problems with COVID-19 vaccine guidelines, and proposes recommendations for future guidelines.
2. We find that most of COVID-19 vaccines guidelines lack clear and transparent reporting of methodology, funding, and conflicts of interest. And we suggest that guideline developers should strictly follow the guideline handbook especially in disclosing conflict of interests. Because a rigorous and reliable guideline development process is essential to avoid potential harm to patients and the healthcare system due to misinformation and misunderstanding.
3. There is a lack of guidelines for COVID-19 vaccines from low- and middle-income countries and published in languages other than English and a lack of recommendations for these countries. Policymakers and funders should further increase their support for researchers to provide higher quality clinical evidence for development of future guidelines and updates.

1. Background

Since the outbreak of COVID-19 at the end of 2019, over 200 million cumulative confirmed cases and 4.6 million deaths have been reported in nearly 200 countries and territories worldwide [1]. Vaccination is the safest way to control the spread of the epidemic in the absence of effective antiviral drugs [2–4]. As of August 22, 2021, 22 vaccines have been approved, among which seven vaccines have been approved for emergency use by the World Health Organization (WHO) [5,6]. According to Our World in Data, 41.8% of the world's population has received at least one dose of a COVID-19 vaccine, and 29.7% have been fully vaccinated [3]. However, this number is far below the level of vaccination needed to produce herd immunity. Vaccination campaigns are hampered by vaccine accessibility, efficacy and hesitancy, for example, there are no approved vaccines for children, and difficulties in obtaining vaccines in low-income countries [7]. To address this problem, practice guidelines have been developed by many organizations and institutions aiming to translate the research findings into recommendations for practice and to provide a guidance for the appropriate use of COVID-19 vaccination [8–16]. There are already many different types of guidelines at present, some of the guidelines are brief, others lengthy, however, the overall picture of the vaccine guidelines is unclear. To our knowledge so far, no study has comprehensively summarized the characteristics

of these guidelines. Therefore, we conducted a systematic survey to comprehensively analyze the methodological and reporting characteristics of guidelines on COVID-19 vaccines to help stakeholders understand the current situation and inform the development of future guidelines.

2. Method

2.1. Search strategy

We systematically searched MEDLINE (via PubMed), Embase, Web of Science, WHO COVID-19 database, Wanfang Data, China Biomedical Literature database (CBM) and China National Knowledge Infrastructure (CNKI) to identify guidelines on COVID-19 vaccines published between January 1, 2020 and July 8, 2021. We used the search terms “vaccine,” “COVID-19,” “guideline” and their derivatives. The official websites (see Table 1) and Google were also searched to identify any guidelines missed in the literature database search. The details of the search strategy are presented in Supplementary File 1.

2.2. Inclusion and exclusion criteria

We included records that fulfilled the following three criteria: (1) the article was an evidence-based or consensus-based practice guideline with one of the words “guideline,” “recommendation,” “statement,” “consensus” and “guidance” in the title; (2) on the article addressed COVID-19 vaccines or the administration and management of complications of COVID-19 vaccination; and (3) the record was the latest available version. There was no language restriction.

The following types of articles were excluded: (1) the number of authors was less than three (when the number of authors is less than three, differences of opinions cannot be reached effectively) and the guideline was not endorsed or supported by any academic or public health organization (e.g., association, society, international organizations or government agencies); (2) guidelines that addressed COVID-19 vaccination amongst other topics (e.g., general COVID guidelines with some items related to vaccines); (3) we failed to access the full text of the article; (4) the article was a summary of recommendations from different guidelines; and (5) duplicates.

2.3. Study selection

Twelve investigators (Zijun Wang, Qianling Shi, Hui Liu, Junxian Zhao, Xufei Luo, Meng Lv, Yunlan Liu, Shouyuan Wu, Xiao Liu, Renfeng Su, Nanyang, and Ling Wang) were divided into six groups of two. The records were divided across six groups, within which both investigators screened the literature independently. The formal selection process consisted of two stages: (1) screening all titles and abstracts to determine whether the record is potentially relevant to the research question and (2) obtaining

