1 A reporting tool for practice guidelines in healthcare: the RIGHT Statement

- 2 Yaolong Chen, Kehu Yang*, Ana Marušić, Amir Qaseem, Joerg J Meerpohl, Signe Flottorp, Elie A
- 3 Akl, Holger J Schünemann, Edwin SY Chan, Yngve Falck-Ytter, Faruque Ahmed, Sarah Barber,
- 4 Chiehfeng Chen, Mingming Zhang, Bin Xu, Jinhui Tian, Fujian Song, Hongcai Shang, Kun Tang,
- 5 Qi Wang, Susan L Norris* for RIGHT Working Group
- 6 Evidence-Based Medicine Center, School of Basic Medical Sciences, Lanzhou University, Lanzhou,
- 7 China (Y Chen PhD, K Yang MMed, J Tian PhD, Qi Wang, MMed);
- 8 Key Laboratory of Evidence Based Medicine and Knowledge Translation of Gansu Province,
- 9 Lanzhou, China (Y Chen PhD, Yang MMed, J Tian PhD);
- 10 Key Laboratory of Chinese Internal Medicine of Ministry of Education, Dongzhimen Hospital,
- 11 Beijing University of Chinese Medicine. China (Y Chen PhD, H Shang MD, PhD)
- 12 Department of Research in Biomedicine and Health, and Cochrane Croatia, School of Medicine,
- 13 University of Split, Soltanska, Croatia. (Ana Marušić MD, PhD)
- 14 American College of Physicians, Philadelphia, USA. (A Qaseem MD, PhD, MHA)
- 15 Centre de Recherche Épidémiologie et Statistique Sorbonne Paris Cité U1153, Inserm / Université
- 16 Paris Descartes, Cochrane France, Hôpital Hôtel-Dieu, Paris, France (JJ Meerpohl MD)
- 17 Cochrane Germany, Medical Center University of Freiburg, Freiburg, Germany (JJ Meerpohl MD)
- 18 Department for evidence synthesis, the Norwegian Institute of Public Health, Oslo, Norway (S 10 Elettern MD, PhD)
- 19 Flottorp MD, PhD)
- 20 Department of Internal Medicine, American University of Beirut, Beirut, Lebanon (EA Akl, MD,
- 21 MPH, PhD)
- 22 Department of Clinical Epidemiology and Biostatistics, McMaster University, Hamilton, Canada
- 23 (HJ Schünemann MD, PhD, EA Akl MD, MPH, PhD)
- 24 Cochrane Singapore, Singapore Clinical Research Institute, Duke-NUS Medical School, Singapore
- 25 (E Chan PhD)
- 26 Department of Medicine, Case and VA Medical Center, Case Western Reserve University, Cleveland,
- 27 USA (Y Falck-Ytter MD)
- 28 Centers for Disease Control and Prevention, Atlanta, USA (F Ahmed PhD)
- 29 South Africa WHO Country Office, Pretoria, South Africa (S Barber PhD)
- 30 Division of Plastic Surgery, Department of Surgery, Wan Fang Hospital, Department of Public
- 31 Health, School of Medicine, College of Medicine, Cochrane Taiwan, Taipei Medical University,
- 32 Taiwan (C Chen MD, MPH, PhD)
- Chinese Cochrane Centre, West China Hospital, Sichuan University, Chengdu, China (M Zhang
 M.Sc)
- 35 Nanjing University of Chinese Medicine, Nanjing, China (B Xu MD)
- 36 Norwich Medical School, Faculty of Medicine and Health Science, University of East Anglia,
- 37 Norwich, UK (F Song PhD)
- 38 Department of Global Health, Peking University, Beijing, China (K Tang PhD)
- 39 Guidelines Review Committee Secretariat, World Health Organization, Geneva, Switzerland (SL
- 40 Norris MD, MPH, MSc)
- 41 * corresponding authors
- 42
- 43

44 Abstract

The quality of reporting of practice guidelines is often poor and there is no widely accepted guidance or standards for the reporting of practice guidelines in healthcare. An international working group (the RIGHT working group) was therefore established to address this gap. The group followed an existing framework for developing health research reporting guidelines and the EQUATOR (Enhancing the QUAlity and Transparency Of health Research) Network approach.

