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The need to prioritize ”insomnia disorder” in public health agendas: “a wakeup call” position paper from European and Canadian experts in sleep and mental health

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ABSTRACT

Objective: Insomnia Disorder is a chronic mental disorder with significant impact on the population across Europe and Canada. While some countries reimburse evidence-based treatments, others fail to recognize insomnia as a chronic condition and do not provide the resources to ensure consistent care for those affected. This document serves as a position paper from sleep and mental health experts across Europe, Switzerland the UK, and Canada, emphasizing the critical need for public health systems to recognize chronic insomnia as a disorder in order to enhance support for patients.
Methods: A consortium of prominent European, Switzerland, UK, and Canadian clinicians and researchers in the field of sleep and mental health decided to produce a position paper. We conducted a narrative review on epidemiology associated with insomnia disorder, the economic and health challenges it poses, and the existing framework of healthcare systems concerning insomnia treatment and reimbursement practices.
Results: Although insomnia disorder poses a significant public health challenge, it is not adequately recognized, and it is frequently deprioritized by healthcare authorities which results in the absence of reimbursement or financial support for any treatments recommended for insomnia disorder.
Conclusions: Pathways for the evaluation and treatment of insomnia disorder result suboptimal across countries increasing the burden of the disease. This paper acts as a crucial reminder for public health systems to prioritize the support of patients throughout their treatment processes: It is a call for integration of chronic insomnia treatment in stepped-care mental health models.

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1. Introduction

Sleep is an essential biological requirement, crucial for the health and well-being of individuals across all ages [1–3]. In 2021, the American Academy of Sleep Medicine published a position paper emphasizing the critical role of sleep for health [4]. Relatedly, the World Sleep Society, the World Health Organization (WHO) and the American Heart Association have affirmed that healthy sleep plays a vital role in health [3,5,6]. This highlights the necessity to incorporate sleep health into global public health agendas [3,7–10].

Among sleep disorders, insomnia disorder such as the chronic form of insomnia is the most prevalent and its occurrence is increasing [11–13]. Individuals suffering from chronic insomnia experience poor quality of life are at increased risk of developing significant comorbid conditions, including mental and physical disturbances [11,14]. Therefore, there is a distinct need to adequately treat chronic insomnia, given its high burden on the patients and on the society [11,14]. Unfortunately, insomnia disorder is often not adequately recognized or treated, and it is frequently deprioritized by healthcare authorities making it difficult to implement effective therapeutic interventions [15,16]. Pathways for the evaluation and treatment of chronic insomnia result often suboptimal across countries increasing the burden of the disease [15,16]. Insomnia has historically been viewed merely as a symptom of other disorders, rather than a condition warranting independent treatment. This outdated perspective persists despite extensive research over the last twenty years showing a reciprocal relationship to various mental and physical health issues [17,18].

This article aims to function as a significant 'wake-up' call for governments and public healthcare systems throughout Europe and Canada, for prioritizing the need to recognize insomnia disorder as a mental and sleep/wake disorder that warrants access to and reimbursement for evidence-based treatments.

2. Methods

A consortium of prominent European, Swiss, UK, and Canadian clinicians and researchers in the field of sleep and mental health decided to produce a position paper for emphasizing the critical need for public health systems to recognize chronic insomnia as a disorder. LP and PAG conducted a systematic search across the last 10 years on chronic insomnia definition, epidemiology, the economic and disease burden it poses, and on existing framework of healthcare systems concerning chronic insomnia treatment and reimbursement practices. The group of specialists reviewed the findings and developed the position paper in a narrative way. Given that the literature on the subject is extensive, we included in this work the most recent meta-analyses, systematic review or population-based data on the following topics: Insomnia disorder definition, epidemiology of chronic insomnia, economic burden of chronic insomnia, disease burden of chronic insomnia including the risk for developing psychiatric disorders, neurological disorders, cardiometabolic disorders, cancer and mortality. We also revised most recent European and Canadian evidence-based therapies, and data on reimbursement for evidence-based treatments for chronic insomnia. Exclusion criteria included: 1) papers not in English language, 2) papers not directly related to insomnia but involving other sleep disturbances.

