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Abstract

Introduction

Adapting guideline means the use of existing trustworthy guidelines, with (adapt) or without (adopt) modifications, to provide local, regional, or national guidance. Adaptation is an increasingly used methodology for the efficient development of contextualised recommendations. Although the Essential Reporting Items of Practice Guidelines in Healthcare (RIGHT) statement can be useful for reporting adapted guidelines, it does not address all important aspects of the adaptation process. The objective of our project is to develop an extension of the RIGHT statement tailored to adapted guidelines (RIGHT-Ad@pt Checklist).

Methods and analysis

To develop the checklist, we will build on the RIGHT statement, use the best available evidence from published methodological research on guideline adaptation, and use a multistep process that includes: 1) establishment of a Working Group; 2) generation of an initial checklist; 3) optimisation of the checklist; and 4) approval of the final checklist. To optimize the checklist we will conduct an initial assessment of adapted guidelines, semi-structured interviews, a Delphi consensus survey, an external review by guidelines developers and users, and a final assessment of adapted guidelines.

Ethics and dissemination

We have obtained a waiver of approval from the Clinical Research Ethics Committee at the Hospital de la Santa Creu i Sant Pau (Barcelona, Spain). The dissemination activities will include: 1) publication of the RIGHT-Ad@pt Checklist in a peer-reviewed journal, 2) presentation the project to relevant stakeholders (e.g., via international conferences, electronic bulletins, related websites (http://www.right-statement.org/, http://www.equator-network.org/), and social media (e.g., Twitter), and 3) translation of the checklist into different languages. The implementation activities will include: 1) engaging with journal editors to encourage the use of the checklist, and 2) evaluating the impact of the checklist on the reporting of adapted guidelines. Finally, we will continuously seek feedback from stakeholders, surveil new relevant evidence and, if necessary, update the checklist.

Keywords

Evidence-based medicine, guideline adaptation, guidelines as topic, practice guideline, quality, reporting standards.

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Strengths and Limitations

- There is no current tool for reporting adapted guidelines. The RIGHT-Ad@pt checklist will full fill this gap and provide a clear guidance for the reporting of guideline adaptation.
- To develop the checklist, we will use the best available methodological research evidence, adopt a systematic and rigorous multistep process, and collect and build on the views and experiences of international stakeholders including guidelines methodologists, policy makers, journal editors, and guideline users.
- The RIGHT-Ad@pt checklist can be used within guideline adaptation to guide reporting, improve the completeness of reporting, evaluate publications, and inform implementation decisions of health care.
- We will not conduct a complete formal validation of the checklist since our current process will not include an assessment of neither construction nor criterion validity

Introduction

The World Health Organization (WHO) defines guidelines as "systematically developed evidence-based statements which assist providers, recipients and other stakeholders to make informed decisions about appropriate health interventions". Guidelines have been increasingly used to provide guidance for policies or public health interventions, changes in resource availability or access to services based on evidence [1]. There is evidence that the methodological quality of guidelines has slowly improved over the last decades [2-4]. However, most guidelines developers do not have enough resources for developing high quality *de novo* guidelines [5]. Most low- and middle-income countries still do not have formal organizations, technical capacity or collaborations to develop evidence-based guidelines [6]. When guidelines are developed in those settings, their quality is typically poor [7-13]. Adapting published high quality, evidence-informed guidelines becomes a more efficient option [14-16].

Adaption of guidelines means the use of existing trustworthy guidelines, with (adapt) or without (adopt) modifications, to provide local, regional, or national guidance [15-17]. Schünemann et al. defined adapted recommendations as recommendations with: 1) potential change in the specific population, intervention, or comparator than the original recommendations, 2) potential change in the certainty of the evidence, and 3) information on "conditions", monitoring, implementation, and implications for research [15]. Adopted recommendations were defined as recommendations with: 1) the same specific population, intervention, and comparators as the original recommendations, 2) the same certainty of the evidence, and 3) information on implementation [15]. Adaptation of guidelines is an increasingly used methodology for the efficient development of contextualised recommendations that are relevant for diverse health systems [15, 17-18]. Guideline adaptation takes into consideration local contextual factors such as language, availability and accessibility of services and resources, the health care setting, and the relevant stakeholders' cultural and ethical values [19]. At the same time, it should be based on similar systematic and transparent approaches as the source guideline in order to benefit from its quality and validity [20]. However, adaptation is not always possible. For example, when a trustworthy guideline is not available, a de novo guideline development process needs to be considered [15, 21].

Despite the increasing need, there is no standard adaptation method implemented internationally [21, 22]. A systematic review of the literature identified eight published frameworks for adaptation of clinical, public health or health system guidelines, concluding

that the "adaptation" phases of the processes were notable different [23]. Moreover, the process for adapting guidelines was usually poorly reported, including WHO guidelines [24]. For example, Godah et al. 2016 systematically assessed the processes employed in the adaptation of World Health Organization (WHO) guidelines for human immunodeficiency virus (HIV) and tuberculosis (TB). Out of 170 eligible adapted guidelines, only 32 (32/170, 19%) reported the methods used in the adaptation process [24]. Similarly, Abdul-Khalek et al. 2017 assessed the methods used for adapting health-related guidelines published in peer-reviewed journals [25]. Out of the 72 included adapted guidelines, 57 reported some degree of detail about the adaptation method used, and only 23 (23/57, 40%) reported using a specific adaptation method. These findings call for a need to optimize the methods used in guideline adaptation, and to improve the reporting of the adaptation process in adapted guidelines [24].

Guidelines for reporting health research have been developed to enhance the accurate, complete, and transparent reporting of health research publications (http://www.equator-network.org/). Moher et al. 2010 defined a reporting guideline as "a checklist, flow diagram, or explicit text to guide authors in reporting a specific type of research, developed using explicit methodology" [26]. Its aim is to indicate the minimum reporting standards, for readers to comprehend the design, conduct, analysis and interpretation of a study, and to assess the validity of results [26-27]. A transparent reporting approach could help guideline developers frame the decision making during the development process, and guideline users about the suitability for adapting, and consequently the adaptation process.

Currently, the main tools available for the reporting of guidelines development are: 1) the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument, including the AGREE Reporting Checklist [28], and 2) the Reporting Items for practice Guidelines in HealThcare (RIGHT) statement to improve the reporting of guidelines [29]. The RIGHT statement was formally developed as a reporting checklist for *de novo* guidelines [29]. Although it could be useful for the reporting of adapted guidelines [30], it does not cover some of the steps that are specific to guidelines adaptation (e.g. description of methods used to search and identify guidelines) [29]. Therefore, to ensure the rigorousness, transparency, clarity, and reproducibility of reporting the adaptation process, we will develop an extension of RIGHT statement for the reporting of adapted guidelines.

Objective

To develop the RIGHT-Ad@pt Checklist, as an extension of the RIGHT statement tailored to adapted guidelines.

Methods and analysis

To develop the checklist, we will build on the RIGHT statement [29], review methodology research evidence on guidelines adaptation [23-25], and adopt a multistep process we have successfully implemented in the development of similar tools [31-32]. Table 1 describes the multistep development process of the RIGHT-Ad@pt Checklist, which includes: 1) establishment of a Working Group; 2) generation of an initial checklist; 3) optimisation of the checklist (an initial assessment of adapted guidelines, semi-structured interviews, a Delphi consensus survey, an external review by guidelines developers and users, and a final assessment of adapted guidelines); and 4) approval of the final checklist. Figure 1 reproduces the process in a graphical format.

1. Establishment of the RIGHT-Ad@pt Working Group

The RIGHT-Ad@pt Working Group will include: 1) a Coordination Team; 2) an Advisory Group; and 3) a Delphi Panel.

1.1. Coordination Team

The Coordination Team (YS, MB, LMG, PAC, EA) will lead and coordinate the RIGHT-Ad@pt development process and ensure its completion according to the set timeline. Specifically, the Coordination Team will be responsible for 1) generating the initial version of the checklist, 2) implementing each step of the process, and 3) reporting the findings of each step of the processes. We have collected the Conflicts of interests (CoIs) of all members of the Coordination Team (Appendix 1).

1.2. Advisory Group

The Advisory Group is a multidisciplinary group (8 to 10 people), including 1) guideline methodological experts (defined as having experience and expertise in guideline methods), 2) guidelines developers (defined as having participated in guideline development groups and/or guideline adaptation groups at least once in the past year), 3) guideline users (defined as healthcare professionals that use guidelines on a regular basis) and; 4) journal editors of guideline related journals [26]. Members of the Advisory Group will review and provide expert

advice during the different steps of the RIGHT-Ad@pt development process. The Advisory Group will approve the final checklist and accompanying guidance. We have collected the CoIs of all members of the Advisory Group (Appendix 1).

1.3. Delphi Panel

The Delphi Panel will be comprised of 20 to 30 members [33], with profiles similar to those of the members of the Advisory Group. We will identify participants from the Guidelines International Network (GIN) Adaptation Guidelines Working Group (http://www.g-i-n.net/working-groups/adaptation), WHO, authors of adapted guidelines [25], and expert colleagues. We will aim for country income and gender representativeness of our participants. The panel's CoIs will be collected.

2. Generation of the initial checklist

The Coordination Team will generate the initial version of the checklist building on the RIGHT statement [29]. We will conduct this step via face to face and online meetings within the Coordination Team. The Coordination Team will review the results, draft a report with a proposal of the initial version for the Advisory Group to review, and produce a final version taken into consideration their feedback.

3. Optimisation of the checklist

3.1. Initial assessment of adapted guidelines

We will survey published adapted guidelines to assess the adequacy of each item of the intial checklist, and refine that checklist. We will also record the main characteristics of the adapted guidelines (e.g. title, year, or adaptation process), and completeness of reporting process for adapting guidelines using the initial checklist (Table 2).

We will assess a convenience sample of ten adapted guidelines available in English and published in the last five years. We will also take into account country income level, type of organization, and region. Two reviewers from the Coordination Team will independently apply the initial version of the checklist to adapted guidelines using an *ad hoc* form. The two reviewers will resolve potential disagreements by discussion, and if necessary, by consulting a third reviewer.

