

GRADE RELATED SERIES

Using evidence to decision frameworks led to guidelines of better quality and more credible and transparent recommendations

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Abstract

Background and Objectives: To determine whether the use of Evidence to Decision (EtD) frameworks is associated to higher quality of both guidelines and individual recommendations.

Methods: We identified guidelines recently published by international organizations that have methodological guidance documents for their development. Pairs of researchers independently extracted information on the use of these frameworks, appraised the quality of the guidelines using the Appraisal of Guidelines, Research and Evaluation II Instrument (AGREE-II), and assessed the clinical credibility and implementability of the recommendations with the Appraisal of Guidelines for REsearch & Evaluation Recommendations Excellence

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(AGREE-REX) tool. We conducted both descriptive and inferential analyses.

Results: We included 66 guidelines from 17 different countries, published in the last 5 years. Thirty guidelines (45%) used an EtD framework to formulate their recommendations. Compared to those that did not use a framework, those using an EtD framework scored higher in all domains of both AGREE-II and AGREE-REX ($P < 0.05$). Quality scores did not differ between the use of the The Grading of Recommendations Assessment, Development and Evaluation–EtD framework (17 guidelines) or another EtD framework (13 guidelines) ($P > 0.05$).

Conclusion: The use of EtD frameworks is associated with guidelines of better quality, and more credible and transparent recommendations. Endorsement of EtD frameworks by guideline developing organizations will likely increase the quality of their guidelines. © 2023 The Author(s). Published by Elsevier Inc. This is an open access article under the CC BY license (<http://creativecommons.org/licenses/by/4.0/>).

Keywords: Practice guidelines; Decision making; Evidence-based practice; Methods; GRADE approach; Policy making

1. Introduction

Clinical practice guidelines are statements informed by a systematic review of evidence and an assessment of the benefits and harms of alternative care options to optimize patient's care [1,2]. Several international organizations have elaborated methodological standards for guideline development, in which the process of moving from evidence to decisions (EtDs) (including recommendations) is a cornerstone [3–6]. This process, hereafter EtD process, is grounded on a systematic and transparent integration of the evidence supporting the criteria influencing the recommendation [3]. In consequence, an EtD framework aims to offer a comprehensive list of criteria that should be considered by both decision-makers and guideline developers to make better-informed decisions [3,7,8].

To date, different EtD frameworks are available in the literature, proposing a variety of criteria to be considered when formulating recommendations [8–10]. For instance, the Guidance on Priority Setting in Health Care, GPS-Health [11] emphasizes equity-related considerations; the 'decision-making triangle' [12] focuses on ethics; and The World Health Organization–INTEGRATE EtD framework [10] emphasizes human rights and sociocultural implications. A well-known framework is the Grading of Recommendations Assessment, Development, and Evaluation (GRADE)-EtD framework, developed by the GRADE Working Group for different types of decisions [13]. The GRADE-EtD framework aims to assist guideline development groups in considering the most relevant criteria that influence a recommendation by structuring discussions, identifying reasons for disagreements, and building the basis for transparent judgements [7,13].

In a recently published study conducted by our group [14], we found that 66% of 68 international guideline developing organizations reported the use of an EtD framework in their guidance documents, and the GRADE-EtD was the most often reported framework among all these guidelines [14]. In addition, we found that using any EtD framework was associated with a more comprehensive set of recommendation-related criteria compared to no use of

a framework, especially for criteria like equity, and acceptability [14]. Although EtD frameworks are proposed for rigorous guideline development [3,6] it remains unknown whether the use of an EtD framework translates into higher-quality guidelines. To bridge this gap, we evaluated if guidelines using an EtD framework are of higher quality and include more credible and transparent recommendations than those which do not apply a framework.

2. Methods

We registered the study protocol in Open Science Framework (<https://osf.io/yzr8s/>). This methodological study was conducted following systematic review methods, and reported according to the guidelines for reporting methodological studies [15].

2.1. Identifying and selecting the guidelines

We included treatment guidelines, updates, or de novo, published by 68 international organizations included in our previous study on the use of EtD frameworks in guidance documents for guideline development [14]. In that study, we included organizations responsible for developing treatment guidelines in any field of health care that have a methodological guidance document available. These organizations were identified through systematic literature searches in the Guidelines International Network library, MEDLINE, Google Scholar, and The Cochrane Methodology Register. The searches were first conducted during October 2018, and further updated in May 2020. The searches had no language restrictions except for Google Scholar, which was restricted to English. Further details, including the search strategy, are available in our previous study [14].