3. Results

For Insomnia Disorder definition three most important classification systems have been described. For the epidemiology of insomnia, 10 papers were discussed, 8 for the economic burden, 3 for disease burden related to the risk to develop psychiatric disorders, 9 for the risk to develop neurological disorders, 3 for cardiovascular disorders, 1 for metabolic disorders, 1 for the risk of cancer and 5 in relation with the risk of mortality. For the section related to evidence-based therapies for chronic insomnia, we found 3 papers representing guidelines for Europe, Canada and UK. Data on reimbursement for evidence-based treatments for chronic insomnia across countries were evinced from different papers already included in the research. In the results section each topic will be discussed.

3.1. Insomnia disorder definition

The diagnostic criteria for chronic insomnia have now been standardized across three classification systems (Table 1). Since 1987, insomnia has been categorized as a mental disorder in the **Diagnostic and Statistical Manual of Mental Disorders (DSM)** published by the American Psychiatric Association [19]. The 2013 edition of the DSM-5 eliminated the differentiation between primary and secondary insomnia, a decision that has been retained in the 2022 revised edition [12,13]. Currently, insomnia Disorder is classified as a mental disorder among Sleep-Wake Disorders and recognized as an independent condition rather than merely a symptom or syndrome associated with other physical or other mental health issues. The criteria for diagnosis include a primary complaint of dissatisfaction with sleep, whether in terms of quantity or quality. This may manifest as trouble initiating sleep, maintaining sleep, or experiencing early morning awakenings with an inability to fall back asleep. Such sleep disturbances must result in clinically significant distress or functional impairment across various domains, including social, occupational, educational, academic, behavioral, or other vital areas. The sleep difficulties should occur at least three nights per week and persist for a duration of at least three months, despite having adequate opportunities for sleep. **The International Classification of Sleep Disorders (ICSD)**, developed by the American Academy of Sleep Medicine (AASM), was first released in 1990. This initial publication outlined various subtypes of insomnia as a sleep/wake disorder. In 2014, the ICSD-3 edition was introduced, which organized all insomnias into three main categories and included chronic insomnia [20]. The criteria for chronic insomnia in the 2014 and 2022 editions (ICSD-3-TR) [21] are comparable to those outlined in the DSM-5 for Insomnia Disorder. In the late 1970s, the World Health Organization (WHO) initiated its first significant effort to integrate a sleep classification system into **The International Classification of Diseases (ICD)**. In earlier editions, insomnia was categorized as both a mental disorder and an "organic" disease. However, in the most recent version, ICD-11 2022 [22], chronic insomnia was classified under sleep-wake disorders. The diagnostic criteria adhere to the standards set forth by the DSM-5 as well as the ICSD-3 and ICSD-3-TR.

Various research teams have proposed complex models to explain the causes and underlying mechanisms of insomnia. Insomnia represents a complex condition that is impacted by genetic, epigenetic, and psychological factors, with a range of alterations in neuroendocrine systems, neurotransmitters, and brain structures playing a crucial role [11,14]. The hyperarousal model of insomnia suggests persistent activation of the stress response system, characterized by heightened arousal in cognitive, emotional, and physiological aspects, serves as both a predisposing factor and a contributor to the chronic nature of the condition [11,14]. From a neurobiological perspective, hyperarousal may result from the predominance of brain regions that promote arousal over those that facilitate sleep, which in turn interact with psychological factors associated with insomnia [11,14] (Table 2)

3.2. Epidemiology of insomnia

Epidemiological data indicates that the prevalence of insomnia symptoms, among adults aged 18 years and older, range from 5.8 % to 51.2 % [11,14,23,24]. Recent studies suggest that the prevalence of insomnia disorder in Europe has increased to around 10 % of the population [11,14]. Similarly it may affect around 16.3 % of the Canadian population [25]. Insomnia is a widespread disorder that affects individuals in both its subsyndromal and chronic form around the world (Fig. 1).