For quantitative variables (characteristics of adapted guidelines, completeness of reporting, and adequacy), we will calculate absolute frequencies and proportions. For qualitative variables (suggestions to improve the checklist), we will use content analysis to summarise and draw conclusions [34]. The Coordination Team will review the results, draft a report and review and agree on the relevant checklist modifications. If members of the Coordination Team do not reach consensus on specific items, they will consult the Advisory Group.

3.2. Semi-structure interviews

We will interview guideline developers (involved in guideline adaptation in the last three years) to explore current practices in adaptation of guidelines. We will also explore the participants' understanding of each item and refine the initial version of the checklist. Each interview will last approximately one hour and will be recorded and transcribed with interviewee´s permission. We will also record the characteristics of participants and their workplaces, and participants' overall assessment of the checklist (Table 2).

We will identify participants for the semi-structure interview with the support of the Advisory Group. We will continue recruitment and collect data until information becomes repetitive and no new information emerges (sampling saturation) [35-36].

For quantitative variables (characteristics of participants and workplaces, participants' understanding of each item, and participants' overall assessment of the checklist), we will calculate absolute frequencies and proportions. For qualitative variables (participants' views and experiences, and suggestions to improve the checklist), we will use content analysis to summarise and draw conclusions [34]. The Coordination Team will review the results, draft a report and review and agree on the relevant checklist modifications. If members of the Coordination Team do not reach consensus on specific items, they will consult the Advisory Group.

3.3. Delphi consensus survey

We will conduct a Delphi consensus survey to reach a consensus with the Delphi Panel about the current version of the checklist. We will also record response rate, characteristics of participants and workplaces, participants' understanding of each item, and participants' overall assessment of the checklist (Table 2).

Before the first Delphi round, we will provide the Delphi Panel Members with a brief background material on the topic. In the first Delphi round, we will ask participants to rate whether each item should be included in the checklist and its understanding using a seven-point Likert scale (1=strongly disagree and 7=strongly agree) [37]. We will calculate the median score for inclusion of each item and will classify them as 1) excluded (median score of 0–3 points), 2) review, modify and retest (median score of 4–5 points or with substantial comments), and 3) included (median score of 6 to 7 points and without substantial comments) [31]. After each Delphi round, we will provide feedback to Delphi Panel Members (all responses will be anonymised prior to circulation). We will conduct additional Delphi rounds until consensus regarding the checklist is reached and no more relevant comments on the items are provided (two or three rounds, as needed). We will use online software to design the survey and collect responses (http://www.clinapsis.com/).

For quantitative variables (response rate, characteristics of participants and workplaces, inclusion score, participants' understanding of each item, and participants' overall assessment of the checklist), we will calculate absolute frequencies and proportions. For qualitative data (suggestions to improve the checklist), we will use content analysis to summarise and draw conclusions [34]. We will not consider questionnaires with no response for more than 20% of the items. The Coordination Team will review the results of the Delphi consensus survey, draft a report with a proposal for the Advisory Group to review, and produce a final version taken into consideration their feedback.

3.4. External review

3.4.1. External review by guidelines developers

We will survey guideline developers who were involved in guideline adaptation over the past three years on the usefulness of each item [38], and refine the initial version of the checklist. We will also record response rate, the characteristics of participants and workplaces, participants' understanding of each item, and participants' overall assessment of the checklist (Table 2).

We will identify participants by contacting professionals associated with the GIN community (http://www.g-i-n.net) and WHO. We will use an online software to design the survey and collect responses (http://www.clinapsis.com/).

For quantitative variables (response rate, characteristics of participants and workplaces, usefulness score, participants' understanding of each item, and participants' overall assessment of the checklist), we will calculate absolute frequencies and proportions. For qualitative data (suggestions to improve the checklist), we will use content analysis to summarise and draw conclusions [34]. We will not consider questionnaires with no response for more than 20% of the items.

3.4.2. External review by guidelines users

We will conduct external review semi-structured interviews with guidelines users who have used adapted guidelines over the past three years, to explore the usefulness of each item and refine the initial version of the checklist. Each interview will last approximately one hour and will be recorded and transcribed with interviewee's permission. We will also record the characteristics of participants and workplaces, participants' understanding of each item, and participants' overall assessment of the checklist (Table 2).

We will identify the participants with the support of the Advisory Group and will continue recruitment and collect data until information becomes repetitive and no new information emerges (sampling saturation) [35-36].

For quantitative variables (characteristics of participants and workplaces, usefulness score, participants' understanding of each item, and participants' overall assessment of the checklist), we will calculate absolute frequencies and proportions. For qualitative data (participants' views and experiences, and suggestions to improve the checklist), we will use content analysis to summarise and draw conclusions [34]. The Coordination Team will review the results of the external review (guideline developers and users), draft a report with a proposal for the Advisory Group to review, and produce a final version taken into consideration their feedback.

3.5. Final assessment of adapted guidelines

We will conduct a final assessment of the validity of each item in a set of adapted guidelines. We will also record the main characteristics of the adapted guidelines (e.g. title, year, or adaptation process), and completeness of the reporting process for adapting guidelines using the initial checklist (Table 2).

We will assess a convenience sample of ten guidelines available in English and published in the last five years. We will also take into account country income level, type of organization, and

region. Two reviewers from the Coordination Team will independently apply the optimized version of the checklist using an *ad hoc* form. The two reviewers will resolve potential disagreements by discussion, and if necessary by consulting a third reviewer.

For quantitative variables (characteristics of adapted guidelines, completeness of reporting, and adequacy), we will calculate absolute frequencies and proportions. For qualitative variables (suggestions from reviewers), we will use content analysis to summarise and draw conclusions [34]. The Coordination Team will review the results, draft a report and review and agree on the relevant checklist modifications. If members of the Coordination Team do not reach consensus on specific items, they will consult the Advisory Group.

4. Approval of the final checklist

The Coordination Team will generate the final version of the checklist. The final checklist will highlight the changes from the RIGHT statement [29], including 1) the items that remained unchanged, 2) the items that were modified, 3) the items that were added as part of the extension, and 4) the items that were omitted. All members of the Coordination Team and the Advisory Group will need to review and approve the final version of the checklist through consensus discussion.

Discussion

Executive summary

The aim of this project is to develop the RIGHT-Ad@pt Checklist, as an extension of the RIGHT statement tailored for guideline adaptation, to improve the rigor and transparency of guideline adaptation reporting. To develop the checklist, we will build on the RIGHT statement, use the best available evidence from published methodological research on this topic, and use a rigorous multistep process involving multiple stakeholders.

Our study in the context of previous research

Adaptation of high quality guidelines is an alternative to developing *de novo* guidelines that saves both time and resources, and avoids duplication of effort. The ADAPTE framework is one of the earliest systematic approaches to adapt guidelines to local context [14, 39]. Building in work done for WHO in 2006, the "GRADE-ADOLOPMENT" framework proposed using the GRADE Evidence to Decision (EtD) frameworks for the adaptation, adoption, and *de novo* development of guidelines [15]. Despite these advances, there is variability in the quality of

reporting of adapted practice guidelines and no guidance for their reporting is available [23, 25]. The proposed checklist might help with reducing the variability of adaptation process and improving the quality of reporting. The checklist is not intended to support guideline development, which will be done through an extension of the GIN-McMaster Guideline Development Checklist [40].

Strengths and Limitations

Our proposal has some limitations. For example, we will include only guidelines published in English in the assessment of adapted guidelines. The checklist will inform about the completeness of the reporting but not necessarily about the quality of the adaptation process. We will not conduct a complete formal validation of the checklist since our current process will not include an assessment of neither construction nor criterion validity [41]; however, our proposed approach will ensure both face and content validity.

Our proposal has several strengths. The development of the checklist will be comprehensive, including the use of previous methodological evidence [23-25, 29, 31-32], and engagement of the multidisciplinary international guideline community. We will collect views and experiences from different stakeholders, including methodologists, guideline developers, guidelines users and journal editors. We will also ensure the diversity of participants in terms of country level of income, gender, and field of expertise. This will allow us to incorporate the different stakeholders' perspective about the adaptation of guidelines. We will address the risk of bias in each step of the development process. To minimise interviewer bias, semistructured interviews will be conducted using an interview guide. To minimise selection bias, we will invite all GIN Adaptation Guidelines Working Group members as well as other stakeholders to join the Delphi Panel and to participate in the external review survey. To minimise non-response bias, we will make the survey available online for four weeks and we will send two reminders prior to the round closing date.

Implications for practice and research

RIGHT-Ad@pt will help improve the completeness when reporting adapted guidelines, therefore contribute to improve their quality, and facilitate their implementation. The checklist will allow the guideline developers to guide their reporting, journals editors to improve the reporting of published adapted guidelines, policy makers to inform on implementation decisions, and guideline users to evaluate the completeness of the reporting

within adapted guidelines. Future research should focus on the performance of a complete formal validation of the checklist and its assessment in a representative sample of contemporary adapted guidelines. Surveillance on the use of the checklist and assessment of its impact could also be a topic of research.

Ethics and Dissemination

The dissemination activities will include: 1) publication of the RIGHT-Ad@pt Checklist in a peer-reviewed journal, 2) presentation the project to relevant stakeholders (e.g., via international conferences, electronic bulletins, related websites (http://www.right-statement.org/, http://www.equator-network.org/), and social media (e.g., Twitter), and 3) translation of the checklist into different languages. The implementation activities will include: 1) engaging with journal editors to encourage the use of the checklist, and 2) evaluation of the impact of the checklist on the reporting of adapted guidelines. Finally, we will continuously seek feedback from stakeholders, surveil new relevant evidence and, if necessary, update the checklist.

List of abbreviations

AGREE II: Appraisal of Guidelines for Research and Evaluation II; CoIs: Conflicts of interests;

GRADE: The Grading of Recommendations Assessment, Development and Evaluation;

EtD: GRADE Evidence to Decision; GIN: Guidelines International Network;

HIV: Human immunodeficiency virus;

RIGHT: Reporting Items of Practice Guidelines in Healthcare;

RIGHT-Ad@pt: Extension of the RIGHT statement for Adapted Practice Guidelines.

TB: Tuberculosis;

WHO: World Health Organization.

Declarations

Author contributions

Y.S., A.D., L.M.G, P.A-C., and E.A.A. wrote the first draft of the manuscript, together with M. B., they form the coordination team and have day to day responsibility for the project. T.A., S.B., Y.L.C., F.C., D.G., P.F.P., E.V.L., H.J.S., and R.W.M.V. are independent advisors of the project and provide methodological contributions for the manuscript. All authors critically reviewed the manuscript and approved its final version.

