



Contents lists available at ScienceDirect

European Journal of Obstetrics & Gynecology and Reproductive Biology

journal homepage: www.elsevier.com/locate/ejogrb

Evaluation of the quality of guidelines for assisted reproductive technology using the RIGHT checklist: A cross-sectional study

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ARTICLE INFO

Article history:

Received 14 March 2019

Accepted 24 July 2019

Keywords:

Clinical practice guideline
Assisted reproductive technology
RIGHT

ABSTRACT

Introduction: In recent years, assisted reproductive technology (ART) has developed rapidly, leading to an increasing number of clinical practice guidelines in this field. However, the reporting quality of current clinical practice guidelines in ART is still unknown.

Objective: To evaluate the reporting quality of clinical practice guidelines in the field of ART using the RIGHT checklist.

Method: Relevant guidelines were identified by electronic search of PubMed, Chinese Biomedical Literature Database (CBM), Wan Fang Database and Chinese National Knowledge Infrastructure (CNKI) from the beginning of the database to October, 2017. We also searched the websites of the guideline development organizations, including Guidelines International Network (GIN), National Guideline Clearinghouse (NGC) and the National Institute for Health and Care Excellence (NICE), as well as from two medical associations, including the European Society of Human Reproduction and Embryology (ESHRE) and the American Society for Reproductive Medicine (ASRM). We used Google Scholar to find additional clinical practice guidelines (CPGs) as well. Two investigators searched the database, selected guidelines independently based on the inclusion criteria, and extracted the relevant information.

Result: Fifteen guidelines (i.e. six developed by individual institutions and 9 by associations) were included. On average, 12.7 out of 35 items in the RIGHT standard (36.3%) were reported in each guideline. Five items were not reported by any of these guidelines. The reporting proportion of the seven domains (i.e. *Basic information; Background; Evidence; Recommendations; Review and quality assurance; Funding and declaration and management of interests; Other information*) were 46.7%, 40.8%, 45.3%, 29.5%, 53.3%, 10.0%, 26.7%, respectively.

Conclusion: At present, the reporting quality of guidelines for ART is poor, especially regarding the funding. In the future guideline development, more consideration should be given to reporting, dissemination and implementation.

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Introduction

Assisted reproductive technology (ART) refers to the interventions that include the in vitro handling of both human oocytes and sperm or of embryos for the purpose of reproduction. This includes, but is not limited to, in vitro fertilization (IVF) and embryo transfer (ET), intracytoplasmic sperm injection (ICSI),

embryo biopsy, preimplantation genetic testing (PGT), assisted hatching, gamete intrafallopian transfer (GIFT), zygote intrafallopian transfer, gamete and embryo cryopreservation, semen, oocyte and embryo donation, and gestational carrier cycles. [1] Previous studies show that infertility affects one in seven couples in the UK [2,3]; it appears there has been no major change in its prevalence but many more couples are seeking help than previously [3]. Because of the serious issue of infertility and the increasing needs for treatment, an increasing number of hospitals have set up infertility centers. The significant development of ART [2] provided new approaches of the diagnosis and treatment of infertile patients worldwide [1]. However, ART is not without dilemmas and debates, and the researchers still fail to reach consensus on many dimensions of the technology. In order to regulate ART and provide standard guidance for specialists in this area, clinical practice guidelines (CPGs) for ART have emerged.

Clinical practice guidelines are statements that include recommendations intended to optimize patient care. High-quality clinical practice guidelines can standardize clinicians' treatment behaviors, reduce the costs and improve the quality of healthcare. [4] AGREE II is an evaluation tool developed for quality assessment and reporting, which has been widely used [5–8]. To evaluate the quality of the guidelines for assisted reproductive technology, some previous studies using AGREE II have already been published, which showed the poor quality of current guidelines [9,10]. However, AGREE II was created by a small group of researchers, and did not separate out reporting and methodological quality of guidelines. The exact reporting quality of the guidelines is still unknown.