Research conducted in general practice and medical specialty environments reveals significantly higher prevalence rates of insomnia [26]. For instance, data from a German study [27] indicates that 20 % of patients visiting a general practitioner experience insomnia disorder, while in Norway and Italy, the figure may reach the 50 % among general practitioner patients [28,29]. In particularly, the study that was conducted in Italy, utilizing the Sleep Condition Indicator, a questionnaire that defines Insomnia Disorder according to DSM-5 criteria, found that over 50 % of patients aged 50 and above were affected [29]. There is an increased frequency observed particularly in women, older individuals, and those dealing with socioeconomic hardships [11,14,29,30].

Patients can suffer from insomnia for years. In fact Morin et et al. [31] findings on the natural history of insomnia in Canada revealed that around 70 % of patients exhibit ongoing symptoms over a one-year period and 46 % of individuals with insomnia continued to experience persistent symptoms after three years. Another Canadian cohort study revealed that 59 % of patients reported persistent insomnia upon their 5-year follow-up [32] (Table 2).

3.3. Economic burden of insomnia

The economic impact of chronic insomnia is considerable, as demonstrated by the direct costs of treatment and, more critically, the indirect costs arising from personal societal burden, reduced quality of life, increased reliance on healthcare service, increased absenteeism and lower productivity related to the disorder, higher likelihood of traffic accidents and potential negative effects on psysical and mental health [11,14,15,23,24,30]. Insomnia represents a serious public health challenge that requires attention through individualized clinical care and widespread sleep health programs at the community level [30].

Recent investigations into the social and economic ramifications of chronic insomnia have found that this disorder is linked to a reduced quality of life in both physical and mental health domains. A study conducted in the United States revealed the annual loss of Quality-Adjusted Life Years due to insomnia was $5.6 billion, which was significantly higher than the losses associated with any of the other 18 medical conditions evaluated, such as arthritis ($4.94 billion), depression ($4.02 billion), and hypertension ($3.63 billion) [33].

Individuals experiencing chronic insomnia are also more likely to demonstrate decreased productivity. The analysis of the NHWS 2020 data indicated a significant economic impact associated with chronic insomnia [24]. Participants experiencing severe insomnia exhibited markedly higher rates of insomnia-related absenteeism (23.4 % compared to 5.6 %), presenteeism (41.2 % versus 0.16.5 %), decreased overall productivity (44.7 % against 18.3 %), and more frequent visits to general practitioners (adjusted mean of 8.55 visits compared to 5.74) when compared to those without insomnia [23,24]. Additionally, chronic insomnia is linked to a heightened risk of workplace errors and accidents (2–2.5 times more than healthy sleepers) which can result in physical injuries and disabilities [15,23–25].

The annual well-being loss caused by chronic insomnia, when applied to the working-age population, may range from $1.5 billion dollars in Norway to $127.1 billion dollars in the United States [11,14,15,23,24,30]. In a 2010 report commissioned by the European Brain Council, chronic insomnia ranked as the ninth most costly brain disorder in the EU27, contributing to 389,753 Daily Adjusted Life Years (DALYs) [15]. This figure comprised €20 billion in direct costs and €15 billion in indirect costs, with direct costs covering clinical management such as diagnosis, treatment, physician consultations, and hospital stays, while indirect costs stemmed from lost productivity due to absenteeism or premature retirement [15].

Similary, the financial impact of insomnia symptoms in Canada for the year 2021 was recorded at $1.9 billion in direct costs, $12.6 billion in indirect costs. This total represents 1.9 % of the overall costs associated with illness in Canada for that year [34].A recent economic analysis [23] suggested that addressing chronic insomnia among the working population could lead to an overall financial benefit with monetary gains in Gross Domestic Product per capita between roughly $4195 and $19,350 (Table 2).