50

We developed a checklist and an explanation and elaboration document. The RIGHT checklist 51 52 includes 22 items that we consider essential for good reporting of practice guidelines. These items 53 encompass basic information (items 1-4), background (items 5-9), evidence (items 10-12), 54 recommendations (items 13-15), review and quality assurance (items 16-17), funding and 55 declaration and management of interests (items 18-19), and other information (items 20-22). The 56 RIGHT checklist can assist developers when reporting their guidelines, support journal editors and 57 peer reviewers when considering guideline reports, and help healthcare practitioners understand and 58 implement a guideline.

59

60 Primary Funding Source: National Natural Science Foundation of China, Grant No. 81503459

61

62 Introduction

63 Clear, explicit and transparent practice guidelines enable healthcare practitioners, health 64 administrators, program managers, and the public to understand and implement recommendations 65 that may positively impact patients and populations (1). However, the quality of reporting of practice 66 guidelines appears to be low (2) and current tools to address this are either outdated, have a narrow 67 focus, or combine reporting and quality assessment in a single instrument. The Conference on Guideline Standardization (COGS) published a checklist for reporting of clinical practice guidelines 68 69 (last updated in 2003) which focuses mainly on clinical medicine, and thus it may not be directly 70 applicable to public health or to other types of guidelines (3). The AGREE instrument was 71 developed for both quality assessment and reporting, although it is widely regarded as an evaluation 72 tool (6.7). Multi-function tools may not be optimal as it is important to distinguish between tools 73 that address reporting and those that assess methodological quality as they differ in purpose, 74 structure and content (8). Recently the AGREE Next Steps Consortium published the AGREE 75 Reporting Checklist based on the AGREE instrument (4,5), however it is limited to items derived 76 from the original tool, was developed by a small group of researchers and does not provide detailed 77 explanation or guidance as to how to use the tool.

78

79 **Development of the RIGHT Checklist**

80 A multidisciplinary international team that included policy makers, methodologists, epidemiologists, 81 clinicians, editors and consumer representatives from 12 countries across Asia, Africa, Europe, 82 Oceania and North America was established in 2013. It aimed to develop a tool focusing on the 83 essential items for reporting of guidelines—RIGHT (Reporting Items for Practice Guidelines in 84 HealThcare). Development of the RIGHT checklist followed the framework for developing health 85 research reporting guidelines (9). We registered the project in the EQUATOR (Enhancing the 86 QUAlity and Transparency Of health Research) library (10). We established two groups: the RIGHT 87 development group and the Delphi panelists group. The RIGHT development group drafted the 88 project proposal, generated suggested items, recruited Delphi panelists, designed the questionnaires 89 for the Delphi survey, and drafted the final report. The Delphi panelists group reviewed the proposal, 90 participated in three rounds of Delphi surveys, came to consensus on the items included in the final 91 checklist, and reviewed the final manuscript.

92

93 The RIGHT development group implemented a four-step approach to generate potential items for 94 the checklist. First, the group reviewed ten representative reporting guidelines highlighted in the EQUATOR library to determine how they generated potential items (11). The ten documents 95 96 encompassed a wide variety of reporting tools, including for randomized controlled trials, diagnostic 97 studies, observational studies, animal research, economic evaluation and systematic reviews. One 98 tool generated items based on a systematic review (12) while the others used surveys, group 99 meetings, literature reviews, or combined approaches (13-21). Second, we conducted a 100 comprehensive search of handbooks and other documents to identify standards or tools for guideline 101 reporting (see Appendix 1). Third, two sub-groups from the RIGHT development group, each 102 composed of two experienced investigators, independently extracted potential checklist items from 103 all documents identified in the first two steps. Last, the RIGHT development group held a face-to-104 face meeting to aggregate all potential items and remove duplicates. After further discussion, 48 105 items were included in the initial list of potential items. Readers can obtain the search results and

106 initial list of items from the RIGHT website (22).

107

108 For the Delphi method, we recruited 17 individuals with experience in the development of practice 109 guidelines or reporting guidelines. These individuals encompassed a broad range of disciplines as 110 well as diverse geographic representation. The Delphi technique followed the recommendations 111 proposed by Murphy and Sinha (23, 24) and included three rounds of email-based surveys. Panelists rated each item on a scale of 1 (not important) to 5 (very important), suggested new items, and 112 113 provided comments that were circulated in subsequent rounds. All panelists were asked to disclose any conflicts of interest before beginning the Delphi survey. The response rate was 100% for all 114 115 three rounds of the Delphi process.

116

This study was funded by National Natural Science Foundation of China and the funder had no rolein study design, data collection and analysis, decision to publish, or preparation of the manuscript.