Two reviewers (J.F.M.E and L.A.T.T) explored each organizations' website in October 2021 to retrieve their most recent guideline, and the accompanying supplementary material. If one organization published several guidelines, we chose the most recently published guideline. All

What is new?

Key finding

- Using an Evidence to Decision (EtD) framework is associated with guidelines of better quality, and more credible and transparent recommendations.

What this adds to what is known?

- Although widely recommended, the use of EtD frameworks in guidelines is still limited.
- Using an EtD framework is associated with a more complete reporting of the supplementary material underpinning the recommendations (e.g., evidence profiles), and details on formal consensus process.

What is the implication, what should change now?

- Guideline developing organizations should endorse EtD frameworks and efforts should be made to ensure a complete use.

publication formats were considered for inclusion (e.g., journal articles, organizational reports, or online versions). Despite many attempts, we could not retrieve guidelines from two organizations, due to a lack of response (Haute Autorité de Santé and Estonian Health Insurance Fund) ([Additional File 1](#)).

2.2. Data extraction

We designed and piloted an ad hoc data extraction form to gather relevant information from each guideline, including characteristics of the organization. We collected details about the use of an EtD framework (e.g., reporting of evidence profiles or summary of findings tables and the use of a voting process). The data extraction form is available at: <https://osf.io/5vaz7>.

We used the Appraisal of Guidelines, Research and Evaluation II Instrument (AGREE-II) tool to appraise guidelines' quality [16–18]. This tool was developed by the AGREE Collaboration to facilitate the systematic assessment of key methodological components of guideline development, and the corresponding quality of reporting, being the most widely used tool for guidelines' quality appraisal [16–18]. AGREE II has 23 items grouped in six domains. Each item and the overall score are rated on a 7-point Likert scale (1–strongly disagree to 7–strongly agree). The final scores are calculated by domain, from 0 to 100% maximum score possible; higher scores mean better quality.

We used the Appraisal of Guidelines for REsearch & Evaluation Recommendations Excellence (AGREE-REX) tool [19], which has nine items, addressing three key concepts related to the clinical credibility and implementability

of the recommendations: clinical applicability; values and preferences, and implementability [19]. The tool can be applied at either guideline or recommendation level. We applied it at the guideline level, one of the approaches suggested by developers [19]. Similar to AGREE-II, higher scores mean better quality.

All reviewers worked on the online resources of AGREE II (AGREE II Overview Tutorial and AGREE II Practice Exercise: www.agreetrust.org) along with virtual meetings, to calibrate extracting data and understanding of both AGREE tools. Reviewers worked in pairs independently and were blinded to others' judgements. If needed, a third reviewer (I.D.F/P.A.C) was involved to solve disagreements. After the training sessions, we obtained high inter-reviewer agreement scores in all pairs of reviewers, as proved by P values <0.2 for both concordance tests (i.e., Kendall's Concordance Coefficient and the Spearman's Rank Correlation Coefficient).

2.3. Data analysis

First, we conducted a descriptive analysis of the main characteristics of the guidelines, including the use of EtD frameworks. Guidelines that used an EtD framework to formulate their recommendations are referred from here onwards as “EtD guidelines”, whereas those that did not use an EtD framework are referred to as “non-EtD guidelines”. Second, we calculated odds ratios, with the corresponding 95% confidence intervals, to evaluate the association between the use of an EtD framework with several characteristics of the EtD process, such as the assignment of weights to the criteria considered, or the use of a formal voting process [20].

Third, we calculated the overall score and the score by domain for each of the two AGREE tools and expressed them as percentages of the maximum possible score (i.e., a score of 7 = 100%), following the recommendations provided by the tool's manuals available at www.agreetrust.org. These data were also reported as means, medians, interquartile ranges (IQRs), and standard deviations (SDs). Fourth, we used the Wilcoxon Signed-Rank Test to explore the association between the use of an EtD framework with the AGREE-II- and AGREE-REX domains and their overall scores. A P value's cutoff of 0.05 was used to determine the statistical significance. We conducted this analysis for all the included guidelines, the EtD guidelines, and those that used the GRADE-EtD framework or another EtD framework. We created box plots and density plots to illustrate the results of these analyses. One reviewer conducted the data analysis (J.F.M.E) using R [21]; I.D.F checked the data accuracy.

