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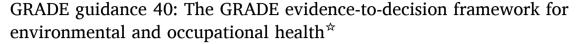
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ABSTRACT

Objective: To provide guidance for the use of the Grading of Recommendations Assessment, Development and Evaluation (GRADE) Evidence-to-Decision (EtD) framework for environmental and occupational health (EOH). Study design and setting: We conducted a systematic review and narrative synthesis of published and public EOH decision frameworks, followed by a modified Delphi process leading to development of a draft GRADE EtD framework for EOH. We pilot tested the provisional framework through a virtual workshop series, which further informed guidance for the framework's application. We presented a summary of the results to all attendees of the GRADE Working Group meeting for feedback in July 2022 and November 2022, and for approval in May 2023. Results: Consistent with existing GRADE EtD frameworks, the EtD framework for EOH includes a scoping and contextualization process and twelve assessment criteria. Modifications to the existing EtD frameworks include: consideration of the socio-political context when making judgments about the priority of the problem and feasibility of different alternatives; the addition of timing when making judgments about benefits and harms, the balance of effects, and feasibility; broadening of the equity criterion to include considerations beyond health equity; and more explicit accommodation of variable or conflicting stakeholder views when considering values and acceptability. The new EtD framework is also accompanied by a user guide intended to support its implementation in the EOH context.

Conclusion: Policymakers, regulators, and other stakeholders may use this GRADE EtD framework to approach decision-making about environmental and occupational exposures and interventions.

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What is new?

Key findings

- The GRADE EtD framework accommodates relevant concepts for decision-making in environmental and occupational health (EOH).
- Limited uptake of the GRADE EtD framework in EOH may be attributed to factors other than incompatibility of the EtD framework with EOH decision-making approaches.
- Guidance for users is essential to support the framework's implementation in EOH.

What this adds to what was known

- There are currently six GRADE EtD frameworks for different types of decisions: individual- and population-level clinical recommendations, health system and public health recommendations, coverage decisions, individual- and population-level diagnostic test recommendations.
- This project introduces a seventh framework that is tailored for environmental and occupational health (EOH) decisions.

What are the implications and what should change?

 Policymakers, regulators, and other decision-makers should consider adopting the GRADE EtD for EOH to enhance consistency, transparency, and stakeholder trust in EOH decisions, including recommendations or regulations.

1. Background

Systematic review (SR) methods are increasingly used to provide comprehensive and rigorous evidence on the health impacts of environmental and occupational (EOH) exposures (Woodruff and Sutton, 2014; Hoffmann et al., 2022; Rooney et al., 2014; Whaley and Roth, 2022; Wolffe et al., 2019; Morgan et al., 2016; Radke et al., 2020; Pega et al., 2022). However, the results of SRs often highlight uncertainty in the available evidence, which presents a challenge to translating systematic review findings into clear policy recommendations. Additionally, values, baseline conditions, and susceptibility to harms may be variable both across and within affected populations. Furthermore, decision-makers must often balance societal, economic, and political considerations, complicating the direct application of scientific evidence in policymaking. Addressing the integration of SR findings with additional considerations is crucial to enhancing the credibility, transparency, and consistency of decisions, ensuring that evidence is meaningfully integrated into EOH guidelines.

GRADE (Grading of Recommendations Assessment, Development, and Evaluation) evidence-to-decision (EtD) frameworks support decision-makers in developing recommendations that are based on informed, transparent judgements about the potential consequences of different options (Alonso-Coello et al., 2016). These frameworks facilitate consideration of potential desirable and undesirable health effects (benefits and harms), while also systematically taking into account values, resource use, equity, acceptability, and feasibility of different alternatives (Alonso-Coello et al., 2016; Andrews et al., 2013; Andrews et al., 2013). The intended result is an evidence-informed recommendation or decision that can be fully explained to stakeholders. The GRADE EtD frameworks, introduced in 2016, address six types of decisions: individual- and population-level clinical recommendations, health system and public health recommendations, coverage decisions, individual- and population-level diagnostic test recommendations (Alonso-Coello et al., 2016; Morgan et al., 2018; Parmelli et al., 2017; Moberg et al., 2018; Schünemann et al., 2016; Mustafa et al., 2017; Evidence to Decision (EtD) framework DECIDE, 2011).

A clear and consistent approach is essential for making decisions

about EOH policy interventions, such as selecting exposure thresholds, or recommending appropriate personal protective equipment (Woodruff and Sutton, 2014; Rooney et al., 2014; Grandjean and Ozonoff, 2013; Hart, 2020). These decisions impact broad and diverse groups of stakeholders (e.g., local communities, business owners, political figures) with serious consequences, yet they are often based on very uncertain evidence (Morgan et al., 2016; Morgan et al., 2018; Morgan et al., 2019). There is no prevailing approach to integrating evidence, such as the output of a hazard identification or risk characterization process, with additional decision factors in EOH (Senerth et al., 2025). Through a systematic literature review of and a modified Delphi study, we identified a patchwork of decision frameworks that have been developed for specific scenarios with limited generalizability beyond their niche (Senerth et al., 2025). For example, a framework for making decisions about decommissioning oil and gas platforms is not applicable to a chemical alternatives assessment, despite some conceptual overlap (consideration of feasibility, cost, and ecological impact) (Malloy et al., 2013; Bernstein, 2015). We propose that the GRADE EtD framework may add value to the formulation of EOH decisions by facilitating a standardized and transparent decision-making process across many different types of decisions (Neumann et al., 2016; Zähringer et al., 2020; Meneses-Echavez et al., 2023). This guidance aims to introduce a new GRADE EtD framework that has been developed to bridge gaps between decision-making approaches in EOH and the existing GRADE EtD framework.

2. Methods

We adopted an inductive approach to identify considerations that are useful to inform EOH decision-making, building on the deductive approach used to develop the GRADE EtD framework (Moberg et al., 2018). We then followed an iterative process to refine a comprehensive list of decision considerations into an organized and well-defined framework. First, we conducted a systematic review and narrative synthesis of published and public EOH decision frameworks; second, an expert panel rated the considerations identified from the literature through a modified Delphi process (Senerth et al., 2025). Finally, we conducted a workshop series to pilot test the provisional GRADE EtD framework for EOH with an example decision scenario, which further informed guidance for the framework's application.

