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Update of Canada's Low-Risk Alcohol Drinking Guidelines: Evaluation of Selected Guidelines

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About this Document

This document was prepared by Hanie Edalati, Ph.D., and Christine Levesque, Ph.D., both of whom are research and policy analysts at the Canadian Centre on Substance Use and Addiction (CCSA). They are members of the Evidence Review Working Group that was established by CCSA to perform some of the tasks required to update Canada's Low-Risk Alcohol Drinking Guidelines (LRDGs). This document was reviewed by members of the LRDGs Scientific Expert Panels.



Introduction

This report was produced by the Evidence Review Working Group of the Canadian Centre on Substance Use and Addiction (CCSA) for the project to update Canada's Low-Risk Alcohol Drinking Guidelines (LRDGs). The report presents evaluations of the previous Canadian LRDGs (2011) and guidelines from the United Kingdom (2016) and Australia (2020) using a standard instrument called the Appraisal of Guidelines for REsearch & Evaluation II (AGREE II; Brouwers et al., 2010). It provides a summary and discussion of the areas that can be adapted from these three guidelines for the update of Canada's LRDGs. It is intended for the members of the LRDG Scientific Expert Panels and those interested understanding in detail the process followed in developing the new guidelines.

Using an appropriate and rigorous evidence-based methodology in developing guidelines is a strong predictor of their successful implementation (Grimshaw & Russell, 1993; Grol, 2001). The LRDG development group is using the GRADE-ADOLPMENT framework (Schünemann et al., 2017) to update the LRDGs. An initial step of any GRADE ADOLPMENT project is to search for recent and relevant guidelines that cover the same topics and questions that the new guidelines aim to address. For this project, it was decided to build on the 2016 alcohol guidelines from the United Kingdom (U.K. Chief Medical Officers, 2016) and the 2020 Australian guidelines to reduce health risks (National Health and Medical Research Council, 2020) to update the 2011 Canadian LRDGs (Butt, Beirness, Gliksman, Paradis, & Stockwell, 2011). Members of the LRDG Scientific Expert Panels agreed to perform due diligence and assess the three guidelines with a standard instrument. The Appraisal of Guidelines for REsearch & Evaluation II (AGREE II) (Brouwers et al., 2010) instrument was applied to the guidelines to ascertain their quality and determine whether they could be adapted or adopted for the new Canadian LRDGs.

Using the AGREE II Assessment Instrument

The AGREE II Instrument was developed to evaluate the strengths and caveats of the guideline development process. Using 23 items, this instrument provides a framework to assess a guideline in six main quality domains:

- **Domain 1. Scope and Purpose**
- **Domain 2. Stakeholder Involvement**
- **Domain 3. Rigour of Development**
- **Domain 4. Clarity of Presentation**
- **Domain 5. Applicability**
- **Domain 6. Editorial Independence**

Each item is rated on a Likert scale from 1 (strongly disagree) to 7 (strongly agree) based on specific criteria and considerations. A quality score for each domain is calculated by adding the scores on the individual items in a domain and by scaling the total percentage of the maximum possible score for that domain. These six domain scores are independent of each other and should not be added up to produce a single quality score. In addition to the scores for each domain, an overall assessment is produced by rating the overall quality of the guidelines on the same Likert scale and recommending whether the guidelines should be used in practice (yes, yes with modifications or no). At least two appraisers should independently assess the guidelines using the AGREE II instrument. (For details on how to calculate and interpret scores, see AGREE Next Steps Consortium, 2017.)



AGREE II Evaluations

Two appraisers from CCSA's Evidence Review Working Group independently assessed the quality of all three guidelines and their related publicly available documents using the AGREE II instrument. Table 1 presents the quality scores for the six domains and overall ratings for the guidelines.

Inter-rater reliability statistics were calculated for each guideline to evaluate the degree of agreement between the two appraisers. Intraclass correlation coefficient (ICC) estimates with 95% confidence intervals (CIs) were calculated based on a mean-rating ($k = 2$), absolute-agreement, two-way mixed-effects model. The resulting ICCs were excellent for all three AGREE II evaluations (Koo & Li, 2016), indicating that the appraisers had a high degree of agreement (see Inter-rater Reliability in Table 1). Both appraisers recommended all three LRDGs for use.

Table 1. AGREE II Evaluations

Domains	Results		
	Canada (2011)	U.K. (2016)	Australia (2020)
1. Scope and Purpose	64%	69%	100%
2. Stakeholder Involvement	56%	83%	92%
3. Rigour of Development	40%	60%	96%
4. Clarity of Presentation	78%	69%	89%
5. Applicability	33%	42%	23%
6. Editorial Independence	21%	38%	79%
Overall Assessment (1-7)	3.5	4.5	6
Inter-rater Reliability*	.94 [.85, .97]	.95 [.88, .98]	.98 [.95, .99]

*Note. Intraclass correlation coefficient (ICC) estimates: 95% confidence intervals.

The following sections summarize the outcomes of evaluating each of the 23 items for the Canadian, U.K. and Australian LRDGs. Recommendations are provided for each item to guide the development of the updated Canadian LRDGs. The final section, Overall Assessment, discusses the areas that can be adapted from these three guidelines for Canada's updated LRDGs, based on the AGREE II evaluations and scores. (Verbatim transcripts of the AGREE II evaluations by the two assessors of the three guidelines for each of the 23 items are available upon request.)

Domain 1. Scope and Purpose

Domain 1 includes three items that assess the guidelines' overall objectives, the health questions covered by the guidelines and their target populations.