3.4. Disease burden of insomnia disorder

3.4.1. Insomnia and risk for psychiatric disorders

Research has consistently demonstrated a strong correlation between chronic insomnia and poor mental health. Two latest meta-analysis one of 21 and one of 22 longitudinal studies, respectively, found that individuals with insomnia are around 3 times more likely to develop depression compared to those without insomnia, and more than 3 times more likely to develop anxiety [35,36]. In a more recent cohort study involving approximately 1 million people, those with untreated insomnia exhibited a higher likelihood of experiencing psychiatric comorbidities (40.1 % vs. 13.2 (Table 1) [37]. Given the well-established bidirectional relationship between insomnia and psychiatric disorders, including depression and suicide risk, the prioritization of insomnia in public health policies may also represent a strategic step toward suicide prevention and overall mental health improvement [38,39] (Tables 2 and 3).

3.4.2. Insomnia and risk for neurological disorders

Chronic insomnia is frequently associated with neurodegenerative dementia and stroke. A meta-analysis involving 5 population-based prospective cohort studies showed that insomnia was associated with a significant risk of all-cause dementia [40]. The latest meta-analysis which included 16 studies revealed insomnia as increasing risks for Alzheimer's Dementia and Vascular Dementia [41]. In another 2025 meta-analysis including different sleep disorders, insomnia was the sleep disorder with the higher risk for all causes of dementia [42]. Subsequently, a different large prospective study have demonstrated this association [37,43]. The research conducted by Wu et al. [44], Hsu et al. [45], Zheng et al. [46] and Sawadogo et al. [47] indicated that insomnia was linked to an increase in the risks of stroke (Tables 2 and 3).

3.4.3. Insomnia and risk for cardiovascular disorders

Extensive prospective research and meta-analyses have demonstrated insomnia elevates the risk of developing cardiovascular diseases (CVD). Two meta-analyses of 13 studies and 21 studies showed that

Table 1
The diagnostic criteria for chronic insomnia are now standardized across three classification systems.

The primary complaint of one or more of the following: pertains to dissatisfaction regarding the amount or quality of sleep, which is linked to one or more of the following symptoms:
- **Night-time symptoms:** Difficulty falling asleep at bedtime (sleep-onset insomnia) • Frequent or prolonged awakenings (sleep-maintenance insomnia) • Early-morning awakenings (late insomnia) or a combination of symptoms.
- **Daytime symptoms**: Deterioration in daily tasks resulting from sleep disturbances, including fatigue and reduced energy, impairment with concentration, memory, mood, behaviours or with social, occupational, educational, academic, or other important areas of functioning.
- **The sleep disturbances and related daytime symptoms must occur at least 3 times a week and have persisted for a minimum of 3 months**
- **The reported issues related to sleep and wakefulness cannot be solely attributed to insufficient opportunity for sleep (adequate amount of time is provided for rest) or to inadequate conditions (the environment is secure and comfortable) for sleeping**
- **Chronic insomnia can manifest as an independent disorder, regardless of the presence of coexisting mental or medical conditions**

Insomnia was associated with an increased risk of developing or dying from cardiovascular disease [48,49]. In the cohort study involving approximately 1 million people, insomnia patients exhibited a higher likelihood of experiencing hypertension, ischemic heart disease and heart failure [37] (Tables 2 and 3). A growing body of evidence supports the delineation of an insomnia phenotype –with objectively verified short sleep duration (5 h) which results particularly related with cardiovascular disorder [50].

3.4.4. *Insomnia and risk for metabolic disorders*

Insomnia disorder is often co-morbid with metabolic disorders. A recent meta-analysis of 12 prospective studies showed that patients with chronic insomnia were at risk to develop hypertension, hyperglycaemia, hyperlipidaemia and obesity 1.41 times, 1.29 times and 1.31 times higher than people without insomnia, respectively [51] (Tables 2 and 3).