119

120 **RIGHT Checklist**

The RIGHT checklist consists of 22 items that we consider essential for good reporting of practice guidelines (Table). These items encompass the following domains: basic information (item 1-4), background (items 5-9), evidence (items 10–12), recommendations (items 13–15), review and quality assurance (items 16–17), funding, declaration and management of interests (items 18–19), and other information (items 20-22).

126 127

128 Discussion

129

The RIGHT checklist can assist guideline developers when reporting their guidelines, support journal editors and peer reviewers when considering guideline reports, and help healthcare practitioners understand and implement a guideline. The checklist is useful for clinical practice guidelines as well as guidelines in public health and other healthcare fields since users and evaluators need a clear, explicit description of the processes and procedures used to develop a guideline, and access to the evidence used to formulate each recommendation.

136

137 The RIGHT checklist does not prescribe a specific format for the reporting of guidelines. Rather, 138 each checklist item should be clearly presented and in sufficient detail somewhere in the guideline. 139 Order and format for each item depend on the developers' preferences, style of the publication, and 140 most importantly, the end-users' needs. We recommend against deriving a score from the RIGHT 141 Checklist: the items may not be equally weighted and scores have been demonstrated to be 142 problematic in research synthesis (25, 26).

143

We emphasize that the RIGHT checklist was not developed as a tool for assessing the quality of published practice guidelines; such instruments exist elsewhere including AGREE (27) and others (28). Rather, RIGHT is intended to complement these existing tools. RIGHT was also not developed as guidance for developing guidelines. Many handbooks exist for this purpose, along with the GIN-McMaster Guideline development checklist - a practical tool for guideline development supported by learning resources (29). Readers should carefully select a tool according 150 to their specific needs.

151

The RIGHT checklist differs from the new AGREE reporting checklist (5) in several important ways. 152 153 First, the structure of the AGREE reporting checklist follows the domains of AGREE II: scope and 154 purpose, stakeholder involvement, rigour of development, clarity of presentation, applicability, and 155 editorial independence. In contrast, the RIGHT checklist emulates the approach used by other reporting guidance statements such as CONSORT(15) and PRISMA(13), ordering items as the 156 157 developer and reader would encounter them. Thus RIGHT starts with the title, then the executive summary, for example. Second, RIGHT includes important items that should be reported in a 158 159 guideline that were not included in the AGREE reporting checklist: quality assurance, access, suggestions for further research, and limitation of the guideline. RIGHT highlights the importance 160 of reporting PICO questions and quality of the body of evidence, and includes seven sub-items on 161 162 the formulation of recommendations from evidence. Finally, the RIGHT explanation and 163 elaboration statement (appendix 2) provides detailed information and examples, which are not part 164 of the AGREE reporting checklist.

165

166 Implementation

Endorsement and implementation of reporting guidelines may help reduce wasteful research and increase the potential impact of research on health (30). We plan to use a number of approaches to promote implementation of the RIGHT checklist: ask authors of international guideline handbooks to add the RIGHT checklist into new versions of their handbooks; contact the editors of the core clinical journals in MEDLINE (https://www.nlm.nih.gov/bsd/aim.html) to elicit their support and encourage them to endorse the RIGHT checklist; and inform guideline developers at international and national agencies, as well as professional societies about RIGHT.

174

175 Strengths and limitations

176 We followed an explicit, transparent and documented process for developing the RIGHT checklist 177 and we provide an accompanying explanation and elaboration statement (See online appendix). 178 Individuals from key international organizations and institutions that focus on development and 179 implementation of guidelines contributed to this work, including the EQUATOR network, 180 Guidelines International Network, the GRADE Working Group, the AGREE Collaboration and the Cochrane Collaboration. The draft checklist and explanation and elaboration statement underwent 181 182 extensive peer review by experts in guideline development with a variety of perspectives. It is 183 possible that we missed important items when we developed our initial list of items, however we 184 made every effort to minimize this possibility by examining a large number of guidance documents 185 and manuals produced by guideline developers and by consulting a broad range of experts in this 186 field.

