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Health Technology Review

Quetiapine for Insomnia

Summary

Main Take-Aways

- Evidence-based guidelines recommend against the use of quetiapine for the treatment of insomnia.
- The findings of this review suggest that antipsychotics such as quetiapine should not be used in the treatment of insomnia.

Key Messages

What Is the Issue?

- Quetiapine is an atypical or second-generation antipsychotic drug that is primarily used for treating schizophrenia and bipolar disorder. Quetiapine extended-release is also indicated by Health Canada for the symptomatic relief of major depressive disorder when currently available approved antidepressant drugs have failed.
- Decision-makers are interested in evidence on the clinical effectiveness, safety, and place in therapy of quetiapine relative to other medications for the treatment of insomnia.

What Did We Do?

- We searched key resources, including journal citation databases, and conducted a focused internet search for relevant evidence published since 2020.

What Did We Find?

- Evidence-based guidelines recommend against the use of quetiapine for the treatment of insomnia due to potential concerns about safety and lack of evidence of clinical benefit.

What Does It Mean?

- Current evidence-based guidelines advise against prescribing quetiapine for the treatment of insomnia due to safety concerns and a lack of demonstrated clinical benefit.
- The findings of this review suggest that antipsychotics such as quetiapine should not be used in the treatment of insomnia.

Table of Contents

List of Tables

List of Figures

Abbreviations

DoD	US Department of Defense
OSA	obstructive sleep apnea
RCT	randomized controlled trial
SR	systematic review
VA	US Department of Veterans Affairs

Context and Policy Issues

What Is Insomnia?

Insomnia is a common sleep disorder. People with insomnia experience dissatisfaction with the quantity or quality of their sleep, have difficulty initiating or maintaining sleep, and/or wake up early in the morning without the ability to return to sleep.[1] For a diagnosis of insomnia disorder, the symptoms must occur at least 3 nights per week for at least 3 months and cause significant distress or impairment in daily functioning.[1] Sleep difficulty must be present despite adequate opportunity for sleep, ruling out of other sleep disorders, and exclude the possibility of being better explained by coexisting mental disorders or other medical conditions.[1] Approximately 10% of the adult population has an insomnia disorder.[2] In 2021, 20.4% of adults aged 18 to 64 years in Canada experienced insomnia symptoms.[3]

Insomnia is a significant health problem that negatively impacts a person's daytime function, safety, and quality of life.[1] It is associated with a range of adverse outcomes, including accidents and injuries, cognitive impairment, cardiovascular disease, diabetes, psychiatric disorders, neurodegenerative disorders, suicide, and self-medication with alcohol and other substances.[1] Insomnia also carries a substantial economic burden for patients, society, and the health system due to the direct costs of treatment and the indirect costs of high rates of absenteeism and lack of work productivity.[4]

What Are Current Treatment Options for Insomnia?

The main interventions for insomnia are cognitive behavioural therapy and pharmacotherapy, including over-the-counter medications, prescription hypnotic drugs, and other nonspecific prescription medications. Cognitive behavioural therapy for insomnia is recommended as the first-line treatment for insomnia in adults; however, there is limited access to this therapy and pharmacotherapy remains the most frequently used treatment in clinical practice.

What Is Quetiapine?

Quetiapine is available in 2 oral formulations — immediate-release tablets in 25 mg, 100 mg, 200 mg, and 300 mg doses of quetiapine fumarate[5] and extended-release tablets in 50 mg, 150 mg, 200 mg, 300 mg, and 400 mg doses of quetiapine fumarate.[6] Quetiapine is an atypical or second-generation antipsychotic drug that is primarily used for treating schizophrenia and bipolar disorder.[5] Additionally, the extended-release formulation is also indicated as an adjunct or augmentation treatment for adults with major depressive disorder when currently available antidepressant drugs have failed due to lack of efficacy and/or lack of tolerability.[6] Off-label use of quetiapine for several conditions, such as agitation, delirium, delusional infestation, posttraumatic stress disorder, and sleep problems, has been documented.[7] The side effects of quetiapine include somnolence, dizziness, dry mouth, withdrawal (discontinuation) symptoms, elevations in serum triglyceride levels, elevations in total cholesterol (predominantly low-density lipoprotein cholesterol), decreases in high-density lipoprotein cholesterol, weight gain, decreased hemoglobin, and extrapyramidal symptoms (involuntary movements induced by medications).[5,6]

Why Is It Important to Do This Review?

