

RIGHT Explanation and Elaboration: guidance for reporting practice guidelines

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1. Introduction

Practice guidelines play a central role in healthcare because, unlike other types of research such as randomized controlled trials and systematic reviews, they directly provide recommendations to decision makers. There is evidence that high quality practice guidelines have the potential to improve healthcare decisions and enhance healthcare quality and outcomes (1, 2). Healthcare practitioners can trust guidelines when they are rigorously developed and explicitly and transparently reported (3).

1.1. The RIGHT statement

Reporting of practice guidelines is often not detailed or sufficiently clear (4-6). In order to improve the reporting of practice guidelines, we developed the Reporting Items for Practice Guidelines in Healthcare (RIGHT) statement (7). The statement includes a checklist of 22 items (Table) and aims to ensure that guidelines contain clear statements of why and how they were developed, and who was involved. The ultimate goal is that healthcare practitioners can better understand and implement the recommendations contained in the guideline.

1.2. How to use this document

This document forms a part of the RIGHT statement and provides readers with a comprehensive explanation and rationale for each item in the checklist. For each checklist item, it also provides examples of good reporting from existing guidelines. However, this does not necessarily mean that the guidelines from which the examples were taken are uniformly well reported, of high credibility, or that the recommendations that they contain are valid. Our intention is to provide guidance on how to report practice guidelines well, not how to develop them, or how to assess their quality. We advise authors to address all items of the checklist somewhere in their guideline, but we do not prescribe a precise location, order, or format.

1.3. The items in the RIGHT checklist

We present and discuss the 22 items of the RIGHT checklist, organized into 7 sections: basic information, background, evidence, recommendations, review and quality assurance, funding, declaration and management of interest, and other information (Table). We provide explanations and examples for each item, and a glossary of key terms (Box).

Table. RIGHT checklist

Section/topic	No.	Item
Basic information		
Title/subtitle	1a	Identify the report as a guideline, that is, with “guideline(s)” or “recommendation(s)” in the title.
	1b	Describe the year of publication of the guideline.
	1c	Describe the focus of the guideline, such as screening, diagnosis, treatment, management, prevention or others.
Executive summary	2	Provide a summary of the recommendations contained in the guideline.
Abbreviations and acronyms	3	Define new or key terms, and provide a list of abbreviations and acronyms if applicable.
Corresponding developer	4	Identify at least one corresponding developer or author who can be contacted about the guideline.
Background		
Brief description of the health problem(s)	5	Describe the basic epidemiology of the problem, such as the prevalence/incidence, morbidity, mortality, and burden (including financial) resulting from the problem.
Aim(s) of the guideline and specific objectives	6	Describe the aim(s) of the guideline and specific objectives, such as improvements in health indicators (e.g., mortality and disease prevalence), quality of life, or cost savings.
Target population(s)	7a	Describe the primary population(s) that is addressed by the recommendation(s) in the guideline.
	7b	Describe any subgroups that are given special consideration in the guideline.
End- users and settings	8a	Describe the intended primary users of the guideline (such as primary care providers, clinical specialists, public health practitioners, program managers, and policy-makers) and other potential users of the guideline.
	8b	Describe the setting(s) for which the guideline is intended, such as primary care, low- and middle-income countries, or in-patient facilities.
Guideline development groups	9a	Describe how all contributors to the guideline development were selected and their roles and responsibilities (e.g., steering group, guideline panel, external reviewer, systematic review team, and methodologists).
	9b	List all individuals involved in developing the guideline, including their title, role(s) and institutional affiliation(s).
Evidence		
Healthcare questions	10a	State the key questions that were the basis for the recommendations in PICO (population, intervention, comparator, and outcome) or other format as appropriate.
	10b	Indicate how the outcomes were selected and sorted.
Systematic reviews	11a	Indicate whether the guideline is based on new systematic reviews

		done specifically for this guideline or whether existing systematic reviews were used.
	11b	If the guideline developers used existing systematic reviews, reference these and describe how those reviews were identified and assessed (provide the search strategies and the selection criteria, and describe how the risk of bias was evaluated) and whether they were updated.
Assessment of the certainty of the body of evidence	12	Describe the approach used to assess the certainty of the body of evidence.
Recommendations		
Recommendations	13a	Provide clear, precise, and actionable recommendations.
	13b	Present separate recommendations for important subgroups if the evidence suggests that there are important differences in factors influencing recommendations, particularly the balance of benefits and harms across subgroups.
	13c	Indicate the strength of recommendations and the certainty of the supporting evidence.
Rationale/explanation for recommendations	14a	Describe whether values and preferences of the target population(s) were considered in the formulation of each recommendation. If yes, describe the approaches and methods used to elicit or identify these values and preferences. If values and preferences were not considered, provide an explanation.
	14b	Describe whether cost and resource implications were considered in the formulation of recommendations. If yes, describe the specific approaches and methods used (such as cost-effectiveness analysis) and summarize the results. If resource issues were not considered, provide an explanation.
	14c	Describe other factors taken into consideration when formulating the recommendations, such as equity, feasibility and acceptability.
Evidence to decision processes	15	Describe the processes and approaches used by the guideline development group to make decisions, particularly the formulation of recommendations (such as how consensus was defined and achieved and whether voting was used).
Review and quality assurance		
External review	16	Indicate whether the draft guideline underwent independent review and, if so, how this was executed and the comments considered and addressed.
Quality assurance	17	Indicate whether the guideline was subjected to a quality assurance process. If yes, describe the process.
Funding, declaration and management of interest		
Funding source(s) and role(s) of the funder	18a	Describe the specific sources of funding for all stages of guideline development.
	18b	Describe the role of funder(s) in the different stages of guideline

		development and in the dissemination and implementation of the recommendations.
Declaration and management of interest	19a	Describe what types of conflicts (financial and non-financial) were relevant to guideline development.
	19b	Describe how conflicts of interest were evaluated and managed and how users of the guideline can access the declarations.
Other information		
Access	20	Describe where the guideline, its appendices, and other related documents can be accessed.
Suggestions for further research	21	Describe the gaps in the evidence and/or provide suggestions for future research.
Limitations of the guideline	22	Describe any limitations in the guideline development process (such as the development groups were not multidisciplinary or patients' values and preferences were not sought), and indicate how these limitations might have affected the validity of the recommendations.

Box. Glossary

Clinical practice guidelines are statements that include recommendations intended to optimize patient care that are informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options (3).

Health systems guidance is systematically developed statements produced at global or national levels to assist decisions about appropriate options for addressing a health systems challenge in a range of settings, and to assist with the implementation of these options and their monitoring and evaluation (8).

Executive summary is a relatively short, stand-alone summary of all the recommendations in a guideline along with other key points. It helps individuals find the recommendations quickly and aids implementation of the guideline. An executive summary differs from a journal abstract which has a fixed structure.

Systematic review (SR): A scientific investigation that focuses on a specific question and that uses explicit, planned scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. It may or may not include a quantitative synthesis (meta-analysis) of the results from separate studies (9).