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Competing Interests

E.A.A. and H.J.S. have intellectual CoIs related to his contribution to the development of methods of guideline adaptation, the RIGHT statement, and methodological studies in the field. S.B. is Analyses Advisor for BMJ and Associate Editor at BMJ Global Health and BMC Systematic Reviews. Other members have clarified they do not have relevant conflicts.

Ethics approval

Clinical Research Ethics Committee at the Hospital de la Santa Creu i Sant Pau (Barcelona, Spain)

Availability of data and material

The information of all participants is available in the Appendix 1

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References

1. World Health OrganizationOrganization.WH. WHO handbook for guideline development: WHO handbook for guideline development, 2014.
2. Alonso-Coello P, Irfan A, Sola I, Gich I, Delgado-Noguera M, Rigau D, et al. The quality of clinical practice guidelines over the last two decades: a systematic review of guideline appraisal studies. Qual Saf Health Care. 2010;19:e58.
3. Armstrong JJ, Goldfarb AM, Instrum RS, MacDermid JC. Improvement evident but still necessary in clinical practice guideline quality: a systematic review. J Clin Epidemiol. 2017;81:13-21.
4. Institute of Medicine: Clinical Practice Guideline We Can Trust. Washington, DC: The National Academies Press 2011.
5. Schünemann HJ, Fretheim A, Oxman AD. WHO Advisory Committee on Health Research. Improving the use of research evidence in guideline development: 1. Guidelines for guidelines. Health Res Policy Syst. 2006;4:13.
6. Bhaumik S. Use of evidence for clinical practice guideline development. Trop Parasitol. 2017;7(2):65-71.
7. Bhaumik S, Jagadesh S, Ellatar M, Kohli N, Riedha M, Moi M. Clinical practice guidelines in India: Quality appraisal and the use of evidence in their development. J Evid Based Med. 2018;11(1): 26-39.
8. Canelo-Aybar C, Balbin G, Perez-Gomez Á, Florez ID. [Clinical practice guidelines in Peru: evaluation of its quality using the AGREE II instrument]. Rev Peru Med Exp Salud Publica. 2016;33(4):732-738.
9. Kredo T, Gerritsen A, van Heerden J, Conway S, Siegfried N. Clinical practice guidelines within the Southern African Development Community: a descriptive study of the quality of guideline development and concordance with best evidence for five priority diseases. Health Res Policy Syst. 2012 5(10):1.
10. Machingaidze S, Zani B, Abrams A, Durao S, Louw Q, Kredo T, et al. Series: Clinical Epidemiology in South Africa. Paper 2: Quality and reporting standards of South African primary care clinical practice guidelines. J Clin Epidemiol. 2017;83:31-36.
11. Machingaidze S, Grimmer K, Louw Q, Kredo T, Young T, Volmink J. Next generation clinical guidance for primary care in South Africa – credible, consistent and pragmatic. PLoS ONE. 2018;13(3): e0195025.

12. Molino CG, Romano-Lieber NS, Ribeiro E, de Melo DO. Non-Communicable Disease Clinical Practice Guidelines in Brazil: A Systematic Assessment of Methodological Quality and Transparency. PLoS One. 2016;11(11):e0166367.
13. Talagala IA, Samarakoon Y, Senanayake S, Abeysena C. Sri Lankan clinical practice guidelines: A methodological quality assessment utilizing the AGREE II instrument. J Eval Clin Pract. 2018.
14. Fervers B, Burgers JS, Haugh MC, Latreille J, Mlika-Cabanne N, Paquet L, et al. Adaptation of clinical guidelines: literature review and proposition for a framework and procedure. Int J Qual Health Care. 2006;18(3): 167–176.
15. Schünemann HJ, Wiercioch W, Brozek J, Etxeandia-Ikobaltzeta I, Mustafa RA, Manja V, et al. GRADE Evidence to Decision (EtD) frameworks for adoption, adaptation, and de novo development of trustworthy recommendations: GRADE-ADOLOPMENT. J Clin Epidemiol. 2017;81:101-110.
16. Fervers B, Burgers JS, Voellinger R, Brouwers M, Browman GP, Graham ID, et al. Guideline adaptation: an approach to enhance efficiency in guideline development and improve utilisation. BMJ Qual Saf. 2011;20(3):228-36.
17. Darzi A, Harfouche M, Arayssi T, Alemadi S, Alnaqbi KA, Badsha H, et al. Adaptation of the 2015 American College of Rheumatology treatment guideline for rheumatoid arthritis for the Eastern Mediterranean Region: an exemplar of the GRADE Adolopment. Health Qual Life Outcomes. 2017;15: 183.
18. Okely AD, Ghersi D, Hesketh KD, Santos R, Loughran SP, Cliff DP, et al. A collaborative approach to adopting/adapting guidelines - The Australian 24-Hour Movement Guidelines for the early years (Birth to 5 years): an integration of physical activity, sedentary behavior, and sleep. BMC Public Health. 2017; 17(Suppl 5): 869.
19. Burgers JS, Anzueto A, Black PN, Cruz AA, Fervers B, Graham ID, et al. Adaptation, evaluation, and updating of guidelines: article 14 in Integrating and coordinating efforts in COPD guideline development. An official ATS/ERS workshop report. Proc Am Thorac Soc. 2012;9(5):304-10.
20. Kristiansen A, Brandt L, Agoritsas T, Akl EA, Berge E, Flem Jacobsen A, et al. Applying new strategies for the national adaptation, updating, and dissemination of trustworthy guidelines: results from the Norwegian adaptation of the Antithrombotic Therapy and the Prevention of Thrombosis, 9th Ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2014;146(3):735-61.
21. Mehndiratta A, Sharma S, Prakash N, Sankar J, Cluzeau F. Adapting clinical guidelines in India—a pragmatic approach. BMJ. 2017;359:j5147.

22. Kredo T, Bernhardsson S, Machingaidze S, Young T, Louw Q, Ochodo E, et al. Guide to clinical practice guidelines: the current state of play. Int J Qual Health Care. 2016;28(1):122-8.

23. Darzi A, Abou-Jaoude EA, Agarwal A, Lakis C, Wiercioch W, Santesso N, et al. A methodological survey identified eight proposed frameworks for the adaptation of health related guidelines. J Clin Epidemiol. 2017; 86:3-10.

24. Godah MW, Abdul Khalek RA, Kilzar L, Zeid H, Nahlawi A, Lopes LC, et al. A very low number of national adaptations of the World Health Organization guidelines for HIV and tuberculosis reported their processes. J Clin Epidemiol. 2016; 80:50-56.

25. Abdul-Khalek RA, Darzi AJ, Godah MW, Kilzar L, Lakis C, Agarwal A, et al. Methods used in adaptation of health-related guidelines: A systematic survey. J Glob Health. 2017;7(2):020412.

26. Moher D, Schulz KF, Simera I, Altman DG. Guidance for Developers of Health Research Reporting Guidelines. Plos Med. 2010; 7(2):e1000217

27. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzshe PC, Ioannidis JPA, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. Plos Med. 2009;6(7):e1000100.

28. Brouwers MC, Kerkvliet K, Spithoff K; AGREE Next Steps Consortium. The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. BMJ. 2016;352:1152.

29. Chen Y, Yang K, Marusic A, Qaseem A, Meerpohl JJ, Flottorp S, et al. A Reporting Tool for Practice Guidelines in Health Care: The RIGHT Statement. Ann Intern Med. 2017;166(2):128-32.

30. Tokalić R, Vidak M, Buljan I, Marusic A. Reporting quality of European and Croatian health practice guidelines according to the RIGHT reporting checklist. Implement Sci. 2018;13(1):135.

31. Vernooij RW, Alonso-Coello P, Brouwers M, Martínez García L; CheckUp Panel. Reporting Items for Updated Clinical Guidelines: Checklist for the Reporting of Updated Guidelines (CheckUp). PLoS Med. 2017;14(1):1002207.

32. Martínez García L, Pardo-Hernandez H, Niño de Guzman E, Superchi C, Ballesteros M, McFarlane E, et al. Development of a prioritisation tool for the updating of clinical guideline questions: the UpPriority Tool protocol. BMJ Open. 2017;7(8):e017226.

33. Akins RB, Tolson H, Cole BR. Stability of response characteristics of a Delphi panel: application of bootstrap data expansion. BMC Med Res Methodol. 2005;5:37.

34. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic reviews. BMC Med Res Methodol. 2008;8:45.
35. Grossoehme DH. Overview of qualitative research. J Health Care Chaplain. 2014;20:109-22.
36. Guetterman TC. Descriptions of sampling practices within five approaches to qualitative research in education and the health sciences. Forum Qual Soc Res. 2015;16:25.
37. Likert R. A technique for the measurement of attitudes. Archives of psychology. 1932.
38. van der Weegen S, Verwey R, Tange HJ, et al. Usability testing of a monitoring and feedback tool to stimulate physical activity. Patient Prefer Adherence. 2014;8:311–22.
39. Schünemann HJ, Fretheim A, Oxman AD. Improving the use of research evidence in guideline development: 13. Applicability, transferability and adaptation. Health Res Policy Syst. 2006,4:25.
40. Schünemann HJ, Wiercioch W, Etxeandia I, Falavigna M, Santesso N, Mustafa R, et al. Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise. CMAJ. 2014;186(3):E123-42.
41. AGREE Collaboration. Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project. Qual Saf Health Care. 2003;12(1):18-23.