Higher doses of quetiapine and concomitant use with central nervous system drugs are associated with an increased risk of adverse effects.[8,9] Given the frequent off-label use and potential for harm associated with quetiapine, it is important to review the current evidence on the efficacy, safety, and place in therapy of quetiapine for the treatment of people with insomnia. An overview of the evidence may aid decision-making with respect to prescribing and recommended use of quetiapine for adults with insomnia.

Research Questions

1. What is the clinical effectiveness and safety of quetiapine versus other drug interventions for adults with insomnia?
2. What are the evidence-based guidelines regarding the use and administration of quetiapine for adults with insomnia?

Methods

Literature Search Methods

An information specialist conducted a literature search on key resources, including MEDLINE, Embase, the Cochrane Database of Systematic Reviews, the International HTA Database, and the websites of Canadian and major international health technology agencies, as well as a focused internet search. The search approach was customized to retrieve a limited set of results, balancing comprehensiveness with relevancy. The search strategy comprised both controlled vocabulary, such as the National Library of Medicine's MeSH (Medical Subject Headings), and keywords. Search concepts were developed based on the elements of the research questions and selection criteria. The main search concepts were quetiapine and insomnia. Search filters were applied to limit retrieval to health technology assessments, systematic reviews (SRs), meta-analyses, indirect treatment comparisons, randomized controlled trials (RCTs), controlled clinical trials, and guidelines. The search was completed on April 29, 2025, and limited to English-language documents published since January 1, 2020.

Selection Criteria and Methods

One reviewer screened citations and selected studies. In the first level of screening, titles and abstracts were reviewed and potentially relevant articles were retrieved and assessed for inclusion. The final selection of full-text articles was based on the inclusion criteria presented in Table 1.

Table 1: Selection Criteria

Criteria	Description
Population	Adults aged ≥ 18 years with insomnia
Intervention	Quetiapine fumarate immediate-release tablets, quetiapine fumarate extended-release tablets
Comparator	Other drug interventions: other second-generation atypical antipsychotics, mood stabilizers, antidepressants (e.g., mirtazapine), nonbenzodiazepine medications (e.g., zolpidem), melatonin, antihistamines, orexin inhibitors, antinauseants (e.g., dimenhydrinate), herbal supplements (e.g., valerian root), magnesium
Outcomes	• Clinical effectiveness (including long-term effectiveness) • Safety outcomes (including potential for misuse or diversion) • Guideline recommendations • Patient-reported outcomes
Study designs	RCTs, systematic reviews, (including MAs and NMAs), evidence-based guidelines,[a] and published HTAs

HTA = health technology assessment; MA = meta-analysis; NMA = network meta-analysis; RCT = randomized controlled trial.

[a]A guideline is defined as a systematically developed statement or set of statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances. A guideline is considered evidence-based if a systematic search of the literature was undertaken to inform the recommendations.

Exclusion Criteria

Articles were excluded if they did not meet the selection criteria outlined in Table 1 or they were duplicate publications. SRs in which all relevant studies were captured in other more recent or more comprehensive SRs were excluded. Primary studies retrieved by the search were excluded if they were captured in 1 or more included SRs. Guidelines with an unclear methodology were also excluded.

Critical Appraisal of Individual Studies

The included publications were critically appraised by 1 reviewer using the Appraisal of Guidelines for Research and Evaluation (AGREE) II instrument as a guide.[10] Summary scores were not calculated for the included studies; rather, the strengths and limitations of each included publication were described narratively.

Summary of Evidence

Quantity of Research Available

A total of 62 citations were identified in the literature search. Following screening of titles and abstracts, 51 citations were excluded and 11 potentially relevant reports from the electronic search were retrieved for full-text review. Four potentially relevant publications were retrieved from the grey literature search for full-text review. Of these 15 potentially relevant articles, 13 publications were excluded for various reasons and 2 publications met the inclusion criteria and were included in this report. The included publications were 2 evidence-based guidelines.[11,12] Appendix 1 presents the PRISMA[13] flow chart of the study selection.

Summary of Study Characteristics

Appendix 2 provides details regarding the characteristics of the included publications.

Included Studies for Research Question 1: What Is the Clinical Effectiveness and Safety of Quetiapine Versus Other Drug Interventions for Adults With Insomnia?

We did not identify any studies that evaluated the clinical efficacy and/or safety of quetiapine versus other drug interventions for the treatment of insomnia that met the inclusion criteria for this review.