2.1. Stage 1: Systematic review & narrative synthesis

2.1.1. Protocol and search strategy

The systematic review protocol was registered on PROSPERO (CRD42022316686) and reported according to Preferred Reporting Items for Systematic Reviews and Meta-Analysis (PRISMA) standards (Page et al., 2021; Emily Senerth et al., 2024). Detailed methods and results from the review are reported separately. In brief, the search strategy was developed in consultation with an experienced health sciences librarian and translated into the following databases: MEDLINE via PubMed, EMBASE, and Cochrane Library. The search was restricted to materials published in English within 10 years prior to the starting date of the review (September 26, 2021) to capture frameworks published both before and after publication of the GRADE EtD that are plausibly still in use. Additionally, we conducted a manual search of gray literature, including websites of government, professional, and public health organizations that produce health guidelines and the federal register.

2.1.2. Study selection

We included primary studies or systematic reviews of frameworks, tools, or templates for making decisions or formulating recommendations, or for priority-setting of interventions or exposures in public health. By employing an inclusive selection strategy, we aimed to identify a comprehensive set of frameworks within the subset of

environmental and occupational health. We excluded sources that: did not have relevance to EOH decision-making, evaluated the effectiveness of specific EOH interventions, did not describe a decision-making framework, or described a framework that is focused exclusively on economic analysis, certainty of evidence assessment, risk assessment, or hazard identification. If multiple documents reported on the same framework, exact duplicates were excluded and duplicated reports of the same framework were only included once. Two reviewers independently screened each title, abstract, and full text in duplicate. At all stages of the review, disagreements were resolved through discussion or by consulting a third reviewer.

2.1.3. Data management and abstraction

Search results were exported to Covidence (Covidence systematic review software, Veritas Health Innovation, Melbourne, Australia. Available at www.covidence.org) to remove duplicates, screen sources, and document reasons for exclusion at the full-text stage. We used Google Forms to develop and pilot a standardized abstraction tool. If any data items were missing from or ambiguous in the published (or public) framework, we abstracted and analyzed the available information at face value, making as few assumptions as possible about the intent of the framework developer. Abstraction was performed by one researcher and reviewed by a second. We did not perform a quality appraisal of the frameworks, as this review was concerned with identifying all relevant criteria for EOH decision-making irrespective of the quality of the studies in which they are reported.

2.1.4. Analysis plan

We conducted a narrative analysis using textual descriptions and tabulation to systematically describe the characteristics of the included frameworks. For the individual decision considerations abstracted from the included frameworks, we designed a coding strategy to map abstracted considerations onto the criteria presented in the GRADE EtD framework for health system and public health decisions. This allowed us to identify: (a) the existence of an EOH decision framework that would make development of a new GRADE EtD framework redundant, (b) any concepts from EOH decision-making that are not part of the GRADE EtD framework, thereby necessitating its extension, and (c) any considerations within the EOH decision frameworks that could inform adaptation of the GRADE EtD framework to improve its applicability to EOH.

2.2. Stage 2: Modified Delphi study

The set of decision considerations resulting from the systematic review and narrative synthesis was presented to a panel of stakeholders (content experts and target users of the EtD framework), who were asked to identify any factors in EOH decision-making that were not discovered in the published or gray literature. Additionally, panelists were instructed to recommend reorganization, consolidation, and rewording of the decision considerations as the basis for development of an integrated decision framework that will be applicable to EOH. This Delphi study was conducted and reported according to published guidance; detailed methods and results are reported separately (Senerth et al., 2025; Hasson et al., 2000; Grime et al., 2016;Jüngeretal., 2017;Turoff, 2002).

2.2.1. Stakeholder panel

Stakeholders were recruited by the research team based on a matrix describing characteristics of anticipated users of an EOH decision framework and consumers of EOH recommendations. We aimed to recruit between 15 and 25 total panelists comprising target users of the GRADE EtD framework for EOH, participants with expertise in GRADE methods, and participants with expertise in several subspecialties of environmental and occupational health. The panel was appointed after ensuring consent to participate and balanced representation across

gender, geographical settings, institutional contexts, and topical expertise. Prior to convening the panel, we collected information on intellectual and financial relationships from participants and did not identify any conflicts that would necessitate recusal for any portions of the process.

2.2.2. Study procedures

Panelists received instructions and survey materials via email; the survey was developed and fielded in Excel (Version 16.67; Microsoft, 2022). Panelists rated decision considerations that were abstracted and consolidated from the systematic review and narrative synthesis, along with criteria and detailed judgements from the GRADE EtD framework as presented in GRADEpro (gdt.gradepro.org) on a 7-point Likert scale. The questionnaire also included multiple opportunities for free text comments: suggestions for revision of the wording, requests for additional guidance, other comments on the considerations, and addition of any new considerations. Questionnaires were completed independently, and panelists were not provided with any information about how others had voted in the prior round. The first round of the Delphi exercise began in March 2022 and lasted 14 days; the second round began in June 2022 and used a modified questionnaire based on iterative feedback and consensus during Round 1; this round also lasted 14 days.

2.2.3. Analysis plan

Survey responses were anonymized by one member of the research team (ES) and processed by three members of the research team (RLM, PW, ES) during a series of virtual meetings. The primary outcome was attainment of panel consensus on the inclusion and wording of each consideration. Responses were analyzed using descriptive statistics. Items that received a median rating of > 6.9 out of 7 automatically advanced to the next round; items that received a median rating of < 4.9 were removed. Items with median scores in between these values and/or items demonstrating large variability in rating (i.e., IQR > 2) were discussed during the consensus meetings, including qualitative analysis of free text comments. These were coded into four categories: "scope (wording should be more specific to environmental health), redundancy (addressed within or duplicated by another item), new (new decision consideration proposed by the respondent), and clarity (the content of the item is unclear to the respondent). Panel ratings and feedback from the second round informed organization of the decision considerations into a decision framework.

2.3. Stage 3: Pilot workshop series

We subjected the provisional GRADE EtD framework for EOH to a series of pilot tests to investigate its capability to accommodate an example EOH decision scenario, and to identify potential barriers to framework implementation in a real-world setting.