Tables

Table 1. Description of the multistep development process

	Establishment of the RIGHT-Ad@pt Working Group	Generation of the initial checklist	Optimisation of the checklist						Approval of the final checklist
			Initial assessment of adapted guidelines	Semi-structured interviews	Delphi consensus survey	External review		Final assessment of adapted guidelines	
						Guidelines developers	Guidelines users		
Main objective	To identify individuals who are relevant to participate in the project	To develop the initial version of the checklist	To assess the adequacy of each item of the checklist	To explore current practices in adaptation of guidelines	To define the list of items to be included in the checklist	To assess the usefulness of each item of the checklist	To assess the usefulness of each item of the checklist	To assess the adequacy of each item of the checklist	To approve the final version of the checklist
Study design	-	-	Methodological survey of adapted guidelines	Semi-structured interviews	Delphi consensus survey	Survey	Semi-structured interviews	Methodological survey of adapted guidelines	-
Participants	- Coordination Team - Advisory Group - Delphi Panel Members	- Coordination Team - Advisory Group	Coordination Team (two reviewers)	Guidelines developers	Delphi Panel Members	Guidelines developers	Guidelines users	Coordination Team (two reviewers)	- Coordination Team - Advisory Group
Main outcome	-	-	Applicability rating of each item of the checklist	Participants' views and experiences with process for adapting guidelines	Items considered relevant to report the adaptation of guidelines	Usefulness rating of each item of the checklist	Participants' views and experiences with the checklist	Applicability rating of each item of the checklist	-
Study size	Convenience sample	-	Convenience sample of 10 adapted guidelines	Sampling saturation	20-30 participants from G-I-N Adaptation Guidelines Working Group, WHO, and authors of adapted guidelines	G-I-N community	Sampling saturation	Convenience sample of 10 adapted guidelines	-

Abbreviations: G-I-N, Guidelines International Network; WHO, World Health Organization.

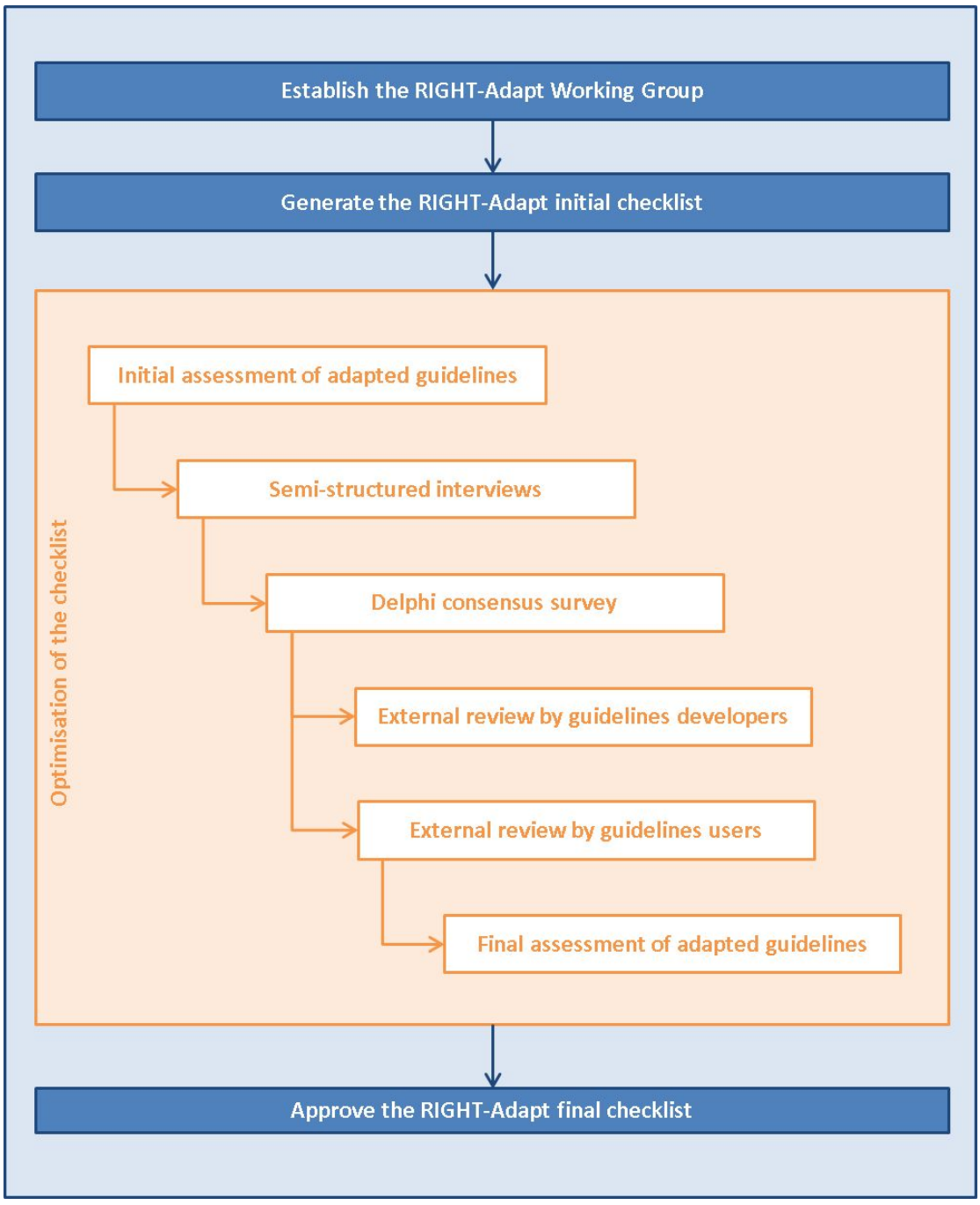
Table 2. Research design steps relevant to the optimisation of the checklist and corresponding variables

	Initial assessment of adapted guidelines	Semi-structured interviews	Delphi consensus survey	External review		Final assessment of adapted guidelines
				Guidelines developers	Guidelines users	
Response rate			X	X		
Characteristics of participants and workplaces		X	X	X	X	
Characteristics of adapted guidelines	X					X
Completeness of reporting	X					X
Participants' views and experiences		XX			XX	
Assessment of each item	XX (adequacy and suggestions)	X (understanding and suggestions)	XX (inclusion, understanding, and suggestions)	XX (usefulness, understanding, and suggestions)	X (usefulness, understanding, and suggestions)	XX (adequacy and suggestions)
Overall assessment of the checklist		X	X	X	X	

Notes: XX: Main outcome; X: Other outcomes.

Figures

Figure1: Multistep development process of RIGHT-Ad@pt



Appendix

Appendix1. Participants' information

Participants	Member Role	Organization	Country	Income Level*	Region*	Conflicts of Interests
Coordination Team						
Participant 1	Guideline methodological expert, guidelines developer	American University of Beirut	Lebanon	Upper middle income	Middle East & North Africa	Intellectual CoIs related to the contribution to the development of methods of guideline adaptation, the RIGHT statement, and methodological studies in the field.
Participant 2	Guideline methodological expert, guidelines developer	Iberoamerican Cochrane Centre	Spain	High income	Europe & Central Asia	None
Participant 3	Guideline methodological expert, guidelines developer	Hospital Universitari Vall d'Hebron	Spain	High income	Europe & Central Asia	None
Participant 4	Guideline methodological expert	Iberoamerican Cochrane Centre	Spain	High income	Europe & Central Asia	None
Participant 5	Guideline methodological expert	Iberoamerican Cochrane Centre	Spain	High income	Europe & Central Asia	None
Advisory Group						
Participant 1	Guideline User	Weill Cornell Medicine-Qatar	Qatar	High income	Middle East & North Africa	None
Participant 2	Journal Editor	The George Institute for Global Health	India	Lower middle income	South Asia	Analyses Advisor for BMJ and Associate Editor at BMJ Global Health and BMC Systematic Reviews.
Participant 3	Methodologist	Lanzhou University	China	Upper middle income	East Asia & Pacific	None
Participant 4	Guideline developer	Imperial College London	United Kingdom	High income	Europe & Central Asia	None

Participant 5	Guideline developer	National Health and Medical Research Council, Australia	Australia	High income	East Asia & Pacific	None
Participant 6	Guideline methodological expert, guideline user	Facultad de Medicina y Odontología, Universidad de Antofagasta	Chile	High income	Latin America & Caribbean	None
Participant 7	Policy maker	World Health Organisation	Switzerland	High income	Europe & Central Asia	None
Participant 8	Policy maker	World Health Organisation	Switzerland	High income	Europe & Central Asia	Oversee the quality of WHO guidelines as an employee of the World Health Organization. Member of the GRADE Working Group. Co-author of the RIGHT paper.
Participant 9	Guideline methodological expert, guidelines developer	McMaster University	Canada	High income	North America	Intellectual CoIs related to the contribution to the development of methods of guideline adaptation, the RIGHT statement, and methodological studies in the field.
Participant 10	Guideline methodological expert	Netherlands Comprehensive Cancer Organisation	Netherlands	High income	Europe & Central Asia	None

*Ref from World Bank: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups

Abbreviation: CoIs: Conflicts of Interests.

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Extending the RIGHT statement for Reporting Adapted Practice Guidelines in Health Care: the RIGHT-Ad@pt Checklist protocol

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Primary Subject Heading:	Evidence based practice
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Extending the RIGHT statement for Reporting Adapted Practice Guidelines in Health Care: the RIGHT-Ad@pt Checklist protocol

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Abstract

Introduction

The adaptation of guidelines is an increasingly used methodology for the efficient development of contextualised recommendations. Nevertheless, there is no specific reporting guidance. The Essential Reporting Items of Practice Guidelines in Healthcare (RIGHT) statement could be useful for reporting adapted guidelines, but it does not address all the important aspects of the adaptation process. The objective of our project is to develop an extension of the RIGHT statement for the reporting of adapted guidelines (RIGHT-Ad@pt Checklist).

Methods and analysis

To develop the RIGHT-Ad@pt Checklist, we will use a multistep process that includes: 1) establishment of a Working Group; 2) generation of an initial checklist based on the RIGHT statement; 3) optimisation of the checklist (an initial assessment of adapted guidelines, semi-structured interviews, a Delphi consensus survey, an external review by guideline developers and users, and a final assessment of adapted guidelines); and 4) approval of the final checklist. At each step of the process, we will calculate absolute frequencies and proportions, use content analysis to summarise and draw conclusions, discuss the results, draft a report, and refine the checklist.

Ethics and dissemination

We have obtained a waiver of approval from the Clinical Research Ethics Committee at the Hospital de la Santa Creu i Sant Pau (Barcelona, Spain). We will disseminate the RIGHT-Ad@pt checklist by publishing into a peer-reviewed journal, presenting to relevant stakeholders, and translating into different languages. We will continuously seek feedback from stakeholders, surveil new relevant evidence and, if necessary, update the checklist.

Keywords

Evidence-based medicine, guideline adaptation, guidelines as topic, practice guideline, quality, reporting standards.

