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Extending the RIGHT statement for reporting adapted practice guidelines in healthcare: 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, semistructured 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.

Strengths and limitations of this study

- There is no current tool for reporting adapted guidelines. The extension of the RIGHT statement for adapted practice guidelines (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 guideline methodologists, policymakers, 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 healthcare.
- 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 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/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]

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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 healthcare 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* systematically assessed the processes employed in the adaptation of WHO guidelines for HIV and tuberculosis. 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* 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 optimise 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* 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 of 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 (eg, 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, semistructured 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.

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]

Coordination Team

The Coordination Team (YS, MB, LMG, PAC, EAA) 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

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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	Semistructured interviews	Delphi consensus survey	External review by guideline developers	External review by guideline 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	Semistructured interviews	Delphi consensus survey	Survey	Semistructured interviews	Methodological survey of adapted guidelines	–
Participants	▲ Coordination Team ▲ Advisory Group ▲ Delphi Panel Members	▲ Coordination Team ▲ Advisory Group	Coordination Team (two reviewers)	Guideline developers	Delphi Panel Members	Guideline developers	Guideline 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 GIN Adaptation Guidelines Working Group, WHO and authors of adapted guidelines	GIN community	Sampling saturation	Convenience sample of 10 adapted guidelines	–

GIN, Guidelines International Network.

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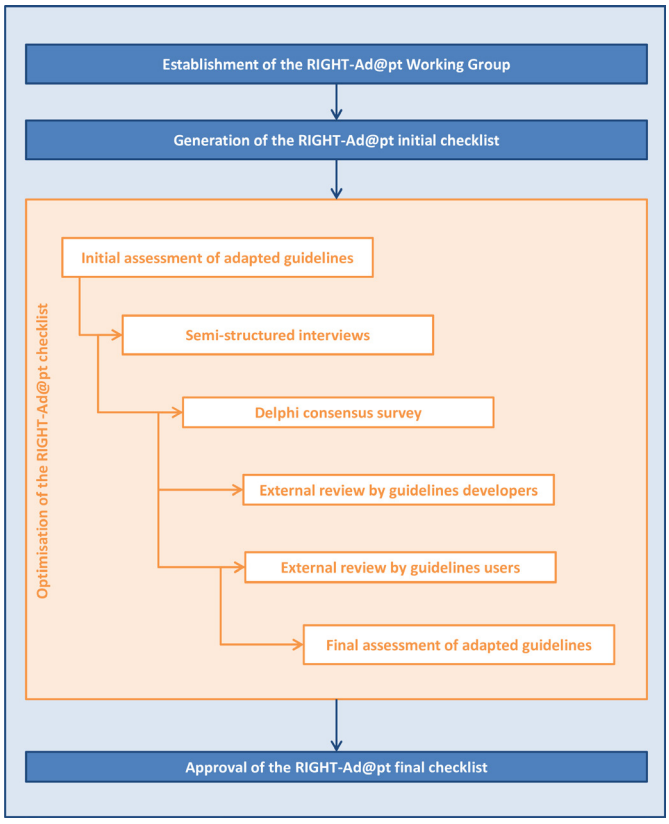


Figure 1 Multistep development process of RIGHT-Ad@pt. RIGHT, Reporting Items of Practice Guidelines in Healthcare.

the conflicts of interests (CoI) of all members of the Coordination Team (online supplementary file 1).

Advisory Group

The Advisory Group is a multidisciplinary group (8–10 people) including (1) guideline methodological experts (defined as having experience and expertise in guideline methods); (2) guideline 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 (online supplementary file 1).

Delphi Panel

The Delphi Panel will be comprising 20–30 members, with profiles similar to those of the members of the Advisory Group (guideline methodological experts, guideline 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.

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.