2.3.1. Workshop participants

Subject matter experts were recruited by the research team, with a focus on outreach to anticipated users of an EOH decision framework and those with experience in EOH decision-making. The first workshop was advertised to the GRADE environmental health project group (n = 82). Additional prospective participants (n = 29) were recruited via social media (Twitter, LinkedIn) and personal emails from the research team detailing the objectives, anticipated process, and timeline. We placed no limit on the number of participants. The first workshop had 18 participants from the GRADE EH project group and the second workshop had three participants from the United States Environmental Protection Agency.

2.3.2. Workshop structure

We conducted two virtual workshops of two hours duration with separate participant groups. The virtual format was selected to be most inclusive of diverse geographic regions and to facilitate recording. Regardless of their current role, participants were instructed to approach the EtD framework from the perspective of decision-makers when providing feedback. They were also advised about the objective of the workshop, provided with background information on the project, and presented with an abbreviated GRADE evidence profile describing the health benefits and harms of the proposed intervention. For the purposes of this exercise, participants were asked to assume that the evidence profile was accurate and comprehensive. After this introduction, participants worked through each of the assessment criteria of the GRADE EtD framework for EOH facilitated by three members of the research team (ES, RLM, PW). These workshops did not include pilot testing of the EtD framework scope and context criteria due to constraints on participants' availability.

2.3.3. Example decision scenario

The research team developed a hypothetical EOH decision scenario so that an accelerated decision-making process would be feasible during a single two-hour workshop. The question presented to workshop participants was: "As a regional government health agency serving Fayette County, West Virginia, USA (Appalachia), you are tasked with providing a recommendation between two options: should a local coal mine be closed or continue to operate as usual?" (Supplement 1).

2.3.4. Analysis plan

One member of the research team (PW) took contemporaneous notes during each workshop. Recordings were subsequently reviewed by a second researcher (ES) to clarify or augment these notes. Three members of the research team who attended both workshops (PW, RLM, ES) conducted thematic analysis through discussion and further annotation of the participant feedback.

2.3.5. Approval of guidance

Throughout the development effort, interim results were shared with the GRADE Working Group and GRADE Environmental Health Project Group, including presentations in October 2021, July 2022, and November 2022. We presented a summary of the final results to the GRADE Environmental Health Project Group (approximately 30 attendees) and all attendees at a subsequent meeting of the GRADE Working Group (approximately 65 attendees) in May 2023. The GRADE EtD framework for environmental health was formally approved by the GRADE Guidance Group on June 8, 2023.

3. Results

The GRADE EtD framework for EOH follows the same structure as its foundational framework, the GRADE EtD framework for health system and public health decisions (Pega et al., 2022). This includes a scoping and contextualization process, and twelve assessment criteria (priority of the problem, desirable effects, undesirable effects, values, balance of effects, certainty of evidence, resources required, certainty of resources required, cost effectiveness, equity, acceptability, and feasibility) (Table 1 and 2). The GRADE EtD framework for EOH differs from other EtD frameworks in the organization and wording of the scoping criteria, and the detailed judgments within each assessment criterion (Table 3). This tailoring is based on cumulative insights from all three phases of the project, reflecting the theoretical and practical considerations that are relevant to EOH decision-making described in detail below. The framework is also accompanied by a user guide intended to support consistent interpretation and application of concepts across different groups (Table 4). Thus, the framework and guidance presented here are grounded in both the original GRADE EtD framework, and existing decision-making approaches that have been applied in EOH.

3.1. Scope & context

There are 10 scoping criteria in the GRADE EtD framework for EOH:

Table 1
Scoping criteria for environmental and occupational health decision-making.

Scoping Criteria	Guidance
Purpose	Specify the health outcomes and expected benefits or harms
Perspective	Specify the perspective that the panel will take when making recommendations: impact on a specific group (e.g., workers) vs. overall population/societal impact, human health vs. one health
Target population	Specify the intended beneficiaries of the recommendation
raiget population	(e.g., people affected by the environmental issue, workers, industry, society)
Setting	Specify level at which the recommendations will be implemented: occupational or non-occupational setting; health care or non-health care setting; regional, national, or international level
Key coexisting conditions	Specify the relevant co-exposures and susceptibility factors: age, gender, socioeconomic status, chronic illness, access to health care, long working hours, etc.
Types of interventions	If applicable, specify the intervention(s) under consideration: prevention (e.g., removal of a harmful exposure), remediation (e.g., clean-up of contaminated areas), public education, new or updated regulation, new or updated exposure threshold, etc.
Key stakeholders / users	Specify all relevant professional groups, institutions, public constituencies, etc. who are target users or beneficiaries of the decision and/or whose views should be sought
Key resources	Specify resources needed for the implementation (e.g., additional human resources, equipment, infrastructure, system changes, etc.)
Key implementation issues	Specify any important barriers or facilitators to implementing the intervention
Existing documents	Consider existing documents, regulations, or guidelines on the same or similar topic that are currently in use (e.g. regulations or guidelines developed by other organizations)

purpose, perspective, target population, setting, key coexisting conditions, types of interventions, key stakeholders/users, key resources, key implementation issues, and existing documents (Table 1). The scoping process is intended to outline the parameters or conditions under which the decision will be made. It is also an opportunity to define the options under consideration. For decisions about exposures, the options may be complete discontinuation of an existing exposure vs. continuation at a specific threshold (e.g., banning the use of polychlorinated biphenyls in manufacturing vs. implementation of a permissible exposure limit), or selection of an alternative to a harmful exposure (e.g., synthetic esters vs. perfluorinated compounds as an alternative to polychlorinated biphenyls). For decisions about interventions, options may be different exposure thresholds (e.g., ≤ 8 h of exposure to 90 dB vs. ≤ 8 h of exposure to 85 dB), or selection of measures to mitigate the effects of exposures that may be harmful (e.g., physical sound barriers vs. lubrication of machinery to reduce decibel levels). Ultimately, the specific options under consideration should be defined by the relevant stakeholders and subject matter experts.