Word count

Abstract	241/300
Manuscript (Introduction - Discussion)	3520/4000

Strengths and Limitations

- There is no current tool for reporting adapted guidelines. The RIGHT-Ad@pt checklist will fill this gap and provide a clear guidance for the reporting of guideline adaptation.
- To develop the checklist, we will use the best available methodological research evidence, adopt a systematic and rigorous multistep process, and collect and build on the views and experiences of international stakeholders including guidelines methodologists, policy makers, journal editors, and guideline users.
- The RIGHT-Ad@pt checklist can be used within guideline adaptation to guide reporting, to improve the completeness of reporting, to evaluate publications, and to inform implementation decisions of health care.
- We will not conduct a complete formal validation of the checklist since our current process will not include an assessment of neither construction nor criterion validity

Introduction

The World Health Organization (WHO) defines guidelines as "systematically developed evidence-based statements which assist providers, recipients and other stakeholders to make informed decisions about appropriate health interventions". Guidelines have been increasingly used to provide guidance for policies or public health interventions, changes in resource availability or access to services based on evidence [1]. There is evidence that the methodological quality of guidelines has slowly improved over the last decades [2-4]. However, most guideline developers do not have enough resources for developing high-quality *de novo* guidelines [5]. Most low- and middle-income countries still do not have formal organisations, technical capacity or collaborations to develop evidence-based guidelines [6]. When guidelines are developed in those settings, their quality is typically poor [7-13]. Adapting published high-quality evidence-informed guidelines becomes a more efficient option [14-16].

Adaption of guidelines means the use of existing trustworthy guidelines, with (adapt) or without (adopt) modifications, to provide local, regional, or national guidance [15-17]. Schünemann et al. defined adapted recommendations as recommendations with: 1) potential change in the specific population, intervention, or comparator with respect to the original recommendations; 2) potential change in the certainty of the evidence; and 3) information on "conditions", monitoring, implementation, and implications for research [16]. Adopted recommendations were defined as recommendations with: 1) the same specific population, intervention, and comparators as the original recommendations; 2) the same certainty of the evidence; and 3) information on implementation [16]. Adaptation of guidelines is an increasingly used methodology for the efficient development of contextualised recommendations that are relevant for diverse health systems [16-18]. Guideline adaptation takes into consideration local contextual factors such as language, availability and accessibility of services and resources, the health-care setting, and the relevant stakeholders' cultural and ethical values [19]. At the same time, it should be based on similar systematic and transparent approaches as the source guideline in order to benefit from its quality and validity [20]. However, adaptation is not always possible. For example, when a trustworthy guideline is not available, a *de novo* guideline development process needs to be considered [16, 21].

Despite the increasing need, there is no standard adaptation method implemented internationally [21, 22]. A systematic review of the literature identified eight published frameworks for adaptation of clinical, public health or health system guidelines, concluding

that the "adaptation" phases of the processes were notably different [23]. Moreover, the process for adapting guidelines was usually poorly reported, including WHO guidelines [24]. For example, Godah et al. 2016 systematically assessed the processes employed in the adaptation of WHO guidelines for human immunodeficiency virus (HIV) and tuberculosis (TB). Out of 170 eligible adapted guidelines, only 32 (32/170, 19%) reported the methods used in the adaptation process [24]. Similarly, Abdul-Khalek et al. 2017 assessed the methods used for adapting health-related guidelines published in peer-reviewed journals [25]. Out of the 72 included adapted guidelines, 57 reported some degree of detail about the adaptation method used, and only 23 (23/57, 40%) reported using a specific adaptation method. These findings call for a need to optimize the methods used in guideline adaptation, and to improve the reporting of the adaptation process in adapted guidelines [24].

Guidelines for reporting health research have been developed to enhance the accurate, complete, and transparent reporting of health research publications (http://www.equator-network.org/). Moher et al. 2010 defined a reporting guideline as "a checklist, flow diagram, or explicit text to guide authors in reporting a specific type of research, developed using explicit methodology" [26]. Its aim is to indicate the minimum reporting standards, for readers to comprehend the design, conduct, analysis and interpretation of a study, and to assess the validity of results [26, 27]. A transparent reporting approach could help guideline developers frame the decision making during the development process, and guideline users about the suitability for adapting, and consequently the adaptation process.

Currently, the main tools available for the reporting of guidelines development are: 1) the Appraisal of Guidelines for Research and Evaluation II (AGREE II) instrument, including the AGREE Reporting Checklist [28]; and 2) the Reporting Items for practice Guidelines in HealThcare (RIGHT) statement to improve the reporting of guidelines [29]. The RIGHT statement was formally developed as a reporting checklist for *de novo* guidelines [29]. Although it could be useful for the reporting of adapted guidelines [30], it does not cover some of the steps that are specific to guidelines adaptation (e.g. description of methods used to search and identify guidelines) [29]. Therefore, to ensure rigour, transparency, clarity, and reproducibility of reporting the adaptation process, we will develop an extension of the RIGHT statement for the reporting of adapted guidelines.

Objective

To develop the RIGHT-Ad@pt Checklist, as an extension of the RIGHT statement tailored to adapted guidelines.

Methods and analysis

To develop the checklist, we will build on the RIGHT statement [29], review methodology research evidence on guidelines adaptation [23-25], and adopt a multistep process we have successfully implemented in the development of similar tools [31, 32]. Table 1 describes the multistep development process of the RIGHT-Ad@pt Checklist, which includes: 1) establishment of a Working Group; 2) generation of an initial checklist; 3) optimisation of the checklist (an initial assessment of adapted guidelines, semi-structured interviews, a Delphi consensus survey, an external review by guideline developers and users, and a final assessment of adapted guidelines); and 4) approval of the final checklist. Figure 1 illustrates the development process, and Figure 2 presents the timeline.

1. Establishment of the RIGHT-Ad@pt Working Group

The RIGHT-Ad@pt Working Group will include: 1) a Coordination Team; 2) an Advisory Group; and 3) a Delphi Panel [26, 31, 32].

1.1. Coordination Team

The Coordination Team (YS, MB, LMG, PAC, EA) will lead and coordinate the RIGHT-Ad@pt development process and ensure its completion according to the established timeline. Specifically, the Coordination Team will be responsible for 1) generating the initial version of the checklist; 2) implementing each step of the process; and 3) reporting the findings of each step of the processes. We have collected the Conflicts of interests (CoIs) of all members of the Coordination Team (Supplement File 1).

1.2. Advisory Group

The Advisory Group is a multidisciplinary group (8 to 10 people) including 1) guideline methodological experts (defined as having experience and expertise in guideline methods); 2) guidelines developers (defined as having participated in guideline development groups and/or guideline adaptation groups at least once in the past year); 3) guideline users (defined as healthcare professionals that use guidelines on a regular basis); and 4) journal editors of guideline related journals [26]. Members of the Advisory Group will review and provide expert

advice during the different steps of the RIGHT-Ad@pt development process. The Advisory Group will approve the final checklist and accompanying guidance. We have collected the CoIs of all members of the Advisory Group (Supplement File 1).

1.3. Delphi Panel

The Delphi Panel will be comprised of 20 to 30 members, with profiles similar to those of the members of the Advisory Group (guideline methodological experts, guidelines developers, guideline users, and journal editors of guideline related journals) [33, 34]. We will aim for country income, gender and profile representativeness of participants. We will identify participants from the Guidelines International Network (GIN) Adaptation Guidelines Working Group (http://www.g-i-n.net/working-groups/adaptation), WHO, authors of adapted guidelines [25], and expert colleagues. The panel's CoIs will be collected.

2. Generation of the initial checklist

The Coordination Team will generate the initial version of the checklist building on the RIGHT statement [29]. We will conduct this step via monthly face-to-face and online meetings within the Coordination Team. The Coordination Team will review the results, draft a report with a proposal of the initial version for the Advisory Group to review, and produce a final version taken into consideration their feedback.

3. Optimisation of the checklist

3.1. Initial assessment of adapted guidelines

We will survey published adapted guidelines using initial checklist. We will explore the adequacy of each item (defined as overall completeness of reporting as well as the quantity of example supporting the item [35]), and refine the checklist. We will also record the main characteristics of the adapted guidelines (e.g. title, year, or adaptation process), completeness of reporting process for adapting guidelines, and suggestions to improve the checklist (Table 2).

We will assess a convenience sample of ten adapted guidelines available in English and published in the last five years [36]. We will also take into account country income level, type of organisation, and region. Two reviewers from the Coordination Team will independently apply the initial version of the checklist to adapted guidelines. The two reviewers will resolve potential disagreements by discussion, and if necessary, by consulting a third reviewer.

For quantitative variables (characteristics of adapted guidelines, completeness of reporting, and adequacy), we will calculate absolute frequencies and proportions. For qualitative variables (suggestions to improve the checklist), we will use content analysis to summarise and draw conclusions [37]. The Coordination Team will review the results, draft a report, review and agree on the relevant checklist modifications. If members of the Coordination Team do not reach consensus on specific items, they will consult the Advisory Group.

3.2. Semi-structure interviews

We will survey guideline developers who were involved in guideline adaptation over the past three years. We will explore participants' views and experiences on guidelines adaptation, and refine the checklist. We will also record the characteristics of participants and their workplaces, participants' understanding of each item, suggestions to improve the checklist, and participants' overall assessment of the checklist (Table 2). Each interview will last approximately one hour and will be recorded and transcribed with participant´s permission. The interview transcripts will be sent to interviewees for approval.

We will identify the participants with the support of the Advisory Group. We will contact via email and conduct online interviews. We will continue recruitment and collect data until information becomes repetitive and no new information emerges (sampling saturation) [38, 39].

For quantitative variables (characteristics of participants and workplaces, participants' understanding of each item, and participants' overall assessment of the checklist), we will calculate absolute frequencies and proportions. For qualitative variables (participants' views and experiences, and suggestions to improve the checklist), we will use content analysis to summarise and draw conclusions [37]. The Coordination Team will review the results, draft a report, review and agree on the relevant checklist modifications. If members of the Coordination Team do not reach consensus on specific items, they will consult the Advisory Group.

3.3. Delphi consensus survey

We will conduct a Delphi consensus survey to reach a consensus with the Delphi Panel about the included items in the checklist. We will also record response rate, characteristics of participants and workplaces, participants' understanding of each item, suggestions to improve the checklist, and participants' overall assessment of the checklist (Table 2).