We planned to carry out a regression analysis to explore the association between the use of an EtD framework, AGREE-II, and AGREE-REX scores with several guideline characteristics, but due to the small number of guidelines and the marked variability of the scores obtained, we did

not conduct this analysis. Having conducted such an analysis could have resulted in misleading inferences concerning the influence of using any EtD framework on the domain scores of the AGREE instruments.

3. Results

3.1. Characteristics of the included guidelines

We included 66 guidelines published between 2015 and 2021 (median 2020) that addressed mainly cardiovascular, respiratory, and musculoskeletal disorders, and were mostly published by organizations from North America and the United Kingdom. [Figure 1](#) shows the geographical distribution of included guidelines. Over half of the guidelines evaluated pharmacological and/or surgical interventions and were developed by professional societies (e.g., American Heart Association). GRADE was the most common approach to rate the certainty of the evidence and the strength of recommendations. [Additional File 1](#) shows the organizations and their guidelines, and [Additional File 2](#) summarizes the characteristics of the included guidelines.

3.2. Use of an EtD framework

Thirty guidelines (45.5%) used a framework to formulate their recommendations (EtD guidelines), and most of them used the GRADE-EtD framework (17, 56.7%). The GuideLines Into Decision Support methodology, the National Institute for Health and Care Excellence framework

and the SIGN framework were used in two guidelines each (6.7%). Six guidelines (20%) used their own EtD framework, mainly adapted from other frameworks, including the GRADE-EtD.

Half of the guidelines (32, 48.5%) presented evidence profiles or summary of findings tables, five guidelines (7.6%) reported modifications made to the original EtD framework, and 30 guidelines (57.6%) reported a voting process or formal consensus process. Of note, this information was more commonly present in EtD guidelines than in non-EtD guidelines. For instance, the odds of presenting evidence profiles were seven times larger in EtD guidelines ([Table 1](#)).

3.3. Guidelines' quality

The mean overall AGREE-II score across the 66 guidelines was 4.3 (SD 1.5), or 56% when expressed as percentage of the maximum possible score. The domains with the highest scores were *Clarity of presentation* (79.6%) and *Scope and purpose* (76.7%), while the *Applicability* (39.7%) domain had the lowest score. Guidelines' *Rigor of Development* achieved 60% of the maximum score possible. [Additional Files 3 and 4](#) present further details on the AGREE-II scores.

3.3.1. Guideline quality and use of EtD frameworks

EtD guidelines showed higher quality scores and less variability than non-EtD guidelines for their overall quality, as well as across all AGREE-II domains (Wilcoxon-test *P*