Table 1. Website

Full name	Short name	Link
World Health Organization	WHO	https://www.who.int/
Guideline International Network	GIN	https://g-i-n.net/
Scottish Intercollegiate Guidelines Network	SIGN	https://www.sign.ac.uk/our-guidelines/
The National Institute for Health and Care Excellence	NICE	https://www.nice.org.uk/
Canadian Medical Association Clinical Practice Guidelines	/	https://joulecma.ca/cpg/homepage
Australian Clinical Practice Guidelines	/	https://www.clinicalguidelines.gov.au/
New Zealand Guidelines Group	NZGG	https://www.health.govt.nz/about-ministry/ministry-health-websites/new-zealand-guidelines-group
Medical Information Network Distribution Service	MINDS	https://minds.jcqh.c.or.jp/english/
Chinese Medical Ace Base	/	http://seleguide.yiigle.com/home/zhinan
Emergency Care Research Institute	ECRI	https://www.ecri.org/

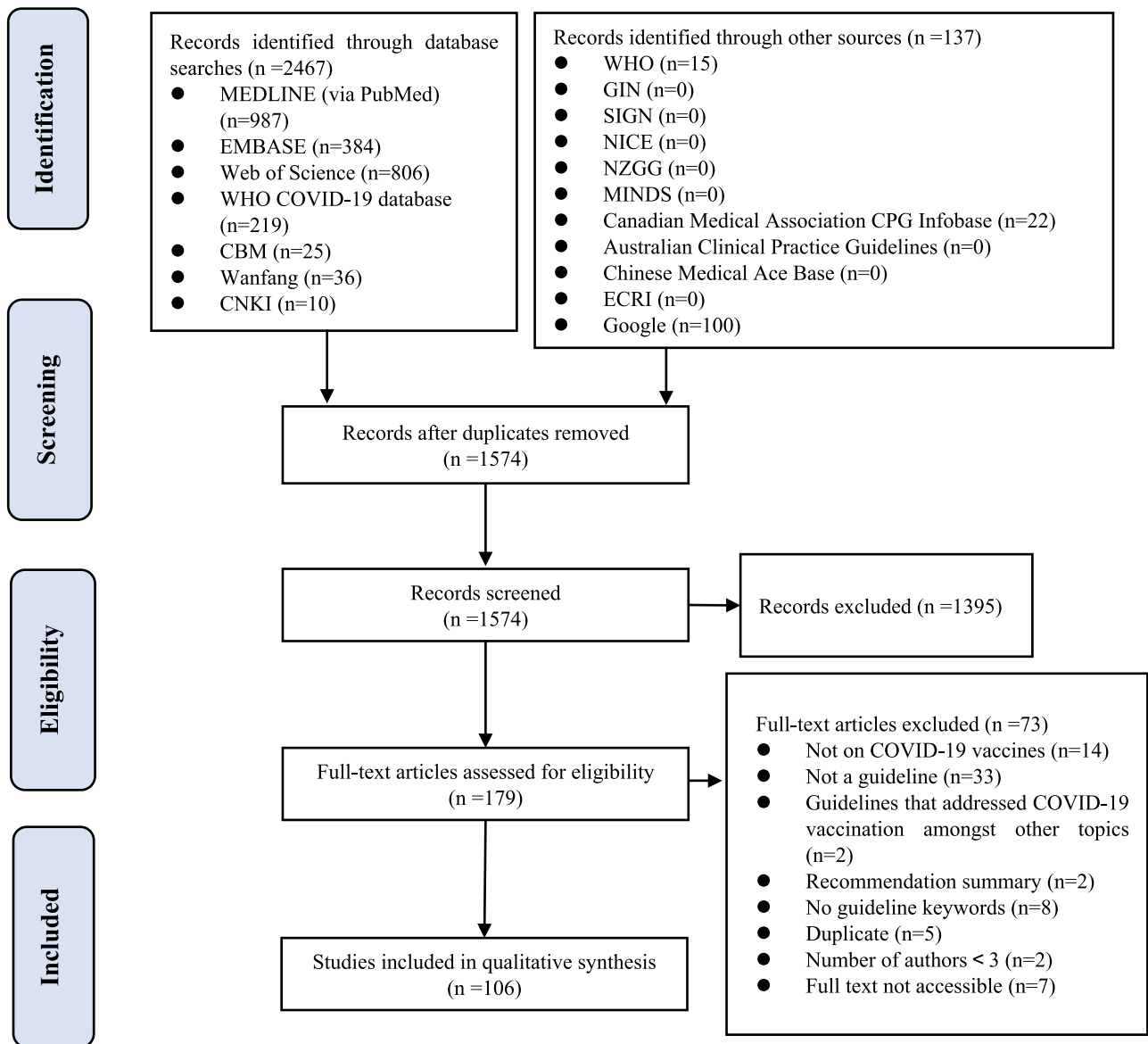


Fig. 1. Flow diagram of the selection process.