Findings: Results of our literature review and modified Delphi process did not suggest any changes to the existing EtD framework scoping criteria. However, stakeholder reactions to the assessment criteria underlined the importance of the scoping components of the EtD. Omitting the scoping process may result in confusion about the intent or target of the assessment criteria questions. Judgments about the acceptability of different alternatives, for example, are contingent on the key stakeholder groups identified during scoping.

Implications: As the scoping criteria are critical to answering subsequent assessment questions, the guidance for users emphasizes their importance and advises decision-makers to refer to their pre-specified parameters to answer related signaling questions (Table 4). This is evident in the following criteria: problem, desirable effects, undesirable effects, values, and acceptability.

We also revised existing guidance for the scoping process to change the terminology and examples from clinical decision types to environmental health (Table A). For example, guidance about selecting a

Table 2 GRADE evidence-to-decision framework for environmental and occupational

Assessment Criteria	Detailed Judgments	General Response Options [apply to criteria questions; apply to detailed judgements unless otherwise specified]	th
Problem Is the problem a priority?	 Are the consequences of the problem serious (i.e., severe, irreversible, or important)? Is the problem urgent, emergent, or unprecedented? 	No Probably no Probably yes Yes Varies Don't know	co
	 Is the problem a recognized priority of the political system (local or national)? Is the problem a recognized occupational or public health concern? Is the problem a 		Reso Ho re: (c
	recognized priority of the local community?		Cert of
Desirable effects How substantial are the desirable anticipated effects?	 How substantial is the anticipated desirable impact (effect) of the intervention or exposure? How substantial is the time span for the intervention or exposure 	Trivial Small Moderate Large Varies Don't know	W. the rec
Undesirable effects How substantial are the undesirable anticipated effects?	 to reach full effectiveness? How substantial is the anticipated undesirable impact (effect) of the intervention or exposure? How substantial is the time span for the undesirable effects of the intervention or exposure 	Large Moderate Small Trivial Varies Don't know	
Certainty of evidence What is the overall certainty of the evidence of effects?	to reach full effectiveness? • [See GRADE evidence profile (or similar analysis)]	Very low Low Moderate High	Cost Do eff in: in: co
Values Is there important uncertainty about or variability in how much people value the main outcomes?	 Is there important uncertainty about how much people value the main outcomes? Detailed judgment answer choices: 	No included studies Important uncertainty or variability Possibly important uncertainty or variability	
	important uncertainty, probably important uncertainty, probably no important uncertainty, no important uncertainty, don't know Detailed judgment answer choices: important variability, probably important variability, probably inportant variability, no important variability, don't know Is there meaningful variability in how much people value the main outcomes?	Probably no important uncertainty or variability No important uncertainty or variability	Equ W im
Balance of effects Does the balance between desirable and undesirable effects favor	 [Based on judgments from prior five criteria] 	Favors the comparison Probably favors the comparison Does not favor either	

Ta

Assessment Criteria	Detailed Judgments	General Response Options [apply to criteria questions; apply to detailed judgements unless otherwise specified]	
the intervention/ exposure or the comparison?		the intervention/ exposure or the comparison Probably favors the intervention/exposure Favors the intervention Varies	
Resources required How large are the resource requirements (costs or savings)?	 For each type of resource, would the intervention or exposure under consideration produce additional costs or savings? 	Don't know Large costs Moderate costs Negligible costs and savings Moderate savings Large savings Varies Don't know	
Certainty of evidence of required resources What is the certainty of the evidence of resource requirements?	 Have all relevant resource types been identified? Detailed judgment answer choices: no, probably no, probably yes, yes, varies, don't know Detailed judgment answer choices: important variability, probably important variability, probably no important variability, no important variability, don't know Is there important variability in the cost of the resource types under consideration? 	Very low Low Moderate High No included studies	
Cost effectiveness Does the cost effectiveness of the intervention favor the intervention or the comparison?	 What is the certainty in the cost effectiveness analysis? Detailed judgment answer choices: very low, low, moderate, high, no included studies 	Favors the comparison Probably favors the comparison Does not favor either the intervention or the comparison Probably favors the intervention Favors the intervention Varies No included studies	
Equity What would be the impact on equity?	● Are there groups or settings (e.g., susceptible populations or life stages, complex or unquantified stressors) that may experience a less advantageous impact (effect) of the intervention or exposure due to variability in baseline conditions across the affected population? Detailed judgment answer choices: no, probably no, probably yes, yes, varies, don't know Detailed judgment answer choices: no, probably no, probably yes, yes, varies, don't know Detailed judgment answer choices: no, probably no, probably yes, yes, varies, don't know Detailed judgment answer choices: no, probably no, probably yes, yes, varies, don't know Detailed judgment answer choices: no, probably no, probably no, probably yes,	Reduced Probably reduced Probably no impact Probably increased Increased Varies Don't know	

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Table 2 (continued) Assessment Criteria
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Acceptability Is the intervention acceptable to key stakeholders?
Feasibility Is the intervention feasible to implement?

Detailed Judgments General Response

Options [apply to criteria questions; apply to detailed judgements unless otherwise specified1

yes, varies, don't know Detailed judgment answer choices: no, probably no, probably ves. yes, varies, don't know

- Are the impacts (effects) disproportionate to particular groups?
- Would implementing the intervention or exposure increase inequities experienced by marginalized members of the affected population?
- Does the intervention or exposure increase inequality (i.e., introducing or perpetuating unequal distribution of benefits/ harms or representation)?
- What is the certainty in the acceptability of the intervention among the affected population?

Detailed judgment answer choices: very low, low, moderate, high, no included studies

Detailed judgment answer choices: important variability, probably important variability, probably no important variability, no important variability. don't know

- Is there variability in the acceptability of the intervention or exposure among intended beneficiaries of the recommendation and other stakeholders?
- Is the intervention (option) sustainable for the relevant duration of
- Are there important barriers (e.g., absence of laws/regulations) that are likely to limit the feasibility of implementing the intervention (option)?
- Are remedies available to address any important barriers to implementing the intervention?
- Are there important enablers (e.g., presence of laws/regulations) that are likely to improve the feasibility of implementing the intervention (option)?

Probably no Probably yes Yes Varies Don't know

No Probably no Probably yes Varies Don't know

perspective was changed from "individual patients, their families, providers caring for those patients, public health, health system, payer, population (the society), etc." to "impact on a specific group (e.g., workers) vs. overall population/societal impact, human health vs. one health.".

