RIGHT-**Ad@pt**

A REPORTING TOOL FOR ADAPTED GUIDELINES IN HEALTH CARE: THE RIGHT-Ad@pt CHECKLIST [USER GUIDE]

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RIGHT-Ad@pt

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1. SUMMARY

Background

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 may be useful for reporting adapted guidelines, but it fails to address all the important aspects of the adaptation process.

Objective

The objective of our project is to develop a reporting checklist for adapted guidelines.

Methods

To develop the RIGHT-Ad@pt Checklist, we have followed a multi-step process that included: (1) establishing a Working Group; (2) generating an initial checklist based on the RIGHT statement and methodological evidence on guideline adaptation; (3) optimising 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 calculated absolute frequencies and proportions, used content analysis for summarising and drawing conclusions, discussed the results, drafted a report and refined the checklist.

Results

The RIGHT-Ad@pt working group contains a Coordination Team, an Advisory Group, a Delphi panel. We generated the initial version of the RIGHT-Ad@pt (RIGHT-Ad@pt Version 01) based on 1) the existing checklist for both guideline assessment and reporting (the RIGHT statement, AGREE II instrument, CAN-Implement, and the CheckUP); 2) published adaptation frameworks (ADAPTE, GRADE-ADOLOPMENT, and SNIP-II process); and 3) the experience of our working group members. We have optimised the RIGHT-Ad@pt checklist and updated the checklist into a new version after each step. We have: 1) assessed ten adapted guidelines (RIGHT-Ad@pt Version 02), 2) explored the current practice of guideline adaptation with semi-structured interviews (RIGHT-Ad@pt Version 03), 3) conducted a Delphi consensus

survey (RIGHT-Ad@pt Version 04), 4) undertaken external reviews with guideline developers and users (RIGHT-Ad@pt Version 05), and 5)assessed a new set of adapted guidelines (RIGHT-Ad@pt Version 06). In addition, we also developed and improved the RIGHT-Ad@pt user guide along with the development process. Finally, the whole RIGHT-Ad@pt working group conducted a final approval discussion (RIGHT-Ad@pt Version 07) and approved it as the final version.

Conclusion

RIGHT-Ad@pt aims to improve completeness of reporting adapted guidelines, focusing on the standardisation, rigor, and transparency of the process and the clarify and explicitness of adapted recommendations

2. INTRODUCTION

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 sufficient resources for developing high-quality de novo guidelines (5). Most low/middle-income countries still do not have formal organizations, technical capacity, well-established mechanisms of funding 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).

Adaptation of guidelines is an increasingly used methodology for the efficient development of contextualised recommendations that are relevant for diverse health systems (16-18). Adapted recommendations can be defined 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. 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 to 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).

Except for the increasing need, there are different adaptation methods implemented globally (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 were notably different (23). Moreover, the process for adapting guidelines is usually poorly reported (24, 25). 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).

A transparent reporting approach could help both guideline developers and guideline users regarding the suitability of the adaptation conducted (26, 27). The RIGHT statement was developed as a reporting checklist for *de novo* guidelines (28). Although it could be of use for the reporting of adapted guidelines (29), 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). Therefore, to

ensure rigor, transparency, clarity and reproducibility of reporting, we developed the RIGHT-Ad@pt checklist for the reporting of adapted guidelines.

The RIGHT-Ad@pt checklist contains seven domains and 34 items.

The domains are:

- Basic information
- Background
- Rigor of development
- Recommendations
- External review and quality assurance
- Funding, declaration and management of interest
- Other information

Each item contains:

- An explanation about “what to do” and “why this is important”
- Several examples extracted from published adapted guidelines
- Three options for users to check the reporting content (“Yes”, “No”, “ Unclear”) with justifications columns

3. APPLYING THE RIGHT-Ad@pt CHECKLIST

What is the RIGHT-Ad@pt checklist?

The RIGHT-Ad@pt checklist was developed as a reporting checklist to inform and assess the reporting of the adapted guidelines. The RIGHT-Ad@pt is not intended for use as an aide to the adaptation process or as a quality assessment tool, but users should pay attention to reporting requirements during the planning stage.

Who can apply the RIGHT-Ad@pt checklist?

The RIGHT-Ad@pt checklist could be used by

- Guideline developers to guide their reporting and inform their adaptation processes
- Journal editors to improve the reporting of published adapted guidelines
- Guideline users to evaluate the completeness of the reporting of adapted guidelines

How to apply the RIGHT-Ad@pt checklist?

The RIGHT-Ad@pt checklist should be used in conjunction with the entire User Guidance. Each judgement made by users should be clearly documented and reported.

We recommend the users select “yes” when the adapted guideline reports all the item contents suggested by RIGHT-Ad@pt; “No” when the adapted guideline does not report all the item contents; and “Unclear” when the reviewers can not judge the content reported by the adapted guideline. The “Notes” column could be used to justify users’ decisions if needed. The provided explanations describe what to report in certain circumstances and why this is important. The examples provided do not imply they represent good quality or high credibility of the adapted guidelines from which the examples were taken.

It is recommended that users of the checklist do not score each item or add them to create an overall score. Instead, we encourage users to interpret the reporting according to the responses and make an overall judgement.

Example for applying the RIGHT-Ad@pt checklist:

Items	Examples	Assessment	Page(s)	Note (s)
Item 3. Report the year of publication and the literature search date of the adapted guideline.	"Received: 13 July 2019 Revised: 4 October 2019 Accepted: 11 October 2019. Abstract - To adapt European Dermatology Forum (EDF) guidelines for AD to the Italian medical–legal context, the EDF guidelines were assessed independently by two independent Italian renowned experts in the field and further integrated with articles published and systematically reviewed before May 2019." (30)	**Yes**	P.1	
	"Received: 7 July 2019 Revised: 11 October 2019 Accepted: 15 January 2020". (31)	**No**	P.1	No literature search date was reported
Item 15. Report which framework or methodology was considered in the guideline adaptation process	"The EDF Consensus based guidelines (Ring et al., 2012a, 2012b; Wollenberg et al., 2018b; on which the present work is based) are an update of the 2012 guidelines (Ring et al., 2012b), integrated with evidence-based national guideline from Germany (Werfel et al., 2009), the Health Technology Report (Hoare, Li Wan Po, & Williams, 2000), as well as the position paper of the European Task Force on Atopic Dermatitis/European Academy of Dermatology and Venereology (Darsow et al., 2010). In 2015, during a meeting in Copenhagen, two authors were chosen to prepare the first draft of the guidelines; this draft was prepared on the basis of full articles only, published before March 2015. Eventual discrepancies were debated during the consensus process. Due to the consensus nature of the document, a systematic review of the literature was not performed to provide the first draft. The specifically appointed European Dermatology Forum (EDF) committee reviewed the first draft, hereby setting as target group	**Unclear**	P. 2	Neither a published or self-developed methodology, nor the adaptation process were reported.

	dermatologists, pediatricians, allergists, general practitioners as well as, more generally any physician involved in the management of AD." (30)			

4. RIGHT-AD@PT CHECKLIST

Section/Topic	No.	Item	Assessment	Page(s)	Note (s)
Basic information					
Title/Subtitle	1	Identify the report as an adaptation of practice guideline(s), that is include "guideline adaptation", "adapting", "adapted guideline/recommendation(s)", or similar terminology in the title/subtitle.	☐ Yes ☐ No ☐ Unclear		
	2	Describe the topic/focus/scope of the adapted guideline.	☐ Yes ☐ No ☐ Unclear		
Cover/First page	3	Report the respective dates of publication and the literature search of the adapted guideline.	☐ Yes ☐ No ☐ Unclear		
	4	Describe the developer and country/region of the adapted guideline.	☐ Yes ☐ No ☐ Unclear		
Executive summary/Abstract	5	Provide a summary of the recommendations contained in the adapted guideline.	☐ Yes ☐ No ☐ Unclear		
Abbreviations and acronyms	6	Define key terms and provide a list of abbreviations and acronyms (if applicable).	☐ Yes ☐ No ☐ Unclear		
Contact information of the guideline adaptation group	7	Report the contact information of the developer of the adapted guideline.	☐ Yes ☐ No ☐ Unclear		
Scope					
Source guideline (s)	8	Report the name and year of publication of the source guideline(s), provide the citation(s), and whether source authors were contacted.	☐ Yes ☐ No ☐ Unclear		
Brief description of the health problem(s)	9	Provide the basic epidemiological information about the problem (including the associated burden), health systems	☐ Yes ☐ No ☐ Unclear		

		relevant issues, and note any relevant differences compared to the source guideline(s).			
Aim(s) and specific objectives	10	Describe the aim(s) of the adapted guideline and specific objectives, and note any relevant differences compared to the source guideline(s).	☐ Yes ☐ No ☐ Unclear		
Target population(s)	11	Describe the target population(s) and subgroup(s) (if applicable) to which the recommendation(s) is addressed in the adapted guideline, and note any relevant differences compared to the source guideline(s).	☐ Yes ☐ No ☐ Unclear		
End-users and settings	12	Describe the intended target users of the adapted guideline, and note any relevant differences compared to the source guideline(s).	☐ Yes ☐ No ☐ Unclear		
	13	Describe the setting(s) for which the adapted guideline is intended, and note any relevant differences compared to the source guideline(s).	☐ Yes ☐ No ☐ Unclear		
Rigor of development					
Guideline adaptation group	14	List all contributors to the guideline adaptation process and describe their selection process and responsibilities.	☐ Yes ☐ No ☐ Unclear		
Adaptation Framework/Methodology	15	Report which framework or methodology was used in the guideline adaptation process.	☐ Yes ☐ No ☐ Unclear		
Source guideline(s)	16	Describe how the specific source guideline(s) was(were) selected.	☐ Yes ☐ No ☐ Unclear		
Key questions	17	State the key questions of the adapted guideline using a structured format, such as PICO (population, intervention, comparator, and outcome), or another format as appropriate.	☐ Yes ☐ No ☐ Unclear		
	18	Describe how the key questions were developed/modified, and/or prioritised.	☐ Yes ☐ No ☐ Unclear		
Source recommendation(s)	19	Describe how the recommendation(s) from the source guideline(s) was(were) assessed with respect to the evidence considered for the different criteria, the	☐ Yes ☐ No ☐ Unclear		

		judgements and considerations made by the original panel.			
Evidence synthesis	20	Indicate whether the adapted recommendation(s) is/are based on existing evidence from the source guideline(s), and/or additional evidence.	☐ Yes ☐ No ☐ Unclear		
	21	If new research evidence was used, describe how it was identified and assessed.	☐ Yes ☐ No ☐ Unclear		
Assessment of the certainty of the body of evidence and strength of recommendation	22	Describe the approach used to assess the certainty/quality of the body/ies of evidence and the strength of recommendations in the adapted guideline and note any differences (if applicable) compared to the source guideline(s).	☐ Yes ☐ No ☐ Unclear		
Decision-making processes	23	Describe the processes used by the guideline adaptation group to make decisions, particularly the formulation of recommendations.	☐ Yes ☐ No ☐ Unclear		
Recommendations					
Recommendations	24	Report recommendations and indicate whether they were adapted, adopted, or *de novo.*	☐ Yes ☐ No ☐ Unclear		
	25	Indicate the direction and strength of the recommendations and the certainty/quality of the supporting evidence and note any differences compared to the source recommendations(s) (if applicable).	☐ Yes ☐ No ☐ Unclear		
	26	Present separate recommendations for important subgroups if the evidence suggests important differences in factors influencing recommendations and note any differences compared to the source recommendations(s) (If applicable).	☐ Yes ☐ No ☐ Unclear		
Rationale/explanation for recommendations	27	Describe the criteria/factors that were considered to formulate the recommendations or note any relevant differences compared to the source guideline(s) (if applicable).	☐ Yes ☐ No ☐ Unclear		
External review and quality assurance					
External review	28	Indicate whether the adapted guideline underwent an independent external review. If yes, describe the process.	☐ Yes ☐ No ☐ Unclear		

Organizational approval	29	Indicate whether the adapted guideline obtained organizational approval. If yes, describe the process.	☐ Yes ☐ No ☐ Unclear		
Funding, declaration and management of interest					
Funding source(s) and funder role(s)	30	Report all sources of funding for the adapted guideline and source guideline(s), and the role of the funders.	☐ Yes ☐ No ☐ Unclear		
Declaration and management of interests	31	Report all conflicts of interest of the adapted and the source guideline(s) panels, and how they were evaluated and managed.	☐ Yes ☐ No ☐ Unclear		
Other information					
Implementation	32	Describe the potential barriers and strategies for implementing the recommendations (if applicable).	☐ Yes ☐ No ☐ Unclear		
Update	33	Briefly describe the strategy for updating the adapted guideline (if applicable).	☐ Yes ☐ No ☐ Unclear		
Limitations and suggestions for further research	34	Describe the challenges of the adaptation process, the limitations of the evidence, and provide suggestions for future research.	☐ Yes ☐ No ☐ Unclear		

5. GLOSSARY AND ABBREVIATION

Key Definitions

Practice guideline

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. (1).