Before the first Delphi round, we will provide the Delphi Panel Members with a brief background material on the topic. In the first Delphi round, we will ask participants to rate whether each item should be included in the checklist using a seven-point Likert scale (1=strongly disagree and 7=strongly agree) [31, 32, 40]. We will calculate the median score for inclusion of each item and will classify them as 1) excluded (median score of 1-3 points); 2) review, modify and retest (median score of 4-5 points or with substantial comments); and 3) included (median score of 6 to 7 points and without substantial comments) [31, 32]. After each Delphi round, we will provide feedback to Delphi Panel Members (data reported will be anonymised). We will conduct additional Delphi rounds until consensus regarding items inclusion is reached (median score of 6-7) and no more relevant comments on the items are provided (two or three rounds, as needed). We will use online software to design the survey and collect responses (http://www.clinapsis.com/). We will not invite non-responders or partial responders (questionnaires with no response for more than 20% of the items) to subsequent Delphi rounds.

For quantitative variables (response rate, characteristics of participants and workplaces, inclusion score, participants' understanding of each item, and participants' overall assessment of the checklist), we will calculate absolute frequencies and proportions. For qualitative data (suggestions to improve the checklist), we will use content analysis to summarise and draw conclusions [37]. We will not consider questionnaires with no response for more than 20% of the items. The Coordination Team will review the results of the Delphi consensus survey, draft a report with a proposal for the Advisory Group to review, and produce a final version taken into consideration their feedback.

3.4. External review

3.4.1. External review by guidelines developers

We will survey guideline developers who were involved in guideline adaptation over the past three years. We will explore usefulness of each item (defined as provision of enough and clear information in order to be used with effectiveness, efficiency and satisfaction to check the reporting of adapted guidelines [41]) using a seven-point Likert scale (1=strongly disagree and 7=strongly agree) [40], and refine the checklist. We will also record response rate, characteristics of participants and workplaces, participants' understanding of each item, suggestions to improve the checklist, and participants' overall assessment of the checklist (Table 2).

We will identify participants by contacting professionals associated with the GIN community (http://www.g-i-n.net) and WHO. We will use online software to design the survey and collect responses (http://www.clinapsis.com/).

For quantitative variables (response rate, characteristics of participants and workplaces, usefulness score, participants' understanding of each item, and participants' overall assessment of the checklist), we will calculate absolute frequencies and proportions. For qualitative data (suggestions to improve the checklist), we will use content analysis to summarise and draw conclusions [37]. We will not consider questionnaires with no response for more than 20% of the items.

3.4.2. External review by guidelines users

We will conduct external review semi-structured interviews with guidelines users who have used adapted guidelines over the past three years. We will explore participants' views and experiences using the checklist, and refine the checklist. We will also record the characteristics of participants and workplaces, participants' understanding of each item, suggestions to improve the checklist, and participants' overall assessment of the checklist (Table 2). Each interview will last approximately one hour and will be recorded and transcribed with participant´s permission. The interview transcripts will be sent to interviewees for approval.

We will identify the participants with the support of the Advisory Group. We will contact via email and conduct online interviews. We will continue recruitment and collect data until information becomes repetitive and no new information emerges (sampling saturation) [38, 39].

For quantitative variables (characteristics of participants and workplaces, usefulness score, participants' understanding of each item, and participants' overall assessment of the checklist), we will calculate absolute frequencies and proportions. For qualitative data (participants' views and experiences, and suggestions to improve the checklist), we will use content analysis to summarise and draw conclusions [37]. The Coordination Team will review the results of the external review (guideline developers and users), draft a report with a proposal for the Advisory Group to review, and produce a final version taken into consideration their feedback.

3.5. Final assessment of adapted guidelines

We will conduct a final assessment of the validity of each item in a set of adapted guidelines. We will also record the main characteristics of the adapted guidelines (e.g. title, year, or adaptation process), completeness of reporting process for adapting guidelines, and suggestions to improve the checklist (Table 2).

We will assess a convenience sample of ten adapted guidelines available in English and published in the last five years [36]. We will also take into account country income level, type of organization, and region. Two reviewers from the Coordination Team will independently apply the final version of the checklist to adapted guidelines. The two reviewers will resolve potential disagreements by discussion, and if necessary, by consulting a third reviewer.

For quantitative variables (characteristics of adapted guidelines, completeness of reporting, and adequacy), we will calculate absolute frequencies and proportions. For qualitative variables (suggestions to improve the checklist), we will use content analysis to summarise and draw conclusions [37]. The Coordination Team will review the results, draft a report, review and agree on the relevant checklist modifications. If members of the Coordination Team do not reach consensus on specific items, they will consult the Advisory Group.

4. Approval of the final checklist

The Coordination Team will generate the final version of the checklist. The final checklist will highlight the changes from the RIGHT statement [29], including 1) the items that remained unchanged, 2) the items that were modified, 3) the items that were added as part of the extension, and 4) the items that were omitted. All members of the Coordination Team and the Advisory Group will need to review and approve the final version of the checklist through consensus discussion.

Patient and Public Involvement

Patient and Public will not be involved in the study.

Discussion

Executive summary

The aim of this project is to develop the RIGHT-Ad@pt Checklist, as an extension of the RIGHT statement tailored for guideline adaptation, to improve the rigour and transparency of

guideline adaptation reporting. To develop the checklist, we will build on the RIGHT statement, use the best available evidence from published methodological research on this topic, and use a rigorous multistep process involving multiple stakeholders.

Our study in the context of previous research

Adaptation of high-quality guidelines is an alternative to developing *de novo* guidelines that saves both time and resources, and avoids duplication of effort. The ADAPTE framework is one of the earliest systematic approaches to adapt guidelines to local context [15, 42]. Building on work done for WHO in 2006, the "GRADE-ADOLOPMENT" framework proposed using the GRADE Evidence to Decision (EtD) frameworks for the adaptation, adoption, and *de novo* development of guidelines [16]. Despite these advances, there is variability in the quality of reporting of adapted practice guidelines and no guidance for their reporting is available [23, 25]. The proposed checklist might help with reducing the variability of adaptation process and improving the quality of reporting. The checklist is not intended to support guideline development, which will be done through an extension of the GIN-McMaster Guideline Development Checklist [43].

Strengths and Limitations

Our proposal has some limitations. For example, we will only include guidelines published in English in the assessment of adapted guidelines. The checklist will inform about the completeness of the reporting but not necessarily about the quality of the adaptation process. We will not conduct a complete formal validation of the checklist since our current process will not include an assessment of neither construction nor criterion validity [44]; however, our proposed approach will ensure both face and content validity.

Our proposal has several strengths. The development of the checklist will be comprehensive, including the use of previous methodological evidence [23-25, 29, 31, 32] and the engagement of the multidisciplinary international guideline community. We will collect views and experiences from different stakeholders, including methodologists, guideline developers, guidelines users and journal editors. We will also ensure the diversity of participants in terms of country level of income, gender, and field of expertise. This will allow us to incorporate the different stakeholders' perspective about the adaptation of guidelines. We will address the risk of bias in each step of the development process. To minimise interviewer bias, semistructured interviews will be conducted using an interview guide. To minimise selection bias, we will

invite all GIN Adaptation Guidelines Working Group members as well as other stakeholders to join the Delphi Panel and to participate in the external review survey. To minimise non-response bias, we will make the survey available online for four weeks and we will send two reminders prior to the round closing date.

Implications for practice and research

RIGHT-Ad@pt will help improve the completeness when reporting adapted guidelines, therefore contribute to improve their quality, and facilitate their implementation. The checklist will allow the guideline developers to guide their reporting, journals editors to improve the reporting of published adapted guidelines, policy makers to inform on implementation decisions, and guideline users to evaluate the completeness of the reporting within adapted guidelines. Future research should focus on the performance of a complete formal validation of the checklist and its assessment in a representative sample of contemporary adapted guidelines. Surveillance on the use of the checklist and assessment of its impact could also be a topic of research.

Ethics and Dissemination

The protocol obtained a waiver of approval (did not involve patients, biological samples, or clinical data) from the Clinical Research Ethics Committee at the Hospital de la Santa Creu i Sant Pau (Barcelona, Spain). Nevertheless, we will request written informed consent from all participants and anonymise all data.

The dissemination activities will include: 1) publication of the RIGHT-Ad@pt Checklist in a peer-reviewed journal; 2) presentation the project to relevant stakeholders (e.g., via international conferences, electronic bulletins, related websites (http://www.right-statement.org/, http://www.equator-network.org/), and social media (e.g., Twitter); and 3) translation of the checklist into different languages. The implementation activities will include: 1) engaging with journal editors to encourage the use of the checklist; and 2) evaluation of the impact of the checklist on the reporting of adapted guidelines. Finally, we will continuously seek feedback from stakeholders, surveil new relevant evidence and, if necessary, update the checklist.

List of abbreviations

AGREE II: Appraisal of Guidelines for Research and Evaluation II; CoIs: Conflicts of interests; EtD: GRADE Evidence to Decision; GIN: Guidelines International Network; GRADE: The Grading of Recommendations Assessment, Development and Evaluation; HIV: Human immunodeficiency virus; RIGHT: Reporting Items of Practice Guidelines in Healthcare; RIGHT-Ad@pt: Extension of the RIGHT statement for Adapted Practice Guidelines; TB: Tuberculosis; WHO: World Health Organization.

Declarations

Authors' contributions

Y.S., A.D., L.M.G, P.A-C., and E.A.A. wrote the first draft of the manuscript. Y.S., M. B., L.M.G, P.A-C., and E.A.A. form the coordination team and have day to day responsibility for the project. T.A., S.B., Y.L.C., F.C., D.G., P.F.P., E.V.L., H.J.S., and R.W.M.V. are independent advisors of the project and provide methodological contributions for the manuscript. All authors critically reviewed the manuscript and approved its final version.

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Competing interests statement

E.A.A. and H.J.S. have intellectual CoIs related to his contribution to the development of methods of guideline adaptation, the RIGHT statement, and methodological studies in the field. S.B. is Analyses Advisor for BMJ and Associate Editor at BMJ Global Health and BMC Systematic Reviews. Other members have clarified they do not have relevant conflicts.

Data availability statement

The information of all participants is available in the Supplement File 1.