Item 1 deals with the overall objectives of the guideline and their potential health impact on society as a whole and populations targeted by the guidelines. The health intent of all three guidelines were



described around “prevention” and “harm reduction” (U.K. guidelines: “to help people understand the risks alcohol may pose to their health and to make decisions about their consumption in the light of those risks, but not to prevent those who want to drink alcohol from doing do”; Australian guidelines: “to provide the Australian population with clear and evidence-based advice about alcohol, to help people make informed choices about their drinking”; Canadian guidelines: “to provide a basis upon which to advise all Canadians on how to minimize risks from their own and others' drinking”). Several expected benefits or outcomes were described in the three guidelines (U.K. guidelines: “to enable people to make informed choices about their alcohol intake”; Australian guidelines: “to prevent and minimise alcohol-related harms by improving awareness and understanding of those harms”; “to form the evidence base for future policymaking and educational materials”; Canadian guidelines: “compliance with these Guidelines would reduce the annual numbers of alcohol caused deaths in Canada by approximately 4,600”). Language used to formulate the recommendations and the definition of target populations was more precise in the Australian and Canadian guidelines than in the U.K. guidelines, as can be seen in the example of their health intent. The Australian guidelines included a section called “Target Audience” and listed the populations who can benefit from using the guidelines. Similarly, the Canadian guidelines listed those who would benefit from implementing the guidelines, including “health professionals, policymakers, communication experts and members of the public who may wish to be informed about low-risk use of alcohol, whether for themselves or to advise others.” The U.K. guidelines described their target population generally as “people.”

Recommendations

- Name health intents of the guidelines (e.g., prevention, harm reduction) and use language that specifically describes the objectives in relation to patterns and levels of alcohol consumption in each guideline (e.g., to prevent harms associated with drinking alcohol during pregnancy; to reduce the harms associated with ...; to inform Canadians of ...).
- Clearly describe general and specific target populations: the general Canadian public, those who drink alcohol, those who are considering starting to drink alcohol and those who abstain from drinking alcohol. Also describe those individuals, organizations and agencies who can use the guidelines for other purposes (e.g., policy makers, health professionals, youth educators, alcohol industry, etc.).

Item 2 evaluates the description of the health questions covered by the guidelines. It is important to provide a detailed description of the original research questions related to the guidelines' key recommendations. Although health questions do not need to be phrased as questions, they should provide enough information for others to initiate the development of a guideline on this topic and to understand the populations and contexts profiled in the guideline. Both the U.K. and Australian guidelines included questions related to each guideline. The Australian researchers followed a standard framework (Population, Exposure and Outcome) to formulate their four main questions. Two of their questions were focused on the short-term and long-term health risks and benefits of varying levels and patterns of alcohol consumption in the general public and the other two were focused on risks and benefits for pregnant and breastfeeding women. The U.K. team developed their questions based on their terms of reference, but did not follow a standard framework. The language used in formulating questions lacked clarity. For example, questions two and three asked about “binge” and “low to moderate” alcohol drinking (“What are the health consequences arising from heavy or episodic ‘binge’ drinking of alcohol?”; “What are the beneficial effects, if any, of low to moderate consumption of alcohol?”); however, these terms are not defined in the questions. The Canadian guidelines did not provide detailed descriptions of health questions covered by them. The



report simply stated that it aims to summarize “the evidence on how different levels of drinking are likely to impact on different aspects of health and safety.”

Recommendations

- Follow a standard framework such as PICO or PECO to formulate questions. These frameworks require explicit descriptions of the populations (P) to whom the guidelines are meant to apply, the interventions (I) or exposures (E), depending on the guidelines, the comparators (C) and the outcomes (O).
- Provide detailed questions and describe how the Evidence Review Working Group arrived at them using PECO (search, evaluation, results) in a document accompanying the guidelines.

Item 3 assesses the clarity and specificity of the populations (patients, public, etc.) covered by the guidelines. All three guidelines described target populations, both general (Canadian guidelines: “Canadians who wish to make healthy choices about their own drinking and who might wish to give sound advice to others”) and specific for each guideline (Australian guidelines: healthy men and women [guideline one], children and people under 18 years of age [guideline two]; women who are pregnant or breastfeeding [guideline three]). All guidelines described excluded populations to some extent (e.g., those with alcohol use disorder, those with comorbid mental health disorders), but descriptions lacked clarity in the Canadian and U.K. guidelines. For example, the Australian guidelines clearly stated that guideline one applies to “healthy adult men and women” who choose to drink alcohol, although some people may have an increased risk of harm if they drink (e.g., “young adults aged 18–25 years, people aged over 60 years, people with a family history of alcohol dependence, and people who use illicit drugs or take medicines that interact with alcohol”). They also briefly described why drinking within guideline one is not recommended for such populations. The U.K. guidelines did not clearly describe their excluded populations, but added some considerations to their recommendations (e.g., “People vary in how they metabolise or react to alcohol, people of differing ages and sizes can be affected differently by drinking similar amounts”). The Canadian guidelines included a recommendation for populations and conditions for which drinking is not recommended (e.g., when operating any kind of vehicle, before breastfeeding), but excluded populations are not clearly described for each recommendation. Some descriptions of the target population were not well defined or easy to find in the Canadian and U.K. guidelines. The Australian guidelines were clearest in describing their target populations.

Recommendations

- Provide specific details (e.g., age, sex, clinical description) about each population covered by the guidelines (e.g., adult healthy men and women).
- Provide details of excluded populations for each guideline and in general.

Domain 2. Stakeholder Involvement

Domain 2 includes three items that assess the appropriateness and expertise of the guideline development group, consideration and integration of the views and preferences of the target population, and clarity in definitions of the intended target users of the guidelines.