Guideline adaptation (GA)

Adaption of guideline means the use of existing trustworthy guidelines, with (adapt), without (adopt) modifications, or including additional *de novo* recommendations, to provide local, regional or national guidance (15, 16, 23).

Adopted recommendations

Are recommendations with:

1) a same specific population, intervention, or comparator as the original recommendations,

2) a same the certainty of the evidence, and

3) information on implementation (16)

Adapted recommendations

Are recommendations with:

1) a change in the specific population, intervention, or comparator from the original recommendations,

2) a change in the certainty of the evidence, or

3) a change in the strength of recommendations by including additional information regarding the conditions, monitoring, implementation, and implications for research. (16)

Abbreviations

ACP	American College of Physicians
AGREE	Appraisal Of Guidelines For Research & Evaluation II
AMSTAR	A measurement tool to assess the methodological quality of systematic reviews
ASCO	American Society of Clinical Oncology
ASH	American Society of Hematology

CCO	Cancer Care Ontario
CHEST	American College of Chest Physicians
COI	Conflicts of Interest
CPG	Clinical Practice Guideline
EtD	Evidence to Decision
GA	Guideline Adaptation
GIN	Guideline-International-Network
GRADE	Grading of Recommendations, Assessment, Development and Evaluations
GRADE-ADOLOPMENT	GRADE Evidence to Decision (EtD) frameworks for adoption, adaptation, and de novo development of trustworthy recommendations
LMIC	Low-middle income country
NHMRC	National Health and Medical Research Council
RCT	Randomised Controlled Trial
RIGHT	Reporting Tool for Practice Guidelines in Health Care

6. ITEMS, EXPLANATIONS, AND EXAMPLES

(Blue words are new modifications)

Basic Information

Title/Subtitle

1. Identify the report as an adaptation of practice guideline(s), that is include "guideline adaptation", "adapting", "adapted guideline/recommendation(s)", or similar terminology in the title/subtitle

What to do

Identify the report by using terms like "guideline adaptation", "adapting", "adapted guideline", or similar in the title/subtitle (i.e., adapted for…; adaptation of xx guideline), to help guideline users easily identify whether a guideline is total *de novo* or majorly/mostly an adapted guideline.

Why is this important?

Guideline adaptation could be a part of the *de novo* guideline development process, as well as guideline updating. However, unlike the *de novo* process, guideline adaptations are based on existing guidelines, using a specific methodology (e.g., ADAPTE or GRADE-ADOLOPMENT), and conducting adapted recommendations for local, regional, or national context (15). Reporting whether the guideline is an adaptation helps users distinguish the types of guidelines, and therefore understand its development process.

Example(s)

1. "Cancer pain management in adults: Evidence-based clinical practice guidelines **adapted for** use in Australia" (32)

2. "Interventions to Address Sexual Problems in People With Cancer: American Society of Clinical Oncology Clinical Practice Guideline **Adaptation of Cancer Care Ontario Guideline**" (33).

2. Describe the topic/focus/scope of the adapted guideline

What to do

Report the adapted guideline health topic/focus/scope in the title/subtitle. Health topic means the relevant health problem, condition, or disease. The focus/scope may be a combination of any or all of the following aspects: prevention, screening, and diagnosis, treatment, or management. Additionally, the perspective of population or individual patient might be taken into account along with the adaptation process and therefore should be reported.

Why is this important?

Guidelines may vary according to different scopes. Reporting the primary focus of adapted guidelines in the title is not only important for readers to quickly identify the relevance, but could also serve as a filter when searching for the relevant information.

Example(s)

1. "**Cancer pain management in adults:** Evidence-based clinical practice guidelines adapted for use in Australia". (32)

2. "**Interventions to Address Sexual Problems in People With Cancer**: American Society of Clinical Oncology Clinical Practice Guideline Adaptation of Cancer Care Ontario Guideline". (33)

Cover/first page

3. Report the the respective dates of publication and the literature search of the adapted guideline

What to do

Report the year of publication, as well as the last literature search date in the first page/cover page of the adapted guideline. Literature search could be specific for the source guideline(s) or the additional evidence.

If the adapted guideline is an updated version, specify what edition or version it is (e.g., 1st, 2nd, 3rd edition/version) to distinguish it from the original (34).

Why is this important?

The year of publication is an indicator as to whether the reader needs to look elsewhere for a valid and up-to-date guideline. As the speed of evidence updating increases (35, 36), readers need to quickly identify the year when the adapted guideline was published.

Example(s)

1. This is an adapted guideline **published in 2020; (last literature search until 2020 July)** (illustrative example).

4. Describe the developer and country/region of the adapted guideline

What to do

Describe the developer of the adapted guideline, as well as the country/region. Guidelines are developed by government bodies, professional societies, academic institutions, or healthcare systems (e.g., big hospital trusts), or other organizations.

Why is this important?

Since guideline adaptation is a modification of the source guideline for implementation in another setting (15), reporting the target country in the title/subtitle or cover page/first page would provide the users with an indication for selecting suitable adaptation products. It could also provide adaptation users with an overview of the quality of the adaptation process since guideline developers and methodologists are more likely to trust guidelines published by well-credentialed guideline development groups (22, 37).

Example(s)

1. "Interventions to Address Sexual Problems in People With Cancer: **American Society of Clinical Oncology Clinical Practice Guideline Adaptation** of Cancer Care Ontario Guideline" (33).

2. "**African Head and Neck Society** Clinical Practice guidelines for thyroid nodules and cancer **in developing countries and limited resource settings**" (31)

3. "Selection of Optimal Adjuvant Chemotherapy Regimens for Human Epidermal Growth Factor Receptor 2 (HER2) –Negative and Adjuvant Targeted Therapy for HER2-Positive Breast Cancers: **An American Society of Clinical Oncology Guideline Adaptation** of the Cancer Care Ontario Clinical Practice Guideline" (38).

Executive summary

5. Provide a summary of the recommendations contained in the adapted guideline.

What to do

Provide a summary of the recommendations contained in the adapted guideline before the main text. A table or bullet list format could help users have an overview of the recommendations and find out quickly if there are recommendations that meet their conditions. In the case there are more than one recommendations under different recommendation sections, provide the list of the key recommendations.

In addition, a good summary should include key points for implementation regarding different specific audiences.

Why is this important?

A well-structured summary, including recommendations and modifications, will help readers locate the recommendations quickly and facilitate their implementation (28).

Example(s):

1. "Overview

   This guideline covers when to offer caesarean section, procedural aspects of the operation and care after caesarean section. It aims to improve the consistency and quality of care for women who are considering a caesarean section or have had a caesarean section in the past and are now pregnant again.

   Recommendations

   This guideline includes recommendations on (with a hyperlink to the recommendations):
   when to offer planned caesarean section
   when a caesarean section may be required during birth
   procedural aspects of caesarean section
   care of the baby and mother after caesarean section
   recovery after caesarean section
   subsequent pregnancy and childbirth after caesarean section

   Who is it for?

   Healthcare professionals
   Commissioners and providers
   Public health and trust managers
   Pregnant women, their families, birth supporters and other carers"(39)

2. "We applied a novel presentation format to 333 recommendations from 11 of the 15 Management chapters in AT9 and condensed and restructured them into 249 recommendations in a multi-layered format. We added

additional relevant information, such as 29 best practice statements about new oral anticoagulants and practical information sections for 121 recommendations. Common reasons for modifications included feasibility of the recommendations in a national context, disagreement with applied baseline risk estimates, and re-evaluation of the balance between the benefits and harms of interventions in relation to assumed typical patient preferences and values. The adapted guideline was published and disseminated online in November 2013."(20)

3. "These Clinical Practice Guidelines and Principles of Care for people with dementia **are written primarily for health and aged care staff (doctors, nurses, allied health and care workers) who work with people with dementia in community, residential and hospital settings.** Health and aged care staff should apply the recommendations in their workplaces while also responding to the needs and preferences of the person with dementia and their carer(s) and family. **The following key points are addressed within the recommendations.** Examples from the whole list of key points:
   - The symptoms of dementia should be investigated the first time they are reported and not dismissed as a 'normal part of ageing'.
   - Health and aged care professionals should talk to the person with dementia and their carer(s) and family about the symptoms of dementia, treatments and services. Written information (such as brochures) should also be provided." (40)

Abbreviations and acronyms

6. Define key terms and provide a list of abbreviations and acronyms (if applicable)

What to do

Report the definition of the key terms as well as the explanations of the acronyms and abbreviations in the adapted guideline or its appendix. An additional link to the abbreviations might be helpful.

In the case that GA groups used a different evidence rating system, report the definition of the levels of evidence and grades. If a translation was conducted, report the definitions used in a particular country or institution.

Why is this important?

Since key terms, abbreviations and acronyms used in across the CPGs might be based on different meanings, it is essential to provide an accurate definition of them to ensure the understandability and implementability of the recommendations of the adapted guideline.

Example(s)

1. "**Keywords:** clinical practice guidelines; complicated intra-abdominal infection" (41).

2. "**ABBREVIATIONS:** AT9 = Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines; DECIDE = Developing and Evaluating Communication Strategies to Support Informed Decisions and Practice Based on Evidence; GRADE = Grading of Recommendations Assessment, Development, and Evaluation; LMWH = low-molecular-weight heparin" (20).

Contact information of the guideline adaptation group

7. Report the contact information of the developer of the adapted guideline

What to do

Report the contact information of those who have a central role in the adaptation project as well as the adaptation organization, for users to enquire or make suggestions. The information should include their affiliation, name, e-mail address, or credentials like the official website (if applicable).

Why is this important?

Reporting the contact information helps users of the adapted guideline communicate their questions, suggestions, or comments to the GA groups. The contact information is particularly useful when reading or implementing adapted guidelines, or for regular monitoring and updating.

Example(s)

1. **Correspond to:** Pablo Alonso-Coello, PhD, MD, Iberoamerican Cochrane Center - Biomedical Research Institute Sant Pau (IIB Sant Pau), Barcelona, Spain; Email: PAlonso@santpau.cat.

Scope

Source guideline (s)

8. Report the name and year of publication of the source guideline(s), provide the citation(s), and whether source authors were contacted.

What to do

Report the name, month (if applicable) and year of the source guideline(s) and provide their citation reference(s). Indicate whether source authors were contacted for permission (if required) or for additional information. If there is no need to contact source authors since the reporting of source guideline(s) are complete, provide one sentence to clarify this.