3.2. Priority of the problem

Findings: The problem, question, or issue that is the subject of discussion (e.g., should incineration vs. landfills be used for disposal of residual polychlorinated biphenyls) is largely assumed to be a priority by the time a decision-making process has begun. Topics may be prioritized through a separate process and EOH decision-makers do not typically reconsider importance or magnitude of the problem when assessing different solutions. Consequently, the purpose of this criterion may be unclear to target users.

Implications: The guidance clarifies that this criterion may be useful for decision-makers to disaggregate and document why some issues are more or less important, and to revisit the stakes of the final decision when assessing the options. This is reflected in the detailed judgments, which ask decision-makers to reflect on the consequences and urgency of the issue at hand, and whether the political system or local community has identified the problem as a priority. Priorities also may evolve from the time a topic is prioritized to when it is addressed; decisionmakers can note that here.

3.3. Magnitude of desirable and undesirable health effects

Findings: The possible benefits and harms (desirable and undesirable health effects) of an exposure or intervention may include health outcomes such as lung disease, and indirect or surrogate effects, such as job loss leading to a loss of health care benefits. Health outcomes are partly a product of the social, economic, and geographic context. EOH interventions may impact health through changing this context, and these effects may be as important to stakeholders as direct outcomes on health. It is also common for EOH exposures to have no potential benefits (e.g., lead). On the other hand, interventions to mitigate harmful exposures (e.g., abatement or encapsulation of lead-based paint) may have benefits, such as reduction in the harmful health effects caused by the exposure. Both types of effects should be explicitly accounted for by the decision-making process. Finally, timing of the desirable and undesirable effects is an important consideration when balancing the benefits and harms of a potential exposure or intervention. Undesirable effects may be immediate (e.g., loss of employment, loss of access to certain chemicals with important uses), while desirable effects manifest over a longer period of time (e.g., reduction in new cases of health

Implications: The guidance clarifies that decision-makers should explicitly state when there are no known benefits, or that benefits were not considered and why not. The organized process of considering both desirable and undesirable effects is useful in any case because decisionmakers may not be able to predict which criteria will be relevant until they begin an assessment of the options, and because it facilitates documentation of factors that were judged to be irrelevant or unimportant. Otherwise, stakeholders may conclude that these factors were not considered at all. Additionally, detailed judgments about the timing of an exposure or intervention to reach full effect were added to the desirable and undesirable effects criteria. Decision-makers should note any relevant time points when documenting judgments about the balance of effects, giving particular attention to the time point that was given the most weight.

3.4. Values

Findings: EOH decision-makers frequently must account for differences in values, even when considering only the intended beneficiaries

Table 3
Summary of research findings informing development of the GRADE EtD framework for environmental and occupational health.

Criteria	Key Features of the EOH EtD Framework	Findings	Implications
Scope & context	Pre-specify the purpose, perspective, target population, setting, key coexisting conditions, types of interventions, key stakeholders/users, key resources, key implementation issues, and existing documents before assessment of options	Judgments about the subsequent assessment criteria are frequently informed by the parameters identified during scoping.	Guidance emphasizes the connection between the two components of the EtD: scoping and contextualization, followed by assessment of options.
Problem priority	Judgment of the severity and urgency of the problem	While the question or issue is assumed to be a priority by the time of decision-making, the detailed judgments allow stakeholders to	Detailed judgments tailored to EOH context (e.g., emergent or unprecedented situations)
	Consideration of political, community, and public health concerns	disaggregate importance across multiple topics and weight (volatility) of the decision.	Guidance details the utility of establishing why the question is a priority, including iteratively informing prioritization across multiple decision topics, anticipating controversial decisions, and beginning the decision process with reflection on the magnitude of the issue at hand.
Desirable and undesirable effects	Judgment about the magnitude of effect and time span to full effect	The benefits and harms under consideration may include primary and indirect or surrogate health outcomes.	Guidance clarifies that decision-makers should make potential benefits and harms explicit, including documentation of factors that were judged to be inapplicable, irrelevant, or
		It is also common for EOH exposures to have no potential benefits.	unimportant.
Values	Judgment about the variability and uncertainty in values of the target population	Values of the target population may vary and additional guidance is needed to help EOH decision-makers consider opposing values	Framework establishes that the values are those of the beneficiary of the decision
		across/within populations.	Guidance emphasize the importance of transparently recording differences in values across/within populations
Balance of effects	Weighting of judgments from the prior criteria (desirable/undesirable effects, certainty, values)	This criterion is sensitive to timing, particularly the balance of short-term benefits with long term harms and vice versa.	Guidance advises decision-makers to document time points where the balance of benefits and harms may differ and specify which time point was given the most weight in decision-making.
Resources required	Consideration of costs or savings associated with implementation of the intervention or exposure.	Existing EOH decision frameworks provide granular resource considerations that are not generalizable outside of the specific scenario they were developed to address.	Detailed judgments for this criterion are intended to be broad enough to accommodate a variety of decision scenarios.
		The issue of funding sources for required resources, or responsibility for providing resources may have particular importance in EOH.	Distribution of responsibility for providing the required resources may be addressed as an implementation consideration.
Cost effectiveness	Consideration of the certainty of any available cost-effectiveness analysis	Decision-makers may intuitively bring downstream costs and benefits into consideration for this criterion.	Guidance for users provides more detail on the intended scope of this criterion, which includes only direct costs and benefits.
Equity	Consideration of multiple dimensions through which an intervention or exposure may impact equity, including indirect contextual impacts and direct health impacts	The scope of the equity criterion extends beyond immediate health equity considerations to include the broader socio-economic context in which EOH decisions occur.	Detailed judgments disaggregate various lenses through which the impact on equity may be assessed.
Acceptability	Judgment about the variability and uncertainty in acceptability of the exposure or intervention to stakeholders	This criterion is especially sensitive to the scope of EOH decisions. Judgments about acceptability are likely to vary significantly depending on which stakeholder views are taken into account.	Framework establishes that the stakeholders are defined during the scoping process and include any groups or individuals who may be impacted by the decision.
Paradikiti:	Continuity Charles 15 West	What had and an along at 1. 1. 1. 1.	Guidance for this criterion explains how to account for variability in attitudes between stakeholder groups.
Feasibility	Consideration of barriers and facilitators to implementation of the exposure or intervention	The legal and regulatory landscape and time span for maintenance of an exposure or intervention are important considerations in EOH decision-	Detailed judgements have been tailored to include consideration of laws and regulations, and the relevant time period for sustainability.
	Consideration of the sustainability of the exposure or intervention	making.	

of the recommendation (e.g., different values within a group of mine workers based on age). The scope of EOH exposures or interventions often includes opposing values both within and across target populations.