Item 4 reports on the guideline development group and their appropriateness for creating the guidelines. This group includes all professionals involved at different stages of the development process, such as chairs, expert panels and the research team. Guidelines should include the following information for each group member: name, discipline or content expertise, institution and



geographic location, and a description of the member's role in the guideline development group. All three development groups included experts from several alcohol-related fields (e.g., epidemiology, policy, prevention, treatment, etc.). Some items (e.g., geographical location and description of member's role) were not provided for all group members in all three guidelines.

Recommendations

- Provide detailed information about the guideline development group, including co-chairs, and members of CCSA Evidence Review Working Group and the Scientific Expert Panels. Include name, discipline or content expertise, institution and geographic location, and a description of the member's role in the guideline development group. This information will establish that the members were an appropriate match for the topic and scope of the guidelines and had the necessary expertise to fulfill their roles in the guideline development process.
- Highlight the expertise of group members (e.g., researcher, policy maker, clinician, content expert, etc.) to show that the guideline development process benefited from the knowledge and expertise of a broad group of professionals in the alcohol field.
- Name at least one methodology expert in the development group, such as a systematic review expert, epidemiologist, statistician or library scientist, to establish that the guideline development process was guided, reviewed and informed by a standard approach.

Item 5 deals with information about the views and preferences of the target population and whether their experiences and expectations were sought and informed development of the guidelines. The U.K. guidelines had an extensive approach to seeking the views and preferences of the target population. First, they conducted a systematic search of literature on understandings and responses to public health guidelines for a range of health-related behaviours and to alcohol consumption guidelines. This research informed the discussions of their Behavioural Evidence Expert Group and development of the guidelines. Second, they conducted qualitative research, including 10 focus groups, 18 individual interviews and six triad groups with a total sample of 110 people, to examine public response to the draft guidelines. Information from public consultation and qualitative research was used to improve the clarity, expression and usability of the U.K. guidelines. The Australian team conducted two public consultations to inform development of their guidelines. First, they made a public call for submission of evidence on health risks and benefits of alcohol consumption to help identify relevant studies and gaps and to identify issues of concern for the public and stakeholders. Second, after draft guidelines were developed, a public consultation was advertised on the National Health and Medical Research Council (NHMRC) website, NHMRC Tracker and social media platforms to provide stakeholders with the opportunity to comment on the draft guidelines. Invitations were also sent to key stakeholders. The outcomes of this public consultation and how the main suggestions provided by the stakeholders were integrated into the final version of the Australian guidelines are available in their Appendix 5: Administrative report. The Australians did not conduct a literature review of values and preferences of stakeholders over the course of developing the draft guidelines. However, a section is included for each guideline describing the expected preferences and values of Australians based on previous data and the annual alcohol poll of the Foundation for Alcohol Research and Education for 2019. The Canadian team did not conduct a literature review of studies on target population experiences, values and expectations. Some studies on Canadian drinking patterns and preferences were presented in the guidelines, but it was not clear if this information was used to inform their development. Some organizations and individuals who were among the target audience of the guidelines, such as policy makers and communication experts, provided feedback in response to the draft guidelines. It was not clear from the review of the documentation if or how their feedback was integrated into the final version of the Canadian guidelines.



Recommendations

- Inform the guideline development process and formulation of the recommendations with the values, experiences and expectations of target populations.
- In the main guideline document, provide clear descriptions of:
 - Strategy used to capture target populations' views and preferences;
 - Methods by which preferences and views were sought (e.g., literature review, surveys, focus groups, public consultation);
 - Outcomes and information gathered; and
 - How this information was used to inform the guideline development process and formulation of the recommendations.
- Clear reference to documents including details of these strategies and processes should be provided.

Item 6 evaluates the clarity of definitions in the guidelines of intended target users and how the guidelines may be used by them. The Australian and U.K. guidelines provided a clear description of their various target users (e.g., the public, clinicians, policy makers, etc.) and how the guidelines may be used by each group (Australian guidelines: “These guidelines apply to everyone in Australia, particularly those who drink alcohol, those who are considering drinking alcohol, and parents of young people who may be considering drinking alcohol. They provide useful information about the risks involved when alcohol is consumed at different levels and frequencies. The guidelines are intended as a resource for individuals, organisations, policymakers and decision-makers, planners, health professionals, parents and family members, educators, industry organisations and those responsible for serving alcohol”). The U.K. alcohol guidelines review included a section on “how clinicians might use new guidelines in public health advice” (Department of Health, 2016). The Canadian guidelines also provided clear definitions of their target audiences and how their recommendation could be communicated, but descriptions on how the guidelines could be used were not provided for all target groups.

Recommendations

- Provide a description of how the guideline may be used by all target users, including policy makers, clinicians, health professionals, parents and family members, and other stakeholders.

Domain 3. Rigour of Development

Domain 3 includes eight items that assess the rigour of the process used to collect and synthesize the evidence, the methods to formulate the recommendations and the strategy to update them.

Item 7 deals with the details of the strategy used to search for evidence, including search method and terms used, electronic databases and evidence sources consulted, and time periods of the literature covered. The Australian guidelines had the most comprehensive search method and covered all aspects of this item. A list of all search terms (e.g., the populations, various physical and mental health, and social outcomes), databases and detailed search strategies are provided in a separate report publicly available on their website (NHMRC Clinical Trials Centre, 2020b). The time period covered by their literature search was January 1, 2007, to January 5, 2017. In addition to systematic reviews of systematic reviews, four systematic reviews were commissioned by the NHMRC to address identified gaps in existing review evidence. These included systematic reviews on



the specific health effects of drinking alcohol on mental health and long-term mild cognitive impairment, and on the fetuses, infants and children of women drinking alcohol while pregnant or breastfeeding. These systematic reviews were evaluated by independent reviewers. The U.K. guidelines also provided detailed methods used for search of evidence in two publicly available reports (Centre for Public Health, 2016a, 2016b). However, the exact time periods searched, including months and years, and detailed search terms used were not provided. The Canadian team did not provide details of strategies used to search for evidence. However, the Canadian team stated that a report, including the systematic search of evidence and its outcomes, was provided for the expert working group. In addition, members of the expert committee also contributed independent systematic reviews and analyses on selected topics.