and screening full texts of potentially eligible articles to decide about the inclusion. Disagreements were resolved by discussion, or by consulting a third investigator.

2.4. Data extraction

Fourteen investigators (Zijun Wang, Siya Zhao, Hui Liu, Junxian Zhao, Xiao Liu, Ling Wang, Shouyuan Wu, Renfeng Su, Nanyang, Yunlan Liu, Xufei Luo, Meng Lv, Qi Zhou, and Qinyuan Li) were divided into seven groups of two. Each group was given a part of the records. All investigators in the group independently extracted the following data using a pre-defined extraction table: (1) basic information: publication year and month (first online publication), country/region of main developer institution, leading organization/institution, number of authors, and target population; (2) information related to guideline development: whether the methodology, strength of recommendations, quality of evidence, funding, conflict of interests and research gap were assessed/reported; and (3) information related to the publication: publication format (journal, website, or both), whether the guidelines were accessible free of charge or not, impact factor (IF) of the journal (Journal Citation Reports 2020) and language. Disagreements were solved by consensus or consultation with a third reviewer. In order to ensure the accuracy and consistency of the extracted data, we conducted two rounds of pilot tests before the formal extraction and calculate the intraclass correlation coefficient (ICC) value of all investigators respectively (ICC value 1 = 0.934; ICC value 2 = 0.984).

2.5. Data analysis

We used Microsoft Excel 2019 for data collection. Dichotomous and categorical variables were presented as absolute numbers and percentages, and continuous variables as means with standard deviation or medians with interquartile range [IQR].

3. Results

3.1. Search results

We identified initially 2604 records. After deduplicating and screening of titles and abstracts, we read the full texts of 179 potentially eligible records. Based on inclusion and exclusion criteria, 106 COVID-19 vaccine guidelines were finally included in our study (Fig. 1).

3.2. Guideline information

3.2.1. Basic information

The 106 included COVID-19 vaccine guidelines were published between May 2020 and July 2021, of which 95 (89.6%) in 2021 (Fig. 2). On average 14.8 ± 1.6 guidelines were thus published monthly between January 2021

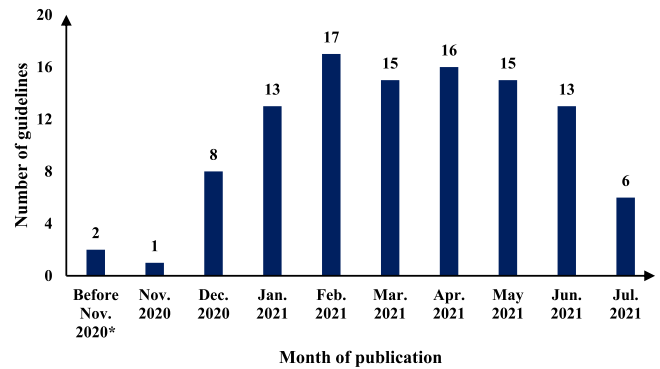


Fig. 2. Time of publication. Before November 2020*: one guideline was published in May 2020 and one in August 2020.