Implications: Detailed judgments within the values criterion aim to identify uncertainty about and unexplained differences (inconsistency or variability) in values within the group or groups that are intended to benefit from the decision. Guidance refers decision-makers back to their scoping process to identify whose values should be considered and how to account for unexplained differences in the values of their target

audience with their response to this criterion.

3.5. Resources required

Findings: Existing EOH decision frameworks have poor generalizability in part due to the specificity of their resource considerations. A framework developed to address decisions about water and sanitation projects, for example, lists specific resource types that may not apply outside of this scenario: non-renewable energy consumption, water consumption, raw material consumption, etc (Garfi and Ferrer-Marti,

Table 4User guide v1.0 for the GRADE EtD framework for environmental and occupational health.

Assessment criteria

Problem

Is the problem a priority?

Desirable effects

How substantial are the desirable anticipated effects?

Undesirable effects

How substantial are the undesirable anticipated effects?

Certainty of evidence

What is the overall certainty of the evidence of effects? Values

Is there important uncertainty about or variability in how much people value the main outcomes?

Balance of effects

Does the balance between desirable and undesirable effects favor the intervention or the comparison?

Resources required

How large are the resource requirements (costs or savings)?

Certainty of evidence of required resources

What is the certainty of the evidence of resource requirements?

Cost effectiveness

Does the cost effectiveness of the intervention favor the intervention or the comparison?

Equity

What would be the impact on equity?

Guidance

Answer "yes" if the question or issue that is being decided is an urgency or emergency with potentially serious consequences (e.g., irreversible damage to population health), and/or is a recognized political, occupational, or community priority (e.g., if there is a political or social mandate to act). Refer to the target population and key stakeholders to identify relevant constituencies. If there is uncertainty about the urgency, consequences, or priority of the issue — perhaps because the situation is unprecedented — decision-makers may prefer to answer "probably yes."

Answer "**no**" or "**probably no**" if some or all the above conditions do not apply.

Answer "varies" if the response changes from "yes" to "no" or vice versa depending on the context or conditions. Answer "don't know" if there is insufficient information to make any judgment. It is not advisable to proceed beyond this point if there is no information about the magnitude of the problem or importance of the question. Answer this criterion based on any beneficial effects that are described in the evidence profile. Skip this criterion (no response) if the exposure or intervention produces exclusively harmful effects (e.g., toxicity). Decision-makers may pre-specify quantitative thresholds to define the response options, or answer based on group consensus. For example:

Answer "trivial" or "small" if the exposure or intervention is expected to have minimal benefit (i.e., a minor improvement across the entire target population or a moderate improvement to a small segment of the target population).

Answer "moderate" if the exposure or intervention would reasonably provide some benefit across the entire target population.

Answer "large" if the exposure or intervention is associated with a noticeable and important benefit to the target population.

The magnitude of the desirable effects may be amplified or attenuated by the **time span** for the intervention or exposure to reach full effectiveness. For example, an intervention that produces a large benefit only after a lengthy period of time may be judged as a "moderate" rather than "large" effect.

Answer this criterion based on any undesirable outcomes that are described in the evidence profile. Decision-makers may pre-specify quantitative thresholds to define the response options, or answer based on group consensus. For example:

Answer "trivial" or "small" if the exposure or intervention is associated with minimal harm (e.g., consequences that would be considered a minor inconvenience).

Answer "moderate" if the exposure or intervention is associated with some harms across the entire target population.

Answer "large" if the exposure or intervention is associated with serious harm to the target population. The magnitude of the undesirable effects may be amplified or attenuated by the time span for the intervention or exposure to have its full effect. For example, an exposure that is associated with trivial harm in the short-term, but moderate harm over time may be judged as a "moderate" effect with documentation of the relevant time point. Answer based on the certainty assessment in the GRADE evidence profile.

Consider the **target population** (i.e., those who will experience the exposure or benefit from the intervention). Do not consider other stakeholders when responding to this criterion; their views will be taken into account as part of a subsequent criterion.

If there is some uncertainty about how the target values the beneficial or harmful effects of the intervention or exposure, answer "important/possibly important uncertainty or variability."

If there is some variability in target population values, meaning that members of the target population have differing opinions on the beneficial or harmful effects, answer "important/possibly important uncertainty or variability."

Answer "no important/probably no important uncertainty or variability" if you are reasonably confident about the target population's values and there is little or no heterogeneity in values.

Answer based on judgments from the previous five criteria. For example, the balance of effects for an exposure that is a recognized priority, has trivial potential benefits, moderate potential harms, low certainty in the evidence, and probably no important uncertainty or variability in attitudes towards the benefits and harms would probably favor the comparison (balanced against the exposure).

If applicable, document time points where the balance of benefits and harms may differ and specify which time point was given the most weight in decision-making.

To answer this question, consider whether the intervention or exposure has greater resource requirements (large/moderate costs) or fewer resource requirements (large/moderate savings) than the other option under consideration. If the comparator involves taking no action (status quo), an intervention can only produce costs. It may be helpful to disaggregate the resource types (e.g., personnel, equipment) and consider how each category would be impacted. Answer "varies" if the intervention or exposure would produce both costs and savings across different resource types.

Answer "don't know" if there is insufficient information to make any judgment.

Answer "very low" or "low" if all relevant resource types have probably not been identified, or if there is probably important variability in the cost of one or more resource types.

Answer "moderate" or "high" if all relevant resource types have probably been identified, or if there is probably no important variability in the cost of the identified resource types.

Answer "no included studies" if the answer to the previous assessment criterion was "don't know."