3.4.5. *Insomnia and risk for cancer*

Insomnia disorder has been recently associated with an increased risk of cancer. A recent meta-analysis of 8 studies, (seven prospective and one retrospective), involving 578,809 participants, demonstrate a 24 % overall increased risk of cancer for individuals with insomnia compared to those without insomnia [52]. (Tables 2 and 3).

3.4.6. *Insomnia and risk for mortality*

Several studies and meta-analyses demonstrated that insomnia is associated with an increased mortality risk. Different cohort studies indicated that insomnia was associated with a higher risk of total and CVD specific mortality [53,54]. Three meta-analyses were conducted including 29, 17 and 21 studies observed an increased risk of mortality in patients with insomnia [49,55,56]. (Tables 2 and 3).

Table 2
Summary of the findings.

Insomnia disorder definition
1. Insomnia disorder is the chronic form of insomnia and it is considered as a mental disorder and sleep wake disorder
2. Insomnia is now considered an independent disorder across all different classifications.
3. Criteria for insomnia are now standardized across various classification systems and consist of nighttime and daytime symptoms lasting at least 3 months and affecting several areas of daily life.
4. The persistent overactivity of the stress system-the hyperarousal- is regarded as the underlying mechanism of chronic insomnia.
Epidemiology of insomnia
1. Insomnia disorder such as the chronic form of insomnia, may affect around 10 %–16 % of the European and the Canadian population, but prevalence may be higher
2. There is an increased frequency of insomnia disorder observed particularly in women, older individuals, patients with low income
3. Insomnia disorder is a chronic condition that affects approximately 40 % of patients for more than five years, often characterized by recurrence and frequent relapses.
Economic burden of insomnia
1. The economic impact of chronic insomnia is considerable, as demonstrated by its direct and indirect costs
2. Indirect costs in Europe are around €20 billion and €15 billion are around indirect costs. In 2010 insomnia ranked as the ninth most costly brain disorder in the EU27
3. Direct and indirect costs in Canada are around $2.9 billion per year
4. Addressing chronic insomnia among the working population could lead to an average increase, globally, of between $1.8 billion to $207.5 billion to Gross Domestic Product
Insomnia and risk of psychiatric disorders
Chronic insomnia is frequently associated with psychiatric disorders and is a risk factor for the development of new psychiatric diseases:
1. Compared to individuals without insomnia, individuals with insomnia report more frequently depression and anxiety as co-morbidities
2. Patients with insomnia experience a higher risk of developing major depression, anxiety disorders, alcohol use disorder, suicidal risk and psychosis compared to individuals without insomnia
Insomnia and risk of neurological disorders
Chronic insomnia is a risk factor for the development of new dementia cases and for stroke:
1. Compared to individuals without insomnia, older adults with insomnia report more frequently dementia (including AD) as co-morbidities
2. Patients with sleep onset insomnia have a higher risk of developing dementia compared to individuals without insomnia
3. Compared to individuals without insomnia, individuals with insomnia report an increased risk of stroke
Insomnia and risk of cardiovascular disorders
Chronic insomnia is frequently associated with cardiovascular morbidity and mortality, and is a risk factor for the development of new cardiovascular diseases:
1. Individuals with insomnia more frequently report hypertension, ischemic heart disease and heart failure as co-morbidities, compared to those without insomnia,
2. Patients with untreated insomnia have a higher risk of developing new CVD than those without insomnia
3. Individuals who sleep $\leq$6 h have a higher risk of CVD and of fatal CVD compared to people who sleep 7-8 h.
Insomnia and risk of metabolic disorders
1. Compared to individuals without insomnia, individuals with chronic insomnia report more frequently cardiometabolic disturbances
Insomnia and risk of cancer
1. Individuals with chronic insomnia have an increased risk of cancer compared to individuals without insomnia
Insomnia and risk of mortality
1. Chronic insomnia, if not adequately treated, increases the risk of both all-cause and cardiovascular disease-related mortality
The importance of treating insomnia disorder according to evidence-based therapies
1. Chronic insomnia, if adequately treated according to evidence-based treatments, may improve quality of life and overall wellbeing
2. Chronic Insomnia, if adequately treated according to evidence-based treatments, may prevent or improve mental or physical comorbidities
3. Managing chronic insomnia may have a favorable impact on direct and indirect costs
Reimbursement or financial support for pharmacological and non-pharmacological evidence-based treatments for insomnia
1. Germany offers the most effective system that supports all evidence-based approaches for managing chronic insomnia
2. Conversely, most of countries do not endorse any form of chronic insomnia treatment except for off-label options.