If only evidence from the source guideline was used — for example, only systematic reviews from source guideline(s) were considered —, then the name and year of those systematic reviews should be reported, and citation(s) provided.

Why is this important?

Reporting source guideline(s) ensures transparency and reproducibility of the adaptation process. It also provides the information for stakeholders to access source guideline(s) and check whether these are up to date.

Example(s)

1. "The STG on Diabetic foot management was developed by a team of experts and relevant stakeholders. The recommendations in the STG were adopted/ adapted from **four source guidelines which are International Working Group on the Diabetic Foot (IWGDF) 2015 - Prevention and Management of Foot, 2012 Infectious Diseases Society of America Clinical Practice Guideline for the Diagnosis and Treatment of Diabetic Foot Infections (IDSA 2012), and the National Institute for Health and Care Excellence (NICE) guidelines- Diabetic foot problems: prevention and management (NG19) (26th August, 2015) on diabetic foot, and Problems in Diabetes Guidance Documents and Recommendations NICE guideline- Lower limb peripheral arterial disease: diagnosis and management (NICE clinical guideline 147) on PAD (Peripheral Arterial Disease) November 2014.**

Available from and full reference below: http://www.iwgdf.org/files/2015/; http://www.idsociety.org; https://www.nice.org.uk/guidance/NG19; https://www.nice.org.uk/guidance/cg147." (42)

2. "The Cognitive Decline Partnership Centre's Clinical practice guidelines and principles of care for people with dementia (Guidelines) was approved by the National Health and Medical Research Council (NHMRC) in February 2016. The Guidelines were developed by **adapting the UK's guidelines for dementia*** by a committee of experts in dementia, including carers of people with dementia and a GP. The Guidelines were released for public consultation and were reviewed by many medical colleges, including The Royal Australian College of General Practitioners (RACGP).
*National Institute for Health and Care Excellence. Dementia: Supporting people with dementia and their carers in health and social care. London: NICE, 2006." (40)

3. "The following guidelines met all criteria and were considered for adaptation:
   - **Scottish Intercollegiate Guidelines Network. Control of pain in adults with cancer. A national clinical guideline [Version amended 18 July 2011] Edinburgh: SIGN; 2008.**
   - **National Comprehensive Cancer Network. NCCN clinical practice guidelines in oncology. Adult cancer pain. Version 1.2012: NCCN; 2012.**" (32)

Brief description of the health problem(s)

9. Provide the basic epidemiological information about the problem (including the associated burden), health systems relevant issues, and note any relevant differences compared to the source guideline(s)

What to do

Report basic epidemiological parameters such as prevalence or incidence, morbidity, mortality and describe the problem arising. Sources (e.g., WHO statistics, etc.) of this information should be reported if applicable.

Highlight any differences in the epidemiological information of the issue specific to the setting, compared to that of the source guideline(s), such as funding and system constraints linked to applicability and feasibility of source guidelines to the local setting.

Several frameworks or websites for health policies/systems/services—such as the EPOC taxonomy (43), the Health systems Evidence database, or Global Burden of Disease—, might be helpful to guide the identification of the current key elements that would need to be reported.

Why is this important?

The epidemiological information provides stakeholders with the essential background of the guideline, justifies and highlights the needs for guideline adaptation, therefore contextualises better the health issue addressed in the adapted guideline.

Example(s)

1. "In 2018, there were an estimated 18.1 million new cases of cancer and 9.6 million cancer deaths worldwide.1 Of these, breast cancer accounted for >2.1 million new cases (11.6% of all cancers) and >626 000 deaths (6.6% of all cancer deaths) and was the leading cause of cancer death in women. The most important risk factors for breast cancer include sex, age, genetic predisposition (around 10% of cases), exposure to estrogens, low parity, a

Western style diet, obesity and alcohol consumption. **In contrast to a relatively small increase in the incidence of breast cancer in Western countries, in Asia the incidence is increasing rapidly with an estimated >900 000 new cases reported for the whole of Asia for 2018 (43.6% of new breast cancer cases worldwide) and >300 000 breast cancer deaths (49.6% of breast cancer deaths worldwide).” (44)**

2. “Psoriatic arthritis (PsA) is a spondyloarthritis that affects up to a third of patients with psoriasis, a common inflammatory skin disease affecting 1–3% of the population. The heterogeneous disease manifestations make management of PsA a challenge. The Group for Research and Assessment of Psoriasis and Psoriatic Arthritis (GRAPPA) and the European League Against Rheumatism (EULAR) have updated their respective recommendations for the management of PsA. These recommendations are based on systematic reviews of literature and provide evidence-based recommenda- tions for the management of PsA. **However, they are primarily based on studies conducted in resource replete countries of Europe and North America; therefore, they may not be applicable to PsA patients in resource-poor countries in the Americas excluding Canada and the USA- (henceforth termed ‘the Americas’) and Africa**.”(45)

3. “**The South African (SA) burden of disease has changed significantly** over the last ten years. There is **an increasing focus on the need for rehabilitation** for chronic conditions and disability, as more lives are saved from communicable diseases. The shift in SA from communicable disease mortality to communicable and non-communicable disease morbidity, **has put the spotlight firmly on the need for evidence-informed rehabilitation**, to ensure that resources are wisely allocated to achieve best health and cost outcomes for people living with chronic disability and health problems.

Stroke is a leading cause of disability worldwide. Over the past 40 years, the rate of stroke in places such as Southern India and rural SA has approximately doubled, whereas rates in more economically developed nations have decreased. **The most striking problem is that disability and mortality rates arising from stroke are at least tenfold greater in medically underserved regions versus high-income countries (HICs).** The causes of these disparities are explained by lack of access to early stroke screening, basic medical management, post-stroke rehabilitation, and secondary stroke prevention. The WHO initiated public health programmes to address stroke management in underserved regions.” (46)

4. “**Methods to detect recurrence**—such as testing for serum cancer antigen 125 (CA125), which has been found to predict recurrence several months before physical symptoms are identified; examinations; and imaging tests—**can vary from one centre to another**, and there is **currently no guidance within Ontario about appropriate tests,** intervals, or models of follow-up care. To fill that gap in the disease management pathway for patients in Ontario, we created this evidence-based guideline.” (47)

Aim(s) and specific objectives

10. Describe the aim(s) of the adapted guideline and specific objectives, and note any relevant differences compared to the source guideline(s)

What to do

Describe the general purpose of the adapted guideline, for example, 1) to implement trustworthy guidelines in the local setting (21, 41); 2) to develop a guideline *de novo* based on other source guideline(s) (48, 49); 3) to reconcile

controversies of existing guidelines (50) or 4) to update their own recommendations (51), etc.; as well as specific objectives.

Objectives are more specific and might reflect the PICO elements of the key questions (28), such as improvements in health indicators (e.g., mortality and disease prevalence), quality of life, health systems performance, or treatment cost-effectiveness. To ensure transparency, differences in objectives compared to the source guideline(s) should also be reported.

Why is this important?

Since guideline adaptation is an alternative to developing *de novo* guidelines or for improving guideline implementation (14), reporting the aim and specific objective of the adapted guideline will help users have an overview of its trustworthiness as well as its key points of implementation.

Example(s)

1. "**The aim of this study was to adapt the international clinical practice guidelines recommendations for people living with dementia (PLWD) to fit the general hospital setting in the Austrian context.** Furthermore, a goal of the adaption was to identify recommendations which are applicable in the healthcare setting and, specifically, to the work performed by nurses." (52)

2. "Recommended strategies vary for breast cancer screening in average-risk women. Ages to start and discontinue mammography, screening intervals, the role of imaging methods other than mammography, and the role of clinical breast examination (CBE) have been points of disagreement among guideline developers.
The goal of this American College of Physicians (ACP) guidance **statement is to critically review selected guidelines from around the world and their included evidence to assist clinicians in making decisions about breast cancer screening in asymptomatic women with average risk for breast cancer.** Included screening methods are CBE and breast imaging (that is, mammography, ultrasonography, magnetic resonance imaging (MRI), and digital breast tomosynthesis. This guidance statement does not address breast self-examination because no evaluated guideline recommends it for screening." (53)

3. "SCOPE AND OBJECTIVE OF THE GUIDELINE.
a) To increase detection of hypertension in adults in India using a systematic, primary care led approach based on standardised measurements of BP and their follow up.
b) To provide guidance on assessment of persons with hypertension appropriate to different levels of care in India.
c) To provide a structured, simplified and standardised treatment guideline for hypertension in adults in India, along with implementation tools (quick reference guide, quality standards, patient information leaflets)
d) To provide guidance on availability of a core list of medications in the public health system for treatment of hypertension.
e) To outline research issues related to hypertension in India." (54)

Target population(s)

11. Describe the target population(s) and subgroup(s) (if applicable) to which the recommendation (s) is addressed in the adapted guideline and note any relevant differences compared to the source guideline(s)

What to do:

Describe the target population to which the recommendation(s) is addressed in the adapted guideline, and whether it matches that in the source guideline(s) (55). The description should include age, gender(s), diagnosis and comorbidities, and geographical location and/or ethnic group, if applicable.

If there are any discrepancies regarding the target population, report the differences compared to the source guideline(s), the rationale for using a guideline whose population of interest is different, and how those differences were addressed.

If there are specific subgroup populations to be considered for the target setting, report the target subgroup population in this section.

Why is this important?

The target population and the differences with the source guideline(s) provide stakeholders with information to understand potential modifications of the source recommendations and distinguish to what extend the adapted guideline is trustworthy and applicable. In addition, it provides considerations for implementing the guideline adaptation product.

Example(s)

1. "**Target Population:** Female patients who are being considered for, or who are receiving, systemic therapy after definitive surgery for early invasive breast cancer, defined largely as invasive cancer stages I to IIA (T1N0-1, T2N0)." (38)

2. "**The target population** for this guidance statement **is women with average risk for breast cancer**. The target audience is all clinicians. Age is the single most important risk factor for breast cancer. **Included guidelines generally define average-risk women as** those who do not have a personal history of breast cancer or a previous diagnosis of a high-risk breast lesion, are not at high risk for breast cancer due to genetic mutations known to increase that risk (such as BRCA1/2 gene mutation or another familial breast cancer syndrome), and were not exposed to radiation therapy to the chest in childhood. However**, definitions of average risk vary among guidelines**. In addition, although risk factors (including early menarche, ...etc.) may put a woman at greater risk for breast cancer than women without these factors, **the evaluated guidelines generally include women with these factors under the umbrella of average risk. Therefore, our guidance statement applies to these women.** Guidelines vary somewhat in target populations and screening methods addressed. Both the U.S. Preventive Services Task Force and the World Health Organization (WHO) include women with dense breasts and those with a single family member with breast cancer in their guideline's target population. The Canadian Task Force on Preventive Health Care guideline also includes women with dense breasts; however, it explicitly mentions that women with a first-degree relative with breast cancer are considered to be at increased risk and are thus excluded from the guideline."(53)

End-users and settings

12. Describe the intended target users of the adapted guideline, and note any relevant differences compared to the source guideline (s)

What to do

Report who the target users of the adapted guideline are, for example, primary care providers, clinical specialists (including sub-speciality), patients/carers, public health practitioners, programme managers, or policymakers.
If the target users of the adapted guideline differ from those in the source guideline(s), indicate similarities and/or differences between them in the background section and provide rationale.

Why is this important?

How the adapted guideline is reported will influence its value and usefulness (56). Previous surveys found that the applicability of published adapted guidelines is often weak (25). Specifying the target users of the adapted guideline in the background and justifying the discrepancy compared to the source guideline(s) will facilitate its implementation.

