

External review of the SBC Guidelines according to the AGREE II tool - Do we need to review our Guidelines?

Revisão externa das Diretrizes da SBC segundo a ferramenta AGREE II - Precisamos rever nossas Diretrizes?

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ABSTRACT | INTRODUCTION: Clinical guidelines should be systematically prepared documents that aim primarily to provide the best available medical information to support the decisions of patients and health professionals. Managers can also use them for the formulation of public policies. **OBJECTIVE:** To evaluate the methodological quality of three clinical guidelines of the Brazilian Society of Cardiology (SBC) according to an internationally accepted tool for this purpose and suggest improvements to the preparation of such documents. **METHODS:** Twelve independent evaluators (four per document) used the AGREE II tool to methodologically evaluate three clinical guidelines of the SBC that address issues of extreme importance and prevalence in the human population: arterial hypertension, diabetes, and dyslipidemia. **RESULTS:** According to the evaluations of the three guidelines, due to the low scores received in the domains Stakeholder Involvement, Applicability of the Guideline, and, especially, Rigor of Development, two of them were deemed to have an unsatisfactory elaboration method. **CONCLUSION:** The methodological quality of the clinical guidelines of the SBC was deemed unsatisfactory. In this article, we suggest strategies to improve the process of preparing future documents.

KEYWORDS: Guideline [Publication Type]. Methods. Cardiology.

RESUMO | INTRODUÇÃO: Diretrizes Clínicas devem ser documentos elaborados de forma sistemática que visam em primeiro lugar apoiar com a melhor informação médica disponível a decisão de um paciente e de um profissional de saúde. Adicionalmente também podem ser utilizadas pelo gestor para a formulação de políticas públicas. **OBJETIVO:** Avaliar a qualidade metodológica de 3 Diretrizes Clínicas da Sociedade Brasileira de Cardiologia (SBC) segundo uma ferramenta aceita internacionalmente para esta finalidade, e sugerir melhorias na elaboração deste tipo de documento. **MÉTODOS:** 12 avaliadores independentes (4 por documento) utilizaram a ferramenta AGREE II para avaliar metodologicamente três Diretrizes Clínicas da SBC que abordam assuntos de extrema importância e prevalência na população mundial: Hipertensão Arterial, Diabetes e Dislipidemia. **RESULTADOS:** Segundo a avaliação das 3 Diretrizes, pelos baixos escores recebidos principalmente nos domínios de Envolvimento das Partes Interessadas, Aplicabilidade da Diretriz e em especial no Rigor do Desenvolvimento, 2 delas foram consideradas com uma metodologia de elaboração insatisfatória. **CONCLUSÃO:** A qualidade metodológica das Diretrizes Clínicas da SBC foi considerada insatisfatória. Sugerimos neste artigo estratégias para aprimorar o processo de elaboração de futuros documentos.

PALAVRAS-CHAVE: Diretriz [Tipo de publicação]. Métodos. Cardiologia.

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Introduction

Clinical guidelines should be systematically prepared documents that aim primarily to provide the best available medical information to support the decision of a patient and a health professional in a specific clinical situation. Managers can also use them to formulate public policies.¹

The potential benefits of a clinical guideline are proportional to the methodological quality with which it was developed. Guidelines published in the medical literature, in general, have not adhered to established standards of methodological rigor.³ As a result, their quality can vary greatly and, in some cases, may fall far short of what we consider ideal, so they can potentially harm the medical care derived from them.³ While all clinical guideline development areas need to evolve, the greatest improvement should be in the identification, evaluation, and synthesis of scientific evidence (rigor of development).⁴

In the Brazilian Cardiology Society (SBC) context, the guidelines are probably the main source of updates for Brazilian cardiologists and references of the cardiology specialist exam.² The guidelines for the SBC's scientific publications, in the introduction chapter, put forth that these documents should always be based on the best available scientific evidence.⁵ Not expending all efforts to seek and evaluate the literature of the best scientific quality deliberately goes against the existence of the SBC Guidelines themselves and against the responsibility of bringing the best education to our professionals.

With the advancement of Evidence-Based Medicine and Health Technology Assessment fields, new methods based on an international effort to achieve increasingly better strategies for elaborating, writing, and revising these documents are emerging. Two of these new tools are used to carry out the main objectives of this study. First, we performed an external evaluation of the quality of three important clinical guidelines of the SBC - Hypertension, Diabetes, and Dyslipidaemia - according to the AGREE II tool.