187

188 Future development and research

189 The RIGHT checklist is currently available in English, German, Croatian, Japanese, Korean,

190 Simplified and Traditional Chinese, and we encourage groups to undertake additional translations.

- 191 We plan to develop RIGHT extensions, including RIGHT-P (for Guideline Proposals), RIGHT-COI
- 192 (for Conflicts of Interest), and RIGHT-A (for Acupuncture). We ask those who aim to develop
- 193 related standards or perform translations to contact the corresponding author of this paper to

- 194 coordinate efforts and to avoid duplication.
- 195

As for any other reporting standard, the RIGHT checklist is an evolving document that needs 196 197 continual assessment, improvement, and updating. We will revise the checklist in the future, taking 198 into account user feedback, results of formal and informal evaluations, and new studies on guideline 199 reporting methods. We encourage users to submit their comments via the RIGHT website.

200

201 Acknowledgements: We are grateful to the individuals who responded to the Delphi survey and for their thoughtful comments. 202

203

204 **Contributors**

205 YC, SLN and KY conceived of RIGHT project and drafted the project proposal. AM, AQ, JM, SF, EA, EC, YFY, FA, SR, CC, MZ, BX were Delphi panelists and gave comments and 206 207 suggestions on the draft item list. YC, KY, FS and KT generated suggested items, designed the questionnaires for the Delphi survey and did the statistical analysis. YC and SLN drafted the 208 209 manuscript and all authors critically reviewed and revised it for important intellectual content. YC 210 is the guarantor of the manuscript, and affirms that the manuscript is an honest, accurate, and 211 transparent account of the study being reported. All authors approved the final version of this 212 article.

213

214 Disclaimer

215 The findings and conclusions in this article are those of the authors and do not necessarily 216 represent the views of WHO or the US Centers for Disease Control and Prevention.

217

Competing interests: All authors have completed the ICMJE uniform disclosure form at 218 219 www.icmje.org/coi disclosure.pdf (available on request from the corresponding author) and 220 declare no financial relationships with any organisations that might have an interest in the 221 submitted work in the previous three years. A number of the authors are active members of the GRADE Working Group (YC, JM, SF, EA, HJS, YFY, FA, SLN). YC is the member of the AGREE-222 223 Health System team.

224

225 Ethics approval: Not needed.

226

227 Funding: This study was funded by National Natural Science Foundation of China, Grant No. 228 81503459; China Fundamental Research Funds for the Central Universities, Grant No. 2016LZU-229 JBZX159; The Open Fund of the Key Laboratory of Evidence-Based Medicine and Knowledge 230 Translation of Gansu Province, Grant No. EBM1305.

- 231
- 232

233 References

234 1. Oxman AD, Fretheim A, Schünemann HJ. Improving the use of research evidence in guideline 235 development: 14. Reporting guidelines. Health Res Policy Syst. 2006;4:26.