In 2016, the International Reporting Items for Practice Guidelines in Health Care (RIGHT) Working Group developed the RIGHT checklist to assist guideline developers in reporting guidelines. Because of the different purpose, structure, and content [11], multifunction tools may not be optimal and must be distinguished

from tools that address reporting and those that assess methodological quality. Thus, RIGHT is better than AGREE II when it is used to evaluate the reporting quality of guidelines. Nowadays, RIGHT has already been widely recognized as the reporting criteria for guidelines [12] and has been translated into several languages [13]. This study aims to evaluate the reporting quality of guidelines for assisted reproduction through the RIGHT checklist, to inform the formulation of future ART-related guidelines.

Method

Searching methods

Relevant guidelines were identified by electronic search of PubMed, Chinese Biomedical Literature Database (CBM), Wan Fang Database and Chinese National Knowledge Infrastructure (CNKI) from the beginning of the database to October, 2017. We also searched the websites of the guideline development organizations, including Guidelines International Network (GIN), National Guideline Clearinghouse (NGC) and the National Institute for Health and Care Excellence (NICE), as well as from two medical associations, including the European Society of Human Reproduction and Embryology (ESHRE) and the American Society for Reproductive Medicine (ASRM). Google Scholar was also searched to find additional CPGs. Search strategies are included in Annex 1.

Inclusion and exclusion criteria

We included clinical practice guidelines which are based on evidence and related to assisted reproductive technology.

The following types of CPGs were excluded: (a) translation of guidelines; (b) guidelines related to psychology and ethics; and (c) older version of guidelines if an updated version was available.

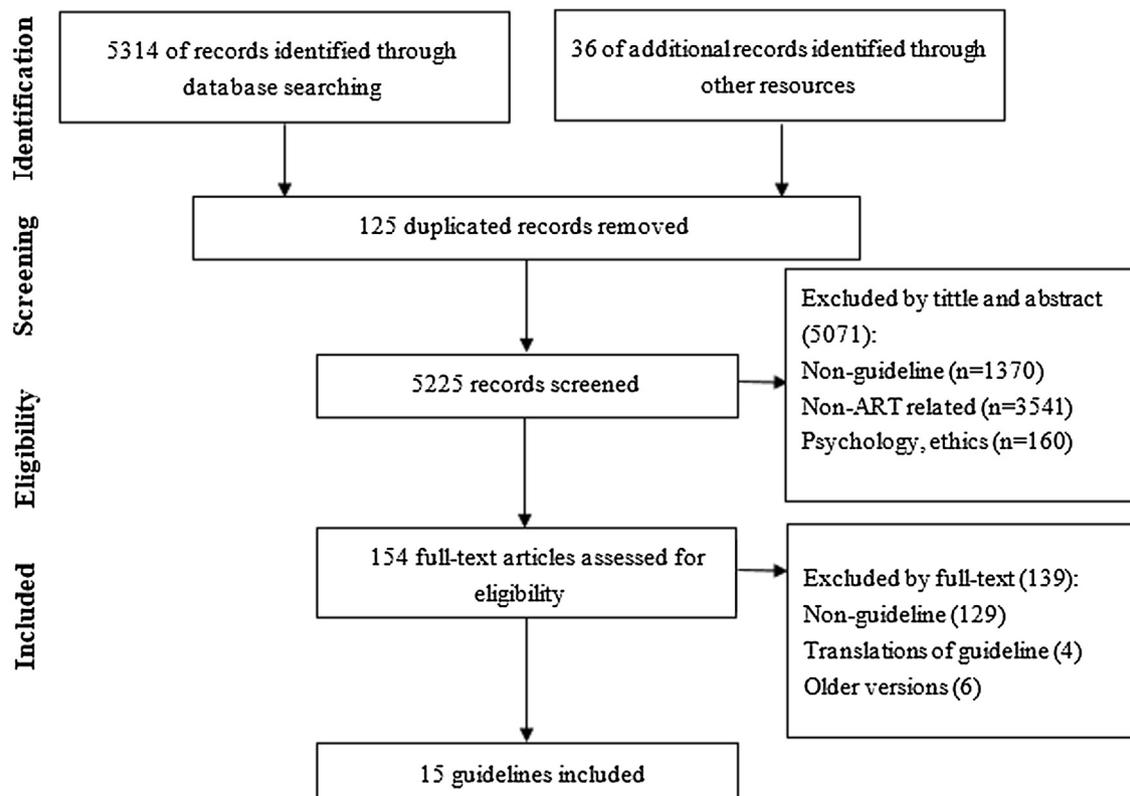


Fig. 1. Flowchart of systematic search.