and June 2021. The country or region of the main developer institution that issued the highest number of guidelines was Canada ($n = 22$, 20.8%), followed by international ($n = 18$, 17.0%) and the United States ($n = 13$, 12.3%) (see Supplementary File 2). About half ($n = 55$, 51.9%) of the guidelines were developed by societies or associations; the highest number of guidelines developed by a single society was four (Advisory Committee on Immunization Practices). International organizations led 18 (17.0%) guidelines, of which seven by the WHO; and national organizations issued 13 (12.3%), nine of which were from the Public Health Agency of Canada National Advisory Committee on Immunization (NACI). Almost half ($n = 50$, 47.2%) of the guidelines addressed people with specific medical conditions; the most commonly addressed condition was rheumatic and/or musculoskeletal diseases ($n = 8$; Fig. 3). Eighteen (17.0%) guidelines targeted adverse effects after vaccination, half of which addressed COVID-19 vaccine associated anaphylaxis and allergic reactions ($n = 9$, Fig. 4). Eighty (75.5%) guidelines reported their authors, ranging from one author to 62 authors across the studies (median 10.5, IQR 6–17). There were 28 different terms in the titles that were used to identify the article as a guideline, of which the most common were “Recommendations” ($n = 17$, 25.5%), “Position Statement” ($n = 16$, 15.1%) and “Statement” ($n = 13$, 12.3%; see Supplementary File 2, Table 2).

3.2.2. Guideline development

A total of 28 (26.4%) guidelines reported methodological details, 14 (13.2%) guidelines reported clear clinical questions, and 64 (60.4%) guidelines reported clear recommendations. In 55 (51.9%) guidelines, the recommendations or explanations were supported by references; the number of recommendations ranged between one and 56 across the guidelines [median 7.5, IQR 5–12]. Eight guidelines (7.5%) assessed the quality of the evidence, seven of them using the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) tool and

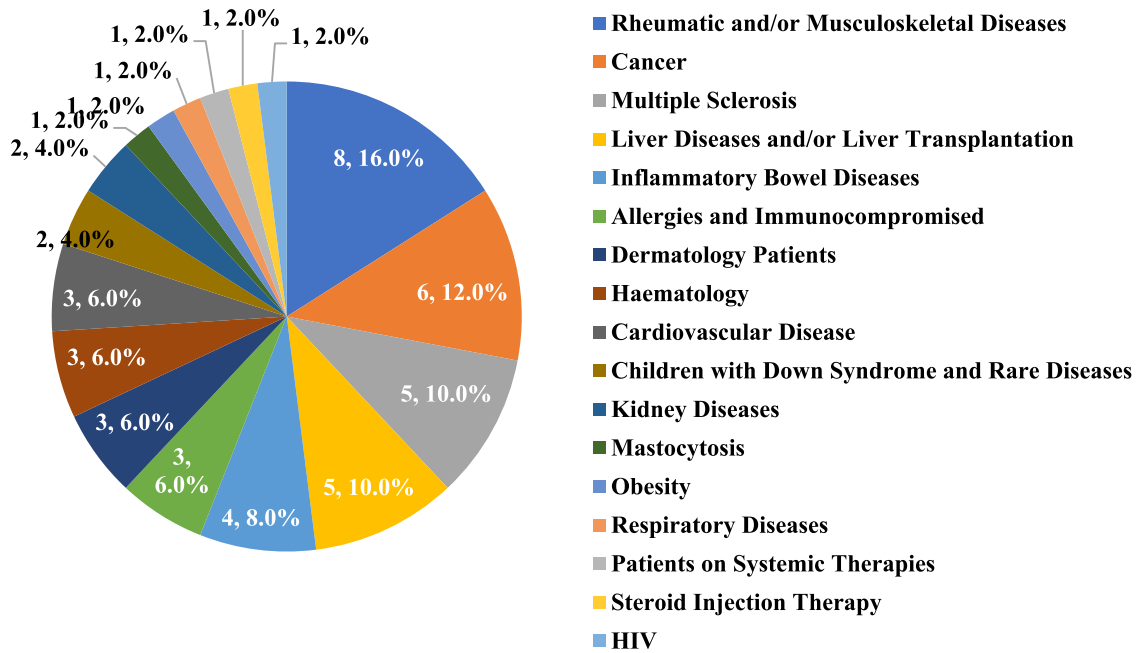


Fig. 3. Number of guidelines for populations with specific medical conditions (n = 50).