Example(s)

1. "**Target Audience Health care practitioners**, such as oncologists, urologists, gynaecologists, primary care providers, surgeons, nurses, physiotherapists, social workers, counselors, psychologists, psychiatrists, and sex therapists/counsellors, and advanced practice providers, such as physician assistants and nurse practitioners." (33)

2. "**These Clinical Practice Guidelines and Principles** of Care for people with dementia **are written primarily for health and aged care staff** (doctors, nurses, allied health and care workers) who work with people with dementia in community, residential and hospital settings." (40)

3. "**This guideline is intended to be relevant to hospital staff** caring for patients with diabetic foot problems in referral centres, non-specialized carers who provide secondary and primary care, prevention podiatrists and patient and their care givers." (42)

4. "**This guideline is intended for use by Canadian health care providers** in diverse clinical or treatment settings. **This guideline is also intended for researchers and decision makers** with an interest in understanding the key elements to a comprehensive smoking cessation system in Canada." (57)

13. Describe the setting(s) for which the adapted guideline is intended, and note any relevant differences compared to the source guideline(s)

What to do

Report the setting(s) for which the adapted guideline is intended. For example: community, primary, secondary, tertiary, or several of these healthcare levels, or out-patient, in-patient facilities.

If there are any differences in the setting between the source and the adapted guidelines, report the differences and explain the rationale of using them with their potential impact on evidence synthesis that will be used from the source guideline(s).

Why is this important?

Guideline adaptation aims to provide local, regional, or national guidance based on existing trustworthy guidelines, with (adapt) or without (adopt) modifications; applicable to a specific context. For example, the point estimate and confidence intervals of the data in the source guideline may not be the same, so the GA group might need to modify the recommendations to avoid over or underestimating. Therefore, it is important to report differences between the source

and the adaptation regarding the target setting to provide a contextual background to the decisions and adapted /adopted recommendations.

Example(s)

1. "**Rehabilitation is currently not included in any national South Africa CPG**. This lack of local guidance perhaps underpins evidence that stroke care varies across the country, and that many stroke sufferers do not have access to rehabilitation. These shortcomings are in accordance with the WHO report, which estimated that in LMICs, only 26% to 55 % of people receive the rehabilitation they need. This World Health Survey revealed that people with disabilities were more than twice as likely to the SA healthcare system for the growing number of people in need of post-stroke rehabilitation." (46)

Rigor of development

Guideline adaptation groups

14. List all contributors to the guideline adaptation process, and describe their selection process and responsibilities

What to do

Report the names of all contributors to the guideline adaptation process and their role; for example: members of the steering group, guideline adaptation panel, external reviewer, systematic review team, methodologist, and guideline users. Their selection process, including whether there is a training process or not, should also be provided to ensure the credibility of guideline adaptation process.

Additionally, all members of the working group should declare any financial and intellectual conflict of interest in the following section (see item 31).

Ideally, GA groups should include key stakeholders affected by the guideline (e.g., clinicians, patients, caregivers, or the public, and policy makers) (55). A summary of the contributors could be included as an appendix or cited from guideline manual of the GA group/organization, if applicable.

Why is this important?

Numerous stakeholders are currently involved in the development and use of guidelines (4). They can contribute to and provide comments on the clinical guideline at various stages of the guideline development. Hence reporting this aspect is essential for transparency.

Example(s)

1. "**Forming a treatment guideline committee:** The development committee consisted of a chairman (Dr. Wie, the Catholic University College of Medicine) and five committee members recommended by the Korean Society for Chemotherapy and the Korean Society of Infectious Diseases, one committee member recommended by the Korean Association of Urogenital Tract Infection and Inflammation, two committee members recommended by the Korean Urological Association, and two committee members recommended by the Korean Society of Nephrology." (58)

2. "The Guideline Development Group (GDG) was formed in 2009 by the CAN-ADAPTT Coordinating Team and the GDG Chair, Dr. Selby. There are seven members of the GDG ranging from family physician to public health

researcher to physician specialists (see page ii for a list of GDG members). Each GDG member was a Section Lead for one of the sections listed on page 3. GDG Members were identified by the Chair to include experts in each topic area while ensuring a multi-disciplinary and nationally representative committee.

1) GUIDELINE DEVELOPMENT GROUP COMMITTEE:

The Guideline Development Group (GDG) was directly responsible for the review of existing guidelines and evidence and the development of summary statements for the CAN-ADAPTT Clinical Practice Guideline.

Dr. xx, MBBS, CCFP, FCFP, MHSc, Dip ABAM

Principal Investigator, CAN-ADAPTT

Chair, CAN-ADAPTT Guideline Development Group

Section Co-Lead: Mental Health and/or Other Addiction(s)

Clinical Director, Addictions Program

Head, Nicotine Dependence Clinic, Centre for Addiction and Mental Health

Associate Professor, Departments of Family and Community Medicine, Psychiatry and Dalla Lana School of Public Health University of Toronto, Toronto, Ontario

Etc.

2) CAN-ADAPTT COORDINATING TEAM

Dr. xxx, BSc

Former Network Manager, CAN-ADAPTT

Centre for Addiction and Mental Health, Toronto, Ontario…" (57)

3. "We asked relevant medical specialty societies to nominate candidate panellists. **We recruited 42 content experts, 11 of whom were designated as chapter editors and took primary responsibility for completing the adapted chapters.** Each panellist reported time spent on the adaptation work." (20)

Adaptation framework/methodology

15. Report which framework or methodology was used considered in the guideline adaptation process

What to do

Provide the adaptation framework(s)/method(s) followed, briefly describe the approach and provide key citations (if applicable). Ideally, GA groups could use one of the published adaptation processes (e.g., ADAPTE process (55), CAN-IMPLEMENT (59)), GRADE-ADOLOPMENT (16), SNAP-IT (20)), adapt/deviate from these methods with justification (e.g., Adapted ADAPTE (60), RAPADAPTE (61)), or use self-established adaptation methodologies (e.g., American Society of Clinical Oncology (ASCO) endorsement/adaptation methodology) (49).

In the case that an informal adaptation process (e.g., simple adoption without a properly reported methodology) was used, this should be stated. If applicable, report any software used in the adaptation process (e.g., GRADEProGDT, MAGIC etc.).

Why is this important?

This will provide users with initial information on the methodological foundation of the adapted guideline, as well as ensure transparency and trustworthiness of the adaptation process.

Example(s)

1. "This guideline adaptation **was informed by the ADAPTE methodology**, which was used as an alternative to de novo guideline development for this guideline." (38, 62).
2. "Adaptation of the 2015 American College of Rheumatology treatment guideline for rheumatoid arthritis for the Eastern Mediterranean Region: an exemplar of the **GRADE Adolopment**" (17)
3. "Adapting AT9 to a Norwegian setting represented an opportunity to apply and evaluate the feasibility of our proposed **adaptation process (MAGIC)**." (20)
4. "After reviewing the existing guidelines in other countries, the Korean CPG on invasive diagnostic testing (https://www.guideline.or.kr/evaluation/sub2.php) was developed using the adaptation process." (63)

Source guideline(s)

16. Describe how the source guideline(s) was(were) selected

What to do

Report the selection process of the source guideline(s) by providing the eligibility criteria (like good quality, trustworthiness, most up-to-date, and context applicability with respect to population, interventions, etc.), search strategy, database(s) used, and screening methods. If specific source guideline(s) were selected without searching, provide the reason for the usage of those specific source guideline(s).

If multiple source guidelines are included, report the reason(s). The prioritisation process might be based on the criteria for selecting guidelines or other approaches (64, 65).

Several tools and websites are available for the GA groups, such as the AGREE II (66) to assess the quality, the NEATS instrument to assess trustworthiness (67), or ECRI guideline trust website that provides guideline quality assessment. For updated guidelines, CheckUp can be used to assess the reporting of updated guidelines (34). Some organizations might use their own criteria too (55, 68).

Why is this important?

Since the quality and trustworthiness of the adapted guideline depends on the source guideline(s), reporting this process is essential.

Example(s)

1. **"Systematic search and critical appraisal of guidelines**

   To assess and utilize existing guidelines during the development of the present guideline, well-established guideline registers and the websites of large periodontal societies were electronically searched for potentially applicable guideline texts:

   - Guideline International Network (GIN)
   - Guidelinecentral.com
   - The National Institute for Health and Clinical Excellence (NICE)
   - Canadian Health Technology Assessment (CADTH)
   - European Federation for Periodontology (EFP)
   - American Academy of Periodontology (AAP)
   - American Dental Association (ADA)

to be potentially relevant, scored highest in the critical appraisal using AGREE II and was, therefore, used to inform the guideline development process.

Table: Results of the guideline search (examples)

Database	Identified	potentially relevant guidelines
GIN International Guidelines Library	Comprehensive periodontal therapy: a statement by the American Academy of Periodontology [citation]	8 years old, recommendations not based on systematic evaluation of evidence, **not applicable**
	DG PARO S3 guideline (Register Number 083-029) - Adjuvant systemic administration of antibiotics for subgingival instrumentation in the context of systematic periodontitis treatment [citation]	Very recent, high methodological standard, very similar outcome measures, – **relevant**

GIN: Guideline International Network"(69)

2. "**Existing guidelines were identified via the reference lists of previous reviews and searches of online databases and clearing houses and were screened according to eight criteria:**
   - Primary focus on adults with chronic cancer pain
   - Relevance across tumour types and stages inclusion of recommendations for assessment and/or management
   - Of pain by means of either pharmacological or non-pharmacological intervention
   - Capacity to inform pain assessment and management across disciplines and settings
   - Published in the previous 3 years (i.e. 2008 or later)
   - National or international (i.e., not centre-specific)
   - Available in English
   - Independently rated as 'recommended' or 'strongly recommended' by two members of the Working Party based on criteria of the Appraisal of Guidelines Research & Evaluation (AGREE) Instrument" (32)

3. "**We selected AT9 because it is an authoritative international CPG that, at the time we began, was current (published in February 2012). Furthermore, AT9 is the largest CPG to rigorously apply the GRADE methodology, providing authoritative assessments of confidence in evidence and explicit rationales for the strength of its recommendations. Finally, AT9 informs practice in a wide variety of clinical contexts** (e.g., hematology, surgery, cardiology, obstetrics)." (20)

4. "Prior to being engaged in the CAN-ADAPTT Project, the Guidelines Advisory Committee had conducted, in November 2006, **a full review of CPGs in the area of smoking cessation published in the English language**. In December 2008, **a new systematic search was conducted for the CAN-ADAPTT Project, to identify CPGs published since the previous review**. This search used the same terms as November 2006, such as smoking, tobacco, or nicotine. The search was conducted in Ovid MEDLINE, Ovid Embase, guideline repositories such as National Guideline Clearinghouse, renowned developers with a history of developing high quality guidelines, as well as websites of national and international specialty societies.

   The 14 guidelines identified in both reviews were evaluated by four independent reviewers using the AGREE Instrument. In addition to the AGREE Instrument, 8 additional questions were included as part of the appraisal. CAN-ADAPTT considered only those guidelines that scored highly in multiple AGREE domains, particularly in the

areas of Rigor of Development and Editorial Independence, as well as guidelines that were 'strongly recommended' by reviewers as being applicable to the Canadian context.

Six guidelines met our criteria and were selected for use in developing the dynamic CAN-ADAPTT CPG [Appendix E]. This process has been developed and was recommended by the Guidelines Advisory Committee (GAC)." (57)

Key questions

17. State the key questions of the adapted guideline using a structured format, such as PICO (population, intervention, comparator, and outcome), or another format as appropriate

What to do

For each key question, justify any changes in the PICO element compared to the source guideline(s). PICO (population, intervention, comparison, and outcomes) is the recommended and standardised framework that should be followed when reporting evidence search in guideline development (70-72).