Meta-analysis is a SR that uses statistical methods to combine quantitatively the results of similar studies in an attempt to allow inferences to be made from the sample of studies and be applied to the population of interest (9).

Health technology assessment (HTA) is the systematic evaluation of properties, effects and/or impacts of health technologies and interventions. It covers both the direct, intended consequences of technologies and interventions and their indirect, unintended consequences (10).

Conflict of interest is a set of conditions in which professional judgment concerning a primary interest (such as a patient's welfare or the validity of research) tends to be unduly influenced by a secondary interest (such as financial or academic gain) (11).

Intellectual conflict of interest is academic or other activity that creates the potential for an attachment to a specific point of view that could unduly affect an individual's judgment about a specific recommendation (12).

2. The RIGHT checklist items, examples and explanations

Title and subtitle

1a. Identify the report as a guideline, that is, with “guideline(s)” or “recommendation(s)” in the title.

Example 1

“HIV prevention in clinical care settings: 2014 recommendations of the International Antiviral Society-USA Panel” (13)

Explanation

Just as for randomized trials and systematic reviews, the ability to identify a report of a practice guideline in an electronic bibliographic database depends to a large extent on how it was indexed. A survey of guidelines at the World Health Organization (WHO) revealed that more than 30 terms were used to represent practice guidelines in their titles (6). Indexers may not classify a report as a practice guideline if the authors do not explicitly report this information (14). To help ensure that a guideline is appropriately indexed and easily identified, authors should use the word “guideline(s)” or “recommendation(s)” in the title.

1b. Describe the year of publication of the guideline.

Example 1

“KDOQI Clinical Practice Guideline for Hemodialysis Adequacy: 2015 Update” (15)

Explanation

Readers need to quickly determine whether a guideline is new or an updated version of an existing guideline along with the year of production. The year of publication is an indicator as to whether the guideline is up to date and thus whether the reader needs to look elsewhere for a valid guideline. The implementation of out-of-date recommendations can be harmful (16, 17). The RIGHT checklist does not cover reporting standards related to updating processes and methods because these are under development elsewhere (18).

1c. Describe the focus of the guideline, such as screening, diagnosis, treatment, management, prevention or others.

Example 1

“The United States Preventive Services Task Force Recommendations for Lung Cancer Screening” (19)

Example 2

“Health Care Guideline: Diagnosis and Treatment of Headache”(20)

Example 3

“2004 Prognosis of pulmonary arterial hypertension: ACCP evidence-based clinical practice guidelines” (21)

Explanation

A description of the primary focus or foci of a guideline will help readers to quickly determine whether it is relevant to their needs. The rapid increase in the number of practice guidelines may be an obstacle to the advancement of evidence-based health care (22). A study on the immediate care of 18 patients at an acute hospital identified 3679 pages of relevant national

guidelines and it was estimated that a physician would need 122 hours to read those guidelines (23). Readers need to rapidly judge a guideline's relevance to a specific clinical situation and thus the title should contain accurate and specific information.

Executive summary

2. Provide a summary of the recommendations contained in the guideline.

Example 1

“Executive Summary: Antithrombotic Therapy and Prevention of Thrombosis, 9th ed: American College of Chest Physicians Evidence-Based Clinical Practice Guidelines” (24)

Example 2

“Executive Summary: HFSA 2010 Comprehensive Heart Failure Practice Guideline Heart Failure Society of America” (25)

Explanation

Abstracts and executive summaries for guidelines vary widely in their content and format. One study (26) reported 42 different structures for abstracts or executive summaries in guidelines including 17 different sub-headings items: background, aim, design, method, result(s), conclusion(s), evidence, limitation, recommendation, population, participants, benefits, harms, cost, data source, evidence acquisition, and evidence synthesis. Some guidelines have both abstracts and executive summaries, some have only one of them, and some have neither. A well-constructed executive summary helps readers to find the recommendations quickly and aids implementation of the guideline. We propose that an executive summary includes the recommendations contained in the guideline along with other key points, and be placed before the main text of the guideline.

Abbreviations and acronyms

3. Define new or key terms and provide a list of abbreviations and acronyms if required.

Example

“Abbreviations and acronyms: ART: antiretroviral therapy; ARV: antiretroviral (drug). Definition of key terms: ART refers to the use of a combination of three or more ARV drugs to achieve viral suppression. This generally refers to lifelong treatment. Synonyms are combination ART and highly active ART.” (27)

Explanation

Clear definitions of new or key terms in a guideline and explanations of abbreviations and acronyms are essential for the end-users' understanding and ability to implement the recommendations. Different guidelines may use the same words to describe different concepts, or they may use different words to describe the same concept. Acronyms may be unfamiliar to the reader and have different meanings to different users. To avoid confusion and promote implementation of a guideline, developers should provide clear and accurate definitions, and explanations of abbreviations and acronyms at either the beginning or end of the guideline.

Corresponding developer

4. Identify at least one corresponding developer or author who can be contacted about the guideline.

Example

“Please send us feedback on this publication and share your experiences. Send your comments to Giuliano Gargioni, Stop TB Department, World Health Organization, 20 Avenue Appia CH-1211 Geneva 27 Switzerland. E-mail: gargionig@who.int” (28)

Explanation

It is common for guideline users to have questions and/or want to provide comments or suggestions to the guideline authors when they read and implement a guideline. It is thus essential that the guideline document include at least one corresponding author’s contact information or an official e-mail address of the developer that is regularly monitored and updated, so that users can submit queries and provide feedback. Ideally there should also be a website or link with up-to-date contact information for the guideline.

Brief description of the health problem(s)

5. Describe the basic epidemiology of the problem, such as the prevalence/incidence, morbidity and mortality, and burden (including financial) resulting from the problem.

Example 1

“...In countries with a low prevalence of HIV, opioid dependent individuals have been found to have an annual mortality of 2–4%, or 13 times that of their peers. Opioid dependence imposes a significant economic burden on society, not only in terms of directly attributable health-care costs (e.g. treatment and prevention services, and other health-care use), but also in terms of its impact on other budgets (notably social welfare and criminal justice services). Opioid dependence also has an effect on productivity, due to unemployment, absenteeism, and premature mortality.” (29)

Example 2

“According to recent estimates, more than 185 million people around the world have been infected with hepatitis C virus (HCV), of whom 350 000 die each year. The prevalence of hepatitis C infection varies substantially around the world. When countries are grouped into Global Burden of Disease regions, the estimated prevalence of HCV infection is highest in Central and East Asia and in the North Africa/Middle East regions. In view of the larger populations in Asia, the South Asia and East Asia regions have by far the largest number of persons living with HCV infection.” (30)

Example 3

“Health Care Burden: In 2007, 44% of AOE [Acute Otitis Externa]visits occurred in June through August, and the disease was least frequent in winter. Ambulatory visits for AOE were most common in the South (9.1 per 1000 population) and least common in the West (4.3 per 1000 population). Data from ambulatory care centers and emergency departments indicate that in 2007 there were about 2.4 million visits for AOE (8.1 visits per 1000 population), affecting 1 in 123 persons in the United States. Just less than half of all visits were for children 5 to 14 years of age. Lifetime incidence is up to 10%. Medical costs include physician visits and prescriptions for analgesics and systemic medications, such as antibiotics, steroids, or both. Direct costs are estimated at about half a billion dollars annually, and ambulatory care providers spent about 600,000 hours treating AOE. The indirect costs of AOE have not been calculated but are likely to be substantial because of severe and persistent otalgia that limits activities, especially work.”(31)

Explanation

Information on the epidemiology of a disease provides important background information for readers, and helps them to understand the disease burden, priorities and rationale for developing the guideline. It also provides important context for assessing applicability to the end-users' specific regional or local settings. The guideline document should include a summary of current key data on prevalence or incidence, morbidity, mortality and other key indicators.