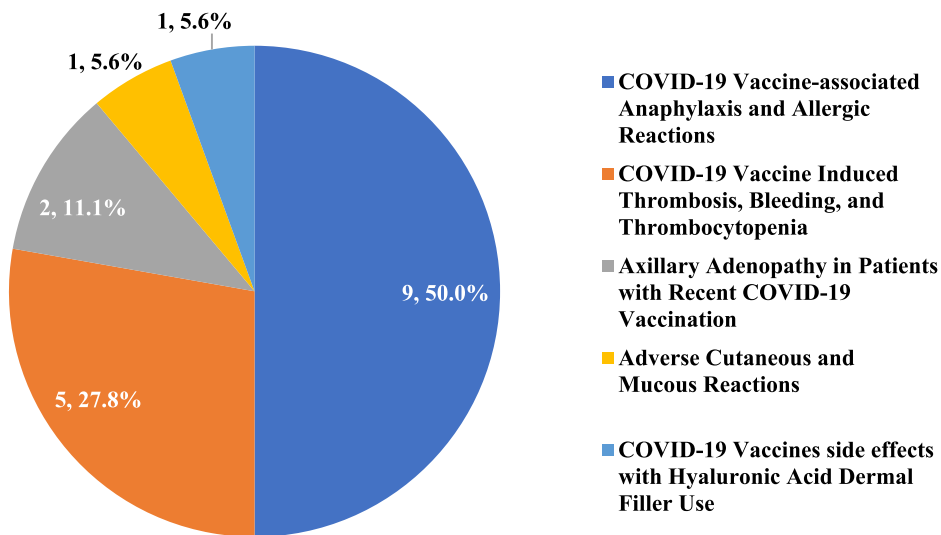


Fig. 4. Number of guidelines for patients experiencing vaccine-related adverse reactions (n = 18).

one with the Oxford tool [17]. Seven (6.6%) guidelines provided the strength of recommendations: six of them used the GRADE tool, and one graded the strength by voting [18]. Only four (3.8%) guidelines provided both the strength of recommendations and evidence quality, all of which used the GRADE tool. Forty-two (39.6%) guidelines reported funding support, of which only one guideline reported receiving commercial funding; 65 (61.3%) guidelines declared the conflict of interests of the individuals involved in the development, of which 35 guidelines reported no conflicts of interest. Seventeen (16.0%) guidelines clearly reported the research gaps or made recommendations for future research directions, such as the

mechanism of allergic reaction to COVID-19 vaccine, the efficacy and safety of COVID-19 vaccines with long-term follow-up, and COVID-19 vaccination in special populations [8–12,14,15]. Sixteen (15.1%) guidelines were updated versions, of which 14 were second editions, and the remaining two the seventh and 15th editions, respectively (Table 2).

3.2.3. Information on the publication

Eighty-one (76.4%) guidelines were published in 73 different journals, seven of which were published in addition on a dedicated website. The journal with the highest number of published guidelines was Morbidity and Mortality

Weekly Report (n = 4, 3.8%) (see Supplementary File 2). Seventy-eight (73.6%) guidelines were accessible without charge, of which 59 (55.7%) were published in fully open access journals. More than half of the guidelines (n = 62, 58.5%) were published in journals listed in the Science Citation Index (SCI), in which the majority (34.0%, 36 guidelines) were published in journals with IF under five. Ninety-two (86.8%) guidelines were published in English; 15 (14.2%) guidelines were published in both English and at least one other language, most of which were developed by either NACI (n = 7) or WHO (n = 5, Table 2).

4. Discussion

Our study showed that more than a hundred COVID-19 vaccine guidelines were developed by a total of 74 institutions in 33 national and international organizations so far. The number is close to the number of clinical practice guidelines of COVID-19 [16]. The majority of these guidelines were published in peer-reviewed journals in English by developers from high-income countries such as Canada and the United States. There is a lack of guidelines for COVID-19 vaccines from low- and middle-income countries and published in languages other than English and a lack of recommendations for these countries. This may be related to the limited ability to develop national guidelines and limited access to COVID-19 vaccine candidates. What's more, COVID-19 will not end anytime soon due to virus variants. The research and application of vaccination is still in high gear and still in an early stage, ditto for the guidelines.