Recommendations

- Provide the full search strategy used, including names of electronic databases and evidence sources used for search (e.g., MEDLINE, PsychINFO), exact time periods searched and detailed search terms used.
- Provide a summary of the method used for systematic search in the main document and the detailed strategy in a separate report available to the public.

Item 8 assesses the criteria used to include and exclude the evidence identified by the search. The inclusion criteria should clearly describe the characteristics of the target population, the study design, comparisons (if relevant), outcomes, language (if relevant), and context (if relevant). A detailed description of the exclusion criteria should also be provided. Inclusion and exclusion criteria should clearly align with the health questions. The Australian and U.K. teams provided detailed criteria and methods for selecting the evidence in the separate reports mentioned in item 7. However, the U.K. guidelines lacked clarity around some inclusion and exclusion criteria. For example, three studies on medical and social outcomes of alcohol were excluded on the grounds that they were not published in English, but no exclusion criteria were provided for the language of studies. Similar to the previous item, the Canadian team did not publish in the public domain the details of inclusion and exclusion criteria used to select the evidence.

Recommendations

- Provide detailed criteria used to include and exclude the evidence in a separate report available to the public.
- Follow the identified PECO questions to create inclusion and exclusion criteria that properly cover and clearly align with the health questions.

Item 9 deals with the strengths and limitations of the evidence. How the body of evidence was evaluated for risk of bias and interpreted by the guideline development group should be described. This evaluation can include use of formal (e.g., GRADE) and informal instruments or strategies. Both the U.K. and Australian guideline groups used A Measurement Tool to Assess Systematic Reviews (AMSTAR) to assess for quality, strength and limitations, and risk of bias of the included systematic reviews and individual studies. Their data extraction and AMSTAR assessment tables are available in their reports. The U.K. team only used this instrument to evaluate the included studies on medical and social health impacts from alcohol consumption and not for the included systematic studies on behavioural evidence (e.g., views, responses to guidelines). The Australian team also used the Risk of Bias in Systematic Reviews (ROBIS) tool, designed specifically for this purpose, and the GRADE approach to guide the assessment of the body of evidence. A detailed description of this process is provided in the Australian evidence evaluation report (NHMRC Clinical Trials Centre, 2020a). The



Canadian team did not use any formal instrument or strategy for evaluating the identified evidence. However, limitations and strengths of the research evidence and risk of bias in individual studies and systematic reviews (e.g., limitations and strengths in the study designs, methodology, consistency of results across studies, magnitude of benefit versus magnitude of harm, etc.) were described and discussed in the main guideline document.

Recommendations

- Use formal instruments to evaluate and summarize quality features of the evidence, including a tool permitting a sex and gender analysis.
- Provide the detailed evaluation of evidence and the strengths and limitations of the included studies in a separate, publicly available report.

Item 10 deals with the methods used to formulate the recommendations and their outcomes, and how final decisions were reached (e.g., voting system, informal consensus and formal consensus techniques such as Delphi). This area also includes discussion of how disagreements are resolved. All three guidelines used a type of mathematical modelling to calculate the relative or absolute risk associated with alcohol consumption and to set an appropriate upper daily and weekly limit for consumption. The Australian guidelines used the GRADE evidence to decision framework to synthesize the evidence and translate it into guideline recommendations and accompanying text. The U.K. and Canadian teams did not provide clear descriptions of the development process or specific methods used to arrive at the final recommendations. They also did not provide clear information about the areas of disagreement and the methods used to resolve them.

Recommendations

- Use a formal process to arrive at the recommendations.
- Under methodology or guideline development process, clearly describe:
 - The recommendation development process (e.g., steps used in GRADE, voting procedures considered);
 - The outcomes of the process (e.g., outcome of voting procedures);
 - How the process influenced the recommendations (e.g., results of voting or GRADE influence on final recommendations); and
 - Areas of disagreement and the methods used to resolve them.

Item 11 evaluates the consideration of the health benefits, side effects and risks in formulating the recommendations. Guidelines should provide supporting data and reports of both harms/risks and benefits and the balance or trade-off between them. Recommendations should reflect consideration of both harms/risks and benefits. All three guidelines provided supporting data and reports of harms/risks and benefits associated with varying levels of alcohol consumption, both in their mathematical modelling and integrated into their recommendations. For example, search questions provided in the U.K. and Australian guidelines and search terms used to identify the evidence included both harms and benefits of alcohol consumption and the search outcomes reflected this. The Canadian guidelines also provided the supporting data and their limitations for both harms/risks and benefits of various levels of alcohol consumption and discussed the findings. In addition, information about the balance or trade-off between harms/risks and benefits were thoroughly described in all guidelines. For example, the U.K. guidelines noted under their weekly drinking guideline that “This advice on regular drinking is based on the evidence that if people drink at or



above the low risk level advised, overall any protective effect from alcohol on deaths is cancelled out and the risk of dying from an alcohol-related condition would then be expected to be at least 1% over a lifetime.” The Australian team provided a summary of “benefits and harms” in the GRADE evidence to decision framework for each guideline. The Canadian guidelines explained and discussed the process for estimating the point at which the potential risks and benefits balance each other out.