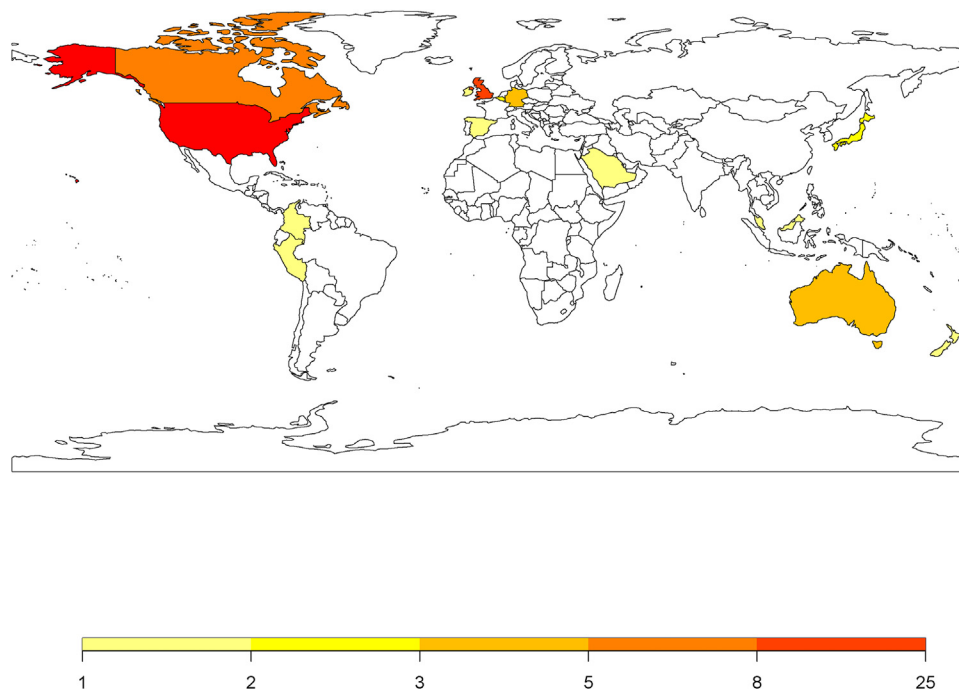


Fig. 1. Geographical distribution of the included guidelines¹. ¹The colors represent the number of guidelines developed in each country. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

Table 1. Use of Evidence-to-Decision frameworks and recommendation formulation process

Recommendation formulation process	All guidelines (N = 66)	EtD guidelines N = 30 (45.5%)	Non-EtD guidelines N = 36 (54.5%)	EtD vs non-EtD guidelines (OR; 95% CI)
Use of an EtD framework	30 (45.5%)	30 (100%)	-	-
EtD framework used				
GRADE-EtD framework	-	17 (56.7%)	-	-
Own approach	-	6 (20%)	-	-
GLIDES methodology	-	2 (6.7%)	-	-
NICE	-	2 (6.7%)	-	-
SIGN	-	2 (6.7%)	-	-
USPSTF	-	1 (3.3%)	-	-
Use of evidence profiles or summary of findings tables	32 (48.5%)	22 (73.3%)	10 (27.8%)	7.3 (2.4–21.2)
Modified EtD framework	-	5 (16.7%)	-	-
Voting process or formal consensus processes	38 (57.6%)	22 (73.3%)	16 (44.4%)	3.4 (1.2–9.7)

Abbreviations: CI, Confidence Interval; EtD, Evidence-to-Decision; GLIDES, GuideLines Into Decision Support; GRADE, The Grading of Recommendations Assessment, Development, and Evaluation; NICE, The National Institute for Health Care and Excellence (UK); OR, odds ratio; SIGN, Scottish Intercollegiate Guidelines Network; USPSTF, The US Preventive Services Task Force.

< 0.05) (Figure 2). For instance, when expressed as the median percentage of the maximum score possible, the *Rigor of development* domain was 81.2% (mean), relative to 40.6% of the non-EtD guidelines ($P < 0.05$) (Additional Files 3 and 4). The distribution of AGREE-II scores between EtD guidelines and non-EtD guidelines showed that overall AGREE-II scores of the EtD guidelines are concentrated in the last tercile of the distribution of AGREE-II scores (i.e., 4–7), whilst AGREE-II scores of non-EtD guidelines are concentrated in the first tercile of the distribution (i.e., 1 to 3) (Figure 3).

The analysis of the EtD guidelines that used the GRADE-EtD framework ($n = 17$), compared to those that used another EtD framework ($n = 13$), revealed no differences neither in the total scores, nor in per-domain score distributions (Additional File 5).

3.4. Clinical credibility and implementability of guideline recommendations

The mean overall AGREE-REX score across the 66 guidelines was 4.1 (SD 1.6), or 52% of the maximum possible score. The *Clinical applicability* domain had the highest score (60.4%), whereas *Values and preferences* domain had the lowest score (26.7%). The AGREE-REX domain scores for the 66 guidelines are shown in Additional Files 6 and 7.