Our results indicated that most guidelines focused on patients with specific medical conditions who may be at a high risk of severe vaccine-related adverse reactions due to their physiological state or to external interventions, and thus a more vaccine hesitancy population. In particular, people with conditions such as rheumatic and/or musculoskeletal diseases, cancer, and dermatological disorders, who are taking immunomodulatory or immunosuppressive drugs, are at higher risk of getting infection or worsening of the clinical course of COVID-19 [19,20]. The prevention and management of adverse effects maybe an issue in all vaccines that guidelines for this topic are necessary, especially in COVID-19 vaccination. This may be due to the successive occurrence of allergic reactions in vaccine recipients, which, although not very frequent, have been of wide concern to researchers and require recommendations to explain and guide the actions of clinicians and healthcare staff [21–24]. However, there was insufficient clinical evidence in the guidelines to support recommendations for specific populations and adverse reactions to vaccines, for example, evidence on COVID-19 vaccination in cancer patients was lacking, and the current evidence on allergies against mRNA vaccines still needs to be updated [25,26]. However, a large number of clinical trials for specific populations and adverse reactions to vaccines are still ongoing

and if these guidelines are updated promptly, the quality of evidence and strength of recommendations will continue to improve [5]. Our study also analyzed research gaps in vaccine guidelines, which provided clues and information for future research priorities.

While there is an urgent need for guidelines that are able to provide stakeholders with recommendations on COVID-19 vaccination and administration, a rigorous and reliable guideline development process is essential to avoid potential harm to patients and the healthcare system due to misinformation and misunderstanding [27]. We found that most guidelines did not report the methodology in detail and information on conflict of interests and funding disclosures was often lacking. The lack of clear recommendations, clear citations of evidence to support the recommendations, and evaluation of the strength of recommendations and evidence quality were the main methodological problems. This finding is similar to that of previous studies on COVID-19 guidelines [27–29]. According to the Institute of Medicine, the development processes and funding of a clinical practice guideline should be transparent, that is described in detail and publicly accessible [30]. The conflict of interests and the funding received throughout the guideline development are both important concerns by stakeholders that will directly affect each step of the guideline development [31]. However, less than half of the COVID-19 vaccine guidelines reported the conflicts of interest and funding. Guidelines that are not evidence-based and have potential conflict of interests do not provide reliable guidance to healthcare professionals and patients and may undermine public trust in the vaccine [32].

Based on our results, we suggest that: (1) guideline developers should strictly follow the guideline handbook especially in disclosing conflict of interests, for vaccine guidelines [31]; also, vaccine guidelines should be published in multiple languages in open access journals and websites whenever possible to facilitate their dissemination; (2) guideline assessors should conduct methodological and reporting quality assessments of COVID-19 vaccine guidelines using tools such as the Appraisal of Guidelines for Research & Evaluation Instrument II (AGREE II) and Reporting Items for Practice Guidelines in Healthcare (RIGHT), in order to gain a more comprehensive understanding of these guidelines [33,34]; and (3) policymakers and funders should further increase their support on the areas of guideline now focusing on, like vaccine-related adverse reactions and research gaps, to provide higher quality clinical evidence for the development of future guidelines and updates.

To our knowledge, this is the first analysis that provides a full summary and presentation of the current overview of COVID-19 vaccine guidelines, identifies problems with COVID-19 vaccine guidelines, and proposes recommendations for future guidelines. The main limitation of this study was that we only included a limited number of local and national databases and websites. However, we expect

Table 2. Characteristics of included guidelines (N = 106)

Category	Characteristic	Number (%)
Basic information		
Country/region of main developer institution (Top three)		
	Canada	22 (20.8)
	Internationality	18 (17.0)
	United States	12 (11.3)
Leading organization/institution		
	Society/association	54 (50.9)
	International organization	19 (17.9)
	National institution/government	13 (12.3)
	Individual persons	10 (9.4)
	Working group	5 (4.7)
	Scientific research institutions	3 (2.8)
	University/hospital	1 (0.9)
Target population		
	Individuals with specific medical conditions	50 (47.2)
	Individuals who experienced adverse reactions	18 (17.0)
	General population	25 (23.6)
	Pregnant and breastfeeding mothers	8 (7.5)
	Others ^d	3 (2.8)
	Children	2 (1.9)
Number of authors		
	1~10	40 (37.7)
	11~20	27 (25.5)
	21~30	7 (6.6)
	>30	6 (5.7)
	Not applicable	26 (24.5)
Terms used in title to identify the document as a guideline (Top three)		
	Recommendations	27 (25.5)
	Position statement	16 (15.1)
	Statement	13 (12.3)
Information on the development process		
Methodology		
	Reported	28 (26.4)
	Not reported	78 (73.6)
Clear clinical question		
	Reported	14 (13.2)
	Not reported	92 (86.8)
Clear recommendations (highlighted/in bold or italics/as separate section)		
	Reported	64 (60.4)
	Not reported	42 (39.6)
Number of recommendations		
	1~10	40 (37.7)
	11~20	17 (16.0)
	21~30	2 (1.9)
	>30	5 (4.7)
	Not applicable ^a	42 (39.6)