Next, we discuss new methodological concepts and suggestions for developing future clinical guidelines based on a literature review of the subject, including innovations proposed by the Grading of Recommendations Assessment, Development, and Evaluation (GRADE) tool.

Methods

This is a study on methods for developing and evaluating the quality of clinical guidelines.

According to the AGREE II tool, twelve independent evaluators performed the methodological analysis of one of three pre-selected clinical guidelines of the SBC (four individual evaluators for each guideline, which is officially the ideal recommendation). All those who had no prior knowledge of the method underwent the training suggested in the official online platform of the tool, and a discussion was conducted before the study to ensure a good understanding of the concepts to be analysed.

AGREE II is internationally accepted as an external validation tool for clinical guidelines and is part of the recommendations of the Equator6 network. The objectives of AGREE are to evaluate the quality of clinical guidelines, provide a methodological strategy for the development of clinical guidelines, and inform which information should be reported in the final documents, and how 1. It has 23 items of analysis divided into six domains: 1) Scope and Purpose of the Guideline; 2) Stakeholder Involvement; 3) Rigor of Development; 4) Clarity of Presentation; 5) Applicability of the Guideline; and 6) Editorial independence. The items and domains of the AGREE II instrument are described in Table 1. The user manual of the AGREE II document has objective and well-described recommendations on what to consider when analysing each item and the rationale behind its scoring, which all evaluators followed.

After scoring all 23 items, each evaluator additionally assigned an overall score to the document and answered whether they would recommend the clinical use of the guideline. Each evaluator assigned a score from 1 (strongly disagree) to 7 (strongly agree) independently for each item analysed, which at the end were combined for each clinical document separately. The final scores of each domain for each clinical guideline (described in the Results section in Table 2) were calculated by summing all the individual scores and scaling the total obtained as a percentage of the maximum possible score for the domain in question. For a more detailed understanding of the evaluation and scoring system, we recommend reading the official document AGREE II.¹

The entire process was performed through the official AGREE platform (<https://www.agreetrust.org/>). The detailed score of each item per guideline is in an electronic document available online, which the authors can share upon request. None of the 12 evaluators participated in developing any clinical guideline of the SBC, nor was part of any national or state board or any specialized department or study group of the SBC.

The guidelines to evaluate were chosen arbitrarily by the authors according to the judgement of their relevance to cardiology and the Unified Health System (Sistema Único de Saúde - SUS). The topics chosen were hypertension², diabetes³, and dyslipidaemia.⁹

Table 1. Items and domains of the AGREE II instrumenta (to be continued)

ITEM	CONTENTS	DOMAIN
1	The general objective(s) of the guideline is (are) specifically described.	1. Scope and Purpose
2	The health issue(s) covered by the guideline is (are) specifically described.	
3	The population (patients, public, etc.) to whom the guideline is intended is specifically described.	
4	The guideline development team includes individuals from all relevant professional groups.	2. Stakeholder Involvement
5	The views and preferences of the target population (patients, public, etc.) have been sought.	
6	The target users of the guideline are clearly defined.	
7	Systematic methods were used to search for evidence.	3. Rigor of Development
8	The criteria for selection of evidence are clearly described.	
9	The strengths and limitations of the body of evidence are clearly described.	
10	The methods for formulating the recommendations are clearly described.	
11	The health benefits, side effects and risks were considered in the formulation of the recommendations.	
12	There is an explicit link between the recommendations and the respective supporting evidence.	
13	The guideline has been externally reviewed by experts prior to its publication	
14	The procedure for updating the guideline is available.	4. Clarity of Presentation
15	The recommendations are specific and unambiguous.	
16	The different options for management of the condition or health issue are clearly presented	
17	The key recommendations are easily identified.	

Table 1. Items and domains of the AGREE II instrumenta (conclusion)

ITEM	CONTENTS	DOMAIN
18	The guideline describes the facilities and barriers to its application.	5. Applicability
19	The guideline provides advice and/or tools on how recommendations can be put into practice.	
20	The potential resource implications of applying the recommendations have been considered.	
21	The guideline presents criteria for its monitoring and/or auditing.	6. Editorial independence
22	The views of the funding body have not influenced the content of the guideline.	
23	Competing interests of guideline development group members have been recorded and addressed	

^a Extracted from the AGREE II instrument.