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References

1. World Health OrganizationOrganization.WH. WHO handbook for guideline development: WHO handbook for guideline development, 2014.
2. Alonso-Coello P, Irfan A, Sola I, Gich I, Delgado-Noguera M, Rigau D, et al. The quality of clinical practice guidelines over the last two decades: a systematic review of guideline appraisal studies. Qual Saf Health Care. 2010;19:e58.
3. Armstrong JJ, Goldfarb AM, Instrum RS, MacDermid JC. Improvement evident but still necessary in clinical practice guideline quality: a systematic review. J Clin Epidemiol. 2017;81:13-21.
4. Institute of Medicine: Clinical Practice Guideline We Can Trust. Washington, DC: The National Academies Press 2011.
5. Schünemann HJ, Fretheim A, Oxman AD. WHO Advisory Committee on Health Research. Improving the use of research evidence in guideline development: 1. Guidelines for guidelines. Health Res Policy Syst. 2006;4:13.
6. Bhaumik S. Use of evidence for clinical practice guideline development. Trop Parasitol. 2017;7(2):65-71.
7. Bhaumik S, Jagadesh S, Ellatar M, Kohli N, Riedha M, Moi M. Clinical practice guidelines in India: Quality appraisal and the use of evidence in their development. J Evid Based Med. 2018;11(1): 26-39.
8. Canelo-Aybar C, Balbin G, Perez-Gomez Á, Florez ID. Clinical practice guidelines in Peru: evaluation of its quality using the AGREE II instrument. Rev Peru Med Exp Salud Publica. 2016;33(4):732-738.
9. Kredo T, Gerritsen A, van Heerden J, Conway S, Siegfried N. Clinical practice guidelines within the Southern African Development Community: a descriptive study of the quality of guideline development and concordance with best evidence for five priority diseases. Health Res Policy Syst. 2012 5(10):1.
10. Machingaidze S, Zani B, Abrams A, Durao S, Louw Q, Kredo T, et al. Series: Clinical Epidemiology in South Africa. Paper 2: Quality and reporting standards of South African primary care clinical practice guidelines. J Clin Epidemiol. 2017;83:31-36.
11. Machingaidze S, Grimmer K, Louw Q, Kredo T, Young T, Volmink J. Next generation clinical guidance for primary care in South Africa - credible, consistent and pragmatic. PLoS ONE. 2018;13(3): e0195025.

12. Molino CG, Romano-Lieber NS, Ribeiro E, de Melo DO. Non-Communicable Disease Clinical Practice Guidelines in Brazil: A Systematic Assessment of Methodological Quality and Transparency. PLoS One. 2016;11(11):e0166367.
13. Talagala IA, Samarakoon Y, Senanayake S, Abeysena C. Sri Lankan clinical practice guidelines: A methodological quality assessment utilizing the AGREE II instrument. J Eval Clin Pract. 2018.
14. Fervers B, Burgers JS, Haugh MC, Latreille J, Mlika-Cabanne N, Paquet L, et al. Adaptation of clinical guidelines: literature review and proposition for a framework and procedure. Int J Qual Health Care. 2006;18(3): 167-176.
15. Fervers B, Burgers JS, Voellinger R, Brouwers M, Browman GP, Graham ID, et al. Guideline adaptation: an approach to enhance efficiency in guideline development and improve utilisation. BMJ Qual Saf. 2011;20(3):228-36.
16. Schünemann HJ, Wiercioch W, Brozek J, Etxeandia-Ikobaltzeta I, Mustafa RA, Manja V, et al. GRADE Evidence to Decision (EtD) frameworks for adoption, adaptation, and de novo development of trustworthy recommendations: GRADE-ADOLOPMENT. J Clin Epidemiol. 2017;81:101-110.
17. Darzi A, Harfouche M, Arayssi T, Alemadi S, Alnaqbi KA, Badsha H, et al. Adaptation of the 2015 American College of Rheumatology treatment guideline for rheumatoid arthritis for the Eastern Mediterranean Region: an exemplar of the GRADE Adolopment. Health Qual Life Outcomes. 2017;15: 183.
18. Okely AD, Ghersi D, Hesketh KD, Santos R, Loughran SP, Cliff DP, et al. A collaborative approach to adopting/adapting guidelines - The Australian 24-Hour Movement Guidelines for the early years (Birth to 5 years): an integration of physical activity, sedentary behavior, and sleep. BMC Public Health. 2017; 17(Suppl 5): 869.
19. Burgers JS, Anzueto A, Black PN, Cruz AA, Fervers B, Graham ID, et al. Adaptation, evaluation, and updating of guidelines: article 14 in Integrating and coordinating efforts in COPD guideline development. An official ATS/ERS workshop report. Proc Am Thorac Soc. 2012;9(5):304-10.
20. Kristiansen A, Brandt L, Agoritsas T, Akl EA, Berge E, Flem Jacobsen A, et al. Applying new strategies for the national adaptation, updating, and dissemination of trustworthy guidelines: results from the Norwegian adaptation of the Antithrombotic Therapy and the Prevention of Thrombosis, 9th Ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines. Chest. 2014;146(3):735-61.
21. Mehndiratta A, Sharma S, Prakash N, Sankar J, Cluzeau F. Adapting clinical guidelines in India—a pragmatic approach. BMJ. 2017;359:j5147.

22. Kredo T, Bernhardsson S, Machingaidze S, Young T, Louw Q, Ochodo E, et al. Guide to clinical practice guidelines: the current state of play. Int J Qual Health Care. 2016;28(1):122-8.

23. Darzi A, Abou-Jaoude EA, Agarwal A, Lakis C, Wiercioch W, Santesso N, et al. A methodological survey identified eight proposed frameworks for the adaptation of health related guidelines. J Clin Epidemiol. 2017; 86:3-10.

24. Godah MW, Abdul Khalek RA, Kilzar L, Zeid H, Nahlawi A, Lopes LC, et al. A very low number of national adaptations of the World Health Organization guidelines for HIV and tuberculosis reported their processes. J Clin Epidemiol. 2016; 80:50-56.

25. Abdul-Khalek RA, Darzi AJ, Godah MW, Kilzar L, Lakis C, Agarwal A, et al. Methods used in adaptation of health-related guidelines: A systematic survey. J Glob Health. 2017;7(2):020412.

26. Moher D, Schulz KF, Simera I, Altman DG. Guidance for Developers of Health Research Reporting Guidelines. Plos Med. 2010; 7(2):e1000217.

27. Liberati A, Altman DG, Tetzlaff J, Mulrow C, Gotzshe PC, Ioannidis JPA, et al. The PRISMA statement for reporting systematic reviews and meta-analyses of studies that evaluate healthcare interventions: explanation and elaboration. Plos Med. 2009;6(7):e1000100.

28. Brouwers MC, Kerkvliet K, Spithoff K; AGREE Next Steps Consortium. The AGREE Reporting Checklist: a tool to improve reporting of clinical practice guidelines. BMJ. 2016;352:1152.

29. Chen Y, Yang K, Marusic A, Qaseem A, Meerpohl JJ, Flottorp S, et al. A Reporting Tool for Practice Guidelines in Health Care: The RIGHT Statement. Ann Intern Med. 2017;166(2):128-32.

30. Tokalić R, Vidak M, Buljan I, Marusic A. Reporting quality of European and Croatian health practice guidelines according to the RIGHT reporting checklist. Implement Sci. 2018;13(1):135.

31. Vernooij RW, Alonso-Coello P, Brouwers M, Martínez García L; CheckUp Panel. Reporting Items for Updated Clinical Guidelines: Checklist for the Reporting of Updated Guidelines (CheckUp). PLoS Med. 2017;14(1):1002207.

32. Martínez García L, Pardo-Hernandez H, Niño de Guzman E, Superchi C, Ballesteros M, McFarlane E, et al. Development of a prioritisation tool for the updating of clinical guideline questions: the UpPriority Tool protocol. BMJ Open. 2017;7(8):e017226.

33. Akins RB, Tolson H, Cole BR. Stability of response characteristics of a Delphi panel: application of bootstrap data expansion. BMC Med Res Methodol. 2005;5:37.

34. 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.
35. Glenton C, Carlsen B, Lewin S, Munthe-Kaas H, Colvin CJ, Tunçalp Ö, et al. Applying GRADE-CERQual to qualitative evidence synthesis findings-paper 5: how to assess adequacy of data. Implement Sci. 2018;13(Suppl 1):14.
36. Arain M, Campbell MJ, Cooper CL, Lancaster GA. What is a pilot or feasibility study? A review of current practice and editorial policy. BMC Med Res Methodol. 2010;10:67.
37. Thomas J, Harden A. Methods for the thematic synthesis of qualitative research in systematic reviews. BMC Med Res Methodol. 2008;8:45.
38. Grossoehme DH. Overview of qualitative research. J Health Care Chaplain. 2014;20:109-22.
39. Guetterman TC. Descriptions of sampling practices within five approaches to qualitative research in education and the health sciences. Forum Qual Soc Res. 2015;16:25.
40. Likert R. A technique for the measurement of attitudes. Archives of psychology. 1932.
41. Van der Weegen S, Verwey R, Tange HJ, et al. Usability testing of a monitoring and feedback tool to stimulate physical activity. Patient Prefer Adherence. 2014;8: 311-22.
42. Schünemann HJ, Fretheim A, Oxman AD. Improving the use of research evidence in guideline development: 13. Applicability, transferability and adaptation. Health Res Policy Syst. 2006,4:25.
43. Schünemann HJ, Wiercioch W, Etxeandia I, Falavigna M, Santesso N, Mustafa R, et al. Guidelines 2.0: systematic development of a comprehensive checklist for a successful guideline enterprise. CMAJ. 2014;186(3):E123-42.
44. AGREE Collaboration. Development and validation of an international appraisal instrument for assessing the quality of clinical practice guidelines: the AGREE project. Qual Saf Health Care. 2003;12(1):18-23.