Data extraction

Two investigators searched the database, selected guidelines independently and determined if the guidelines retrieved met inclusion criteria of this study. They then extracted the main characteristics of the guidelines. Disagreements between reviewers were resolved through consensus or consulting an independent expert adjudicator.

The RIGHT instrument was used to assess the eligible guidelines included in this study (Annex 2). This instrument contained 22 key items (35 items, if sub-items are calculated) categorized into the following seven domains: “Basic information”, “Background”, “Evidence”, “Recommendations”, “Review and quality assurance”, “Funding and declaration and management of interests”, and “Other information”. [14] Before data collection, three training sessions about using the RIGHT checklist and four pilot tests of assessment were conducted in order to ensure that the standards of assessment were met. Quality assessment was performed independently by four trained reviewers, who independently reviewed the quality of each eligible guideline. Disagreements between reviewers were resolved through consensus or consulting an independent expert adjudicator.

Most items were rated with a dichotomous scale (i.e., ‘Reported’-Y or ‘Not Reported’-N). ‘Reported’ means that the relevant information was fully reported, whereas ‘Not Reported’ was assigned when the relevant information was completely missing. For items containing more than one content, for example, “Indicate the strength of recommendations and the certainty of the supporting evidence”, we included a third category, ‘Partially Reported’ (P), which was used when only part of the contents were reported. When the items did not apply to the guidelines, “Not applied (NA)” was used. We reported the results in absolute number and percentage of guidelines reporting each item. For each item, we also reported the numbers and percentage of items reported by each guideline. If the reporting proportion of a guideline was less than 50%, we considered that the reporting quality is low. Data was abstracted and analyzed with Excel 2013.

Results

Guideline characteristics

A total of 5314 records were identified through database search. Thirty-six additional records were identified through the websites

Table 1
Characteristics of included guidelines.

Serial number	Title	Published date	Developer	Nation	Published journal
01	Recommendations on the management of services for in vitro fertilisation from the WHO (regional office for Europe) 1990 [15]	1990	World Health Organization (WHO)	International	BMJ
02	Royal College of Obstetrics and Gynaecologists. Clinical Guideline no 4. The management of infertility in tertiary care [16]	2001	Royal College of Obstetrics and Gynaecologists (RCOG)	UK	BJU International
03	ESHRE PGD Consortium ‘Best practice guidelines for clinical preimplantation genetic diagnosis (PGD) and preimplantation genetic screening (PGS) [17]	2005	European Society of Human Reproduction and Embryology (ESHRE)	USA	Human Reproduction
04	Guidelines for the number of embryos to transfer following in vitro fertilization [18]	2008	the Society of Obstetricians and Gynaecologists of Canada (SOGC)	Canada	International Journal of Gynecology and Obstetrics
05	Guidelines on number of embryos transferred [19]	2009	Practice Committee of the Society for Assisted Reproductive Technology(PCSART) and the Practice Committee of the American Society for Reproductive Medicine(PCASRM)	USA	Fertility & Sterility
06	Human oocyte cryopreservation: Evidence for practice [20]	2009	Association of Clinical Embryologists(ACE) AND British Fertility Society(BFS)	UK	Human Fertility
07	Elective Single Embryo Transfer Following In Vitro Fertilization [21]	2010	the Joint Society of Obstetricians and Gynaecologist of Canada–Canadian Fertility(JSOGCCF) and Andrology Society Clinical Practice Guidelines Committee(ASCPGC)	Canada	Journal of Obstetrics & Gynaecology Canada
08	The Boston IVF Handbook of Infertility A Practical Guide for Practitioners who Care for Infertile Couples Third Edition [22]	2012	Boston IVF and Harvard Medical School	USA	Not published in journal
09	Mature oocyte cryopreservation a guideline [23]	2013	Practice Committee of the Society for Assisted Reproductive Technology(PCSART) and the Practice Committee of the American Society for Reproductive Medicine(PCASRM)	USA	Fertility & Sterility
10	Fertility problems: assessment and treatment [24]	2013	The National Institute for Health and Care Excellence (NICE)	UK	Not published in journal
11	Fertility: assessment and treatment for people with fertility problems [25]	2013	National Collaborating Centre for Women’s and Children’s Health(NCCWCH)	UK	Not published in journal
12	Pregnancy Outcomes After Assisted Human Reproduction [26]	2014	the Genetics Committee(GC)	Canada	J Obstet Gynaecol Can
13	Elective Single Embryo Transfer: an update to UK Best Practice Guidelines [27]	2015	The Association Of Clinical Embryologists(ACE) and The British Fertility Society(BFS)	UK	Human Fertility
14	Performing the embryo transfer: a guideline [28]	2017	Practice Committee of the American Society for Reproductive Medicine(PCASRM)	USA	Fertility & Sterility
15	[Guideline for diagnosis and treatment of infertility in advanced age women] [29]	2017	Chinese Society of Reproductive Medicine(CSRM)	China	Chinese Journal of Reproduction and Contraception