Results

The evaluation results of each clinical guideline by domain; the mean, median, and standard deviation (SD) of these scores per guideline; and overall evaluation and final recommendation on its use are found in Table 2. There were low scores in the domains of Stakeholder Involvement, Applicability of the Guideline, and, especially, Rigor of Development—domain concerning the literature search methods, analysis of included articles, and extraction of scientific evidence, representing the core of the quality of the information contained in the final document. Although the score of each domain is useful for comparing clinical guidelines and determining their recommendation for use, the AGREE II tool does not establish a minimum score that differentiates good- or poor-quality documents, leaving this decision to the user's judgement within the clinical context at hand. Based on these results, only the Hypertension guideline was recommended for clinical use by most of its evaluators.

Table 2. Results of the evaluation of the SBC guidelines according to the AGREE II tool

DOMAINS - AGREE II	HYPERTENSION ¹	DIABETES ²	DYSLIPIDAEMIA ³
1 - Scope and Purpose of the Guideline	78%	81%	46%
2 - Stakeholder Involvement	35%	43%	24%
3 - Rigour of Developmental	42%	32%	33%
4 - Clarity of Presentation	78%	69%	61%
5 - Applicability of the Guideline	38%	10%	43%
6 - Editorial Independence	60%	42%	42%
Median score per guideline	51%	43%	43%
Mean score per guideline	55%	46%	42%
Standard deviation per guideline	17%	22%	11%
Global evaluation of the guideline	58%	38%	42%
Recommendation for clinical use (No. of evaluators):			
YES	1	0	0
YES, with modifications	3	1	1
NO	0	3	3

Legend: The AGREE II tool consists of 23 items of analysis divided into six domains. The scores of each domain are calculated by summing all the scores of the individual items in each domain and scaling the total obtained as a percentage of the maximum possible score for the domain in question. For a more detailed understanding of the evaluation and scoring system, we recommend reading the official document of the AGREE II tool.¹

Discussion

The results presented in this article on the methodological quality of our clinical guidelines are not surprising. The elaboration of this type of document is not an exclusive difficulty of the SBC but rather of virtually all medical societies worldwide. Medicine has been evolving more and more rapidly, and its scientific method does so at the same speed. Keeping up with this evolution is a huge challenge, not only with regard to technological innovations but also in the form of absorbing new conceptual ideas that improve the literature and medical reasoning. Clinical guidelines in general need to evolve in their methods of creation, and it is up to us members of the SBC, as a fundamental part of our entity, to contribute to this continuous improvement.

Clinical guidelines, like any medical strategy, have potential benefits and harms. Among the benefits is the possibility of improving the quality of patient care, promoting interventions with evidence of significant clinical benefit, and discouraging strategies with little or no clinical benefit to the patient. Clinical guidelines also can improve treatments' uniformity, minimizing the discrepancies between different doctors and regions when giving the same care. Finally, they influence public health policies, impacting more just and efficient spending by the health system. The potential harms of clinical guidelines are the promotion of erroneous information by doctors, managers, or health systems, which may encourage, if not institutionalize, the provision of ineffective and harmful services and wasteful interventions. The same parties that should benefit from guidelines—patients, professionals, and the health system—may be harmed by poorly prepared documents. Even when the information contained in these documents is correct, doctors often find them difficult and time-consuming to read. Clinical guidelines of different medical entities can be conflicting and generate confusion and frustration among professionals.^{10,11} Therefore, a central goal of the improvements proposed here should be to simplify their reading and provide a universal understanding.

Due to the need for improvements in medical documents and practices worldwide, new fields of study in health have been developing, mainly since the 1980s. At this time, Evidence-Based Medicine and Health Technology Assessment were still being considered. The first clinical documents of SBC date from the early 1990s—the I Brazilian Consensus for the Treatment of Hypertension (I CBH) was developed in 1990.¹² Therefore, the new methods proposed here were far from existing at the time of developing the first guidelines.