Aim(s) of the guideline and specific objectives

6. Describe the aims of the guideline and specific objectives, such as improvements in health indicators (e.g., mortality and disease prevalence), quality of life, or cost savings.

Example 1

“The aims of the guideline are to: reduce global barriers to the effective treatment of opioid dependence; contribute to the development of evidence-based and ethical treatment policies for opioid dependence; contribute to improvement of the quality of pharmacological treatment of opioid dependence; facilitate implementation of effective treatment policies and programmes for opioid dependence.” (29)

Example 2

“The aims of the guideline are to: evaluate and summarise the clinical and cost evidence relating to all aspects of the diagnosis and treatment of Irritable Bowel Syndrome (IBS); highlight gaps in the research evidence; formulate evidence-based cost effective clinical practice recommendations relating to the diagnosis and treatment of IBS; and formulate consensus recommendations shaped around available evidence and expert GDG [Guideline Development Group] opinion in those areas of diagnosis and treatment of IBS where there is no clear clinical and cost effective evidence base.” (32)

Explanation

Aims are the general purpose of the guideline, for example to reduce global barriers, develop policies, reduce mortality, etc. Objectives are more specific and might usually reflect the PICO (population, intervention, comparator and outcomes) questions being addressed. They may be formulated as specific hypotheses or as focused questions that the guideline is designed to address and guideline developers should report them as clearly as possible.

Target population(s)/subgroup

7a Describe the primary population(s) that is addressed by the recommendation(s) in the guideline.

Example 1

“The target population is people who use opiates, cocaine or amphetamine type stimulants in a dependent or harmful way, especially those who inject drugs.” (33)

Example 2

“This guideline, however, does not apply to patients younger than 18 years or to patients of any age with complicated rhinosinusitis.” (34)

Example 3

“The target patient is aged 2 years or older with diffuse Acute Otitis Externa (AOE), defined as generalized inflammation of the external ear canal, with or without involvement of the pinna or tympanic membrane. This guideline does not apply to children younger than 2 years or to patients of any age with chronic or malignant (progressive necrotizing) otitis externa. AOE is

uncommon before 2 years of age, and very limited evidence exists regarding treatment or outcomes in this age group.” (31)

Explanation

The primary population(s) refers to the individuals and populations that will be primarily affected by the recommendations in the guideline. The description of the primary population(s) helps the reader decide to what extent the guideline is relevant and may meet their needs. Developers should also state any population(s) for which the guideline is not applicable.

7b. Describe any subgroups which are given special consideration in the guideline.

Example 1

“Tables 4.1–4.4 also summarize the chapter and section number of key recommendations and guidance for specific populations: pregnant and breastfeeding women, adolescents, children and infants, and key populations.” (27)

Example 2

“An initial consideration in the decision to offer screening to the population is the burden of disease overall and in age-specific subgroups. To address the question of age to begin and to stop screening, the Guideline Development Group examined a range of indicators, including age-specific incidence, mortality, age-specific incidence-based mortality, and years of potential life lost.” (35)

Explanation

It is important to describe how the recommendations in a guideline apply to different subpopulations: interventions may be more effective, less harmful, or only relevant to certain specific populations. Some populations may also need customized recommendations. Consideration of the needs of different subpopulations will help to focus on the needs of disadvantaged and under-served populations.

8a Describe the intended primary users of the guideline (such as primary care providers, clinical specialists, public health practitioners, program managers, and policy-makers) or other potential users of the guideline.

Example 1

“The target users are health care professionals who care for pregnant women, most frequently primary care physicians and obstetricians/gynaecologists. However, researchers and policy makers will also find it useful.” (36)

Example 2

“These guidelines are primarily targeted at policy-makers in ministries of health working in low- and middle-income countries who formulate country-specific treatment guidelines and who plan infectious diseases treatment programmes.” (30)

Example 3

“The guideline is intended for primary care and specialist clinicians, including otolaryngologists, head and neck surgeons, pediatricians, family physicians, emergency physicians, internists, nurse practitioners, and physician assistants.” (31)

Explanation

To promote the use of recommendations at the point of care delivery or in other settings where decisions are made, guidelines should have a clearly defined target audience, and the

recommendations need to be tailored to that audience. We suggest that developers distinguish between primary and secondary users. The primary users of the guideline can be defined broadly or described in detail, depending on the aims and content of the guideline. Examples of important distinctions to consider include clinicians versus public health agents and primary care physicians versus specialists.

8b Describe the setting(s) in which the guideline is intended to be primarily used, such as general practice (primary care), low- and middle-income countries, in-patient facilities.

Example 1

“The manual is intended primarily for use in low- and middle-income countries or regions that have already implemented or are successfully implementing the directly observed treatment, short-course (DOTS) strategy to control Tuberculosis (TB), at least within the government health infrastructure setting; or have adopted a national policy to develop, expand and strengthen primary health care (PHC) services; or have a high prevalence of HIV infection (since respiratory diseases are frequent complications in HIV-seropositive individuals).” (37)

Example 2

“Clinical practice guideline for the patient safety at surgery settings” (38)

Example 3

“The guideline is applicable to any setting in which children, adolescents, or adults with diffuse AOE would be identified, monitored, or managed.” (31)

Explanation

The description of the intended settings and locations is crucial to judge the applicability of recommendations to the user’s needs. For health policy and system guidance, developers should state whether the guidance is suitable globally or in specific regions, such as low- and middle-income countries. For clinical practice guidelines, settings might include, for example, community versus specialty hospitals, or inpatient versus outpatient settings.

Guideline development groups

9a Describe how all contributors to guideline development were selected and their roles and responsibilities (e.g., steering group, guideline panel, external reviewers, systematic review team, and methodologists).