Recommendations

- Provide supporting data and reports of both benefits and harms/risks associated with varying levels and patterns of alcohol consumption.
- Provide details on how final recommendations included considerations of both benefits and harms/risks and trade-off (e.g., data from both benefits and harms/risks should be included in mathematical modelling and in formal or informal consensus techniques).

Item 12 assesses if the guidelines provided an explicit link between the recommendations and the evidence on which they are based. The link should be described so the guideline user can understand how the body of evidence informed each recommendation. The Australian and U.K. guidelines clearly summarized how the evidence informed the recommendations, linking each recommendation to the key scientific evidence found for it. For example, the Australian guideline three summarized the link between the evidence of potential harms to the fetus and to babies when mothers drink alcohol while pregnant or breastfeeding and the guideline as follows: “The evidence does not indicate a safe amount of alcohol that pregnant women and breastfeeding mothers can drink. As there is a risk of harm to the fetus, this guideline takes a precautionary approach and recommends not drinking alcohol when pregnant. Similarly, as there is a risk of harm to the baby, this guideline takes a precautionary approach and recommends not drinking alcohol when breastfeeding.” Another example is the U.K. guideline on “single occasion drinking episodes,” which summarized the link between evidence and recommendation as follows: “This advice for any single occasion of drinking is based on evidence that clearly showed substantially increased risk of short term harms (accidents, injuries and even deaths) faced by people who drink high levels of alcohol within a single day.” The Canadian guidelines described how they linked and used the evidence to inform recommendations throughout the document. However, links between the recommendations and supporting key evidence were not summarized well and not easy to find in the guidelines. All three guidelines clearly stated and described if evidence was not clear or certain. For example, the Australian team included a section in the GRADE evidence to decision framework for each guideline to describe the certainty of the evidence linked to it. For guideline one, they note: “The quality of the evidence included in these systematic reviews varied across the critical outcomes. GRADE rates the type of epidemiological evidence typical of broad public health exposures as low to very low; hence, the certainty in the overall evidence was rated accordingly as very low.” They added a similar note to guideline three.

Recommendations

- For each recommendation, provide a key information section, evidence summary section or evidence table that clearly summarizes the key evidence used to inform that recommendation.
- In the results section of the guidelines, explicitly describe how evidence was linked to recommendations and informed their development.
- Clearly state and describe if a recommendation is informed primarily by consensus of the guideline development group or panels and if evidence is lacking or not sufficient.



Item 13 deals with the external review of guidelines by experts before their publication and the methods used to conduct it. Guidelines should describe the purpose and intent of the external review (e.g., to improve quality), methods used (e.g., rating scale), the external reviewers, the outcomes of review and how these outcomes were used to inform the final guidelines. No information on the external review of the U.K. guidelines by experts before their publication was found. The Canadian guidelines were reviewed by three invited experts in alcohol epidemiology and received feedback from concerned individuals and organizations. However, no information was provided on the methods used to undertake the external review, the outcomes or information gathered from the review, and how the information gathered was used to inform the final guidelines. Organizations associated with the alcohol industry also reviewed and provided feedback on the Canadian draft guidelines, which raises an issue of conflict of interest that was not clearly addressed in the final report. The Australian guidelines went through an independent expert review from July to September 2020, following the public consultation. The intent of the external review (quality assurance), and the names of reviewers, their affiliations and how they were nominated are provided. Outcomes and information gathered from the external review, including the summary of expert review feedback and key actions taken to address the feedback, are also provided in the Australian guidelines. The methods used to perform the external review are not provided.

Recommendations

- Provide a separate section in the guidelines, preferably under the methodology or results section, on the methods used for the external review.
- Clearly describe how the external review's outcomes informed the final guidelines.

Item 14 describes the methodology and procedure for updating the guidelines. There should be a clear statement that the guidelines will be updated, in addition to an explicit time interval or explicit criterion that would trigger the update. We did not find any statement that the U.K. guidelines will be updated. The Canadian guidelines recommended that “the proposed Guidelines are reviewed on a regular basis as this area of knowledge develops”; however, no specific procedure for updating the guidelines was provided. The Australian guidelines included a statement that they would be updated if evidence suggests they need updating. In addition, they used the MAGICapp digital authoring and publication platform to present the recommendations and other information as “living” guidelines, where the NHMRC can update elements or modules of a guideline and display a version history for updates. However, a clear method for updating the guidelines was not provided.

Recommendations

- Include a clear statement about updating the guidelines indicating an explicit time interval or explicit criterion (e.g., these guidelines will be updated should the relevant body of evidence change; these guidelines will be reviewed every five years) that will trigger an update.
- Provide the methodology for the updating procedure.

Domain 4. Clarity of Presentation

Domain 4 includes three items that evaluate the language, structure and format of the guidelines and recommendations.

Item 15 evaluates the precision and unambiguity of the guidelines. They should clearly describe the recommended actions and their intent or purpose, identify the relevant populations for each option or situation, and explain any relevant caveats or uncertainties. The Australian guidelines provided



concrete and precise descriptions for all recommendations according to this item's criteria. Patients or conditions for whom the recommendations would not apply were clearly described (e.g., people with a family history of alcohol dependence, people taking medications, when supervising children, when taking part in activities that require attention, mental and physical skills, or concentration). Similarly, the U.K. and Canadian guidelines described their recommendations according to this item's criteria, although some information lacked clarity and precision. For example, the U.K. guideline on "single occasion drinking episodes" was vague (e.g., "advice for men and women who wish to keep their short term health risks from single occasion drinking episodes to a low level is to reduce them by: limiting the total amount of alcohol you drink on any single occasion"). Another example is guideline one of the Canadian guidelines, which seems to describe the excluded populations of guidelines two and three, rather than provide a recommendation with clear intent.