of guideline development organizations and Google Scholar. After screening, fifteen guidelines (i.e. seven guidelines developed by institution and eight guidelines developed by association.) that eventually met the inclusion criteria were included (Fig. 1). The characteristics for each included guideline are presented in Table 1.

Reporting result of guidelines included

On average, 12.7 (36.3%) of the 35 items in the RIGHT standard were reported. The number of reported items ranged from 5 (14.3%) and 24 (68.6%) across the guidelines (Fig. 2).

The most frequently reported items among the 35 items in the RIGHT standard were item 5 (i.e. *Brief description of the health problem(s)*) and item 13a (i.e. *Provide clear, precise, and actionable recommendations*) which were both reported in 14 (93.3%) guidelines. These were followed by 11a (i.e. *Indicate whether the guideline is based on new systematic reviews done specifically for this guideline or whether existing systematic reviews were used*), which were reported in 13 (86.7%) guidelines. None of the guidelines reported item 6 (i.e. *Describe the aim(s) of the guideline and specific objectives, such as improvements in health indicators, quality of life, or cost savings*), 9a (i.e. *Describe how all contributors to the guideline development were selected and their roles and responsibilities.*), 11b (i.e. *If the guideline developers used existing systematic reviews, reference these and describe how those reviews were identified and assessed and whether they were updated*), 18b (i.e. *Describe the role of funder(s) in the different stages of guideline development and in the dissemination and implementation of the recommendations*) or 22 (i.e. *Describe any limitations in the guideline development process (such as the development groups were not multidisciplinary or patients' values and preferences were not sought), and indicate how these limitations might have affected the validity of the recommendations*). (Table 2).

The reporting proportion of the 7 domains (i.e. Basic information, Background, Evidence, Recommendations, Review and quality assurance, Funding and declaration and management of interests and Other information) in RIGHT standards were 46.7%, 40.8%, 45.3%, 29.5%, 53.3%, 10.0%, 26.7%, respectively.

Discussion

Among the fifteen guidelines included, the reporting proportion of 14 guidelines were less than 50%, only one guideline reported the items with the rate more than 50%. Most of the guidelines in this analysis were of low reporting quality. Items related to the description of the health problems, health care questions, recommendations or other key contents of the

guidelines, were often well reported. However, when it comes to the items related to the details of the guideline development process, such as how the outcomes were selected and sorted, specific sources of funding for all stages of guideline development, or the role of funders in the different stages of guideline development, the reporting proportion tended to be low. This finding is consistent with the study by Chen et al. [30]

The reporting proportion of the domain “basic information” was comparatively high among all the 7 domains, but there were still many details which needed improvement. For example, in the item “Identify the report as a guideline, that is, with ‘guideline(s)’ or ‘recommendation(s)’ in the title.” (Item 1a), 5 guidelines (33.3%) could not be identified as a guideline by its title. If a guideline uses an uncommon term or does not report this information in the title, it will be difficult for researchers and practitioners to retrieve it from a database nor identify it as a practice guideline. [31] Eight guidelines summarized the recommendations, but only two guidelines summarized the recommendations in the executive summary as required by item 2 (i.e. “Executive summary”, “Provide a summary of the recommendations contained in the guideline”). Summarizing and presenting recommendations in the executive summary helps the guideline users to obtain the key information quickly and effectively, and hence improves the efficiency of reading and using the guidelines, as well as its dissemination and implementation. Therefore, it is necessary and meaningful to promote and strengthen the reporting of this item.