A review article on the quality of clinical guidelines published in 2000 already showed the low methodological quality of these documents around the world and suggested that international standards for their development should be created.¹³ Burgers et al. investigated 15 type 2 diabetes clinical guidelines from 13 countries to identify variables that most influenced their clinical recommendations. In essence, the authors corroborated previous findings suggesting that the scientific literature is not always the most important contributor to the contents of a guideline. Instead, their results showed little consistency in the studies selected for the various documents; the references were highly variable across the 15 guidelines investigated.¹⁴ In a 2004 article, Raine et al. suggested that scientific evidence was used to confirm pre-existing opinions of those who elaborated them, instead of changing them. The recommendations of the guidelines were not based on the evidence in the literature but rather on the interpretation, experience, beliefs, and values of the physicians involved.¹⁵

The original AGREE instrument was published in 2003 by an international group of clinical guideline developers and researchers, the 'AGREE Collaboration'. The objective of the group was to develop a tool to evaluate the methodological quality of clinical guidelines. The tool underwent constant revision, which resulted in the publication in 2009 of the AGREE II¹ instrument, an internationally accepted tool to evaluate the quality of the preparation of and information contained in a clinical guideline, constituting an external validation of this type of document.

The present study and the AGREE II tool itself have limitations that should be understood. There is undoubtedly a degree of subjectivity in the individual scores assigned by each evaluator, so there is an ideal recommendation that four professionals evaluate each clinical document to help dilute the inevitable evaluation disagreements. In the 12 evaluations performed by the authors of this paper (four per clinical document), there was a good correlation between the evaluations of the Diabetes guideline and the Dyslipidaemia guideline—ranging from 0.74 to 0.94 (mean = 0.84; median = 0.84, SD = 0.08) and from 0.45 to 0.95 (mean = 0.65; median = 0.64, SD = 0.18), respectively. The interobserver agreement for the Hypertension guideline was lower, ranging from 0 to 0.83 (mean = 0.38; median = 0.43, SD = 0.39). Not all methodological fields are addressed in this evaluation tool, but rather those that the AGREE Collaboration deemed most relevant were included. The main intention in using AGREE II is not to criticize a document that requires so much effort to prepare but to decrease the variability of the quality of publications and support the preparation of more effective, complete, simple, and transparent documents in the future.^{1,16}

According to AGREE II described in this article, the evaluation results show important gaps in three main domains: Stakeholder Involvement, Guideline Applicability, and, especially, Rigor of Development. Among the items evaluated in the Stakeholder Involvement domain, we need to increase the participation of the target medical population of the guidelines, characterized not only by cardiologists but also by students, clinical professionals, and the Ministry of Health itself, considering all their preferences and values. As for Guidelines Applicability, we need to measure the scope of the guidelines, the facilitators and the barriers to their implementation, and the impact of these documents on Brazilian cardiology practice by testing different methods and media that help disseminate and implement best practices, determining the success metrics of their dissemination, and continuously monitoring this process. Finally, Rigor of Development is the domain that most impacts the accuracy of the information in the clinical guidelines. We need to improve, systematize, and disseminate the methods for searching for and selecting articles in the literature, clarifying the strengths and limitations of the scientific

evidence found and how the recommendations were formulated based on this information. Perhaps the greatest contribution of a clinical guideline should be to facilitate understanding the magnitude of the benefits and harms of each strategy, making it easier for the patient to decide along with their medical professional.

The norms for the development of SBC guidelines suggest that they avoid texts that discuss physiology, pathology, and pathogenesis; include analyses of clinical relevance (number needed to treat, or a number of patients required to be treated to avoid a clinical outcome); that they should be based on systematic reviews³—as other academic institutions in the world demand. The American Institute of Medicine defines clinical guidelines as statements that include recommendations guided by a systematic review of evidence and that evaluate the benefits and harms of the various care options.¹⁷ As a criterion for including clinical guidelines in the National Guideline Clearinghouse, an American repository of guidelines, developers must present the underlying systematic review documentation as a prerequisite.¹⁸

Recommendations from expert opinions are classified as a 'very low' level of evidence. Expert opinion is not formally characterized as scientific evidence, and it is preferable to seek other sources of information, such as noncomparative observational studies (case series or case reports).¹⁹

Systematic reviews—documents prepared systematically that review the scientific literature on a given subject in the most comprehensive and transparent manner possible—should ideally be the basis of the information contained in a clinical guideline.^{16,19} These documents have been in use in medicine longer than clinical guidelines and whose method has evolved considerably in recent decades. Therefore, many improvements that have already been implemented in the development of systematic reviews can be adapted to clinical guidelines.