3.4.1. Guideline recommendations appraisal and use of EtD frameworks

Recommendations made by EtD guidelines scored better in all AGREE-REX domains than those not formulated using an EtD framework ($P < 0.05$) (Figure 4). Furthermore,

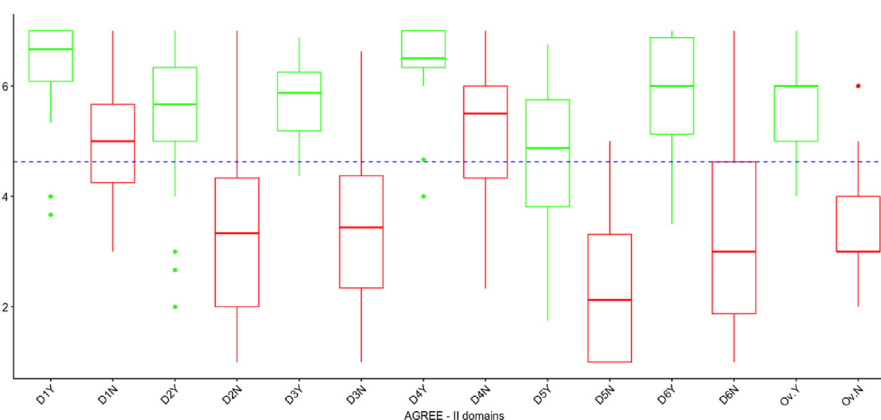


Fig. 2. AGREE-II scores in EtD guidelines and non-EtD guidelines^a. ^aEtD guidelines (Y) ($n = 30$) are shown in green and non-EtD guidelines (N) ($n = 36$) are shown in red. The box plot displays the median and Interquartile range (IQR); all differences were statistically significant, Wilcoxon Signed-Rank Test ($P < 0.05$). Abbreviations: D1, Scope and purpose; D2, Stakeholder involvement; D3, Rigor of development; D4, Clarity and presentation; D5, Applicability; D6, Editorial independence; Overall score. The dotted line indicates an average score across domains. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

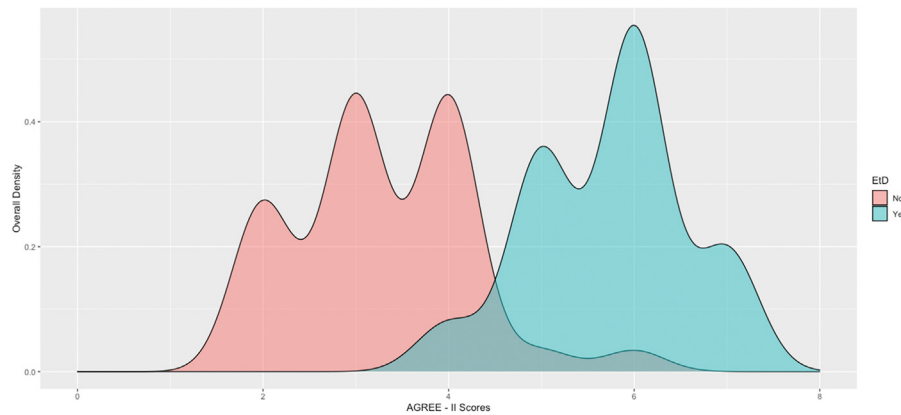


Fig. 3. Overall AGREE-II scores in EtD guidelines and non-EtD guidelines.

EtD guidelines' recommendations showed higher overall AGREE-REX scores (EtD guidelines 76.1% vs. non-EtD guidelines 31.9%; Wilcoxon-test $P < 0.05$) (Figure 4). Moreover, the overall AGREE-REX scores of the recommendations of EtD guidelines were concentrated in the highest tercile of the distribution (i.e., 4–7), while the overall recommendation scores of the non-EtD guidelines were concentrated in the first tercile (i.e., 1 to 3) (Figure 5).

The analysis of the recommendations from EtD guidelines that used the GRADE-EtD framework ($n = 17$), compared to those that used another EtD framework ($n = 13$), revealed no differences neither in the total scores nor in per-domain score distributions (Additional File 8).

4. Discussion

4.1. Main findings

Our study presents the first empirical evidence on the use of any EtD framework for a better quality of guidelines and their recommendations. Guidelines grounded on an

EtD framework were of better quality and made more credible and implementable recommendations, compared to those that did not use any framework. In addition, GRADE was the most commonly used method for grading the certainty of the evidence and the strength of recommendations as well as the most common EtD framework across guidelines. However, our findings revealed no differences on the quality of guidelines and recommendations across the types of frameworks.