To answer this criterion, weigh the direct costs of an exposure or intervention against its direct benefits. Do not consider the downstream chain of events that may produce additional costs or benefits.

The response may be attenuated by certainty in the cost effectiveness analysis. For example, decision-makers may prefer to answer "probably favors..." or "no included studies."

Answer "does not favor either the intervention or the comparison" if the costs and benefits are evenly balanced. Answer "varies" if the magnitude of either the costs or benefits differs based on the context.

Answer "reduced" or "probably reduced" if an intervention or option...

Answer "varies" if the intervention or option both reduces and increases equity depending on the context.

(continued on next page)

Table 4 (continued)

Assessment criteria	Guidance
	Answer "don't know" if there is insufficient information to make any judgment.
	Negatively affects susceptible populations
	 Places differential burdens on particular groups
	 Increases inequities experienced by marginalized populations
	 Perpetuates unequal distribution of benefits, harms, or representation
Acceptability	Consider all stakeholders identified during the scoping phase when responding to this criterion.
Is the intervention acceptable to key stakeholders?	If there is uncertainty about whether stakeholders would find the intervention or exposure acceptable, answer
	"probably no" or "probably yes."
	If stakeholder groups have differing opinions on whether the intervention or exposure is acceptable, answer "varies."
	Answer "don't know" if there is insufficient information to make any judgment.
Feasibility	Answer "no" or "probably no" if an intervention or option
Is the intervention feasible to implement?	Answer "varies" if the intervention or option may or may not be feasible depending on the context.
, ,	Answer "don't know" if there is insufficient information to make any judgment.
	 Is not sustainable for the relevant duration of time Has important barriers to implementation Does not have remedies to address any important barriers Does not have important enablers to facilitate implementation

2011). EOH decision-makers also raised the issue of financial responsibility for implementation of an intervention or threshold, including reference to the "polluter pays" principle (Senerth et al., 2025).

Implications: The GRADE EtD framework aims to describe concepts that are generalizable to many EOH decision types. Detailed judgments about resources prompt decision-makers to identify the resource types that are relevant to their scenario rather than providing a checklist of possible resources to consider. Additionally, distribution of responsibility for providing the required resources may be a particularly salient implementation consideration in EOH decision-making.

3.6. Cost effectiveness

Findings: Cost-effectiveness is a relevant consideration in EOH and may be used to inform a final decision. Users can consult EOH organizations or other offices to solicit information on cost effectiveness, if it exists. However, there may be situations in which the relative cost effectiveness of an exposure or intervention does not drive decision-making in EOH, and evidence on cost effectiveness is often unavailable. Due to the consideration of both short- and long-term benefits and harms discussed above, decision-makers may also intuitively consider downstream, hypothetical costs and benefits in addition to the direct costs and benefits of an exposure or intervention.

Implications: We simplified the detailed judgements for the cost effectiveness criterion to address certainty in the cost effectiveness analysis, if available. Guidance for users elaborates on the intended scope of this criterion, which is to assess direct costs and benefits.

3.7. Equity

Findings: EOH decision-makers often must account for both intended and unintended impacts on a community or target population. Deliberate consideration of the socio-political and economic context is important to recognize when an intervention or option may perpetuate or increase inequity, as these conditions are instrumental in shaping patterns of exposure. Failure to consider context may result in "interventions [with targets] that are resistant to change for unrecognized reasons." (Link and Phelan, 1995) Social context is partially accommodated in other EtD framework criteria, such as values, acceptability, feasibility, but also should be accommodated in equity. This will account for disparities that are immediately connected to health outcomes, as well as further upstream from these outcomes. Consideration of equity in EOH decision-making extends beyond immediate health equity

considerations to include the broader socio-economic context in which exposures or interventions occur.

Implications: Other GRADE EtD frameworks explicitly limit the scope of the equity criterion to "health equity." To improve applicability of the framework for EOH, we removed the "health" qualifier to accommodate all of the relevant dimensions by which equity may be assessed, including environmental justice. The detailed judgments have also been revised accordingly to provide guidance for decision-makers to conduct a comprehensive assessment of equity.

3.8. Acceptability

Findings: EOH exposures or interventions may be involuntary (e.g., installation of a wind farm adjacent to a residential area) or compulsory (e.g., imposition of maximum allowable exposure threshold). Additionally, exposures may be situated within a specific time span and geographic space (e.g., seasonal use of pesticides containing glyphosate). These factors impact judgments about whether an exposure or intervention is acceptable. Additionally, the response to this criterion will differ based on which constituencies are considered. For example, owners of a coal mine would presumably view closure of the mine differently than members of the surrounding community.

Implications: Pre-specifying the stakeholders is essential to making transparent and explainable judgments about whether an option is acceptable. The detailed judgements and user guidance for this criterion also explain how to account for uncertainty about or variability in attitudes between disparate stakeholder groups.

3.9. Feasibility

Findings: When assessing feasibility, EOH decision-makers may consider whether the legal and regulatory context provides an enforcement mechanism for a recommendation or exposure threshold. They may also be interested in a specific duration of time through which the exposure or intervention must be maintained.

Implications: The detailed judgements and user guidance for this criterion have been augmented to include consideration of laws and regulations as potential barriers or facilitators to implementation, and to encourage specification of the relevant time period for sustainability.

4. Discussion

Through all phases of the development effort, we did not identify any concepts applied in EOH decision-making that are distinct from those

described in the GRADE EtD framework. For example, criteria such as consideration of acceptability, feasibility, and resource use are commonly seen in EOH decision approaches and also represented in the EtD framework. Thus, incompatibility of the framework content with EOH contexts does not explain why the GRADE EtD framework is not currently being used in EOH decision-making. Other possible explanations plausibly include some combination of the following factors: lack of awareness about the EtD framework due to relatively recent adoption of the GRADE approach in EOH; rejection of the EtD framework because of an appearance of incompatibility with EOH decision scenarios, due to the clinical terminology and examples through which the framework is presented; hesitancy about the applicability and veracity of a framework that was not explicitly developed to address EOH decisions; and challenges for new users in interpreting and implementing the framework, especially in situations where evidence to inform judgments may be lacking. We have aimed to address these factors through development of a new GRADE EtD framework for EOH and accompanying guidance.