Depending on the scope of the adapted guideline, other formats may be used as appropriate, such as the PICOTS (population, intervention, comparison, outcomes, timeframe of the outcome of interest, and healthcare setting), the PIPOH (Population, Intervention/diagnostic, Professionals, Outcomes, Healthcare settings) for guideline adaptation (55), or the PIRD (Population, Index Test, Reference Test, Diagnosis of Interest) for diagnostic questions (73).

Why is this important?

A set of clear and focused key questions are important considerations for GA groups to complete the adaptation process while identifying which questions are not applicable to the target context (55).

Example(s)

1. **PICO 1:** Which anti-viral therapy is the preferred treatment option for persons with chronic Hepatitis C infection?
    - **Population:** Adults and Children with chronic HCV infection
    - **Intervention:** combination of direct-acting anti-viral therapy with or without ribavirin therapy
    - **Comparison:** pegylated interferon and ribavirin therapy with or without DAA or other DAA
    - **Outcomes:** Rate of SVR, decompensated liver disease, hepatocellular carcinoma, all-cause mortality, and treatment-related adverse events leading to discontinuation of therapy, Quality of life, resource use, cost-effectiveness. (74)

18. Describe how the key questions were developed/modified and/or prioritised

What to do

Briefly describe the process used to develop and/or identify the key questions. Some GA groups develop their key questions upfront, and some others use the source guideline(s) to identify, prioritise, and develop/adapt them. An online survey might be useful to facilitate the prioritisation process for considering whether the key questions are relevant or not (16).

The source guideline(s) might not include a question of interest to the group conducting the adaptation. In that case, *de novo* questions need to be created (16, 48, 51). GA groups should report the key questions in an inclusive way and

highlight which questions in the adapted guideline were developed *de novo,* and provide the rationale. A summary of this process could be included as an appendix.

Why is this important?

Reporting the process for identifying key questions could highlight the different importance and relevance of each question for the target context, ensure the transparency of the rigorous development of adaptation, and allow adaptation users to differentiate the reason behind each question.

Example(s)

1. "This guideline was designed to answer a series of practical questions (Chapter 11) about how to treat people with borderline personality disorder (BPD), how to support families and carers of people with BPD, and how the configuration of health services can best meet the needs of people with BPD. Special needs of Aboriginal and Torres Strait Islander people with BPD were also considered.

   Clinical questions appropriate for literature searching, including twenty-one clinical questions adapted from the source guideline (UK national BPD clinical practice guideline) and five new clinical questions, were formulated using the PICO structure (population, intervention/indicator, control/comparator, outcome), with the assistance of the methodologist.

   Chapter 11: clinical questions (Examples):
   The clinical questions on which the recommendations are based are listed below.
   Italics indicates a new question formulated by the Committee. All other clinical questions were
   previously addressed in the UK national BPD clinical practice guideline.
   Additional literature searches were conducted to identify studies involving Aboriginal and Torres Strait Islander people with BPD, and for evidence on cost-effectiveness of BPD management strategies.
   11.1 Identifying and assessing BPD
   1. What can help clinicians identify features of BPD in young people?
   2. Are there tools/assessments that could be used?
   11.2 Managing risk factors and preventing BPD
   3. What are the risk factors for BPD? (New clinical questions)
   4. What preventative interventions are available to reduce the incidence of BPD?
   (as a primary or secondary outcome) (New clinical questions), etc." (76)]

2. "The broad Cancer Care Ontario (CCO) guideline addressed the overarching question, What is the optimal adjuvant systemic therapy for female patients with early operable breast cancer when patient and disease factors are considered? The specific subset of recommendations from that guideline being considered in this ASCO adaptation addressed the optimal use of cytotoxic chemotherapy and HER2-directed therapy. CCO recommendations relating to the role of the patient and disease factors in selecting adjuvant therapy for women with early breast cancer and relating to the use of adjuvant endocrine therapy are the subject of a separate ASCO guideline endorsement and guideline, respectively." (38)

3. "For each selected guideline, we used a formal process to prioritize approximately 3 - 10 key clinical questions for inclusion during wave 1 and 10 - 5 questions during wave 2, based on the questions addressed in existing evidence syntheses. Guideline panel members completed online surveys to rate the relative importance of clinical questions for the Saudi Arabia health care setting. We used a 9-point Likert scale (1-least important; 9-most

important). Panellists were asked to consider the patient's perspective, the availability of the interventions, and legal issues (e.g., intervention not available in KSA), but not to exclude questions for resource considerations (e.g., potential financial barriers for implementation of the proposed interventions). Mean and median importance ratings of questions guided inclusion in the guideline. To ensure that guidelines comprehensively addressed the topic with a complete set of recommendations, questions deemed complementary to those rated as important (e.g., questions that together addressed a complete diagnostic strategy) were also included. The selected questions were sent to panelists for approval, with opportunity for further input before finalization." (16)

Source recommendations(s)

19. Describe how recommendation(s) from the source guideline(s) was(were) assessed with respect to the evidence considered for the different criteria, the judgements and considerations made by the original panel

What to do

Describe the process followed to assess the source recommendation(s), and report the review of the different criteria (e.g., effects, resources, values, and preferences), including the supportive evidence and the judgments made by the original panel. If there are other relevant considerations, such as implementation or monitoring, these should also be similarly assessed and reported. A summary of the process could be included as an appendix.

If several recommendations for the same question are available from the selected source guidelines, some GA groups may find it useful to map recommendations using a table (55).

For groups of source guideline(s) using GRADE, the use of Evidence to Decision frameworks can help structure the process (16) (77).

More recent tools have been developed that are available to assess, and might be used; such as, the TRANSFER approach to assessing the transferability of systematic reviews (78), or the AGREE-REX tool to assess the clinical credibility and implementability of recommendations (79).

Why is this important?

For guideline adaptation, only relying on the source guideline(s) is not sufficient. GA groups need to assess each recommendation in order to decide whether they should be adapted or adopted.

Example(s)

1. "**The content review is completed by an ad hoc panel convened by ASCO that includes representatives of several disciplines.** …

   On the basis of a preliminary content review of the draft CCO guideline by two members of ASCO's Breast Cancer Advisory Group, the CCO recommendations on the selection of optimal adjuvant chemotherapy regimens and the selection of adjuvant targeted therapy for HER2-positive cancers were selected as a possible adaptation opportunity. **The Advisory Group subsequently ranked the adaptation of the CCO recommendations on chemotherapy and targeted therapy as one of its top three priorities for breast cancer guideline development.**

   On the basis of the content review of the CCO guideline, the ASCO Panel agreed that, in general, the recommendations were clear and thorough and were based on the most relevant scientific evidence, and they

presented options that will be acceptable to patients. **However, for some topics addressed in the CCO guideline, the ASCO Panel formulated a set of adapted recommendations on the basis of local context and practice beliefs of the Panel members:** "Selection of Optimal Adjuvant Chemotherapy Regimens for Human Epidermal Growth Factor Receptor 2 (HER2) –Negative and Adjuvant Targeted Therapy for HER2-Positive Breast Cancers: An American Society of Clinical Oncology Guideline Adaptation of the Cancer Care Ontario Clinical Practice Guideline" (38)

2. "**In addition to our review of each guideline, we examined the evidence supporting the 4 that scored highest (ACS, CTFPHC, USPSTF, and WHO).** We also considered recommendations for adoption or adaptation from these 4 guidelines when developing our own guidance.

Several factors were important in considering guideline quality. The ACS, CTFPHC, USPSTF, and WHO guidelines best articulated benefits, harms, and strength of the evidence and how these link to recommendations. The lower-scoring guidelines often inadequately described how they considered these factors in developing the recommendations, or they relied on lower-quality evidence. The guidelines varied in the studies they reported, weighting of observational or modelling studies relative to randomized controlled trials (RCTs), and emphasis on relative versus absolute effects. The guidelines rarely addressed the small absolute effect on breast cancer mortality; the long lead time to any reduction in this mortality, especially in women with estimated life expectancy less than 15 to 20 years; and the low incidence of breast cancer for women younger than 60 years." (53)

Evidence synthesis

20. Indicate whether the adapted recommendation(s) is/are based on existing evidence from the source guideline(s), and/or additional evidence

What to do

Explicitly indicate whether the research evidence comes from the source guideline(s) or not, and provide the citation(s)it. GA groups could review and adapt recommendations based on the research evidence considered in the source guideline(s) (e.g., systematic reviews, cost-effective studies), or on other existing research evidence (e.g., local data, or primary studies for target context).

Why is this important?

Reporting this information provides users with all the evidence used in the adaptation process and helps the GA panels justify any modifications/differences in the adapted recommendations.

Example(s)

1. "The located meta-analyses, systematic reviews, and randomized controlled trials **were used as a supplementary evidence** base for the recommendations and are cited where appropriate in the text." (62)

2. "For each topic, **the Committee considered evidence identified in the systematic literature review undertaken for this guideline,** as well as earlier evidence presented in the UK national borderline personality disorder (BPD) clinical practice guideline." (76)
3. "**In addition, we searched the literature for studies and data relevant to patients' values and preferences and economic data** ... **we solicited panellists for additional studies on baseline risks and economic data**." (17)

4. "A search for new evidence was conducted by ASCO guidelines staff to identify relevant randomized controlled trials, systematic reviews, and meta-analyses published since the CCO guideline was completed." (38)

21. If new research evidence was used, describe how it was identified and assessed.

What to do

Report the process of identifying new research evidence in addition to the source evidence, by providing the search strategies, the eligibility criteria, and describing how the risk of bias/methodological limitations were assessed (e.g., AMSTAR II for systematic reviews (80), Cochrane risk of bias for RCT (81), Newcastle-Ottawa Scale (NOS) or ROBINS-I tool for non-randomised studies (82, 83).

If the GA group updated the search of the source evidence, indicate any changes that were made (e.g., changes in eligibility criteria, additional outcomes, etc.).

Additional evidence could be synthesised with the evidence used in the source guideline(s) or reported separately in a subsection along with each recommendation. A summary of the identification process could be included as an appendix.

Why is this important?

Reporting the process of identifying other research evidence will increase the trustworthiness of the adapted guideline and ensure its reproducibility.

Example(s)

1. "The updated search was guided by the "signals" approach that is designed to identify only new, potentially practice-changing data—signals—that might translate into revised practice recommendations. The approach relies on targeted routine literature searching and the expertise of ASCO Expert Panel members to help identify potential signals. **The Methodology Supplement (available at www.asco.org/survivorshipguidelines) provides additional information about the signals approach.** The updated search yielded 159 records. A review of these results plus studies identified by searching reference lists and known seminal papers resulted in 19 new, recommendation changing studies being included. **Table 2** summarizes the number and types of studies included per sexual dysfunction condition." (33)

Table 2. Symptoms and Interventions for Sexual Dysfunction (adapted from CCO guideline) (Example)

Symptom	Possible Intervention	Evidence
For women with cancer		
Difficulty with sexual response, such as desire, arousal, or orgasm	Psychosocial counselling, psychosexual counselling Regular stimulation (including masturbation) Flibanerin for premenopausal women	Two systematic reviews[14,15] Two RCTs [56,57] Three other [58-60]

2. "**Figure 1 depicts the process of searching and using the identified evidence for the recommendation questions selected by the panel**. We ran two searches for systematic reviews and primary studies respectively. **We searched Medline, Embase, Cochrane and Epistemonikos electronic databases from the last search date of the source**

guideline in September 2014, till February 2016. We used the same search terms as the source guideline search; we only added study design filters for primary studies and systematic reviews respectively. The search terms included both medical subject headings (MeSH) and text words.