In the domain of “background,” the reporting proportion of items 7a (10, 66.7%), 8a (6, 40.0%) and 8b (3, 20.0%), which are related to the target population, scope, and users of the guidelines, were not high enough. Reporting the setting, target audience and users of the guideline determines whether the guideline can be used and implemented accurately. For example, the recommendations of a guideline whose setting was “UK healthcare settings” would not necessarily be valid in Asia and other geographic locations, given the potential differences in patient characteristics and regional/national conditions. A guideline can be applied properly only for the target population and settings, otherwise the recommendations of which may sometimes result in counterproductive effects. This is also why a revised version of a guideline is necessary when the settings or audience are different compared with the original one [32].

The reporting proportion of items in the domain “evidence” was low. Several studies used AGREE II to evaluate the methodological quality of guidelines, finding that the quality in items related to this domain was also low, especially for evidence identification and evaluation [33–36]. The low quality of reporting may be one of the reasons for the result of the poor methodological evaluated by

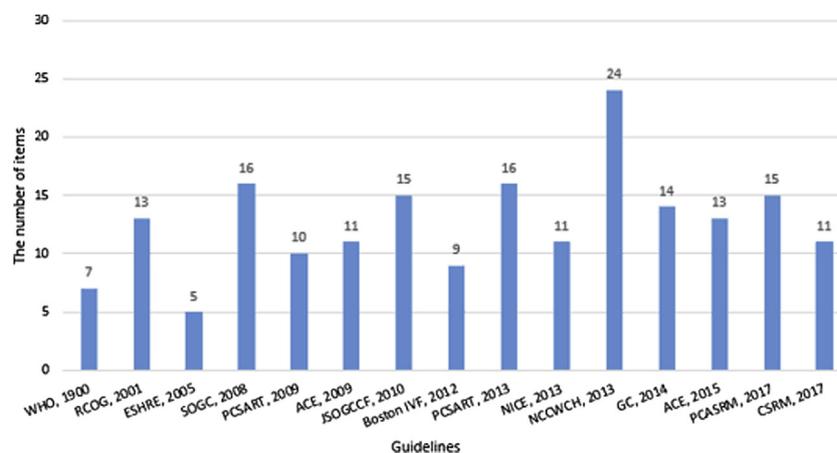


Fig. 2. The number of reported items of each guideline.

Table 2
The details of reporting quality.