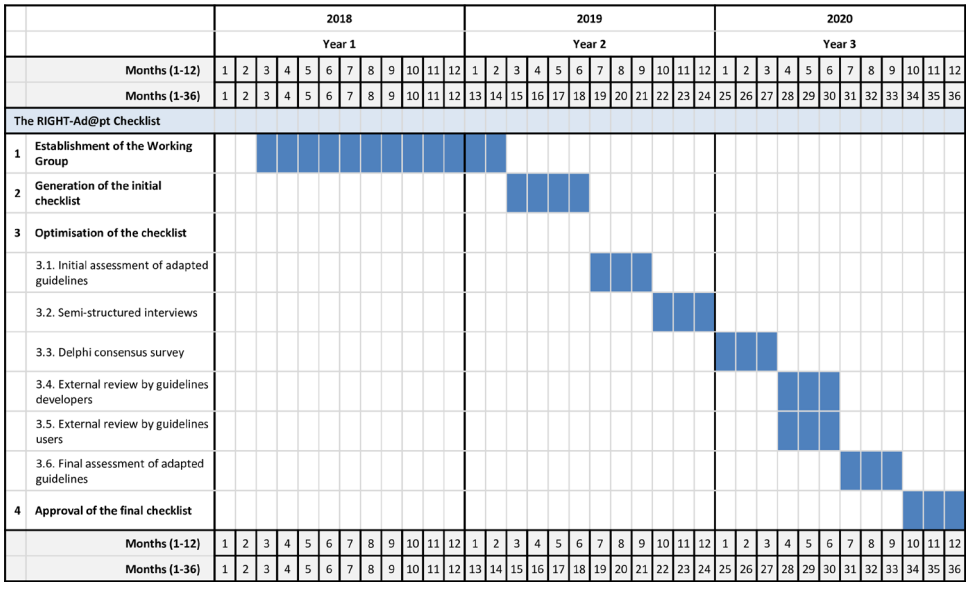


Figure 2 Timeline of RIGHT-Ad@pt. RIGHT, Reporting Items of Practice Guidelines in Healthcare.

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

	Initial assessment of adapted guidelines	Semistructured interviews	Delphi consensus survey	External review		Final assessment of adapted guidelines
				Guideline developers	Guideline 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	

XX: main outcome; X: other outcomes.

Optimisation of the checklist

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 (eg, 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 10 adapted guidelines available in English and published in the last 5 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.[36] 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.

Semistructured interviews

We will survey guideline developers who were involved in guideline adaptation over the past 3 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 1 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).[37 38]

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.[39] 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.

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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 7-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 6–7 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.[39] 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.

External review

External review by guideline developers

We will survey guideline developers who were involved in guideline adaptation over the past 3 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 7-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.[39] We will not consider questionnaires with no response for more than 20% of the items.

External review by guideline users

We will conduct external review semistructured interviews with guideline users who have used adapted guidelines over the past 3 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 1 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).[37 38]

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.[39] 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.

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 (eg, 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 10 adapted guidelines available in English and published in the last 5 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 final

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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.[39] 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.

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 Grading of Recommendations Assessment, Development and Evaluation (GRADE) Evidence to Decision 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, guideline 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, semi-structured 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 4 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, journal editors to improve the reporting of published adapted guidelines, policymakers 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,

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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 of the project to relevant stakeholders (eg, via international conferences, electronic bulletins, related websites (http://www.right-statement.org/, http://www.equator-network.org/) and social media (eg, 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.

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Contributors YS, AD, LMG, PAC and EAA wrote the first draft of the manuscript. YS, MB, LMG, PAC and EAA form the coordination team and have day-to-day responsibility for the project. TA, SB, YC, FC, DG, PFP, EVL, HJS and RWMV 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 EAA and HJS have intellectual CoIs related to his contribution to the development of methods of guideline adaptation, the RIGHT statement and methodological studies in the field. SB is the Analyses Advisor for BMJ and Associate Editor at BMJ Global Health and BMC Systematic Reviews. All other members have nothing to declare.

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

Provenance and peer review Not commissioned; externally peer reviewed.

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