Included Studies for Research Question 2: What Are the Evidence-Based Guidelines Regarding the Use and Administration of Quetiapine for Adults With Insomnia?

Study Design

Two evidence-based guidelines were included to answer research question 2. The guidelines are the 2023 European Insomnia Guideline[11] and the 2025 VA/DoD Clinical Practice Guidelines, from the US Department of Veterans Affairs (VA) and US Department of Defense (DoD),[12] for chronic insomnia disorder and/or obstructive sleep apnea (OSA).

The systematic literature search for the 2023 European Insomnia Guideline[11] primarily focused on meta-analyses on the diagnosis and treatment of insomnia. The guideline was developed by a task force comprised of researchers and clinicians in the European Sleep Research Society and the European Insomnia Network. The evidence was reported as graded using the hierarchy of evidence from level 1a, representing highest quality (SRs and meta-analyses of RCTs), to level 5, representing expert opinion. The translation of levels of evidence into grades of recommendation was based on the hierarchy of evidence and consensus among the guideline authors. Four steps of recommendations were used: A (very strong recommendation), B (strong), C (weak), and D (very weak recommendation).

To develop the 2025 VA/DoD guideline[12] for chronic insomnia disorder and/or OSA, an SR of both clinical and epidemiological evidence was conducted. A working group of multidisciplinary experts interpreted the systematic evidence review's findings and rated both the quality of the evidence and the strength of the recommendation. The evidence was assessed using the Grading of Recommendations, Assessment, Development, and Evaluation (GRADE) methodology and assigned a rating of very low, low, moderate, or high.

Country of Origin

The European Insomnia Guideline[11] is an international guide developed for multiple European countries. The VA/DoD guideline[12] was developed in the US.

Guideline Population and Audience

The target patient population in the VA/DoD guideline[12] is adult beneficiaries of VA or DoD health care delivery systems with chronic insomnia disorder and/or OSA who are eligible for care in VA, DoD, or community-based locations. Though OSA was included in the guideline, only the recommendations for patients with insomnia are discussed in this report. The European Insomnia Guideline[11] focuses on adults with chronic insomnia.

The 2025 VA/DoD guideline[12] is intended for use by VA, DoD, community-based, and other health care providers who are involved in evaluating and managing adults with chronic insomnia disorder and/or OSA.

The 2023 European Insomnia Guideline[11] is meant for health professionals, including general practitioners, specialists, and sleep medicine experts, who diagnose and treat insomnia in various clinical settings, especially where advanced expertise or facilities may be limited.

Interventions and Practice Considered

Both guidelines have a broad scope and included recommendations for pharmacological and nonpharmacological treatments. The 2023 European Insomnia Guideline[11] includes recommendations for cognitive behavioural therapy and pharmacological treatments (e.g., herbal, other forms of psychotherapy, exercise, light therapy, music, and noninvasive brain stimulation). Only the recommendations relevant to quetiapine (or antipsychotics as a therapeutic class) will be discussed in this report.

Outcomes

Both guidelines[11,12] considered a range of outcomes relevant to this review, including insomnia severity, sleepiness, daytime functioning, fatigue, sleep efficiency, sleep onset latency, wake after sleep onset, sleep quality, total sleep time, quality of life, and harms.

Summary of Critical Appraisal

Both guidelines[11,12] provided a description of their scope and purpose, in terms of the objectives, guideline questions, intended users, and target populations. The VA/DoD guideline[12] clearly reported comprehensive evidence synthesis methods, including the key research questions, search strategy, criteria for selection based on population, intervention, comparison, outcome, timing, and setting (i.e., PICOTS framework), and methods for assessing quality and synthesizing the evidence. The European Insomnia Guideline[11] reported the electronic databases, search date limits, study designs, and keywords that were used for the literature search but detailed information on a comprehensive literature search strategy, selection criteria, process for study selection, and synthesis methods was missing. The systemic reviews conducted for each guideline did not identify evidence from SRs and RCTs; as such, the quality of evidence was not reported.

The VA/DoD guideline[12] engaged multidisciplinary parties, including clinicians and patients living with insomnia and/or OSA, which ensured a broad spectrum of perspectives were represented in the process of the guidelines' development. Although the European Insomnia Guideline[11] states that an update will occur when new important evidence is available in the future, no dates were indicated. The VA/DoD guideline[12] indicates it aims to review the evidence at least every 5 years for an update and/or reaffirmation of recommendations in the emergence of new evidence. Both guidelines[11,12] were reviewed independently by relevant professional experts, professional colleges and societies, or a guideline committee. Funding sources and competing interests of authors were reported in the guidelines.[11,12]

Additional details on the critical appraisal of the included guidelines are provided in Appendix 3.