Domain	Item	Guidelines WHO, 1900	RCOG, 2001	ESHRE, 2005	SOGC, 2008	PCSART, 2009	ACE, 2009	JSOGCCF, 2010	Boston IVF, 2012	PCSART, 2013	NICE, 2013	NCCWCH, 2013	GC, 2014	ACE, 2015	PCASRM, 2017	Reporting proportion CSRM, 2017		
Basic information	1a	Y	Y	Y	Y	Y	N	N	Y	Y	N	N	N	Y	Y	Y	66.7%	
	1b	Y	N	N	N	Y	N	N	Y	Y	Y	Y	N	N	Y	N	46.7%	
	1c	Y	Y	Y	Y	Y	Y	Y	N	Y	Y	Y	N	N	Y	Y	80.0%	
	2	N	N	N	Y	N	Y	Y	N	N	N	Y	Y	Y	Y	N	46.7%	
	3	N	N	N	N	N	N	P	P	N	P	Y	P	N	N	N	6.7%	
4	N	P	Y	N	N	Y	N	P	Y	N	N	N	Y	N	Y	33.3%		
Reporting proportion		50.0%	33.3%	50.0%	50.0%	50.0%	50.0%	33.3%	33.3%	66.6%	33.3%	66.6%	16.7%	50.0%	66.7%	50.0%		
Background	5	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	93.3%	
	6	N	P	N	P	P	P	P	P	N	N	P	P	P	P	P	0	
	7a	N	Y	N	Y	N	Y	Y	Y	Y	Y	Y	Y	N	N	Y	66.7%	
	7b	N	Y	N	Y	Y	N	Y	N	Y	Y	Y	Y	N	N	Y	60.0%	
	8a	N	Y	N	N	Y	N	N	Y	Y	N	Y	N	N	Y	N	40.0%	
	8b	N	N	N	N	N	N	N	N	N	N	Y	Y	N	N	Y	20.0%	
	9a	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0	
	9b	N	N	N	Y	N	N	N	Y	Y	N	Y	Y	N	Y	Y	46.7%	
	Reporting proportion		12.5%	50.0%	0	50.0%	37.5%	25.0%	37.5%	50.0%	62.5%	37.5%	75.0%	62.5%	12.5%	37.5%	62.5%	
	10a	N	Y	Y	Y	N	Y	Y	Y	N	Y	Y	Y	Y	Y	Y	Y	80.0%
10b	N	N	N	N	N	P	N	N	N	N	Y	N	N	N	N	N	6.7%	
11a	Y	Y	Y	Y	Y	Y	Y	Y	N	Y	N	Y	Y	Y	Y	Y	86.7%	
11b	N	N	N	N	N	N	N	NA	P	NA	P	N	N	NA	N	N	0	
12	N	Y	N	Y	N	Y	Y	N	N	N	Y	Y	Y	Y	Y	N	53.3%	
Reporting proportion		20.0%	60.0%	40.0%	60.0%	20.0%	60.0%	60.0%	20.0%	20.0%	20.0%	80.0%	60.0%	60.0%	60.0%	40.0%		
Recommendations	13a	Y	Y	P	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	Y	93.3%	
	13b	NA	NA	NA	Y	Y	NA	Y	NA	Y	Y	Y	Y	N	NA	NA	46.7%	
	13c	NA	P	NA	Y	NA	P	Y	NA	P	NA	P	Y	P	P	NA	20.0%	
	14a	N	N	N	N	N	N	Y	N	N	N	Y	N	N	N	N	13.3%	
	14b	N	N	N	N	N	N	Y	N	N	N	Y	N	N	N	N	13.3%	
	14c	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	N	6.7%	
	15	N	Y	N	N	N	N	N	N	N	N	Y	N	N	N	N	13.3%	
	Reporting proportion		14.3%	28.6%	0	42.9%	28.6%	14.3%	71.4%	14.3%	28.6%	28.6%	85.7%	42.9%	14.3%	14.3%	14.3%	
Review and quality assurance	16	N	N	N	Y	N	N	Y	N	Y	Y	Y	Y	Y	Y	N	53.3%	
	17	N	N	N	Y	N	N	Y	N	Y	Y	Y	Y	Y	Y	N	53.3%	
Reporting proportion		0	0	0	100%	0	0	100%	0	100%	100%	100%	100%	100%	100%	0		
Funding and declaration and management of interests	18a	N	N	N	N	N	N	N	N	N	N	Y	N	N	N	P	6.7%	
	18b	NA	NA	NA	NA	NA	NA	NA	NA	NA	N	N	NA	NA	NA	NA	0	
	19a	N	N	N	N	Y	Y	N	N	N	N	N	N	Y	N	N	20.0%	
	19b	N	N	N	N	N	N	N	N	Y	N	N	N	N	Y	N	13.3%	
Reporting proportion		0	0	0	0	25.0%	0	0	0	0	25.0%	0	25.0%	25.0%	0	0		
Other information	20	N	Y	N	Y	N	N	N	Y	N	Y	N	N	Y	N	N	33.3%	
	21	Y	Y	N	N	N	Y	N	N	Y	N	Y	N	Y	Y	N	46.7%	
	22	N	N	N	N	N	N	N	N	N	N	N	N	N	N	N	0	
Reporting proportion		33.3%	66.6%	0	33.3%	0	33.3%	0	33.3%	33.3%	33.3%	33.3%	0	66.6%	33.3%	0		
Total reporting proportion		20%	37%	14.3%	45.7%	28.6%	31.4%	42.9%	25.7%	45.7%	31.4%	68.5%	40%	37.1%	42.8%	42.9%		

AGREE II. Because the assessment of the methodological quality of the guideline depends on the content and form of the reporting to some extent [36,37]. However, it is regrettable that some guidelines did not report relevant information in the text even if relevant actions (such as the process of searching systematic reviews and the search strategies) were carried out during the guideline development process [38]. In this domain, item 11b is particularly complicated. It includes several judgments on whether the guideline reported the search strategies, the selection criteria and the evaluation of the risk of bias, and whether they were updated. The judgment of multiple factors in a single item will cause inconvenience to the researchers. Therefore, the RIGHT Working Group planned to expand the items related to systematic reviews [39], which would subsequently improve the convenience and operability of the use of the RIGHT checklist. In addition, it is worth noting that, in the field of assisted reproductive technology, the primary evidence is lacking, or relatively old. Thus some of the guidelines have only been partly, if at all, based on systematic reviews. In this situation, evaluating the reporting quality of the guidelines in the domain of “evidence” has been challenging.