Recommendations

- Provide specific and precise recommendations on what option is appropriate for each specific population (e.g., healthy adult men and women drink no more than X standard drinks per week; women who are pregnant or planning a pregnancy should not drink alcohol).
- Include the intent or purpose of the recommendation (e.g., to reduce the risk of harm from alcohol-related disease; to reduce the risk of harm to an unborn child).
- Provide qualifying statements such as excluded populations or conditions for each recommendation.

Item 16 assesses the description of different options for managing the condition or health issue. This item may not be directly relevant to LRDGs as it is oriented toward guidelines for managing a disease by providing options for screening, prevention, diagnosis and treatment. Nonetheless, all three LRDGs provided some practical options for their key recommendations. For example, the Canadian LRDGs noted that if a decision to start drinking is made by youth, drinking should occur in a safe environment, under parental guidance and at low levels. The Australian guidelines provide practical information for all their guidelines (e.g., tips on "When should I drink less?" for guideline one, "How can I reduce the chances of my children drinking alcohol?" for guideline two, and "But what if I decide to drink alcohol?" for breastfeeding women for guideline three). In addition, both the Canadian and the U.K. guidelines mentioned that if you choose to drink, it is important to drink with food and to alternate with caffeine-free non-alcoholic drinks. All three LRDGs provided recommendations about conditions and populations with potentially increased risk of harm from alcohol consumption.

Recommendations

- Consider different possible options for individuals who will make the decision not to follow the guidelines by providing practical additional information. This information should be located next to the related guidelines.

Item 17 evaluates the presentation of the key recommendations and whether they are easy to identify in the guidelines (e.g., summarized in a box, in bold or coloured ink). The key recommendations were clearly written, properly grouped and easy to find in all three guidelines. They were presented in a summarized box, in bold, or with coloured font or background.

Recommendations

- Present key guidelines in a coloured box, in bold.
- Present a summary of the key evidence underlying the guideline in a summary box.



Domain 5. Applicability

Domain 5 includes four items that evaluate the potential facilitators and barriers to the guidelines' implementation, strategies and tools to improve their uptake, potential resource implications of implementing the guidelines, and criteria for monitoring or auditing them.

Item 18 describes the facilitators and barriers that impact the guidelines' implementation. These facilitators and barriers were not clearly identified in the Australian and Canadian guidelines. The U.K. guidelines identified and discussed some of the facilitators and barriers that may impact their guidelines' application for both clinical populations and the general public (e.g., public funding, industry influence, duration of the launch campaign, etc.).

Recommendations

- Investigate and identify facilitators and barriers to implementing the guidelines.
- Present the methods used to identify them and the information that emerged from these investigations.
- Describe how the information influenced the guideline development and its recommendations.

Item 19 evaluates the tools and resources presented to facilitate the application of the guidelines (e.g., summary document, educational tools, solutions linked to barrier analysis, tools to capitalize on guideline facilitators). The U.K. guidelines included a section that discussed the tools and resources that facilitate the application of new guidelines for both clinical populations and the general public. The U.K. guidelines also provided links to guideline documents, a checklist and the outcomes and lessons learned from a pilot test with the public. The Canadian guidelines provided recommendations for the communication of the guidelines and descriptions of tools and resources to facilitate their implementation (e.g., web-based interactive materials, introduction of materials that enable people who use alcohol to better understand the number of standard drinks they consume). The Australian guidelines stated that the Australian Government is responsible for implementing the guidelines and would develop a range of resources to reach individuals and communities. The Australian guidelines used two main tools to facilitate application: the MAGICapp digital authoring and publication platform was used to allow for a "living" guideline; and an appendix of "practical information" for applying the guidelines was provided, covering each guideline and its implementation for different groups of target users.

Recommendations

- Include an implementation section in the guidelines and provide information on tools and resources that can facilitate the guidelines' implementation (e.g., guideline summary documents, outcomes and lessons learned from pilot tests, educational tools, solutions linked to barrier analysis, tools to capitalize on guideline facilitators).
- Include directions on how guideline users can access tools and resources.

Item 20 evaluates acknowledgement of the resource implications of applying the recommendations. None of the three LRDGs discussed the types or estimates of cost associated with implementing their recommendations.



Recommendations

- Identify the types of cost associated with implementing the guidelines, even if the guideline development group is not responsible for implementing them. The development group may not be able to directly calculate the costs associated with implementation because they are not responsible. However, the group should name the potential resources and the types of cost needed for implementation by stakeholders.
- Present the methods by which the cost information was sought and a description of how the information influenced the guideline development and its recommendations.

Item 21 evaluates the proposed monitoring or auditing criteria derived from the key guideline recommendations. These criteria can be used to measure the application of the guidelines and can include process measures, behavioural measures, and clinical or health outcome measures. All three LRDGs included quantitative recommendations that are well suited for evaluation through national surveys. For example, the U.K. guidelines recommended to drink no more than 14 units a week on a regular basis and spread the drinking evenly over three or more days, while the Australian guidelines recommended to drink no more than 10 standard drinks per week and no more than four standard drinks on any one day. The Canadian guidelines recommended that women should drink between zero and two standard drinks a day or a weekly maximum of 10 standard drinks, whereas men should drink between zero and three standard drinks a day or a weekly maximum of 15 standard drinks. However, other recommendations do not have specific thresholds, making it difficult to evaluate adherence to them. For example, the U.K. guidelines recommend limiting the amount of alcohol one drinks on any single occasion to keep short-term health risks from single occasion drinking episodes to a low level, but do not specify an amount.

Recommendations

- Identify criteria to assess guideline implementation or adherence to recommendations.
- Provide operational definitions of how the criteria should be measured.
- Provide advice on the frequency and interval of measurement, including a baseline measure.