This article presents some suggestions for improvement based on the GRADE methodology ("Grading of Recommendations Assessment, Development and Evaluation"). GRADE is a tool developed by a collaborative group of researchers that aims to create a universal, transparent, and

sensitive system for grading the quality of evidence and the strength of recommendations, in addition to being the most commonly used method to evaluate the information of systematic reviews qualitatively. More than 80 international institutions use GRADE, including the World Health Organization, the National Institute for Health and Clinical Excellence, the Centers for Disease Control and Prevention, and the Cochrane Collaboration.¹⁹ Therefore, GRADE can contribute to developing future clinical guidelines beyond evaluating systematic reviews. We cite three of these new concepts below.

The first innovation concerns the presentation format of the levels of evidence and strength of recommendation. Currently, different medical societies use different formats, with complex systems and little understanding by medical professionals. The system of classification into levels of evidence and strength of recommendations of the clinical guidelines of the SBC began to appear more consistently in its documents in 2000, but little has been revised since then. In an article published in 2004, six evaluation methods were applied to the levels of evidence and strength of recommendations of well-known institutions—some very similar to those used by the SBC. The conclusion was that all the approaches used to classify the levels of evidence and the strength of the recommendations had important deficiencies.²⁰ These same authors recommended adopting the GRADE method to evaluate the strength of recommendations of each clinical strategy.²¹ Although the methodological quality of the selected articles is of paramount importance, other considerations should influence the level of recommendation. These include the relevance of the available evidence to a patient with particular characteristics predicted in the scenario of the key question; the amount (i.e., volume and integrity) and consistency (i.e., conformity of the conclusions between the different studies) of the available evidence; the nature and estimated magnitude of specific impacts of that specific clinical practice; and value judgements of the clinical importance of these different impacts.¹⁷ The GRADE tool suggests facilitating this information by classifying the evidence only as high, moderate, low, and very low. These levels represent our confidence in estimating the effects presented in medical studies and are much simpler to understand.^{16,19,22,23} This method increases the user's understanding of the suggested recommendations.¹⁷

A second relevant characteristic that we can extract from GRADE and even from documents already published by other relevant medical societies²⁴ is to guide the development of a clinical guideline based on one or more structured questions according to the Population, Intervention, Comparator, and Outcome (PICO) method²⁵, as well as to establish the scenario in which the recommendation will be implemented. These questions should be evident in the scope of the primary document so that the medical professional knows in advance what content they will be reading and what kind of objective response to expect at the end of each recommendation.

The third aspect that represents an evolution of the preparation of medical documents is the prioritization of critical clinical outcomes from the patient's perspective. In cardiology, these would be primarily death, infarction, and stroke. Substitute or secondary outcomes provide a lower quality of evidence due to their indirect nature, such as laboratory parameters (e.g., low-density lipoprotein cholesterol) or results of imaging tests (e.g., calcium score). Although important to the patient, subjective clinical outcomes such as hospitalization and pain should be considered at a level of intermediate relevance. Therefore, in a clinical guideline, evaluating the importance of outcomes for that specific document should precede the discussion of the quality of scientific evidence. This ranking of the different outcomes should be apparent to the reader. Ideally, a clinical guideline's structured questions and recommendations should consider only outcomes relevant to the patient whenever possible.¹⁹

In addition, we should prioritize the development of small clinical guidelines that answer only one or a few structured questions common to a topic. The ideal is to start with the questions about the most relevant outcomes, showing first the recommendations of strategies that provide the most significant benefit according to the hierarchy of the effect size—from the most effective to the least effective. We should present this effect size objectively (number needed to treat). The main document could contain in its introduction only the scope, the proposal of the guideline, the editorial board, and its conflicts of interest—in an objective manner—allowing that most of the document be reserved for the structured questions and their respective answers (objective

medical recommendations with their confidence levels). All other information (methods, stakeholders, factors that influence its applicability, funding, etc.) could be digitally supplemented.¹⁶

We should encourage the existence of lay-language versions of the guidelines, helping to disseminate the best technical information among the general population and stimulating a greater involvement of the public in the search for best practices. The publication of summarized documents for the lay public is done by several institutions recognized for the excellence of their scientific literature reviews (e.g., Cochrane Collaboration²⁶ and the American Task Force on Preventive Medicine²⁷) and helps to inform the population, generating greater participation in the individual care and the healthcare decision-making process.