Example 1

“The ACCP AT9 [American College of Chest Physicians - Antithrombotic 9] Executive Committee selected panel members for each article. A topic editor and a deputy editor led each of the AT9 panels issuing recommendations. The Executive Committee chose these individuals on the basis of their previous experience with guideline development and, in particular, their familiarity with methods developed by the Grades of Recommendation, Assessment, Development, and Evaluation (GRADE) Working Group.” (39)

Example 2

“The guideline working committee consisted of clinicians, cardiologists, electrophysiologists (including those specialized in pediatrics), and a nurse (in the role of patient representative) and included representatives from the ACC [American College of Cardiology], AHA [American Heart Association], and HRS [Heart Rhythm Society].”(40)

Example 3

“Group member selection and meeting process: The KDIGO Co-Chairs appointed the Co-Chairs of the Work Group, who then assembled the Work Group to be responsible for the development of the guideline. The Work Group consisted of domain experts, including individuals with expertise in nephrology, critical care medicine, internal medicine, pediatrics, cardiology, radiology, infectious diseases and epidemiology. For support in evidence review, expertise in methods, and guideline development, the NKF contracted with the Evidence Review Team (ERT) based primarily at the Tufts Center for Kidney Disease Guideline Development and Implementation at Tufts Medical Center in Boston, Massachusetts, USA. The ERT consisted of physician-methodologists with expertise in nephrology and internal medicine, and research associates and assistants. The ERT instructed and advised Work Group members in all steps of literature review, critical literature appraisal, and guideline development. The Work Group and the ERT collaborated closely throughout the project. The Work Group, KDIGO Co-Chairs, ERT, liaisons, and NKF support staff met for four 2-day meetings for training in the guideline development process, topic discussion, and consensus development.”
(41)

Explanation

In this item, guideline developers should report in detail the following information: 1) who was involved in development of the guideline (number of contributors and description of their expertise); 2) how these individuals were recruited and selected; and 3) how many subgroups were formed and the specific mission of each group. Studies have shown that the disciplines represented within a guideline development group have considerable influence on the recommendations (42). The guideline panel should achieve a topic-appropriate balance of relevant technical expertise and should include stakeholders with a wide variety of experiences and perspectives.

9b List all individuals involved in developing the guideline, including their title, roles and institutional affiliation(s).

Example 1

“Work Group Membership: Work group co-chairs: John A Kellum, MD, FCCM, FACP, University of Pittsburgh School of Medicine, Pittsburgh, PA; Work group: Peter Aspelin, MD, PhD, Karolinska University Hospital, Stockholm, Sweden; Evidence review team: Katrin Uhlig, MD, MS, Project Director; Director, Guideline Development, Tufts Center for Kidney Disease Guideline Development and Implementation, Tufts Medical Center, Boston, MA, USA. KDIGO [Kidney Disease: Improving Global Outcomes] Board Members: Founding KDIGO Co-Chairs: Norbert Lameire, MD, PhD; KDIGO Co-Chair: Kai-Uwe Eckardt, MD. NKF-KDIGO guideline development staff: Kerry Willis, PhD, Senior Vice-President for Scientific Activities; Michael Cheung, MA, Guideline Development Director; Sean Slifer, BA, Guideline Development Manager.” (41)

Explanation

The description of roles, professional background, expertise, and prior training of individuals involved in developing the guideline helps readers judge the quality and credibility of the guideline. It also enables readers to contact or collaborate with those individuals. The information can either be in the body of the guideline or in an appendix.

Healthcare questions

10a State the key questions that were the basis for the systematic reviews in PICO (population, intervention, comparator(s) and outcome) or other formats as appropriate.

Example 1

“Narrative review question: Are behavioral interventions targeting alcohol consumption effective among persons with chronic HCV infection?”

PICO question:

Population: Individuals with chronic HCV infection

Intervention: Behavioral alcohol-reduction interventions

Comparison: No behavioral alcohol-reduction intervention

Outcomes: Reduction or cessation of alcohol intake, sustained virologic response (SVR), liver fibrosis, decompensated liver cirrhosis (DCC), hepatocellular carcinoma (HCC), quality of life, all-cause mortality” (30)

10b Indicate how the outcomes were selected and sorted.

Example 1

These important outcomes were applied to the published results as well as data that were provided to WHO by the drug manufacturer (Otsuka). Subsequently, the following outcomes were evaluated for the evidence profile:

1. Sputum culture conversion at two months
2. Time to sputum culture conversion over the first two months of treatment
3. Sustained sputum culture conversion at 24 months
4. Cure at 24 months
5. Mortality at 24 months
6. Serious adverse events
7. Acquired resistance to delamanid.

These different outcomes were scored by the EG (Expert Group) members on a scale from 1 to 9 based on their relative importance; all were considered “critical.” (44)

Example 2

“Eight potentially important outcomes were initially identified by two reviewers (MK, ADO). This list was circulated to the panel chair (HJS), WHO staff, and the scientific reviewers by email for independent scoring of the relative importance of each outcome. Scores were rated on a scale from 1 to 9: a rating of 7–9 indicated the outcome was critical for a decision or recommendation, 4–6 indicated that it was important, and 1–3 indicated that it was not important. Because the relative importance of some outcomes depended on whether a drug was being used for treatment or chemoprophylaxis, these two methods were considered separately. For all ratings, the means of the panel members’ ratings established the relative importance of the outcomes. The Cochrane Consumers network was consulted and this generated four responses, but the ratings did not differ substantially from those of the panel.” (45)

Explanation

A good healthcare question should be clear and focused. The PICO framework is a helpful, structured approach for developing questions about interventions. The PICO framework also helps to guide the literature searches and evidence syntheses that inform the recommendations in a guideline. For guidelines on screening, diagnosis, prognosis, or prevention, developers may choose a different structured approach to form questions. The choice of outcomes is critical in

the development of PICO questions because they impact the balance of benefits and harms upon which recommendations are based and readers need to know how and why outcomes were selected.

Systematic reviews

11a Indicate whether the guideline is based on systematic reviews, and in that case whether those were new done specifically for this guideline or whether existing systematic reviews were used or update.

11b If the guideline developers used existing systematic reviews, reference these and describe how those reviews were identified and assessed (provide the search strategies and the selection criteria, and describe how the risk of bias was evaluated) and whether they were updated.

Example 1

“By the end of July 2011 a set of scoping questions had been finalized. These were then used to guide searches for relevant systematic reviews that had been performed within the last two years and met inclusion criteria (see evidence profiles 1–21 in Annex 5 for specific inclusion and exclusion criteria). Where relevant systematic reviews (a) did not exist, (b) were not recent (had not been done within the last two years) or (c) were not of suitable quality or applicability, new systematic reviews were commissioned. For the new commissioned systematic review on medicines for post-traumatic stress disorder (PTSD), specific additional searches were carried out to identify studies in Japanese, Chinese, French, Portuguese, Russian and Spanish. Jonathan Bisson (Cardiff University) led the development of a new systematic review on pharmacological interventions for posttraumatic stress disorder.” (43)

Example 2

“The McMaster University guideline group updated the systematic reviews that were related to the selected questions by searching for trials that were subsequently published in the Cochrane Central Register of Controlled Trials, MEDLINE, and EMBASE until November 2013. When relevant, the meta-analyses were updated.” (46)

Example 3

“An independent Evidence Review Committee (ERC) was commissioned to perform a systematic review of key clinical questions, the results of which were considered by the Guideline Writing Committee (GWC) for incorporation into this guideline. The systematic review report on the management of asymptomatic patients with Wolff-Parkinson-White (WPW) syndrome is published in conjunction with this guideline.” (47)

Explanation

The U.S. Institute of Medicine revised the definition of a clinical practice guideline in 2011, which now emphasizes that a guideline should be based on systematic reviews (3). The guideline should explicitly indicate whether it was based on systematic reviews, and link to those reviews. If developers use existing systematic reviews, it is critically important that they report how they were identified and evaluated. The Cochrane Library, Epistemonikos (48) and PROSPERO (49) are useful databases for identifying published and registered systematic reviews. The guideline should specify which if any quality assessment tool was used (for example, ROBIS (Risk of Bias in Systematic Reviews) (50) to assess the reviews and whether those systematic reviews were updated.