The benefits of using an EtD framework were consistent across all domains of the methodological appraisal tools (i.e., AGREE-II and AGREE-REX). Of note, guidelines' rigor of development in EtD guidelines doubled that of non-EtD guidelines. Similar differences were seen in clinical credibility and implementability of the recommendations. Some guideline developing organizations have developed or adapted their own EtD framework, grounded mainly on GRADE's methods. Finally, the use of EtD frameworks was associated with a more complete reporting of supplementary information, such as evidence tables, and formal consensus processes.

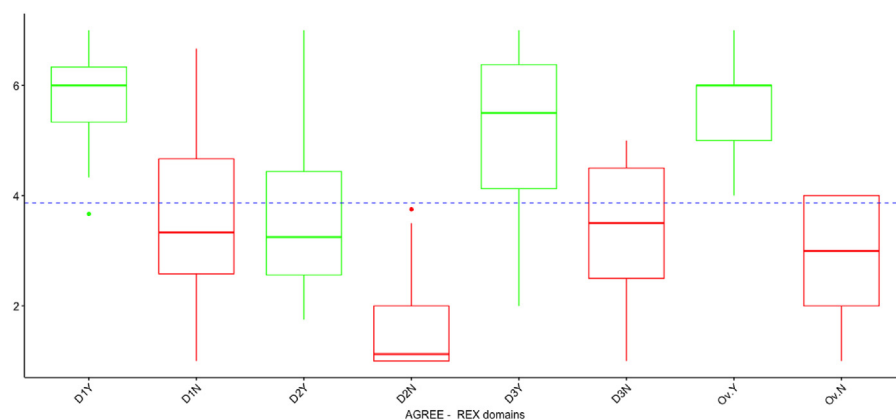


Fig. 4. AGREE-REX domains' scores in EtD guidelines and non-EtD guidelines^a. ^aEtD guidelines (Y) are shown in green ($n = 30$) and non-EtD guidelines (N) are shown in red ($n = 36$). The box plot displays the median and interquartile range (IQR); all differences were statistically significant, Wilcoxon Signed-Rank Test ($P < 0.05$). Abbreviations: D1, Clinical applicability; D2, Values and preferences; D3, Implementability; Overall score. The dotted line indicates an average score across domains and serves just as a reference. (For interpretation of the references to color in this figure legend, the reader is referred to the Web version of this article.)

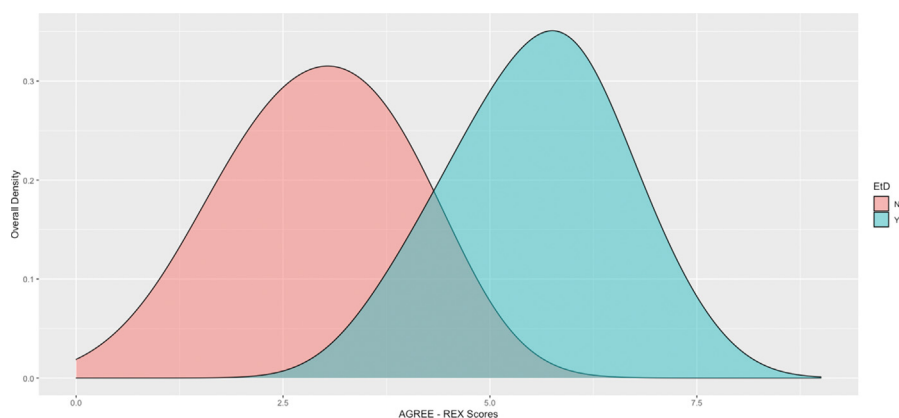


Fig. 5. Overall AGREE-REX scores in EtD guidelines and non-EtD guidelines.

4.2. Our results in the context of previous research

Our evaluation builds on our previous study in which we analyzed the EtD processes and frameworks reported in guidance documents from guideline organizations [14]. The overarching aim of an EtD framework is to help decision-makers to achieve fairness and transparency when formulating recommendations [7,8]. A growing number of studies are supporting this notion [8,10,14,22,23]. Our main finding that using an EtD framework may lead to better quality of guidelines and recommendations, coincides with those from previous studies, in which the GRADE-EtD framework was essential to structure panel meetings and consider all relevant criteria [23]; being favorably accepted by different stakeholders [22,24].