Among the 15 guidelines included, the reporting proportion in the domain of “recommendations” was only 29.5%, especially in the three items related to the rationale and explanation of recommendations (i.e. items 14a, 14b and 14c). The reporting proportion were only 13.3%, 13.3%, and 6.7%, respectively. These items are necessary for the completeness of the guideline methodology. If this content is reported incompletely, the AGREE quality evaluation results of the guidelines would be affected.

The reporting proportion in the domain of “review and quality assurance” was the highest among all seven domains. However, the completeness of the reporting on these items still needs to be improved, especially for the item 16 “Indicate whether the draft guideline underwent independent review and, if so, how this was executed and the comments considered and addressed”, for which most of the guidelines reported only partially. Although 8 guidelines reported some relevant information, only three guidelines comprehensively reported the details of the reviewers, reviewing process, and feedback process. The guidelines should strengthen the integrity by reporting the reviewing process, as well as improving the reporting quality in this domain.

The domain of “Funding and declaration and management of interests” had been rarely reported among the seven domains, with a reporting proportion of less than 10%. In particular the item “Describe the role of funder(s) in the different stages of guideline development and in the dissemination and implementation of the recommendations.” (Item 18b) was poorly reported. This finding is consistent with the study by Xiaoqin et al [41]. Most of the guidelines did not take into account the dissemination and implementation process, and thus most of the reporting evaluation results were “not applicable”. This may be caused by the fact that the dissemination and implementation of the guidelines was often not managed by the guideline developers themselves [40]. With the gaps between clinical practice and evidence reported by J Wilkinson et al. [42], we suggested the guideline developers consider the implementation and dissemination when developing a guideline and report them in the text, which may help the recommendations to be properly implemented and widely used.

In the domain of “other information”, nearly half of the guidelines reported the recommendations for future research and the limitations of the present evidence. This information helps the relevant researchers to determine the direction for further research. [38] It also disposes that better evidence with higher quality is needed, which have also been proved by some studies [43–45]. However, none of the included guidelines reported any limitations of the guidelines. Reporting these aspects can increase the credibility of the guideline, while also

helping guideline users to select and use recommendations with necessary caution.

Strengths and limitations

We only searched the English databases and Chinese data bases in the study. Consequently, the result of this study did not cover all the guidelines of ART in other languages.

The main strength of this study lies in the fact that the researchers independently conducted a systematic search and evaluation. This is the first time that the RIGHT criteria were used to evaluate ART guidelines.

Conclusion

At present, the general quality of reporting of ART guidelines has been poorly conducted, especially regarding the declaration of funding and the acknowledgement of limitations. In future guideline development processes, consideration should be given to reporting the guidelines with reference to the RIGHT checklist [46], which not only helps improve the overall reporting quality, but also its dissemination and implementation.

Data sharing

No additional data are available

Ethics approval and consent to participate

Not applicable

Consent for publication

Not applicable

Provenance and peer review

Not commissioned; externally peer reviewed

Patient and public involvement

No patients or public were involved

Author contributions

YX and LJ are joint first authors. JH and CG searched the database, selected guidelines and extracted the main characteristics of the guideline. YX, YT and LL analyzed the data. YX drafted the manuscript. LJ, XL, LK, LY, QZ, JE and YC contributed to the interpretation of the results and critical revision of the manuscript for important intellectual content and approved the final version of the manuscript. All authors have read and approved the final manuscript. HS and YC are the study guarantors.

Funding

National Natural Science Foundation of China, Grant No. 81503459 Translation and Training Cooperation Base for Standards of Traditional Chinese Medicine of Belt and Road Initiative No. GZYYGJ2018042.

Declaration of Competing Interest

None declared.

Acknowledgements

We thank our colleagues at the Key Laboratory of Evidence-Based Medicine and Knowledge Translation of Gansu Province for their help. We are also grateful to all researchers who devote to the study for their rigorous work.

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