Summary of Findings

Guidelines Regarding the Use of Quetiapine

The study findings from all included publications are provided in Appendix 4.

- The VA/DoD guideline[12] made a weak recommendation against using antipsychotic drugs, including quetiapine, for the treatment of chronic insomnia disorder due to lack of clinical effectiveness evidence and potential safety concerns. Regarding safety, the guideline indicated harms associated with antipsychotics, including low-dose quetiapine (e.g., sedation, hypotension, hyperglycemia, dyslipidemia, and weight gain). The quality of evidence was not reported as no evidence was identified that met the guideline's inclusion criteria.
- The 2023 European Insomnia Guideline[11] does not recommend quetiapine and other antipsychotics for the treatment of insomnia due to lack of clinical effectiveness evidence and potential safety concerns. The recommendation was rated as very strong (A) while the quality of evidence was not reported as no evidence was identified.

Limitations

This report is limited by the lack of available evidence on the clinical effectiveness and safety of quetiapine for the treatment of insomnia in adults. Evidence from published SRs and RCTs to evaluate the clinical effectiveness and safety of quetiapine versus other drug interventions was not identified in our literature search spanning the previous 5 years (i.e., from 2020 to 2025). The European Insomnia Guideline[11] did not provide a detailed description of the SR that informed the recommendations. Although the recommendation against antipsychotics was rated as very strong (A), the quality of evidence was not reported as no evidence was identified. None of the guidelines were specifically developed for Canada; however, the VA/DoD guideline[12] recommendations may be applicable to the health care systems in Canada as the quetiapine formulations included in the guideline are available in Canada.

Conclusions and Implications for Decision- or Policy-Making

Two evidence-based guidelines were identified that reviewed the use of antipsychotics, including quetiapine, for insomnia. Both the 2023 European Insomnia Guideline[11] and the 2025 VA/DoD guideline[12] for chronic insomnia disorder recommend against using antipsychotic drugs, including quetiapine, for the treatment of insomnia due to concerns about safety and lack of evidence on clinical benefit.s

Implications for Clinical Practice

The findings of this review suggest that antipsychotics such as quetiapine should not be used in the treatment of insomnia.

Acknowledgement

Clinical Expert

This individual has kindly provided comments on the report:

Diane McIntosh, BSc Pharmacy, MD, FRCPC

Psychiatrist

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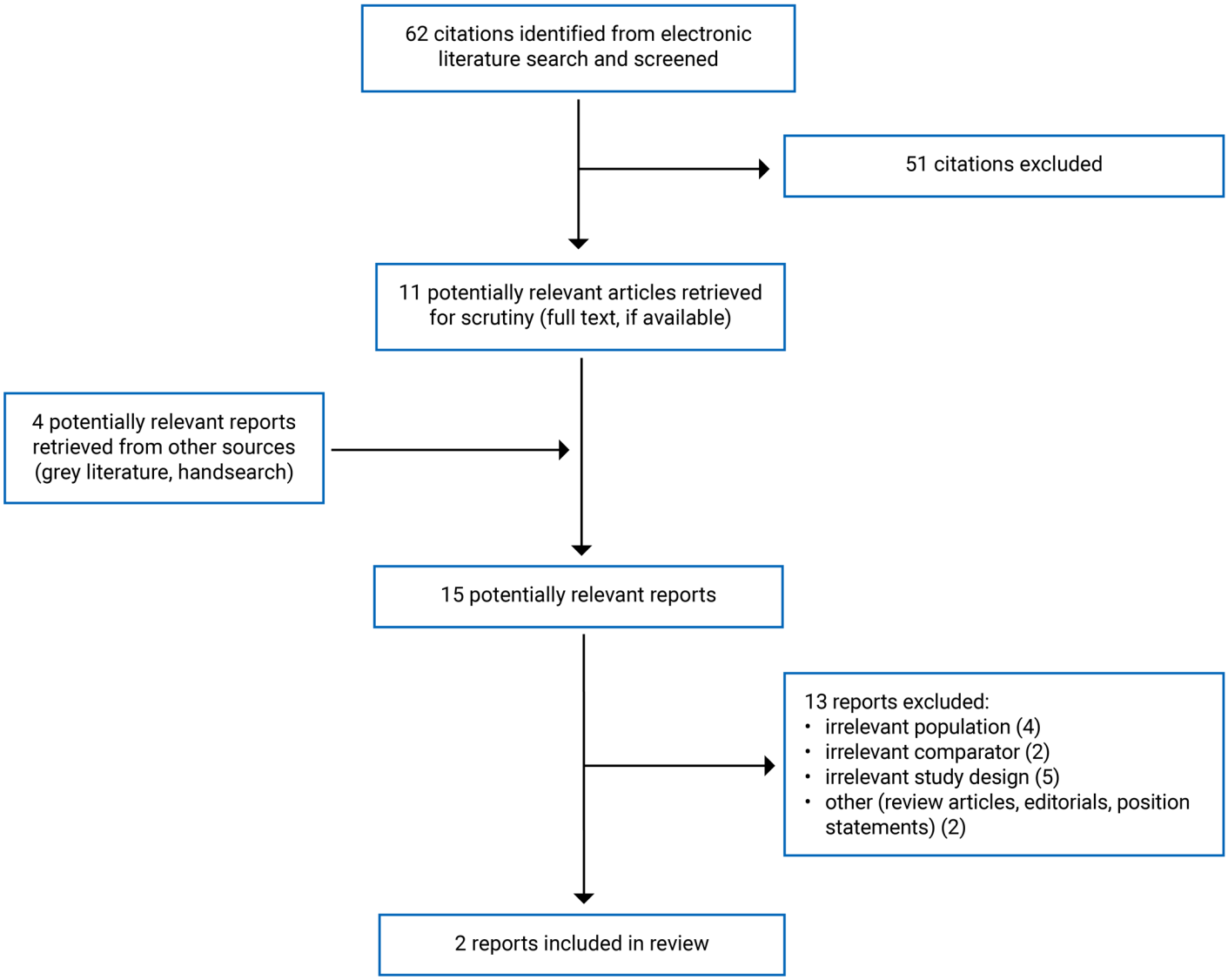
Appendix 1: Selection of Included Studies