4.3. Limitations and strengths

Although we included 66 guidelines from well-known organizations, we make no claims of exhaustiveness or representativeness of our sample; further studies may confirm or rebut our results by including a larger (and more diverse) number of guidelines. Our analysis is mainly drawn from guidelines published in recent years by professional societies from North America and Western Europe, which restricts its generalizability to other contexts where fewer resources may be allocated to guideline development. However, in these other settings, guidelines are less likely to have a guidance document or use an EtD framework.

A strength of this project is our team's expertise, including, mostly, evidence synthesis and guideline methodologists; including authors of the AGREE-II tool, and most importantly for the goal of this study, authors of the GRADE-EtD frameworks. The potential bias of a favorable analysis and interpretation about this framework is unlikely, given the results, showing a similar signal across different types of frameworks. Furthermore, we worked independently and were blinded to others' decision both at data extraction and data analysis. Moreover, our analysis was reliant on the information presented in the guideline. Lastly,

our findings were strengthened by the prospective registration of our protocol, and the use of widely validated methodological tools.

4.4. Implications for practice and research

Our results indicate that organizations should embrace EtD frameworks, as the use of these frameworks was associated with guidelines of better quality and more credible recommendations. Furthermore, guideline developing organizations should ensure a complete reporting of supplementary material underpinning the recommendations (e.g., evidence profiles), and details on formal consensus process.

Using EtD frameworks requires significantly more resources, as it demands skilled methodologists. Higher-resourced organizations can convene larger developing groups, which will get more time (and people) to use an EtD framework. As a consequence, if used and reported adequately, these guidelines may obtain better quality scores than those from less-resourced organizations. Different practical considerations, such as a good-sized group of methodologists and panelists, should be arranged for the EtD frameworks to be used adequately, and make a difference on the quality of both guidelines and their recommendations.

To date, the barriers for not using an EtD framework remain largely unexplored. Lack of awareness of the EtD frameworks, training, time, and human resources may explain organizations' low uptake of EtD frameworks. However, organizations may benefit from online free training resources, and can choose from the various EtD frameworks that exist nowadays; some of them being flexible and allowing tailoring of criteria [8,10]. Besides, panelists and methodologists' experiences of using the EtD frameworks merit further research [7,8]. Both qualitative and quantitative methods may be used to tackle these research gaps, such as user-oriented approaches. This will help us better understand the context and nuances in which decisions are made.

The methods developed by the GRADE Working Group stand out as the most used approach in guideline development [3,7,25]. However, the linkages between the different EtD frameworks with guideline- and recommendation quality remains inconclusive, as our study lacked power. This research gap warrants further investigation, as the EtD frameworks available differ from one another, not only in terms of the criteria underpinning the recommendations but also in how the information is presented to stakeholders and the approach to consensus achievement. The relationship between the use of EtD frameworks and the adoption or adaptation of guideline recommendations emerges as another area of research. Our data revealed notable advantages of the use of the frameworks across AGREE-II domains, most importantly on rigor of development (81% vs 40%); a crucial domain when deciding upon adaptation or adoption of recommendations [26]. Other additional research areas are the potential implications of not using an EtD framework on end-users and other stakeholders, and the study of organizations and stakeholders' views toward the use of this type of frameworks.

5. Conclusion

Our findings suggest that using EtD frameworks is associated with guidelines of better quality and more credible and transparent recommendations; therefore, guideline developing organizations should use EtD frameworks to formulate their recommendations. Future research should help the refinement of the frameworks and their use when formulating recommendations.

Declaration of competing interest

The authors declare that they have no competing interests. Jose Meneses-Echavez is a doctoral candidate in Public Health and Methodology of Biomedical Research, at the Department of Pediatrics, Obstetrics, Gynecology and Preventive Medicine at Universitat Autònoma de Barcelona, Spain. Pablo Alonso-Coello, Signe Flottorp, and Holger Schünemann were involved in the development of the GRADE-EtD framework. Ivan Dario Florez and Pablo Alonso-Coello were involved in the development of the AGREE-REX tool. Most of the authors are active members of the GRADE Working Group.

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The preliminary results of this work were presented as a conference paper in the 17th Guidelines International Network (GIN) Conference 2022: Making Health Choices Transparent, Equitable and Efficient, 21-24/9/2022, in Toronto, Canada [27].

Supplementary data

Supplementary data related to this article can be found at <https://doi.org/10.1016/j.jclinepi.2023.07.013>.

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