A guideline should describe the process its panel members used to reach a consensus and, if applicable, should have this process validated by the sponsoring organization. The same should be established before beginning the development of the guideline. Objective and pre-established methods have been shown to result in a less biased and more evidence-based process than informal methods.¹⁶

Before its publication, all clinical guidelines must undergo independent external validation¹⁶ following an objective and internationally accepted protocol such as AGREE II. This review should criticize content-related quality, the methods of gathering scientific evidence, and the development of the guideline. It is essential to consider those most likely to provide comments based on scientific and clinical knowledge when selecting external reviewers. The review/validation process should be disclosed upon the publication of the final document and used for improvements in future updates.¹⁷

To provide the best scientific information transparently and impartially to our professionals through clinical guidelines, we should consider clear rules for selecting the editorial board to prepare this kind of document. The ideal is to involve as many stakeholders as possible, including health technology assessment professionals, methodologists, clinicians, and consumers, at a final number of 10 to 20 participants.¹⁶ Ideally, the group responsible for drafting the document should avoid professionals with conflicts of interest, or when this is not possible,

they should represent the minority of the editorial board.¹⁶ A practical and neutral editor should lead the group to ensure balanced contributions from all members. Its primary role is to facilitate discussion and consensus. The editor should have general knowledge but not be an expert on the topic. Putting an expert in charge of drafting a guideline increases the risk that preconceived opinions will influence deliberations.¹⁶ In 2017, the American College of Cardiology and the American Heart Association, partners of the SBC, decided not to allow professionals who had relationships with the various medical industries to participate in the writing of their clinical guidelines for hypertension and only to participate in the revision of the final document.²⁸ For this same publication, they established a specific committee to formulate systematic reviews to evaluate topics without consensus in the literature.

Finally, stricter standards for the funding of clinical guidelines should be established. Guidelines should fully disclose the financial support given to developing the systematic reviews and to the guidelines themselves.¹⁶ The funding of clinical studies by the pharmaceutical and medical device industries not infrequently influences the results of the documents sponsored by them.²⁹ Recognizing the great importance of these industries in the overall technological development of the healthcare sector, these corporations certainly can contribute in various forms not involving direct advertising and potential conflicts of interest in the preparation of transparent scientific documents such as clinical guidelines.

Conclusion

This study demonstrated that the clinical guidelines of the SBC, in agreement with the international scenario of other medical societies, present important opportunities for improvement in their methods of elaboration, presentation, and external validation.

Clinical guidelines were initially developed to guide health professionals in their decision-making process. However, in line with general medical practice, these documents have undergone significant changes in recent decades. Like the medical professional, the clinical guidelines should move towards prioritizing the point of view of the user and other interested parties (to the detriment of the medical specialist's

view exclusively), should impartially base their recommendations on the best scientific information (and relying less on the opinions of experts), should be simple to read (clearly explaining the question to be answered and the final recommendation on this question), should follow systematized methods (elaboration of critical questions, method of literature search, evaluation of the individual quality of the separate articles, and preparation of the final recommendation), and should use wording that clarifies the benefits and harms of the different medical strategies (the importance of the clinical outcome to the patient, the size of the clinical effect of each strategy in comparison with others, costs). Health as a whole has evolved in this direction, and our official SBC documents should follow this path without looking back.

Author contributions

Luna LC conceived and coordinated the project, evaluated the guidelines, and participated in the writing and review of the article. Magliano CA evaluated the guidelines and participated in the review of the article. Dos Santos RM, De Almeida BM, Fatorelli A Barata PASB, De Andrade LC, Maiolino PA, Santos M, Pereira R, Albuquerque TDC, and Ribeiro J evaluated the guidelines.

Conflicts of interest

No financial, legal, or political conflicts involving third parties (government, companies, private foundations, etc.) are declared for any aspect of the submitted work (including but not limited to grants and funding, participation in advisory councils, study design, preparation of manuscript, statistical analysis, etc.).

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