Domain 6. Editorial Independence

Domain 6 includes two items to assess whether the formulation of recommendations has been unduly biased by competing interests.

Item 22 deals with the potential influence of funding bodies or sources of funding on the guidelines' content. External support can be in the form of financial contribution for the complete development or for parts of it. Guidelines should provide the name of the funding body and include an explicit statement about its influence on the content of the guidelines. The funding sources were cited in all three LRDGs. However, none provided an explicit statement about the funding body's influence on the content of the guidelines. All guidelines were reviewed by or received feedback from the funding bodies. However, it was not clear how the guideline development groups addressed potential influence from the funding bodies. For example, the Australian guidelines stated that "The Australian Government Department of Health commissioned NHMRC to update the 2009 guidelines, and contributed funding to the comprehensive evidence evaluation and other project costs. NHMRC provided funding for staffing, committee costs and mathematical modelling. NHMRC sought input from the Australian Government Department of Health, NHMRC's Consumer and Community Advisory Group and its Principal Committee Indigenous Caucus to finalise the draft guidelines before



public consultation.” Despite this mention of input from the Australian Government Department of Health to finalize the guidelines, there is no explicit statement about the influence the department may have had on the content of the guidelines.

Recommendations

- State the name of the funding body or source of funding.
- Include an explicit statement that the views or interests of the funding body have not influenced the final recommendations.

Item 23 is concerned with the declaration of interest by group members. There should be an explicit statement in the guidelines that all members have declared whether they have any competing interests. The declaration of interest process was thoroughly described in the Australian guidelines. Declarations of interest by members of the guideline development group were also publicly available on their guideline webpage. While the U.K. guidelines documented declarations of interest for each member, separately from the main guideline document, there was no explicit statement about declarations of interest in the guideline document itself and it was not explained how any competing interests were considered or addressed. The Canadian guidelines did not provide any explicit statement in the guidelines or in a separate document showing that group members had declared their competing interests. Some alcohol industry organizations provided feedback to an earlier consultation draft of the Canadian LRDGs, raising concerns about potential conflicts of interest. It is not known how their comments influenced the process for developing the guidelines.

Recommendations

- Provide a description of the types of competing interests considered and the methods by which potential competing interests were sought.
- Declarations of interest should be completed by all members and made publicly available on the guidelines webpage.
- Provide a description of how competing interests were addressed in the guidelines development process.
- Include an explicit statement in the guidelines document that all members have declared their competing interests.

Overall Assessment

Both appraisers rated the overall quality of the guidelines from 1 (lowest possible quality) to 7 (highest possible quality). Of the three LRDGs, the Australian guidelines received the highest score of 6, followed by the U.K. guidelines at 4.5 and the Canadian guidelines at 3.5. (See Table 1.)

The Australian LRDGs received nearly maximum scores on all items related to methodology for identifying and selecting the scientific evidence (Domain 3, items 7–12) and on many items in the other five domains. The use of an internationally recognized approach, the GRADE framework, for searching and selecting the evidence, synthesizing it and translating it into recommendations increased the quality of the Australian guidelines. In addition, by providing precise, clear and detailed methods for each step of their guideline development process they have made it possible for others to replicate or update their work. The Australian guidelines and their modelling went through independent expert reviews and public consultations for quality assurance. The outcomes and information gathered from the external reviews and public consultations was used to improve the



quality of the final version of the guidelines. Despite impressive rigour in the development process, the Australian guidelines received low scores on items related to applicability and implementation (Domain 5). Although the Australian government is responsible for implementing the guidelines, it would have been helpful if the guideline development team had provided information on barriers and facilitators of implementation and advice, strategies and tools to help put the recommendations into practice.

An important strength of the U.K. LRDGs is the range of considerations taken into account in translating the evidence into the final guidelines. These considerations included mathematical models, knowledge and lessons learned from previous guidelines, and views and preferences of the target populations. Of note, the U.K. team used a comprehensive approach to identify the views and preferences of stakeholders (i.e., systematic search, focus groups and surveys with target populations, public consultations) and then integrated them in the final recommendations. They also performed a comprehensive search of the scientific literature and evaluated the evidence, although they did not use the GRADE approach. Documents on their website are not well organized, making it difficult to find information. The guidelines development processes and methodology would also benefit from being better described (e.g., detailed search terms, details of the decision-making processes). In addition, the guidelines were not reviewed by independent expert reviewers.

Among the strengths of the Canadian LRDGs were their clear and explicit recommendations, and concrete examples of implementation, as well as knowledge translation and the production of educational material. The two main issues with these guidelines related to the rigour of their development (Domain 3) and the question of editorial independence (Domain 6). First, although a comprehensive body of evidence was used to develop these guidelines, detailed methodology and scientific reports (e.g., literature review, studies selected, inclusion and exclusion criteria for selecting the evidence, etc.) were not released. Given this gap, it was not possible to appraise and comment on the methodology used for developing the guidelines. In addition, the methods for formulating the recommendations were not clearly described. Second, there was no explicit statement about members' declaration of competing interests and how the competing interests influenced the guidelines development process. Organizations related to the alcohol industry reviewed and provided feedback on a draft of the guidelines, which raises the issue of conflict of interest. No information was available on their review and if their feedback was considered and integrated into the final version of the guidelines.

In addition to the strength and limitations mentioned for each of the LRDGs, all three guidelines are limited to some degree in describing items related to the applicability and implementation of their recommendations (Domain 5). Several other areas and items were not sufficiently developed or clearly described. For example, none of the guidelines provided a clear plan for updating their recommendations.