Figure 1: PRISMA[13] Flow Chart of Study Selection



Appendix 2: Characteristics of Included Publications

Table 2: Characteristics of Included Guidelines

Intended users, target population	Intervention and practice considered	Major outcomes considered	Evidence collection, selection, and synthesis	Evidence quality assessment	Recommendations development and evaluation	Guideline validation
2025 VA/DoD						
Intended Users: VA, DoD, community providers, and others involved in the health care team evaluating and managing adults with chronic insomnia disorder Target Population: adults of VA or DoD with chronic insomnia disorder eligible for care in the VA, DoD or community-based care	• Non-pharmacological treatments • Pharmacological treatments	Benefits and harms of interventions	Systematic evidence review, guided by 12 clinically relevant key questions of high priority for the VA and DoD populations.	The GRADE approach was used to assess the overall quality of the body of evidence for each outcome and rated as high, moderate, low or very low. GRADE was applied in a more rigorous way than previous iterations of the guideline.	To develop recommendations, the Work Group of multidisciplinary experts interpreted the systematic evidence review's findings. Each recommendation's strength (strong/ weak) and direction (for/against/neither for or against) was determined based on 4 domains as per GRADE: confidence in the quality of evidence, balance of desirable and undesirable outcomes, patient values and preferences, and other implications (e.g., resource use, equity, feasibility, patient subgroup considerations). Recommendations were categorized The Work Group used an iterative review process to solicit	• Feedback from the Work Group on draft guideline • External peer review by experts • VA/DoD Evidence-based Practice Work Group

Intended users, target population	Intervention and practice considered	Major outcomes considered	Evidence collection, selection, and synthesis	Evidence quality assessment	Recommendations development and evaluation	Guideline validation
					feedback on 3 drafts of the CPG and made revisions.	
2023 European Insomnia Guideline						
Intended Users: general practitioners, specialists, and sleep medicine experts who diagnose and treat insomnia in various clinical settings Target Population: adult patients with chronic insomnia	• Non-pharmacological treatments • Pharmacological treatments	Sleep quality, insomnia symptoms, daytime functioning	Systematic literature search focused on meta-analyses on the diagnosis and treatment of insomnia	The evidence was graded according to the hierarchy of evidence. The grading scheme ranged from 1 to 5 with level 1a representing the highest quality of evidence (systematic review and meta-analysis of RCTs) to level 5 representing expert opinion	The guideline was developed by a task force comprised of researchers and clinicians in the ESRS, and the EIN. The transformation of grades of evidence into grades of recommendations was performed according to this grading scheme and through consensus decision between all involved authors	• Feedback from authors • Guideline committee of the ESRS and by the ESRS board • External review by journal

CPG = clinical practice guideline; DoD = US Department of Defense; EIN = European Insomnia Network; ESRS = European Sleep Research Society; GRADE = Grading of Recommendations Assessment, Development, and Evaluation; VA = US Department of Veterans Affairs

Note: This table has not been copy-edited.