(continued on next page)

Table 2 (continued)

Category	Characteristic	Number (%)
Recommendations or their explanation supported by references	Yes	55 (51.9)
	No	9 (8.5)
	Not applicable ^a	42 (39.6)
Strength of recommendations	Assessed	7 (6.6)
	Not assessed	99 (93.4)
Quality of evidence	Assessed	8 (7.5)
	Not assessed	98 (92.5)
Guideline development group	Grouped by criteria other than function	5 (4.7)
	Grouped by function	5 (4.7)
	Not grouped	96 (90.6)
Funding	No funding	21 (19.8)
	Non-commercial funding	20 (18.9)
	Commercial funding	1 (0.9)
	Not reported	64 (60.4)
Conflict of interest	Financial conflicts of interest exist	0 (0.0)
	Non-financial conflicts of interest exist	1 (0.9)
	Report disclosure of interests only	27 (25.5)
	Disclosure of interest and no conflict of interest	2 (1.9)
	Report no conflict of interests only	35 (33.0)
Updated version	Yes	16 (15.1)
	No	90 (84.9)
Information on publication	Journal only	74 (69.8)
	Website only	25 (23.6)
	Journal and website	7 (6.6)
Type of journal ^b	General	15 (14.2)
	Specialty	66 (62.3)
Open Access status of journal	Full Open Access journal	59 (55.7)
	Hybrid Open Access	3 (2.8)
	Not Open Access	19 (17.9)
Accessible free of charge	No	3 (2.8)
	Yes	78 (73.6)
Impact factor (IF) of the journal		

(continued on next page)

Table 2 (continued)

Category	Characteristic	Number (%)
	IF>10	14 (13.2)
	5<IF≤10	12 (11.3)
	IF≤5	36 (34.0)
	Not indexed in SCI ^e	19 (17.9)
Language of the abstract		
Single language		62 (58.5)
	English	61 (57.5)
	German	1 (0.9)
Multiple languages		10 (9.4)
	English and Spanish	4 (3.8)
	English and Chinese	2 (1.9)
	English and German	1 (0.9)
	English and Portuguese	1 (0.9)
	English and Polish	1 (0.9)
	English and Russian	1 (0.9)
Not Applicable ^c		34 (32.1)
Language of the full text		
Single language		91 (85.8)
	English	77 (72.6)
	Spanish	4 (3.8)
	Chinese	4 (3.8)
	German	3 (2.8)
	Polish	1 (0.9)
	Russian	1 (0.9)
	Portuguese	1 (0.9)
Multiple languages		15 (14.2)
	English and French	8 (7.5)
	English, Chinese, Arabic, French, Spanish and Russian	2 (1.9)
	English and Bulgarian	1 (0.9)
	English, French, Arabic and Russian	1 (0.9)
	English, French, Spanish, Italian, Turkish and Arabic	1 (0.9)
	English and Spanish	1 (0.9)
	English, Chinese and Arabic	1 (0.9)

^a Not applicable: Guidelines without clear recommendations.

^b General journal means a general, multidisciplinary journal; Specialty journal means a specialized, discipline-specific journal.

^c Not applicable: Guidelines without abstracts.

^d Others: respiratory health care professionals (1), staff of medical institutions (1) and not clear (1).

^e SCI: Science Citation Index.

that the number of such guidelines is small enough to not essentially affect our main conclusions.

5. Conclusions

Although a number of COVID-19 vaccine guidelines have been developed in the past year, most do not follow established methodological requirements. These limitations make it challenging for clinicians and other users to select and appropriately utilize the guidelines. To promote the

quality of vaccine guidelines, a more critical evaluation and systematic analysis of these guidelines are needed.

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Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.jclinepi.2021.12.015](https://doi.org/10.1016/j.jclinepi.2021.12.015).

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