We used standards systematic review methodology including duplicate and independent approach to title and abstract screening, full-text screening, and data abstraction. We conducted calibration exercises, used standardized and pilot tested forms, and relied on a third reviewer to resolve disagreements.

When evaluating the potential use of identified systematic review, we considered the following three characteristics as important:

- Relevance (directness): we assessed the relevance of identified systematic reviews by matching their PICO to the PICO of the guideline questions. The minimum requirement was for the Population, Intervention and Control elements to match to a reasonable degree, i.e., not to have serious indirectness for more than one of the three elements.
- Quality (risk of bias): we assessed the risk of bias of relevant systematic reviews using AMSTAR (80). If we identified more than one relevant systematic review we prioritized the one with the highest quality.
- Being Up to date: we assessed whether the systematic review judged to be relevant and of highest quality was up to date. In case we had identified more than one systematic review, the judgment of relative up-to-dateness would have considered whether the systematic reviews included all relevant studies. When we identified new primary studies, we integrated the findings in the chosen systematic review.

When we identified no usable systematic review (based on the three above criteria), we updated the systematic review conducted by the source guideline-working group using the results of the search for primary studies." (17)
Figure 1: Algorithm of our search and use of the identified evidence (see the end of this document)

3. "Search for Systematic Reviews and Primary Studies: A search of MEDLINE, EMBASE, and the Cochrane Database of Systematic Reviews for systematic reviews or primary literature that had been published between January 2010 and March 2015 used search terms related to ovarian cancer and to asymptomatic detection of recurrence and follow-up adopted from Cancer Australia's systematic review. Systematic reviews found to be directly relevant to the present guideline were assessed using the AMSTAR tool. The Clinicaltrials.gov database was also searched for in-progress randomized controlled trials (RCTs)." (47)

Assessment of the certainty of the body of evidence and strength of recommendations

22. Describe the approach used to assess the certainty/quality of the body (ies) of evidence and the strength of recommendations in the adapted guideline and note any differences compared to the source guideline(s)

What to do

Report the approach used to assess the certainty of the body of evidence and the strength of recommendations, such as the GRADE rating system, Oxford Centre for Evidence-based Medicine (84), the GRADE-CERQual for qualitative evidence (85), or self-established rating system. If the adapted guideline used the same approach as source CGs, the authors should indicate this.

If the rating system used is different to that of the source guideline(s), explain why (e.g., source guideline(s) lacks a rating process, or it is not appropriate), and how GA groups moved from the ratings of the source guideline(s) to the ratings with the new system. A summary of the differences could be included as an appendix.

Why is this important?

The certainty (or quality) of evidence indicates the extent to which we can be confident that an estimate of effect is correct, while the strength of recommendation indicates to what extend we can be confident that the recommendation will do more good than harm (86, 87). Rating the certainty of evidence and strength of recommendations is essential for guideline development and adaptation processes.

Example(s)

1. "An adapted version of the 'Infectious Diseases Society of America-United States Public Health Service Grading System' was used to define the level of evidence and strength (grade) of each recommendation (Table 1)." (44)

Table 1. Voting on levels of agreement and definition of levels of evidence and grades of recommendation used by the panel of Asian experts in evaluating the ESMO consensus guidelines for the diagnosis, treatment and follow-up of patients of Asian ethnicity with early breast cancer

Level of evidence	
I	Evidence from at least one large randomised, controlled trial of good methodological quality (low potential for bias) or meta-analyses of well-conducted randomised trials without heterogeneity
II	Small randomised trials or large randomised trials with a suspicion of bias (low methodological quality) or meta-analyses of such trials or of trials with demonstrated heterogeneity
III	Prospective cohort studies
IV	Retrospective cohort studies or case-control studies
V	Studies without control group, case reports, experts' opinions
Grades of recommendation	
A	Strong evidence for efficacy with a substantial clinical benefit, strongly recommended
B	Strong or moderate evidence for efficacy but with a limited clinical benefit, generally recommended
C	Insufficient evidence for efficacy or benefit does not outweigh the risk of the disadvantages (adverse events, costs, etc.), optional
D	Moderate evidence against efficacy or for adverse outcome, generally not recommended
E	Strong evidence against efficacy or for adverse outcome, never recommended

2. "The panel rated the certainty of evidence supporting each recommendation according to the GRADE methodology, as "high," "moderate," "low," or "very low". The panel graded the strength of each recommendation as either strong or conditional (also known as or called weak). The factors considered when grading the strength of recommendation were as follows: priority of the problem, benefits and harms of the option, certainty of the evidence, values and preferences, resource use, feasibility, acceptability, and equity." (88)

3. "The grades range from very low to high and were assigned using the Grading of Recommendations Assessment, Development and Evaluation (GRADE) approach (Table 5)." (40)

Table 5. Definitions of GRADE ratings of the quality of the evidence

GRADE of quality of the evidence	Description
High	Further research is very unlikely to change our confidence in the estimate of effect
Moderate	Further research is likely to have an important impact on our confidence in the estimate of effect and may change the estimate
Low	Further research is very likely to have an important impact on our confidence in the estimate of effect and is likely to change the estimate
Very low	Any estimate of effect is very uncertain

Decision-making processes

23. Describe the processes used by the guideline adaptation group to make decisions; particularly the formulation of recommendations

What to do

Report the decision-making process and the methods used to achieve consensus (such as iterative discussions, a Delphi approach, the nominal group technique, or a consensus development conference). The participants and the definition of consensus should also be reported. If consensus is not reached, GA groups should report how the discrepancies were solved, for example, by vote.

Why is this important?

Decisions should be made following an explicit and rigorous process of negotiation. This process allows GA group members to explicitly express their expectations through a respectful and productive process, therefore helping to avoid potential decision-making biases and produce a higher-quality, more credible guideline (89).

Example(s)

1. "**Where there was full agreement between all voting parties that a recommendation could be adapted for use in their country, no further discussion was required. Where there was an absence of full agreement, however, a modified Delphi process was used during the final voting process at the face- to-face working meeting** in Seoul, to develop each of the disputed recommendations towards a consensus. **The Asian experts were asked to vote, based on the evidence available, on a scale of A to E (Table 1)**." (44)

Table 1. Voting on levels of agreement and definition of levels of evidence and grades of recommendation used by the panel of Asian experts in evaluating the ESMO consensus guidelines for the diagnosis, treatment and follow-up of patients of Asian ethnicity with early breast cancer

Voting on level of agreement	
A	Accept completely
B	Accept with some reservation
C	Accept with major reservation
D	Reject with some reservation
E	Reject completely

2. "During a 2-day in-person meeting, followed by online communication and conference calls, the panel developed clinical recommendations based on the evidence summarized in the EtD tables. For each recommendation, the panel took a population perspective and came to consensus on the following: the certainty in the evidence, the balance of benefits and harms of the compared management options, and the assumptions about the values and preferences associated with the decision. The guideline panel also explicitly took into account the extent of resource use associated with alternative management options. The panel agreed on the recommendations (including direction and strength), remarks, and qualifications by consensus or, in rare instances, by voting (an 80% majority was required for a strong recommendation), based on the balance of all desirable and undesirable consequences. The final guidelines, including recommendations, were reviewed and approved by all members of the panel." (90)

3. "A content expert (rheumatologist) and a guideline methodologist co-chaired the final panel meeting. They facilitated and steered the discussion, reflected on and summarized the panellists viewpoints, raised issues/concerns that could inform the decision-making process; and attempted to achieve consensus whenever possible. The methodologist co-chair did not vote while the content co-chair did." (17)

Recommendations

Recommendations

24. Report recommendations and indicate whether they were adapted, adopted, or *de novo*

What to do

List all the recommendations in a clear and accurate way, and be explicit about whether the recommendations were adapted, adopted, or developed *de novo*.

If multiple source guidelines were considered, report the name and publication year of the source guideline(s) on which the recommendations were based.

Why is this important?

Clear and accurate recommendations are more likely to promote the implementation by guideline users (4). GA groups may modify (adapt), use verbatim (adopt) recommendation(s) from the source guideline(s), or develop a *de novo* clinical question when lacking appropriate source recommendation(s) (16). Reporting of all the recommendations and stating where they come from also ensures transparency of the adapted guideline.

Example(s)

1. "Recommendations (example):
   Instruct a high-risk patient with diabetes to monitor foot skin temperature at home to prevent a first or recurrent plantar foot ulcer. This aims at identifying the early signs of inflammation, followed by action taken by the patient and care provider to resolve the cause of inflammation. (Weak; Moderate) International Working Group on the Diabetic Foot (IWGDF) 2015 (Adopted)" (42)

2. "RECOMMENDATIONS (example):
   Screening *(Modified from pan-Canadian guideline and NCCN Guideline for Cancer-Related Fatigue)*:

- All Health care providers should routinely screen for the presence of fatigue from the point of diagnosis onward, including after completion of primary treatment.
- All patients should be screened for fatigue as clinically indi- cated and at least annually.

Laboratory Evaluation *(NCCN Guideline for Survivorship verbatim)*:

- Consider performing laboratory evaluation based on presence of other symptoms, onset, and severity of fatigue.
- Complete blood cell count with differential: compare end-of- treatment hemoglobin/hematocrit with current values; assess other cell lines (WBC and platelets).
- Comprehensive metabolic panel: assess electrolytes; assess hepatic and renal function." (62)

3. "Recommendation (example)

G1 – Assessment of Capacity and Consent	
G 1.2 **N C**	G 1.2 A formal evaluation of the capacity of the person with traumatic brain injury should be conducted, if needed, by an appropriately qualified professional. Periodic re-evaluation should be conducted as indicated clinically. (INESSS-ONF, 2015)

*N: New recommendations formulated by the expert panel have been identified with the letter "N" and referenced as INESSS-ONF, 2015.

INESSS-ONF Level of Evidence

C: Recommendation supported primarily by expert opinion based on their experience, though uncontrolled case series without comparison groups that support the recommendations are also classified here."(91)

25. Indicate the direction and strength of the recommendations and the certainty/quality of the supporting evidence and note any differences (if applicable) compared to the source recommendation(s)

What to do

Report the strength of the recommendations and the certainty of the evidence together with the recommendations.

If the strength of the recommendations and/or the certainty/quality of the evidence is graded or rated differently, differences should be reported. A summary of the differences could be included as an appendix. Using a table format or software might be helpful. If there is no difference between source recommendations and adapted ones, the authors should indicate this.

Why is this important?

It could help users identify differences between the adapted guideline and the source guideline(s), and to what extent they could trust the recommendations.

Example(s)

1. "Recommendation (example):
   4.8.8 Consider Achilles tendon lengthening, joint arthroplasty, single or pan metatarsal head resection or osteotomy to prevent a recurrent foot ulcer when conservative treatment fails in a high-risk patient with diabetes and a plantar foot ulcer. (weak; low) International Working Group on the Diabetic Foot (IWGDF) 2015 (Adopted)" (42)

2. "Change in the certainty of evidence and the strength of recommendation: After we formulated the eight final recommendations, we compared the certainty and strength of each of the adoloped recommendations to

corresponding recommendations from the source guideline. **The certainty of the evidence of three of the eight recommendations changed: one from moderate to very low and two from low to very low. The factors that justified a very low certainty of the evidence in these three recommendations were: serious risk of bias and very serious imprecision. The strength of five out of the eight recommendations changed from strong to conditional. The factors that justified the conditional strength of these 5 recommendations were the following: cost (n = 5), impact on health equities (n = 4), the balance of benefits and harms (n = 1) and acceptability (n = 1).”** (17)

3. “Tests for women with high mammographic breast density **(example from *de novo* guideline)**
   In the context of an organised screening programme:
   - for asymptomatic women
   - with high mammographic breast density

   The ECIBC's Guidelines Development Group (GDG) **suggests:**
   - **screening with** either digital breast tomosynthesis (DBT) or digital mammography **(conditional recommendation, very low certainty of the evidence)**
   - **not implementing** tailored screening with both DBT and digital mammography **(conditional recommendation, very low certainty of the evidence)**
   - **not implementing** tailored screening with magnetic resonance imaging (MRI) **(conditional recommendation, very low certainty of the evidence)” (92)**

26. Present separate recommendations for important subgroups if the evidence suggests important differences in factors influencing recommendations and note any differences (if applicable) compared to the source recommendation(s)

What to do

The same as for *de novo* guidelines: present recommendations separately for relevant subgroups (i.e., age, sex, ethnicity, and others).