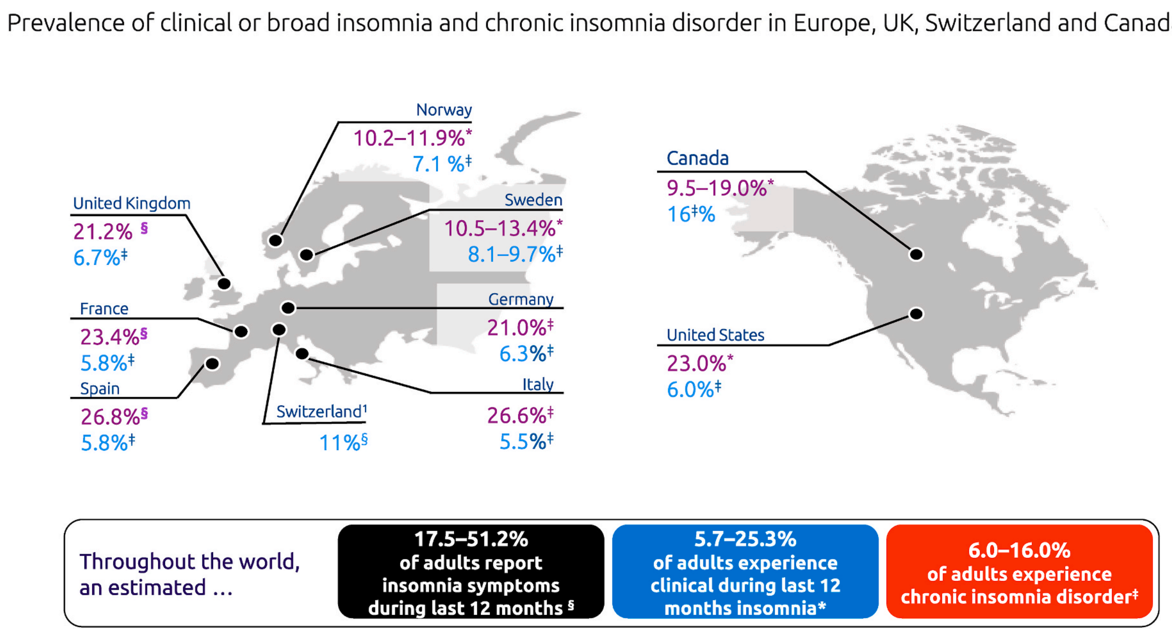

Fig. 1. Prevalence of clinical or broad insomnia and chronic insomnia disorder in Europe, UK, Switzerland and Canada.
Prevalence of insomnia across countries. From 17.5 to 51.2 % subjects report insomnia symptoms, 5.7–25.3 % experience clinical significant insomnia with daytime impairment, from 6 to 16 % experience chronic insomnia.