Assessment of the certainty of the body of evidence

12 Describe the approach used to assess the certainty of the body of evidence.

Example

“We assessed evidence across studies on an outcome-by-outcome basis using criteria suggested by the GRADE Working Group. We defined quality of evidence as our confidence in the estimate of the effect to support a recommendation.” (39)

Explanation

Guidelines developers should report which rating system they used, the rationale for that choice, and briefly describe the approach and provide key citations. They should indicate whether this assessment was done in duplicate and the experience of those who conducted the assessment. Ideally guidelines developers should use an established and standardized approach such as GRADE.

Recommendations

13a Provide clear, precise, actionable recommendations

Example 1

“In patients with AR [allergic rhinitis], we suggest that clinicians do not administer and patients do not use oral decongestants regularly (conditional recommendation | low quality evidence). Underlying values and preferences: This recommendation places a relatively high value on avoiding adverse effects of oral decongestants, and a relatively low value on possible small reduction in symptoms of rhinitis.”

“Remarks: Oral decongestants may be of benefit for some patients as a rescue or “as needed” medication.”(51)

Example 2

“Adults aged 18–64 should do at least 150 minutes of moderate-intensity aerobic physical activity throughout the week or do at least 75 minutes of vigorous-intensity aerobic physical activity throughout the week or an equivalent combination of moderate- and vigorous-intensity activity.” (32)

Example 3

“We recommend metoclopramide at a dose of 10–20 mg IV for the acute treatment of migraine. Strong recommendation, moderate-quality evidence.” (52)

Explanation

Ambiguity and vague recommendations reduce the likelihood of uptake of and adherence to guideline recommendations. In addition, unclear recommendations can lead to inconsistent interpretation and possibly to medical errors and inappropriate variation in practice (53). To improve clarity and to facilitate implementation, the components of PICO can be used when writing recommendations related to interventions.(54). Presenting information in the same sequence as in a typical patient encounter (e.g., diagnosis before treatment) may improve clinicians’ understanding (55). Lists, tables, bolded subheadings, and algorithms are preferred over lengthy uninterrupted text (56). Also, the recommendations might be followed by ‘remarks’ that clarify the “conditions” under which the recommendation’s benefits would be maximized (e.g., a subgroup or specific approach to implementing the intervention).

13b Present separate recommendations for important subgroups if the evidence suggests that

there are important differences in factors influencing recommendations, particularly the balance of health benefits and harms across subgroups.

Example

“Serum TSH [Thyroid-stimulating hormone] should be measured during the initial evaluation of a patient with a thyroid nodule. (Strong recommendation, Moderate-quality evidence).” (57)

Explanation

The strength of a recommendation informs users of the degree of the guideline panel’s confidence about the balance between the desirable and undesirable consequences of implementing the recommendation. The certainty of evidence reflects the degree of confidence in the estimates of effect of an intervention considered in the recommendation. Guideline panels should use widely accepted rating systems to present these indicators (58). If a letter or number system is used, provide a clear and transparent explanation for the interpretation of each category (59, 60).

13c Indicate the strength of recommendations and the certainty of evidence.

Example

“1) We recommend targeted temperature management as opposed to no targeted temperature management for adults with OHCA [out-of-hospital cardiac arrest] with an initial shockable rhythm who remain unresponsive after ROSC [return of spontaneous circulation] (strong recommendation, low-quality evidence). 2) We suggest targeted temperature management as opposed to no targeted temperature management for adults with OHCA with an initial nonshockable rhythm (weak recommendation, very low-quality evidence) who remain unresponsive after ROSC. 3) We suggest targeted temperature management as opposed to no targeted temperature management for adults with IHCA [in-hospital cardiac arrest] (weak recommendation, very low-quality evidence) with any initial rhythm who remain unresponsive after ROSC.” (61)

Explanation

Recommendations may differ across subpopulations for a number of reasons, including differences in the baseline risk of an outcome, and different relative effects of the intervention on specific outcomes. For instance, warfarin therapy is associated with both a higher risk of serious bleeding and inconvenience, and therefore is more strongly recommended for patients with atrial fibrillation who are at substantial risk of stroke than for general populations. Thus when there is evidence of potentially important differences in outcomes across subpopulations, guideline developers should define separate questions, produce separate evidence summaries, and consider specific recommendations for specific subpopulations (62).

Rationale/explanation for recommendations

14a Describe whether values and preferences of the target population(s) were considered in the formulation of each recommendation. If yes, describe the approaches and methods used to elicit or identify these values and preferences. If values and preferences were not considered, provide an explanation.

Example 1

“The AT9 panel has accelerated that process by conducting a systematic review of the relevant research of empirical investigations of values and preferences of patients regarding

antithrombotic therapy. Based on that review, AT9 panelists conducted a value rating exercise that provided the basis for values and preference judgments within AT9, judgments that are summarized in the introductory section of each article.” (63)

Example 2

“The GDG agreed with evidence from qualitative studies about patient values and preferences. This evidence suggests women could fear screening and could have high anxiety related to colposcopy/treatment, and experience greater burden with a second visit for treatment. However, once women decide to undergo screening, they find screening tests and immediate treatment acceptable. Women also showed preference for more frequent screening and active management as opposed to treatment when screening is positive for CIN1. Additionally, evidence from controlled trials shows that women probably find cryotherapy and LEEP acceptable treatments, and are satisfied with screen-and-treat programs.” (64)

Explanation

To be implementable, guidelines should consider the values and preferences of the populations that will be affected by the recommendations. There is evidence that patient preferences and motivation for treatment positively affect outcomes (65). However, only one-fifth of guidelines reported the precise role of patient preferences in decision making, and only 6 percent of guidelines described how the values were considered by developers when formulating recommendations (66). This item will encourage developers to report whether the uncertainty and variability of values and preferences was taken into account when recommendations were developed.

14b Describe whether cost and resource implications were considered in the formulation of recommendations. If yes, describe the specific approaches and methods used (such as cost-effectiveness analysis) and summarize the results. If resource issues were not considered, provide an explanation.

Example 1.