If there is new research evidence suggests additional important subgroups in factors of influencing adaptation of recommendations — particularly the balance between the benefits and harms across subgroups, report the additional subgroups and note the difference compared to the source recommendation(s), including the corresponding research evidence and summary of findings. Whether the subgroup was predefined should also be indicated.

Why is this important?

Due to different reasons (e.g., baseline risk, value assigned to the outcomes, costs of resources, or equity), source recommendations for subpopulations might differ. In addition, subgroups relevant for GA groups might differ from the ones considered in the source guideline(s). Subgroups considered by the source guideline panel might or might not be relevant for the target context. Subgroups not considered by the source guideline(s) can be relevant in the context of the adapted guideline and should be reported as such.

Example(s)

1. See **Table 7**

Table 7. Final Recommendations for Selection of Optimal Adjuvant Chemotherapy Regimens for HER2-Negative and Adjuvant Targeted Therapy for HER2-Positive Breast Cancers: ASCO Guideline Adaptation of the CCO Clinical Practice Guide (examples)

Original CCO Guideline Clinical Topic	ASCO Final Recommendations* Recommendations for HER2-Negative Breast Cancer	Rationale for ASCO Adaptation
Capecitabine in patients age 65 years or older (CCO recommendation 11)	In patients age 65 years or older, capecitabine is not recommended as an adjuvant chemotherapy option in lieu of standard regimens such as doxorubicincyclo phosphamide or cyclophosphamide methotrexate-fluorouracil (oral cyclophosphamide)	The ASCO Panel modified the CCO recommendation to reflect that patients in the clinical trial reported by Muss et al were age 65 years or older.

"*Recommendations designated by an asterisk are taken verbatim from the CCO guideline. Otherwise, recommendations have been substantively adapted or reworded for clarity by the ASCO Panel." (38)

2. "Recommendations (example):
   Women aged less than 20 years: For women younger than 20 years of age, we recommend not routinely screening for cervical cancer (Strong recommendation; high-quality evidence). Our recommendation is based on a very low incidence of and mortality due to cervical cancer in this age group, no studies addressing effectiveness for this age group, and evidence of minor harms to about 10% of women who undergo screening and more serious harms for some women who go on to further treatment. A strong recommendation against screening reflects our judgment that the potential harms of screening for women in this age group outweigh the benefits." (93)

Rationale/explanation for recommendations

27. Describe the criteria/factors that were considered to formulate the recommendations or note any relevant differences compared to the source guideline(s) (if applicable)

What to do

Report the criteria considered when formulating the recommendations if this information is not available in the source guideline(s), or note any relevant differences compared to the source guideline(s) (if any), and provide the corresponding justifications. The criteria can include the magnitude of the problem, the magnitude of the desirable and undesirable effects, the certainty of the evidence of effects, how people value the outcomes, balance of effects, economic considerations, impact on equity, acceptability, or feasibility.

Why is this important?

Strength of recommendations—and even direction—may change depending on the considered criteria (94, 95). Explicit reporting of the criteria considered by GA groups is crucial to understanding the formulated recommendations and any potential discrepancies with respect to the source guideline(s).

Example(s)

1. "Strong recommendation: It is recommended that soap and water should be used for hand hygiene when hands are visibly soiled.
   - Benefits and harms (Substantial net benefits of the recommended alternative): The benefits of using soap on visibly soiled hands clearly outweighs any undesirable effects. Plain soap can loosen and remove transient flora. If visible soiling is not removed, the effect of any alcohol-based hand rub is minimised, and effective hand hygiene is threatened.

- **Certainty of the Evidence (High):** The evidence supporting the recommendation is from experimental, clinical or epidemiological studies and these were judged as either being well designed and/or based on a strong theoretical rationale.
- **Preference and values (No substantial variability expected):** It is expected that all patients and staff of Australian healthcare facilities would highly value minimising infections during any episode of care. This would include maximising the potential effects of all types of hand hygiene.
- **Resources and other considerations (no important issues with the recommended alternative):** Appropriate hand hygiene practices have an extremely high clinical impact across Australia's healthcare system. Practices are easy and feasible to implement. To maximise effectiveness, most healthcare facilities use a wide range of promotional and educational campaigns/signage." (96)

2. See **Table 8**.

"Table 8. Adapted – adopted recommendations (examples)" (42)

MoHFW guideline	Adopted/ Adapted	Original Guideline	Remarks
4.7.2 Refer the person with suspected Charcot's foot early (within one week) to the multidisciplinary foot care service Diabetic Foot care centre to confirm the diagnosis and offer non-weight-bearing treatment until definitive treatment can be started.	**Adapted**	NICE 2015 Guidelines on Diabetic Foot (NG19) says - Refer the person urgently (within 24 hours) to the multidisciplinary foot care service to confirm the diagnosis and offer non-weightbearing treatment until definitive treatment can be started.	**Urgently (within 24 hours) may not be possible in Indian context. So the word early (within one week) is used.** Diabetic Foot care centre: **In India, since there are no minimum standards of services offered to the diabetic foot patients**, in our recommendations we have used this term to denote this facility, which may exist at the General Practitioner's office, Primary health centre, Secondary care centre or at a tertiary care centre. Preferably, the diabetic foot care centre should consist of at least a surgeon, a physician, and an orthotist.

3. **"The panels often made modifications because of the feasibility of applying the recommendation in a Norwegian setting. Interventions excluded across chapters because they are not readily available in Norway were cilostazol, triflusal, and intermittent pneumatic compression devices;** For most recommendations, **low-dose unfractionated heparin was excluded in preference for the commonly used subcutaneous low-molecular-weight heparin (LMWH),** the latter in general having a slightly better risk-benefit profile and not requiring regular blood monitoring. Based on an absolute risk reduction of 17 per 1,000 pregnancies, the panel believed that most women would prefer thromboprophylaxis and, thus, concluded with a weak recommendation in favor of antepartum and postpartum prophylaxis." (20)

External review and quality assurance

External review

28. Indicate whether the adapted guideline underwent an independent external review. If yes, describe the process

What to do

Describe the external review process explicitly and in detail, including how the comments were compiled for discussion and how the modifications were determined if needed. External reviewers may include different types of professionals or relevant stakeholders (e.g., users, clinical experts, or allied organizations, etc.). They should be appropriately chosen, and complete details of the external reviewers, including full name, affiliation, location, discipline, and management of conflict of interest should be reported.

The external review process should preferably include a review of the clinical content and of the methodology process of the adapted guideline. In the absence of an external review process, a statement would be required.

Why is this important?

Considering representative experts and perspectives in the guideline group are limited, the current guideline development process undergoes an external review process to ensure its comprehensiveness and quality (4). Reporting this information enhances the transparency and trustworthiness of the adapted guideline.

Example(s)

1. "This report was externally reviewed by the Association of Indonesian Digestive Surgeons (IKABDI) and one expert from the Ethics Committee of the Faculty of Medicine, Universitas Indonesia". (41)

2. "External Review:
   Based on survey results, the guideline was revised by members of the executive and sent to three expert reviewers outside the province for further review. Comments provided by the external reviewers were minor and general in nature (for example, "Good work by the group. Many comments are quite minor and intended to prompt consideration, nothing else"). Thus, the guideline, with minor changes, was published on the Alberta Health Services Web site." (75)

Organizational approval

29. Indicate whether the adapted guideline obtained organizational approval. If yes, describe the process

What to do

Indicate if the adapted guideline obtained organizational approval (from organization that adapted guidelines and/or from organization/s that developed source guideline(s)) and describe the process, such as: whether they submitted their guidelines and whether the guideline was approved.

Why is this important?

Formal support by professional organization(s) is helpful for a wide implementation of the guideline adaptation, and enhances approval by organization's members (55, 97). Sometimes guidelines developed by large organizations are more likely with better quality (37). For some guideline developers, it is often necessary to obtain organizational approval. This type of approval can increase the guideline´s credibility, acceptability, adoption, and implementation. Many countries are conducting quality assurance of guidelines and approving implementation processes, like Ireland (98) and Germany (48).

Example(s)

1. "**The guidelines** (recommendations) on pages 7-20 **were approved by the Chief Executive Officer of the National Health and Medical Research Council (NHMRC) on 1 February 2016 under section 14A of the National Health and Medical Research Council Act 1992.** In approving the guidelines (recommendations), NHMRC considers that they meet the NHMRC standard for clinical practice guidelines. This approval is valid for a period of five years." (52)
2. "**On 30 July 2018, the ASH Guideline Oversight Subcommittee and the ASH Committee on Quality approved that the defined guideline development process was followed, and on 3 August 2018, the officers of the ASH Executive Committee approved submission of the guidelines for publication under the imprimatur of ASH**." (90)

Funding, declaration and management of interest

Funding source(s) and funder role(s)

30. Report all sources of funding for the adapted guideline and source guideline(s), and the role of the funders

What to do

Report all sources of funding for both the adapted guideline and the source guideline(s), and whether it will interact with the adaptation development process or not, as well as how this may have affected the content of the guideline. The funding source for adapted guideline(s) should be differentiated from those for source guidelines(s). If there was no funding (i.e. self-funded guideline group), this should be explicitly stated as well.

Why is this important?

Since guideline adaptation is a methodology for providing guidance based on existing guideline(s), it inherits the merits of the source guideline(s) while retaining the potential bias. In order to help adaptation users evaluate the potential impact of funding, the funding sources, as well as the role of the funders, need to be declared for both adapted and source guideline(s).

Example(s)

1. "**FUNDING/SUPPORT:** Innlandet Hospital Trust, the Southern and Eastern Norway Regional Health Authority, and the Norwegian Research Council have provided research grants. The Norwegian Medical Association has provided grants to support completion of the adaptation process.
   Role of sponsors: The sponsors had no role in the design of the study, the collection and analysis of the data, or the preparation of the manuscript." (20)

2. "**Funding:** The development and publication of this guideline by the National Health and Medical Research Council (NHMRC) was funded by the Australian Government Department of Health and Ageing. **The involvement of the Department of Health and Ageing was limited to determining the scope of the guideline, and it had no involvement in the committee process of assessing evidence and formulating recommendations.** At the first committee meeting in February 2011, the borderline personality disorder (BPD) Guideline Development Committee agreed on the scope and target audience for the guideline and developed the clinical questions that the guideline would address." (76)

Declaration and management of interests

31. Report all conflicts of interest of the adapted and the source guideline(s) panels, and how they were evaluated and managed

What to do

Report any sources of conflicts of interest (COI) (e.g., financial or intellectual, etc), as well as how the COIs were evaluated and managed, for both the adapted and source guideline(s), including the exclusion process of specific members with a conflict of interest from the voting panel. The COIs from adapted guideline(s) should be differentiated from those from source guidelines(s). Ideally, the COI could be managed according to an established method, like the Guideline-International-Network (GIN) principles for COI management (99) or American College of Physicians (ACP) methods (100), or other methods as appropriate.