Tables

Table 1. Description of the multistep development process

	Establishment of the Working Group	Generation of the initial checklist	Optimisation of the checklist						Approval of the final checklist
			Initial assessment of adapted guidelines	Semi-structured interviews	Delphi consensus survey	External review by guidelines developers	External review by guidelines users	Final assessment of adapted guidelines	
Main objective	To identify individuals who are relevant to participate in the project	To develop the initial version of the checklist	To assess the adequacy of each item of the checklist	To explore current practices in adaptation of guidelines	To define the list of items to be included in the checklist	To assess the usefulness of each item of the checklist	To assess the usefulness of each item of the checklist	To assess the adequacy of each item of the checklist	To approve the final version of the checklist
Study design	-	-	Methodological survey of adapted guidelines	Semi-structured interviews	Delphi consensus survey	Survey	Semi-structured interviews	Methodological survey of adapted guidelines	-
Participants	- Coordination Team - Advisory Group - Delphi Panel Members	- Coordination Team - Advisory Group	Coordination Team (two reviewers)	Guidelines developers	Delphi Panel Members	Guidelines developers	Guidelines users	Coordination Team (two reviewers)	- Coordination Team - Advisory Group
Main outcome	-	-	Applicability rating of each item of the checklist	Participants' views and experiences with process for adapting guidelines	Items considered relevant to report the adaptation of guidelines	Usefulness rating of each item of the checklist	Participants' views and experiences with the checklist	Applicability rating of each item of the checklist	-
Study size	Convenience sample	-	Convenience sample of 10 adapted guidelines	Sampling saturation	20-30 participants from G-I-N Adaptation Guidelines Working Group, WHO, and authors of adapted guidelines	G-I-N community	Sampling saturation	Convenience sample of 10 adapted guidelines	-

Abbreviations: G-I-N, Guidelines International Network; WHO, World Health Organization.

Table 2. Research design steps relevant to the optimisation of the checklist and corresponding variables

	Initial assessment of adapted guidelines	Semi-structured interviews	Delphi consensus survey	External review		Final assessment of adapted guidelines
				Guidelines developers	Guidelines users	
Response rate			X	X		
Characteristics of participants and workplaces		X	X	X	X	
Characteristics of adapted guidelines	X					X
Completeness of reporting	X					X
Participants' views and experiences		XX			XX	
Assessment of each item	XX (adequacy and suggestions)	X (understanding and suggestions)	XX (inclusion, understanding, and suggestions)	XX (usefulness, understanding, and suggestions)	X (understanding, and suggestions)	XX (adequacy and suggestions)
Overall assessment of the checklist		X	X	X	X	

Notes: XX: Main outcome; X: Other outcomes

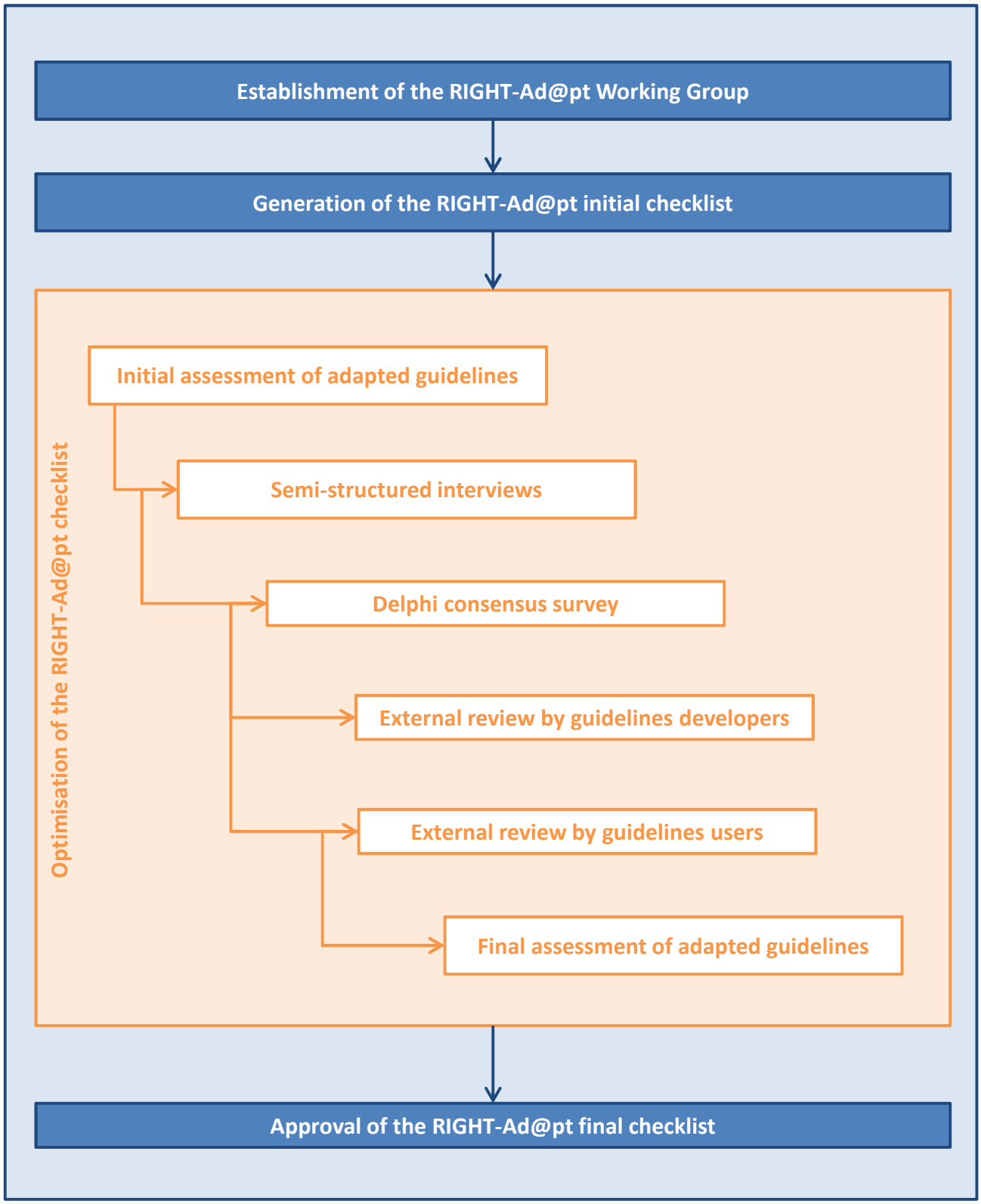
Figures

Figure 1. Multistep development process of RIGHT-Ad@pt

Figure 2. Timeline of RIGHT-Ad@pt

Supplement File

Supplement File 1. Participants' information


Establishment of the RIGHT-Ad@pt Working Group
Generation of the RIGHT-Ad@pt initial checklist
Optimisation of the RIGHT-Ad@pt checklist
Initial assessment of adapted guidelines
Semi-structured interviews
Delphi consensus survey
External review by guidelines developers
External review by guidelines users
Final assessment of adapted guidelines
Approval of the RIGHT-Ad@pt final checklist

		2018												2019												2020											
		Year 1												Year 2												Year 3											
	Months (1-12)	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
	Months (1-36)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36
The RIGHT-Ad@pt Checklist																																					
1	**Establishment of the Working Group**																																				
2	**Generation of the initial checklist**																																				
3	**Optimisation of the checklist**																																				
	3.1. Initial assessment of adapted guidelines																																				
	3.2. Semi-structured interviews																																				
	3.3. Delphi consensus survey																																				
	3.4. External review by guidelines developers																																				
	3.5. External review by guidelines users																																				
	3.6. Final assessment of adapted guidelines																																				
4	**Approval of the final checklist**																																				
	Months (1-12)	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12	1	2	3	4	5	6	7	8	9	10	11	12
	Months (1-36)	1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20	21	22	23	24	25	26	27	28	29	30	31	32	33	34	35	36

Extending the RIGHT statement for Reporting Adapted Practice Guidelines in Health Care: the RIGHT-Ad@pt Checklist protocol

Supplement File 1. Participants' information

Participants	Member Role	Organization	Country	Income Level*	Region*	Conflicts of Interests
Coordination Team						
Participant 1	Guideline methodological expert, guidelines developer	American University of Beirut	Lebanon	Upper middle income	Middle East & North Africa	Intellectual CoIs related to the contribution to the development of methods of guideline adaptation, the RIGHT statement, and methodological studies in the field.
Participant 2	Guideline methodological expert, guidelines developer	Iberoamerican Cochrane Centre	Spain	High income	Europe & Central Asia	None
Participant 3	Guideline methodological expert, guidelines developer	Hospital Universitari Vall d'Hebron	Spain	High income	Europe & Central Asia	None
Participant 4	Guideline methodological expert	Iberoamerican Cochrane Centre	Spain	High income	Europe & Central Asia	None
Participant 5	Guideline methodological expert	Iberoamerican Cochrane Centre	Spain	High income	Europe & Central Asia	None
Advisory Group						
Participant 1	Guideline User	Weill Cornell Medicine-Qatar	Qatar	High income	Middle East & North Africa	None
Participant 2	Journal Editor	The George Institute for Global Health	India	Lower middle income	South Asia	Analyses Advisor for BMJ and Associate Editor at BMJ Global Health and BMC Systematic Reviews.
Participant 3	Methodologist	Lanzhou University	China	Upper middle income	East Asia & Pacific	None
Participant 4	Guideline developer	Imperial College London	United Kingdom	High income	Europe & Central Asia	None

Participant 5	Guideline developer	National Health and Medical Research Council, Australia	Australia	High income	East Asia & Pacific	None
Participant 6	Guideline methodological expert, guideline user	Facultad de Medicina y Odontología, Universidad de Antofagasta	Chile	High income	Latin America & Caribbean	None
Participant 7	Policy maker	World Health Organisation	Switzerland	High income	Europe & Central Asia	None
Participant 8	Policy maker	World Health Organisation	Switzerland	High income	Europe & Central Asia	Oversee the quality of WHO guidelines as an employee of the World Health Organization. Member of the GRADE Working Group. Co-author of the RIGHT paper.
Participant 9	Guideline methodological expert, guidelines developer	McMaster University	Canada	High income	North America	Intellectual CoIs related to the contribution to the development of methods of guideline adaptation, the RIGHT statement, and methodological studies in the field.
Participant 10	Guideline methodological expert	Netherlands Comprehensive Cancer Organisation	Netherlands	High income	Europe & Central Asia	None

*Ref from World Bank: https://datahelpdesk.worldbank.org/knowledgebase/articles/906519-world-bank-country-and-lending-groups
Abbreviation: CoIs: Conflicts of Interests.