- Grilli R, Magrini N, Penna A, Mura G, Liberati A. Practice guidelines developed by specialty
 societies: the need for a critical appraisal. Lancet. 2000;355(9198):103-6.
- Shiffman RN, Shekelle P, Overhage JM, Slutsky J, Grimshaw J, Deshpande AM. Standardized
 reporting of clinical practice guidelines: a proposal from the Conference on Guideline
 Standardization. Ann Intern Med. 2003;139(6):493-8.
- 4. Brouwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al. AGREE II:
 advancing guideline development, reporting and evaluation in health care. CMAJ.
 2010;182(18):E839-42.
- Brouwers MC, Kerkvliet K, Spithoff K, Consortium ANS. The AGREE Reporting Checklist:
 a tool to improve reporting of clinical practice guidelines. BMJ. 2016;352:i1152.
- 6. Oxman AD, Schünemann HJ, Fretheim A. Improving the use of research evidence in guideline
 development: 16. Evaluation. Health Res Policy Syst. 2006;4:28.
- Wilson KC, Irwin RS, File TM, Schünemann HJ, Guyatt GH, Rabe KF. Reporting and publishing
 guidelines: article 12 in Integrating and coordinating efforts in COPD guideline development. An
 official ATS/ERS workshop report. Proc Am Thorac Soc. 2012;9(5):293-7.
- 8. Huwiler-Muntener K, Juni P, Junker C, Egger M. Quality of reporting of randomized trials as a
 measure of methodologic quality. JAMA. 2002;287(21):2801-4.
- 9. Moher D, Schulz KF, Simera I, Altman DG. Guidance for developers of health research reporting
 guidelines. PLoS Med. 2010;7(2):e1000217.
- Reporting Items for Guidelines in Health Systems. [Internet]. Minervation Ltd. [cited 2015 Jul 9].
 Available from: <u>http://www.equator-network.org/library/reporting-guidelines-under-development</u>.
- Reporting guidelines for main study types. [Internet]. Minervation Ltd. [cited 2015 Jul 9]. Available
 from: http://www.equator-network.org/library/.
- Chan AW, Tetzlaff JM, Altman DG, Laupacis A, Gotzsche PC, Krleza-Jeric K, et al. SPIRIT 2013
 statement: defining standard protocol items for clinical trials. Ann Intern Med. 2013;158(3):200-7.
- Moher D, Liberati A, Tetzlaff J, Altman DG. Preferred reporting items for systematic reviews and
 meta-analyses: the PRISMA statement. BMJ. 2009;339:b2535.
- 263 14. Gagnier JJ, Kienle G, Altman DG, Moher D, Sox H, Riley D. The CARE guidelines: consensus264 based clinical case report guideline development. J Clin Epidemiol. 2014;67(1):46-51.
- Schulz KF, Altman DG, Moher D. CONSORT 2010 statement: updated guidelines for reporting
 parallel group randomised trials. BMJ. 2010;340:c332.
- von Elm E, Altman DG, Egger M, Pocock SJ, Gotzsche PC, Vandenbroucke JP. Strengthening the
 Reporting of Observational Studies in Epidemiology (STROBE) statement: guidelines for reporting
 observational studies. BMJ. 2007;335(7624):806-8.
- Tong A, Sainsbury P, Craig J. Consolidated criteria for reporting qualitative research (COREQ): a
 32-item checklist for interviews and focus groups. Int J Qual Health Care. 2007;19(6):349-57.
- 18. Bossuyt PM, Reitsma JB, Bruns DE, Gatsonis CA, Glasziou PP, Irwig LM, et al. Towards complete
 and accurate reporting of studies of diagnostic accuracy: the STARD initiative. BMJ.
 2003;326(7379):41-4.
- 275 19. Davidoff F, Batalden P, Stevens D, Ogrinc G, Mooney SE. Publication guidelines for quality
 276 improvement studies in health care: evolution of the SQUIRE project. BMJ. 2009;338:a3152.
- 20. Husereau D, Drummond M, Petrou S, Carswell C, Moher D, Greenberg D, et al. Consolidated
 Health Economic Evaluation Reporting Standards (CHEERS) statement. BMJ. 2013;346:f1049.
- 279 21. Kilkenny C, Browne WJ, Cuthill IC, Emerson M, Altman DG. Improving bioscience research

- reporting: The ARRIVE guidelines for reporting animal research. J Pharmacol Pharmacother.
 2010;1(2):94-9.
- 282 22. The RIGHT Statement. [Internet]. [cited 2015 Jul 9]. Available from: <u>http://www.right-</u>
 283 <u>statement.org/</u>.
- 284 23. Murphy MK, Black NA, Lamping DL, McKee CM, Sanderson CF, Askham J, et al. Consensus
 285 development methods, and their use in clinical guideline development. Health Technol Assess.
 286 1998;2(3):i-iv, 1-88.
- 24. Sinha IP, Smyth RL, Williamson PR. Using the Delphi technique to determine which outcomes to
 measure in clinical trials: recommendations for the future based on a systematic review of existing
 studies. PLoS Med. 2011;8(1):e1000393.
- 290 25. Greenland S, O'Rourke K. On the bias produced by quality scores in meta-analysis, and a
 291 hierarchical view of proposed solutions. Biostatistics. 2001;2(4):463-71.
- 292 26. Juni P, Witschi A, Bloch R, Egger M. The hazards of scoring the quality of clinical trials for meta 293 analysis. JAMA. 1999;282(11):1054-60.
- 27. Brouwers MC, Kho ME, Browman GP, Burgers JS, Cluzeau F, Feder G, et al. The Global Rating
 Scale complements the AGREE II in advancing the quality of practice guidelines. J Clin Epidemiol.
 2012;65(5):526-34.
- 28. Grimmer K, Dizon JM, Milanese S, King E, Beaton K, Thorpe O, et al. Efficient clinical evaluation
 of guideline quality: development and testing of a new tool. BMC Med Res Methodol. 2014;14:63.
- 299 29. Schünemann HJ, Wiercioch W, Etxeandia I, Falavigna M, Santesso N, Mustafa R, et al. Guidelines
 300 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise.
 301 CMAJ. 2014;186(3):E123-42.
- 302 30. Glasziou P, Altman DG, Bossuyt P, Boutron I, Clarke M, Julious S, et al. Reducing waste from
 303 incomplete or unusable reports of biomedical research. Lancet. 2014;383(9913):267-76.

304