Appendix 3: Critical Appraisal of Included Publications

Please note that this appendix has not been copy-edited.

Table 3: Strengths and Limitations of Guidelines Using AGREE II[10]

Item	2025 VA/DoD	2023 European Insomnia guideline
Domain 1: scope and purpose		
1. The overall objective(s) of the guideline is (are) specifically described.	Yes	Yes
2. The health question(s) covered by the guideline is (are) specifically described.	Yes	Yes
3. The population (patients, public, etc.) to whom the guideline is meant to apply is specifically described.	Yes	Yes
Domain 2: stakeholder involvement		
4. The guideline development group includes individuals from all relevant professional groups.	Yes	Yes
5. The views and preferences of the target population (patients, public, etc.) have been sought.	Yes	No
6. The target users of the guideline are clearly defined.	Yes	Yes
Domain 3: rigour of development		
7. Systematic methods were used to search for evidence.	Yes	Yes
8. The criteria for selecting the evidence are clearly described.	Yes	Partial
9. The strengths and limitations of the body of evidence are clearly described.	Yes	Yes
10. The methods for formulating the recommendations are clearly described.	Yes	Partial
11. The health benefits, side effects, and risks have been considered in formulating the recommendations.	Yes	Yes
12. There is an explicit link between the recommendations and the supporting evidence.	Yes	Yes
13. The guideline has been externally reviewed by experts prior to its publication.	Yes	Yes
14. A procedure for updating the guideline is provided.	Yes	Partial
Domain 4: clarity of presentation		
15. The recommendations are specific and unambiguous.	Yes	Yes
16. The different options for management of the condition or health issue are clearly presented.	Yes	Yes
17. Key recommendations are easily identifiable.	Yes	Partial
Domain 5: applicability		
18. The guideline describes facilitators and barriers to its application.	Yes	Yes

Item	2025 VA/DoD	2023 European Insomnia guideline
19. The guideline provides advice and/or tools on how the recommendations can be put into practice.	Partial	Partial
20. The potential resource implications of applying the recommendations have been considered.	Yes	Yes
21. The guideline presents monitoring and/or auditing criteria.	Yes	Partial
Domain 6: editorial independence		
22. The views of the funding body have not influenced the content of the guideline.	Yes	Yes
23. Competing interests of guideline development group members have been recorded and addressed.	Yes	Yes

AGREE II = Appraisal of Guidelines for Research and Evaluation II; DoD = US Department of Defense; GRADE = Grading of Recommendations Assessment, Development, and Evaluation; VA = US Department of Veterans Affairs.

Appendix 4: Main Study Findings

Please note that this appendix has not been copy-edited.

Table 4: Summary of Recommendations in Included Guidelines

Recommendations and supporting evidence	Quality of evidence and strength of recommendations
2025 VA/DoD[12]	
Antipsychotic drugs (including quetiapine), benzodiazepines, diphenhydramine and trazodone are not recommended for treatment of chronic insomnia disorder. **Supporting evidence:** "Evidence on using low-dose quetiapine for the treatment of chronic insomnia disorder is limited to a few studies and case series with short duration, small sample sizes, and vague and incomplete details, thus making any determination regarding efficacy inconclusive…. Quetiapine has a black box warning indicating a 1.6 to 1.7 fold increase in mortality in elderly populations with dementia-related psychosis." p.157	Quality of evidence: NR Strength of recommendation: Weak against
2023 European Insomnia Guideline[11]	
Quetiapine and other antipsychotics are not recommended for the treatment of insomnia **Supporting evidence:** "no randomized controlled clinical studies on these substances (*antipsychotics*) concerning insomnia disorder either with or without comorbidities. Therefore, at present the scientific evidence does not recommend the use of antipsychotics (including quetiapine) in the treatment of insomnia without comorbidities, in either the short or long term." p.17 "Because of insufficient evidence and in light of their side-effects, antipsychotics are not recommended for insomnia treatment" p.23	Quality of evidence: NR Strength of recommendation: Very strong (A)

NR = not reported in guideline publication.

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