Conclusions and Future Directions

In conclusion, both appraisers recommend adapting elements of the existing LRDGs for the update of the Canadian LRDGs. The results of systematic searches and associated evaluations on the risks and benefits of alcohol consumption conducted by the Australian guideline development group may be adopted from these guidelines after credibility assessment of their GRADE tables. The four additional systematic reviews conducted by the Australian group to address gaps in existing evidence should be evaluated using standard tools, such as AMSTAR and ROBIS, for their quality, strength and limitations, and the risk of bias of the included studies. An update of their systematic searches to cover more recent years is also needed (the Australian searches cover January 1, 2007, to January 5, 2017). New literature searches may be needed to include search terms about the social impact of alcohol consumption (e.g., domestic violence, child neglect). The expert panels also recommended examining the uptake of sex- and gender-based analysis (SGBA) in the identified evidence and included systematic reviews.

We also recommend using some of the work done by the U.K.'s Behavioural Evidence Expert Group to better integrate the views, preferences and expectations of the stakeholders, public and specific target groups of the guidelines in the Canadian context. Use of the U.K. work will require reviewing their methodology and materials, including their systematic search of literature on understandings and responses to official public health guidelines and their public consultation and qualitative research study to improve the clarity and usability of the guidelines. Some of the tools and resources that facilitate the application of new guidelines for both clinical populations and the general public were discussed in the Canadian and U.K. guidelines. We recommend expanding on this discussion and including more tools and resources appealing to younger audiences.



References

- AGREE Next Steps Consortium. (2017). *The AGREE II instrument [electronic version]*. Retrieved from <https://www.agreetrust.org/wp-content/uploads/2017/12/AGREE-II-Users-Manual-and-23-item-Instrument-2009-Update-2017.pdf>
- Brouwers, M. C., Kho, M. E., Browman, G. P., Burgers, J. S., Cluzeau, F., Feder, G., . . . AGREE Next Steps Consortium. (2010). AGREE II: Advancing guideline development, reporting and evaluation in health care. *Canadian Medical Association Journal*, 182(18), E839–E842. Retrieved from <https://www.cmaj.ca/content/182/18/E839>
- Butt, P., Beirness, D., Gliksman, L., Paradis, C., & Stockwell, T. (2011). *Alcohol and health in Canada: A summary of evidence and guidelines for low risk drinking*. Ottawa, Ont.: Canadian Centre on Substance Abuse.
- Centre for Public Health. (2016a). *Appendix 3 CMO Alcohol Guidelines Behavioural Review*. Liverpool, U.K.: Liverpool John Moores University. Retrieved from <https://app.box.com/s/wlludrmim3gd83r28c4oqb3upj68cqia/file/46692289837>
- Centre for Public Health. (2016b). *Appendix 4 CMO Alcohol Guidelines Health Evidence Expert Report*. Liverpool, U.K.: Liverpool John Moores University. Retrieved from <https://app.box.com/s/wlludrmim3gd83r28c4oqb3upj68cqia/file/46692289869>
- Department of Health. (2016). *Alcohol guidelines review – Report from the guidelines development group to the UK Chief Medical Officers*. London, U.K.: Author. Retrieved from https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/545739/GDG_report-Jan2016.pdf
- Grimshaw, J. M., & Russell, I. T. (1993). Effect of clinical guidelines on medical practice: A systematic review of rigorous evaluations. *The Lancet*, 342(8883), 1317–1322. Retrieved from [https://www.thelancet.com/journals/lancet/article/PII0140-6736\(93\)92244-N/fulltext](https://www.thelancet.com/journals/lancet/article/PII0140-6736(93)92244-N/fulltext)
- Grol, R. (2001). Successes and failures in the implementation of evidence-based guidelines for clinical practice. *Medical Care*, 39(8), II-46–II-54.
- Koo, T. K., & Li, M. Y. (2016). A guideline of selecting and reporting intraclass correlation coefficients for reliability research. *Journal of Chiropractic Medicine*, 15(2), 155–163.
- National Health and Medical Research Council. (2020). *Australian guidelines to reduce health risks from drinking alcohol*. Canberra, Aust.: Author. Retrieved from <https://www.nhmrc.gov.au/about-us/publications/australian-guidelines-reduce-health-risks-drinking-alcohol#block-views-block-file-attachments-content-block-1>
- NHMRC Clinical Trials Centre. (2020a). *Evaluating the evidence on the health effects of alcohol consumption: Evidence evaluation report*. Sydney, Aust.: University of Sydney. Retrieved from <https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Alcohol/1-evidence-evaluation-report.pdf>
- NHMRC Clinical Trials Centre. (2020b). *Evaluating the evidence on the health effects of alcohol consumption: Technical report*. Sydney, Aust.: University of Sydney. Retrieved from <https://www.nhmrc.gov.au/sites/default/files/documents/attachments/Alcohol/2-technical-rep-evaluating-evidence.pdf>



- Schünemann, H. J., Wiercioch, W., Brozek, J., Etzeandía-Ikobaltzeta, I., Mustafa, R. A., Manja, V., . . . Akl, E. A. (2017). GRADE evidence to decision (EtD) frameworks for adoption, adaptation, and de novo development of trustworthy recommendations: GRADE-ADOLOPMENT. *Journal of Clinical Epidemiology*, *81*, 101–110. Retrieved from [https://www.jclinepi.com/article/S0895-4356\(16\)30482-6/fulltext](https://www.jclinepi.com/article/S0895-4356(16)30482-6/fulltext)
- U.K. Chief Medical Officers. (2016). *UK Chief Medical Officers' low risk drinking guidelines*. London, U.K.: Department of Health. Retrieved from https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/545937/UK_CMOs__report.pdf