If the information of the COI management from source guideline(s) is unavailable, a statement should be included. The full declarations of all the members could be included as an appendix.

Why is this important?

COI is an important potential source of bias in the development of clinical practice guidelines. It may influence the decision making or recommendation formulating process and should be clearly declared (99, 101). Considering that the quality of an adapted guideline relies on the source guideline(s), reporting COIs and their management for both source and adapted guideline(s) is crucial for users to detect potential bias and assess the quality of the adapted guidelines.

Example(s)

1. "**Conflicting interest statements and management**
   Working Party members were asked to declare any interests relevant to the guideline development, prior to commencement. Members were asked to update their information if they became aware of any changes to their interests.
   All declarations were added to a register of interests as listed in the table of "The Australian Adult Cancer Pain Management Guideline Working Party". The register was made available to the Working Party throughout the development of the guideline, allowing members to take any potential conflicts of interest into consideration during discussions, decision making and formulation of recommendations.
   The guidelines have now entered the updating phase. Guideline Working Party members are responsible to update their conflict of interest statements if a new interest arises." (32)

2. "**All members of the Panel completed ASCO's disclosure form**, which requires disclosure of financial and other interests, including relationships with commercial entities that are reasonably likely to experience direct regulatory or commercial impact as a result of promulgation of the guideline." (38)
3. "**Financial/non-financial disclosures:** The authors have reported to CHEST the following conflicts of interest: Drs Akl, Guyatt, and Vandvik participated in the writing of the American College of Chest Physicians original guideline (Antithrombotic Therapy and Prevention of Thrombosis, 9th ed)." (20).

Other information

Implementation

32. Describe the potential barriers and strategies for implementing the recommendations (if applicable)

What to do

Report potential barriers and facilitators that may need to be taken into account when implementing the adapted guideline, as well as the resources needed (e.g., guideline summary documents, or links to the "how-to manual", etc.). In the case that recommendations against intervention/management have been widely used, de-implemeting plan should be considered and reported. There are several tools that might be useful to assess the barriers and facilitators for implementation, e.g., GLIA (102), EPOC(43), or Cochrane equity methods.

The implementation plan should emphasise the new and changed recommendations in the adapted version, and the improvements based on the success of the implementation plan from the source guideline. A statement may be made about the differences in the methodology of the implementation plans/strategies between the source and adapted guidelines (34).

Ideally, GA groups should provide details about potential implementation tools (e.g. clinical algorithms, integrated care pathway, medication table(s), performance/ quality measures, patient education information, online resources, mobile apps, etc.). Where an implementation plan was not developed/funded, this should be clearly stated.

Why is this important?

An implementation plan helps health-related practice guidelines maintain their effect (103) while helping policy-makers facilitate optimal health care measurement (104). Provide advice and/or additional materials, such as adapted guideline summary documents, that could support correct implementation (105).

Example(s)

1. "September 28, 2017: New content has been added to the sections on "Tools and resources" as well as on "Key indicators". The "Tools and resources" tab offers suggestions of tools and resources that can be used to support the implementation of the recommendations in each section of the guidelines. The "Key indicators" tab proposes examples of indicators that can be used to monitor the implementation of specific recommendations in each section of the guidelines. Downloadable PDF document with all Key indicators and Tools and resources are also available.—

   Tools and r Tools and Resources

   - Complete list of suggestions of tools and resources
   - Length of Stay (LOS) - Reference table (to support recommendations C 2.1, C 2.2. and C 3.1)
     - Ontario data
     - Quebec data
   - Medication Algorithm (to be used by physicians making decisions regarding Pharmacological Management of Agitation and Aggression following TBI) (pertinent to Section R10, P 1.1 and I 2.2)
   - Indications of use (Health Canada) and insurance coverage (for Quebec only) for the Pharmacological Management of TBI related Impairments (pertinent to multiple sections)" (91)

2. "DISSEMINATION AND IMPLEMENTATION

   Four regional coordinators representing Western Canada, Ontario, Quebec and Atlantic Canada provided information on the CAN-ADAPTT initiative, and collaborated with regional providers, researchers, policy makers and other stakeholders on guideline dissemination strategies. The guideline was disseminated to regional

provider networks, at conferences and workshops, integrated into existing educational efforts, and summary articles were published in newsletters and journals.
CAN-ADAPTT members were encouraged to disseminate the guideline by e-mail, and to discuss the guideline with colleagues. Members have also been incorporating the guideline into training or educational sessions.
National and professional organizations have been promoting the guideline primarily through passive dissemination such as publishing articles in newsletters, and providing links to the CAN-ADAPTT Guideline on their websites.
The CAN-ADAPTT website provides a virtual networking space where CAN-ADAPTT members are invited to comment on the guideline, suggest smoking cessation tools and resources and identify additional research gaps. Any member can post to an existing subject thread or create a new discussion topic." (57)

3. "Practice point (PP): **Consultation with culturally and linguistically diverse (CALD) community representatives who have appropriate knowledge and skills should occur in the development, implementation and review of any dementia initiative for CALD communities**." (52)

Update

33. Briefly describe the strategy for updating the adapted guideline (if applicable)

What to do

Report if there is a plan regarding the forthcoming updates of the adapted guideline.

If yes, describe the specific time frame with rationale and methodology that will be using for updating. If specific cases occur that trigger an update before the established time frame, such as the updating of source guideline(s), these should be reported as well.

If updating is not applicable, provide justification, for example, lacking funding support.

Why is this important?:

Guideline updating requires a three-stage process: identifying new evidence, determining whether that new evidence warrants an update, and updating the recommendations (34). Updating is a crucial process for maintaining the validity of recommendations and, by stating when updates are planned, users will be informed about a period of time during which the adapted guideline remains credible.

Example(s)

1. "**Updating the guideline:** This guideline will be updated each year from 2013 to include recommendations added to new editions of the source guidelines or any new guidelines that meet criteria for quality and applicability". (32)

2. "Practice guidelines developed by the Alberta Provincial Head and Neck Tumour Team **are reviewed on an annual basis**—or earlier, if critical new evidence or contextual information is brought to the attention of executive members of the team." (75)

3. "**An update of this guideline was not scheduled or required by our funder**, Health Canada. Funding support of CAN-ADAPTT continues until March 2012. Dr. Peter Selby will seek funding opportunities to continue the work of CAN-ADAPTT including an update to the guideline." (57)

4. "**Future Updates:** We plan to dynamically update the recommendations at least every 3 months by the same team that produced the adapted guideline". (20)

Limitations and suggestions for further research

34. Describe the challenges of the adaptation process, the limitations of the evidence, and provide suggestions for future research

What to do

The GA groups should report the limitations of the evidence. For example, poor reporting and low quality of source guideline(s), the discrepancies between source guidelines, COIs of source(s) and adapted guidelines panels. In addition, suggestions for future research should be provided. In case there are limitations related to the adaptation methodology, the GA groups should report and highlight how these limitation(s) could impact the validity of the recommendations.

Why is this important?

Guideline adaptation faces many limitations when put into practice (104). Acknowledging these limitations increases the trustworthiness of the guideline adaptation and provides suggestions to help guideline adaptation developers to highlight future research needs (106), especially for their target users and settings.

Example(s)

1. "CLARIFICATION AND LIMITATIONS
   Most research in the area of smoking cessation has examined cigarette use; it is important to note this limitation when using this guideline with smokeless tobacco users. More research is needed on smokeless tobacco products and the people who use smokeless tobacco to understand the impact of smoking cessation interventions." (57)

2. "The evidence supporting cardiac rehabilitation in heart failure (HF) are concrete. **However, further studies should assess which type(s) of multidisciplinary rehabilitation programs are beneficial under current Korean circumstances.** Regarding the surgical treatments of HF, the use of mechanical circulatory support (MCS) is expected to increase in Korea. Korean data about the indication and management of MCS are needed" (107)

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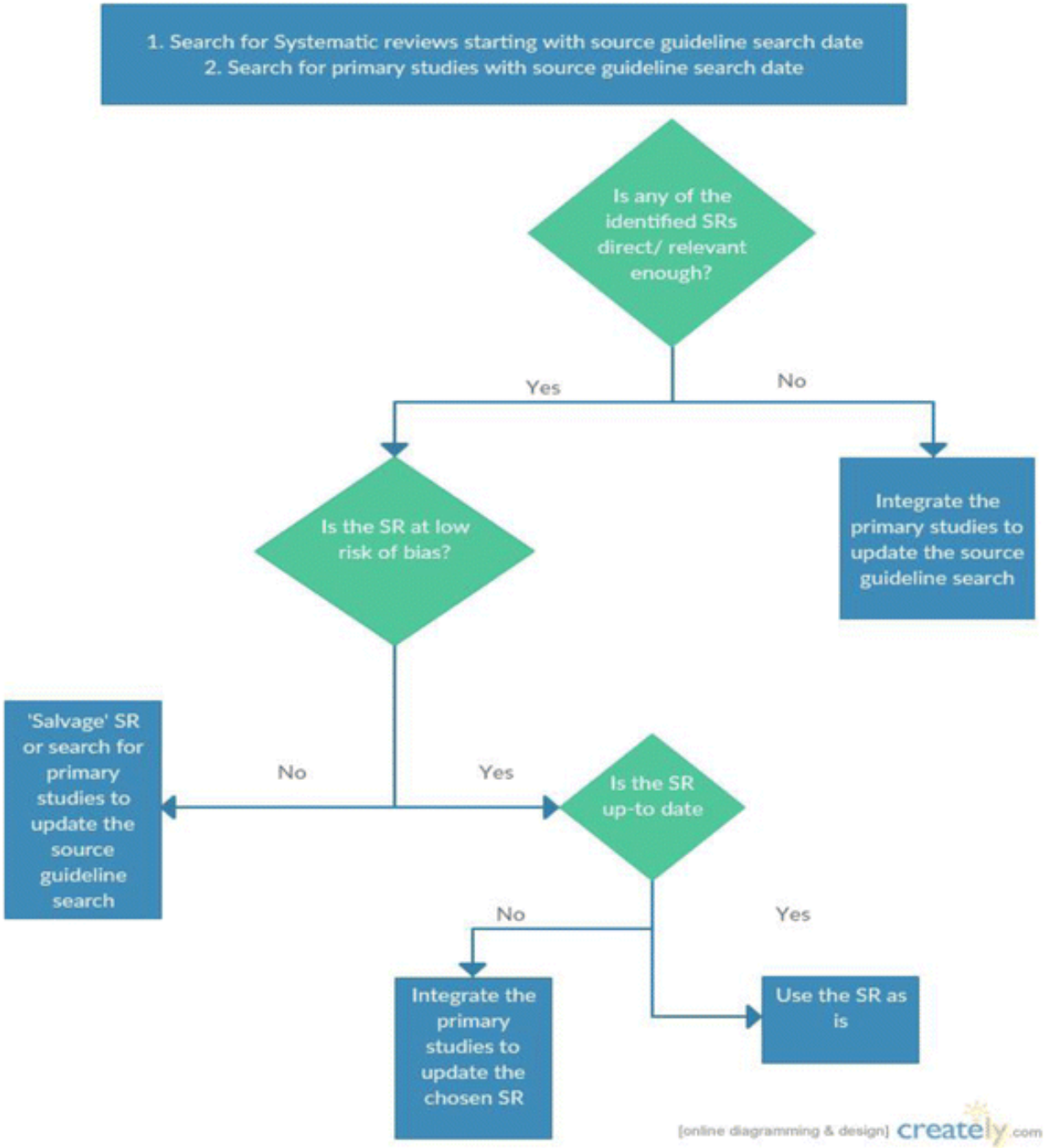
7. Figures

Figure 1: Algorithm of our search and use of the identified evidence



Example extracted from: 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(1):183