Decision-makers may find the structure of the GRADE EtD framework for EOH useful when evaluating complex tradeoffs between potential benefits and harms over time, assessing options with only adverse health outcomes (no potential benefits), accounting for both direct and indirect effects on equity, and balancing opposing stakeholder views. For example, in a recent regulatory impact analysis on emissions standards for ethylene oxide (EtO), the EPA weighed an estimated reduction in cancer risk to local populations (long-term benefit) alongside potential constraints to the medical device supply chain resulting in shortages (short-term harm), among many other considerations. In addition to the differing impacts over time, affected stakeholders (local residents, companies that use EtO for sterilization, patients of the health system, and others) may have very different values about the possible consequences of changing the emission standard. Further, the EPA conducted an environmental justice analysis to support this decision and found that African Americans and households with income below the poverty line are disproportionately represented in areas with higher risk sterilization facilities, representing variability in baseline conditions across the target population of local communities (Health et al., 2024). The framework and guidance presented herein have been developed with the aim of accommodating many common EOH decision-making circumstances. The GRADE EtD framework for EOH reflects concepts that are evident in existing approaches to decision-making but may be applied inconsistently across different decisions and organizations. Given the unique challenges described above, using a standard framework to document and explain the judgments that inform a decision may be useful to establish the credibility of the process and, ultimately, foster understanding and acceptance of the decision by stakeholders.

Although we primarily aimed to address barriers to EtD framework implementation that were surfaced by EOH stakeholders, certain modifications to the GRADE EtD framework criteria and detailed judgments may also be applicable beyond the EOH context. These include the addition of timing as a consideration for the desirable effects, undesirable effects, balance of effects, and feasibility criteria, and the broadened scope of the equity criterion to include contextual factors in addition to direct effects on health.

The resulting guidance also contains information that may have cross-cutting relevance to all of the GRADE EtD frameworks. This includes clarification of common terms, introduction of new examples, and further elaboration on the intended application of various response options. One key message of the guidance is that decision-makers may have difficulty answering the assessment criteria questions if they have not addressed the preceding scope and context issues. The scoping component of the GRADE EtD framework for EOH establishes the parameters for decision-making that facilitate analysis of different options.

Another key message is that while decision-makers may judge any component of the EtD framework as inapplicable to their scenario, the function of the framework is to provide a standard list of prompts and document any judgments about their relevance for justification and explanation to stakeholders. Alternately, the evidence available to inform judgments about a relevant criterion (e.g., undesirable effects, cost-effectiveness, etc.) may be very low certainty or entirely unavailable. In this case, systematic consideration of all the relevant decision factors and identification of the evidence gaps is particularly important. Decision-makers may reasonably elect to make a judgment for any criterion based on indirect or modeled evidence, or cumulative experience with documentation of the process and uncertainty (Mustafa et al., 2021). In the context of an emergency, urgent, or rapid response, decisions may be necessary regardless of whether high certainty evidence is available (Thayer and Schünemann, 2016). In other words, the framework does not supplant judgment by EOH decision-makers, but rather provides a tool to make these judgments transparent and replicable.

The guidance also aims to address a common scenario in which there is more than one reasonable response to an assessment criterion. For example, decision-makers who are split between two neighboring options (e.g., "small" vs. "trivial" undesirable effects) should pick the best fit based on group consensus or majority vote. A split between options that are more than one degree apart (e.g., "moderate" vs. "trivial" undesirable effects) necessitates further discussion to elucidate and document the justification for each possible answer, followed by group consensus or majority vote. Decision-makers are encouraged to define thresholds for consensus and procedures for resolving disagreement before beginning the assessment process. Finally, decision-makers may also find it helpful to engage an external facilitator with experience applying the GRADE EtD framework, whether or not they are approaching the process from an EOH perspective.

4.1. Strengths and limitations

We followed a robust process to adapt an existing GRADE EtD framework for a new context, including conducting a systematic review and narrative synthesis of environmental and occupational health decision frameworks, a modified Delphi study to collect and organize feedback from subject matter experts, and a series of workshops to test the framework assessment criteria.

However, this work has several important limitations. Engagement of target audiences was challenging due to logistical constraints that limited workshop participation. The perspectives represented by the Delphi panel and workshop participants are not comprehensive of all EOH decision-makers. Judgments by these investigators to interpret and operationalize information are inherently subjective and may not be replicable. Finally, we were unable to include the scoping component of the framework in the piloting exercise due to time constraints.

4.2. Implications for practice, policy, and research

Future research will involve additional testing and validation of the framework, specifically the scope and context criteria. This may include additional qualitative research into current practices and attitudes towards decision-making in environmental and occupational health, and user acceptance testing of the GRADE EtD for EOH in simulated or reallife decision scenarios. Feedback from and testing with users will inform modifications, if needed. Finally, it may be useful to explore the generalizability of findings from the development of the GRADE EtD for EOH and accompanying guidance to other EtD frameworks, such as an EtD framework that considers planetary health which GRADE is currently exploring.

5. Conclusion

This article describes the development, composition, and guidance for operationalization of a new GRADE EtD framework for EOH. This work was undertaken to provide a standardized and transparent method for integrating research evidence and other relevant factors when formulating EOH decisions. Approaches to reduce barriers to GRADE EtD framework implementation in EOH may also be helpful in other contexts.

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CRediT authorship contribution statement

Emily Senerth: Writing – original draft, Visualization, Project administration, Methodology, Investigation, Formal analysis, Data curation, Conceptualization. Paul Whaley: Writing – review & editing, Supervision, Methodology, Formal analysis, Conceptualization. Elie Akl: Writing – review & editing, Methodology. Brandy Beverly: Writing – review & editing. Pablo Alonso-Coello: Writing – review & editing, Methodology. Andrew Rooney: Writing – review & editing, Methodology. Holger J. Schünemann: Writing – review & editing, Methodology. Kristina A. Thayer: Writing – review & editing, Methodology. Katya Tsaioun: Writing – review & editing. Rebecca L. Morgan: Writing – review & editing, Supervision, Methodology, Formal analysis, Conceptualization.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi. org/10.1016/j.envint.2025.109314.

Data availability

Data will be made available on request.

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