“a. Strong recommendation favoring A when high quality evidence from economic evaluations shows that A costs up to 3 times the gross domestic product (GDP) per capita (up to approximately US \$150,000) per quality-adjusted life year (QALY) gained relative to B.

b. Weak recommendation favoring A when high quality evidence from economic evaluations shows that A costs 3 to 5 times the GDP per capita (\$150,000-\$250,000) per QALY gained relative to B.

c. Weak recommendation favoring B when high quality evidence from economic evaluations shows that A costs more than 5 times the GDP per capita (> \$250,000) per QALY gained relative to B.” (39)

Example 2.

“Modelling of the incremental cost-effectiveness of adding bedaquiline to WHO [World Health Organization] recommended MDR-TB [multi-drug-resistant tuberculosis] regimens was conducted by an independent consultant contracted by WHO for review by the EG [expert group]. The model assumed that bedaquiline would be added to treatments for all patients starting MDR-TB treatment. Data from WHO were available on current MDR-TB treatment

costs (excluding programme costs) and effectiveness in several high TB burden settings. Several scenarios were explored to appraise the cost-effectiveness of bedaquiline in these settings. Under the model assumptions, the bedaquiline-containing regimens were assessed as relatively cost effective in most settings, but results were ambiguous in low-income settings and highly dependent on the assumptions made about the generalizability of trial results to routine settings. The EG noted that further analysis would be needed to test the robustness of the assumptions in various settings and to separately assess affordability.

As the recommendation of the EG was to use bedaquiline only for selected sub-groups of the full MDR-TB patient population, as opposed to all patients with MDR-TB that were considered in the cost-effectiveness analysis, the cost-effectiveness model needs to be further refined such that results are available for these sub-groups specifically.” (67)

Explanation

Resource considerations are generally included in the formulation of recommendations, unless there is a deliberate and explicit decision to omit them. The reason for considering costs is clearly stated: ‘Health interventions are not free, people are not infinitely rich, and the budgets of [healthcare] programs are limited. For every dollar’s worth of healthcare that is consumed, a dollar will be paid. While these payments can be laundered, disguised or hidden, they will not go away’ (68). The strength of a recommendation and even its direction may change after taking into account the resource implications of alternative management strategies (39). Guideline developers should report the resource implications of recommendations (e.g., estimates of resource needs) and the methods used to inform those implications (e.g., a search for existing economic evaluations or the conduct of economic analyses) (69).

14c Describe other factors taken into consideration when formulating the recommendations, such as equity, feasibility and acceptability.

Example 1

“A field test with a pre-post design was conducted in two district-level hospitals each in Ghana, India, Pakistan and Uganda in 2008-9. The objectives of the field test were to evaluate the feasibility and acceptability of implementing the guidelines and to document the effect of guideline implementation on the knowledge and skills of health workers and mothers.” (70)

Example 2

“Other considerations: The SEP [Saudi Expert Panel] judged home treatment of DVT [deep venous thrombosis] to be acceptable to physicians and the Saudi MoH [Ministry of Health]. However, they were concerned with the lack of ultrasound service after 4:30 P.M. and on weekends in emergency rooms.” (46)

Explanation

In addition to efficacy, safety and resource use, other issues such as equity, feasibility and acceptability can be relevant to the formulation of recommendations. These factors have particular importance in the development of public health, health system and health policy recommendations. For example, many factors can influence the feasibility of implementing population health interventions, including the available resources, programmatic considerations, existing and necessary infrastructure, and health worker expertise and the availability of training. Options that are considered to be less feasible (i.e. the greater the barriers to its implementation), are less likely to be strongly recommended. Acceptability is affected by

several factors, such as who benefits from an intervention and who is harmed by it; who pays for it or saves money on account of it; and when the benefits, harms and costs occur. The more acceptable an option is to all or most stakeholders, the more likely it is that a strong recommendation will be issued (71).

Evidence to Decision Processes

15 Describe processes and approaches used by the guideline development group to make decisions, particularly the formulation of recommendations (such as how consensus was defined and achieved and whether voting was used).

Example 1

“An expert consensus process was conducted using the Delphi method. The Delphi process was conducted by e-mail. Each set of seed statements to be rated was identified by an identification (ID) number. The Delphi process was conducted in a blinded manner, so that neither the panelists nor the core committee knew the identity of the raters or those who had made any individual comments, during the development of consensus. The guideline developers considered consensus present when both the median rating was 7 or higher and at least 80% of the panelists gave a rating of 7 or higher. Rounds were to be repeated until consensus was reached.” (72)

Example 2

“An iterative course of action ensued, using a Modified Delphi technique with the National Advisory Panel (NAP), to produce final recommendations. NAP member identities were blind to the Research Group and each other until the last round of review. NAP received material via email and responded using an on-line survey tool to rate their opinion on relevance, feasibility, clarity, and their degree of agreement with each recommendation. They also provided open-ended narrative comments. Consensus was defined as 80% of NAP members supporting a recommendation. Recommendations that did not receive this level of consensus were revised using feedback provided by NAP and re-rated in the next round. With each round of review, each NAP member received a complete transcript of all written comments made by NAP in the previous round.” (73)

Explanation

The processes and procedures used by the guideline panel to formulate the recommendations and to make other group decisions should be clearly described in the final guideline to ensure transparency of the development process. Evidence suggests that formal consensus development methods generally work as well as, or better than, informal methods (74). If the decision-making process was based on consensus, guideline developers should report the method used to achieve this (e.g., iterative discussions, the Delphi approach, or Nominal Group Technique) and who specifically contributed. If voting was used to make decisions on recommendations, the authors should indicate whether voting was anonymous (e.g., using an audience response system), and present the results while maintaining anonymity of the participants. Evidence-to-decision frameworks (75) are extremely helpful in facilitating decision-making by whatever process is used.

External reviewer and quality assurance

16 Indicate whether the draft guideline underwent independent review, and if so, how this was executed and the comments considered and addressed.

Example 1

“In total 78 people (from all six WHO regions) were contacted to review evidence profiles with draft recommendations, and 22 people responded within the time allotted (two weeks). Their names, affiliations and geographical base are given in Annex 3 and their declarations of interest are summarized in Annex 4. In November 2012, selected external reviewers were also asked to review an early version of this final guideline document. Their compiled and processed responses should help to ensure that the document is understandable. A limitation of the process was that peer reviewers were not asked to comment early in the process on scoping questions and outcomes.” (43)

Example 2

“This document was reviewed by 8 official reviewers nominated by the ACC [American College of Cardiology], AHA [American Heart Association], and HRS [Heart Rhythm Society], and 25 individual content reviewers. Reviewers’ RWI [Relationships With Industry] information was distributed to the GWC [Guideline Writing Committee] and is published in this document (Appendix 2).” (40)

Explanation

A limited number of experts and perspectives can be represented within a guideline development team, hence guideline developers may share protocols, lists of questions to be addressed, and draft recommendations with a diverse group of external reviewers. These may include guideline users, specialty groups, and representatives from relevant industries. External review promotes scientific accuracy, clarity, and the ultimate usefulness of the guidelines. After all comments have been received, guideline group members should compile the comments and discuss them with the panel members to determine if changes in the draft guideline are needed. External reviewers should be acknowledged in the guideline document. To ensure transparency, the detailed process of external review (such as the approach for selection of external reviewers, the time provided for the reviews and the methods used to evaluate and dispose of reviewer comments) should be reported in the guideline.

17 Indicate whether the guideline was subject to a quality assurance process. If yes, describe the process.

Example 1

“The work group submits the final guideline for approval by the Committee on Evidence Based Quality and Value, Council on Research and Quality, and Board of Directors. These decision-making bodies are described in Appendix II and are not designated to modify the contents. Their charge is to approve or reject its publication by majority vote.” (76)

Example 2

“This document was approved for publication by the governing bodies of the ACC, the AHA, and the HRS.” (40)

Explanation

For guideline development, it is often necessary to obtain organizational approval, and political, technical or financial support. Approval from organizations or governments can promote the guideline’s credibility, acceptability, adoption and implementation. Approval differs from

external review because the former emphasizes accreditation and accountability while the later focuses on the methods and procedures of guideline development. Different guidelines are approved by different agencies or organizations. For example, guidelines from the American Dental Association are subject to the approval of American Dental Association Council on Scientific Affairs (CSA) (77). Developers should report when and to whom they submitted their guidelines and whether the guideline was approved.

Funding sources and roles

18a Describe the specific sources of funding for all stages of guideline development.

Example

“Funding/Support: This work is supported and funded by the IAS [International Antiviral Society]-USA, a mission-based, non-membership, 501(c) (3) not-for-profit organization. The IAS-USA appointed panel members to develop the guidelines and provide staff support.” (78)

Explanation

The funder of a guideline may have interests that conflict with the objective assessment, synthesis and presentation of the evidence, and with the unbiased formulation of recommendations. Thus the reader needs to know who the funder was so that they can evaluate the potential impact. Guideline developers should disclose all sources of financial and non-financial support for their guideline.

18b Describe the role of funder(s) in the different stages of the guideline development and in the dissemination and implementation of the recommendations.

Example 1

“Role of the Sponsor: The IAS-USA determined the need for updated recommendations, selected the panel members based on expertise in research and care to broadly represent developed-world settings affected by HIV disease, and provided administrative oversight and financial support. The panel itself is responsible for the design and conduct of the study; collection, management, analysis, and interpretation of the data; and preparation, review, or approval of the manuscript.” (78)

Example 2

Sponsor’s Role: None (79)

Explanation

Guideline development should be objective and independent: they should not be influenced by any institutions, organizations or companies with direct financial or other interests. Guideline developers should report any interactions with or potential influence of funders during the development process and note how this may have affected the recommendations.

Declaration of conflicts of interest

19a Describe what types of conflicts (financial and non-financial) were relevant to guideline development.

Example 1

“All nominated GDG [Guideline Development Group] members, external reviewers and consultants completed WHO declaration of interest forms. Several GDG members declared interests at the time of their nomination. These were then reviewed by the WHO Secretariat for

potential conflicts of interest (see summary in Annex 4). It was decided that none of the nominated GDG members had a conflict of interest that would preclude their participation. At the beginning of the recommendation drafting meeting (Amman, July 2012), the natures of all types of conflict of interest – financial, academic/intellectual, non-academic – were explained by WHO consultants with substantial experience in WHO guideline development. Each participant then described in detail the areas where they had potentially real or perceived conflicts of interest, including intellectual conflicts of interest. The session took about one hour. At this time, all participants were asked to review and, if necessary, update their declaration of interest forms.

Upon review of the declaration of interest forms, the WHO Secretariat and one GDG member (Dr Seedat) agreed that Dr Seedat may have a perceived conflict of interest on decisions related to pharmacological treatment of PTSD [Post-traumatic stress disorder], because she had received financial support to attend conferences (total limited to \$5000 over nine years) from pharmaceutical companies. She recused herself from decision-making and drafting of recommendations involving pharmacological management of PTSD. Dr Cohen, a GDG member who according to her form may have had a perceived conflict of interest related to psychological treatment of PTSD did not attend the meeting.” (43)

Example 2

“Kidney Disease: Improving Global Outcomes (KDIGO) makes every effort to avoid any actual or reasonably perceived conflicts of interest that may arise as a result of an outside relationship or a personal, professional, or business interest of a member of the Work Group. All members of the Work Group are required to complete, sign, and submit a disclosure and attestation form showing all such relationships that might be perceived or actual conflicts of interest. This document is updated annually and information is adjusted accordingly. All reported information is published in its entirety at the end of this document in the Work Group members’ Biographical and Disclosure Information section, and is kept on file at the National Kidney Foundation (NKF), Managing Agent for KDIGO.” (41)

Explanation

Conflict of interest (COI) is an important potential source of bias in the development of practice guidelines. Biased practice guidelines can have profound implications for health care and ultimately patient outcomes. In addition to personal financial interests, institutional interests as well as professional and intellectual interests are increasingly recognized and may be powerful motivators for researchers, systematic reviewers, and guideline authors. Levinsky compared financial to nonfinancial COI and described the latter as “more subtle yet more pervasive and [they] cannot be eliminated” (80). The guideline report should indicate whether individuals who had direct input into the guideline signed and updated their declaration of interest forms.

19b Describe how conflicts of interest were evaluated and managed, and how users of the guideline access the declarations.

Example 1

“Potential Conflicts of Interest: Disclosure forms from USPSTF [US Preventive Services Task Force] members can be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNumM12-1607.” (81)

Example 2

“Committee members signed a confidentiality agreement and disclosed all potential conflicts of interest according to the ATS [American Thoracic Society] and ERS [European Respiratory Society] policies. Two of the co-chairs (G.R. and H.J.S.) reviewed all potential conflicts of interest of committee members with the staff of the ATS conflict of interest and documents units. All of the eight pulmonologists with recognized IPF expertise (G.R., F.J.M., H.R.C., A.U.W., J.B., L.R., A.A., and M.S.) were considered to either have major financial or intellectual conflicts based on disclosures or participation in IPF [Idiopathic Pulmonary Fibrosis] clinical trials/studies (6); although they were permitted to participate in the discussions of the evidence with the rest of the committee, they were instructed to abstain from discussions related to the evidence to decision framework (described later), formulating and grading recommendations, and voting on recommendations if necessary. This approach was applied to all questions, not just those in which they had a perceived conflict of interest. Conflicted members were allowed to stay in the same room while discussions among non-conflicted members took place to provide expert input; however, they could do so only when specifically requested by non-conflicted members. Adherence to the rules was strict, with one of the co-chairs (H.J.S.) responsible for monitoring the discussions for adherence to these rules. The remaining nine non-conflicted committee members (A.T., S.H., H.H., H.J.S., J.L.B., D.R., T.J., J.M., and W.C.) were allowed unrestricted participation. Two of the voting members were members of the MG; they are clinicians with extensive expertise in the guideline development process (H.J.S. and J.L.B.). The rest of the MG [Methods Group] and the librarian also participated in discussions, but were nonvoting participants.” (82).

Explanation

The guideline should indicate how declarations of interests were evaluated and how management plans for any conflicts were developed. The management plan for significant conflicts disclosed by individual contributors should be summarized in the guideline Declaration of interests should be securely stored according to local regulations, and the information readily available. Most guideline development agencies, for example the National Institute for Health and Care Excellence (NICE) (83) and the World Health Organization (WHO) (84) publish conflicts of interest of any contributors in the final guideline.

Access

20 Describe where the guideline, its appendices, and other related documents can be accessed.

Example 1

“The standardized criteria used in grading the evidence, the narrative summaries of evidence and GRADE tables are not included in this document. This material has been published in a separate document entitled “WHO recommendations for postpartum haemorrhage: evidence base” and can be accessed online at:

www.who.int/

reproductivehealth/publications/maternal_perinatal_health/9789241548502/en/” (85).

Example 2

“More information, including a Data Supplement with additional evidence tables, a Methodology Supplement with information about evidence quality and strength of

recommendations, slide sets, and clinical tools and resources, is available at <http://www.asco.org/guidelines/metastaticbreastmarkers>. Patient information is available at <http://www.cancer.net>" (86).

Explanation

Ideally, guideline developers should disseminate their guidelines as widely as possible. Guidelines can be published as papers in journals or as books. They can also appear on the internet in a variety of formats, including applications for portable devices. In some cases, guideline developers may publish decision support tools along with the guidelines (e.g., decision aids, risks calculators). Developers must make sure that all documents relevant to the guideline's development and implementation are readily available, with linkages or references to sources available elsewhere in the public domain. These documents help users to understand the development process and to implement the recommendations.

Suggestions for further research

21 Describe the gaps in the evidence and/or provide suggestions for future research.

Example 1

"Future Research: Several questions in the treatment of venous thromboembolism (VTE) need to be answered. Current evidence relating to these questions is of moderate or low quality. We list the questions roughly as they arise in this article rather than in order of importance. We are pleased to note that many of these questions are being addressed in ongoing trials.

- Should patients with an isolated distal DVT routinely be treated with anticoagulant therapy, or should they have serial testing to determine whether the DVT is extending and only be treated if extension is detected?
- Which patients with unprovoked proximal DVT or PE or cancer-associated VTE should stop anticoagulant therapy at 3 months, and which should remain on extended anticoagulant therapy?" (87)

Example 2

"Research Recommendations: The influence of urinary output criteria on AKI staging needs to be further investigated. Influence of fluid balance, percent volume overload, diuretic use, and differing weights (actual, ideal body weight, lean body mass) should be considered. Also, it is currently not known how urine volume criteria should be applied (e.g., average vs. persistent reduction for the period specified)." (41)

Example 3

"5.3. Research implications

The EG [Expert Group] strongly supported the need for an acceleration of Phase III trials to expand knowledge on safety and efficacy of bedaquiline, with particular attention to mortality (including causes of death), in the treatment of MDR-TB. The EG identified further research gaps, including:

- development of a reliable drug susceptibility test for bedaquiline;
- pharmacokinetics, safety and efficacy studies in specific populations (infants and children, HIV patients – especially those on antiretroviral therapy (ART), alcohol and substance users, elderly people, pregnant or nursing women, people with extrapulmonary TB, people with diabetes);

- safety studies, including type, frequency and severity of adverse events (short and long term), and mortality (including cause of death);
- drug–drug interactions, including with other existing and newly developed TB drugs and ART [antiretroviral therapy];
- acquisition of resistance to bedaquiline and to other TB drugs;
- identification of optimal combination of drugs including bedaquiline and determination of optimal duration and dosing of treatment;
- patient acceptability;
- appropriate cost-effectiveness studies.” (44)

Explanation

A research gap is a topic or area for which missing or inadequate information limits the ability of developers to reach a conclusion on a given question. Identifying gaps in the scientific evidence, providing suggestions to help guide future research, and discussing topics with limited evidence allow guideline developers to highlight future research needs and suggest how to best fill existing gaps (88). These gaps could relate to the benefits and harms of the interventions, the baseline risk of the outcomes of interest, the values and preferences of persons affected by the recommendations, cost or resource impact, effects on equity across sub-populations, and to the feasibility and acceptability of implementation of the intervention.

Limitations of the guideline

22 Describe any limitations in the guideline development process (such as the development groups were not multidisciplinary or patients’ values and preferences were not sought), and indicate how these limitations might have affected the validity of the recommendations.

Example 1

“No medical librarian was involved in searching evidence and no social worker and parents participated in guideline development. We restricted our search languages in Chinese and English, and did not retrieval the grey literature. Five Meta analyses used in this guideline were mainly based on published data. The pediatricians of the panel meeting were all from the mainland China. Although experts who participated the meeting have signed the declaration of interest form before Delphi voting, we still felt difficult to judge the influence of their conflicts of interest on the guideline.” (89)

Explanation

Even the best-developed guidelines are likely to have limitations and acknowledgment of those limitations increases the trustworthiness of the guideline. It is particularly important to discuss whether limitations might have affected the recommendations, and what their potential impact might be. We suggest that the following topics should be discussed, if applicable.

1. Risk of bias in data collection: for example, whether the scientific evidence that supports the recommendations is based on systematic reviews, or if the evidence is lacking or of poor quality.
2. Conflicts of interest: for example, if recommendations might have been influenced by pharmaceutical companies and/or opinion leaders.
3. The development process: for example, if the guideline development group was multidisciplinary and if formal consensus methods were used.

4. Determinants of each recommendation: for example, whether the values and preferences of patients, use of resources, effects on equity across subpopulations, and feasibility were considered when making the recommendations.

Discussion

Evidence suggests that reporting standards improve the reporting quality of research. (90-92). To our knowledge, the RIGHT checklist is the first document that provides a comprehensive list of items that should be reported in a high-quality practice guideline. We hope that this explanatory paper will become a pedagogical document that will be used not only by guideline developers, but also by guideline users. Peer reviewers, editors, and other interested readers may also find the paper helpful when reading and using practice guidelines. Journal editors as well as funders and sponsors of guidelines can encourage authors of practice guidelines to comply with the RIGHT checklist. We invite readers to provide feedback on the RIGHT checklist and we welcome suggestions and comments regarding how it can be improved and kept relevant as the science of research synthesis and guideline development evolves.

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Current author addresses and author contributions are available at www.annals.org.

Disclaimer

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

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reports other (part-time salary report) from the Singapore Ministry of Health outside the submitted work. Dr. Falck-Ytter is a member of the GRADE Working Group. Authors not named here have disclosed no conflicts of interest. Disclosures can also be viewed at www.acponline.org/authors/icmje/ConflictOfInterestForms.do?msNum=M16-1565.

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