3.4.7. The importance of treating insomnia disorder according to evidence-based therapies

Recent evidence suggests that targeting insomnia might be a modifiable factor that improves overall health [15]. Insomnia treatment guidelines have been recently updated in Europe, UK and Canada [14, 57,58]. Cognitive Behavioral Therapy for Insomnia (CBT-I) is considered the first-line treatment for insomnia, including digital forms [14, 55,56]. Based on clinical and research data, when CBT-I is either ineffective or unavailable the first-line pharmacological treatment for insomnia, both short-term and long-term, are Dual Orexin Receptor Antagonists (DORAs) [14,58]. In Europe, UK and Switzerland, daridorexant is the only DORA, while in Canada both daridorexant and lemborexant are the avalable DORAs [14,57,58]. Gamma-aminobutyric acid (GABA)A receptor agonists, such as benzodiazepines and Z-drugs (eszopiclone, zolpidem, zaleplon, zopiclone) are only recommended for short term periods (less than 4 weeks, except for eszopiclone, with data up to six months) [14,57,58]. In Europe and Switzerland a prolonged-release (PR) formulation of melatonin at 2 mg is recomended for individuals over 55 years old [14]. Other medications, including arousal-system antagonists such as sedative antidepressants, neuroleptics, or antihistamines with antihistaminic or 5HT2 antagonism, which have been employed for decades as 'off label' approaches to insomnia, are not reccomended [14,57,58]. That said, a significant number of individuals with insomnia find themselves relying on prolonged use of medications like GABA receptor agonists or off label medications, often for durations significantly longer than the approved [15,16].

On the other hand, implementing evidence-based therapies for insomnia disorder has the potential to elevate quality of life, enhance global well-being, and boost work productivity, preventing and improving mental and medical comorbidities with favorable impact on direct and indirect costs [59–74].

3.4.8. Reimbursement or financial support for pharmacological and non-pharmacological evidence-based treatments for chronic insomnia

Clinical care for patients with chronic insomnia varies across Europe, UK, Switzerland and Canada due to regional disparities in practices and access to healthcare [15,16]. In some countries public insurance is universal and the national healthcare system is funded by taxes; some other countries provide health services funded primarily through general taxation and secondarily from private insurance and out-of-pocket payments. In others the system is more related to private insurance and in other to out-of the pocket payments completely. Table 4 is a summary of reimbursement or financial support for insomnia treatment across countries.

Currently, "off label" medications for chronic insomnia receive reimbursement across all different countries. On the other side evidence-based chronic insomnia treatments are reimbursed in very few countries. In Europe, Germany offers the most effective system that economically supports all evidence-based approaches for managing chronic insomnia while regulating the duration of z-drugs and benzodiazepine treatments. In fact Germany offers economical support for CBT-I including digital forms and for DORA daridorexant. Germany also supports the treatment with melatonin 2 mg PR and with z-drugs or benzodiazepines approved for insomnia, but in these cases the reimbursment lasts for a duration of 4 weeks, in alignment with the guidelines for chronic insomnia management. Germany also reinbourses among off label drugs the use of doxepin for 4 weeks, it is an antidepressant which is not present in other european countries.

In line with Germany, Austria offers reiboursment for most of the pharmacological and non-pharmacological evidence-based treatments for chronic insomnia including CBT-I, DORA daridorexant, z-drugs or benzodiazepines for insomnia with no limitations for the duration. Conversely melatonin 2 mg PR is not reimbursed.

Beside Germany and Austria most of the countries do not support CBT-I even if it is the first line treatment for chronic insomnia. In some contries, such as Switzerland, UK and Canada, the treatment may be reinboursed via private insurance, including digital forms.

In addition to Germany and Austria, France and the UK offer support for the treatment with DORA daridorexant. In some countries, the request for reimbursement is currently under review of government, while others, such as Italy and Sweden, have denied reimbursement for the treatment with DORA daridorexant, despite being the first-line treatment among pharmacological options for chronic insomnia in Europe.

In Canada, lemborexant is also available and both lemborexant and daridorexant may be reimbursed by private insurance. Similarly to Austria most of the countries, excluding Italy, provides economic support for the use of z-drugs or benzodiazepines to treat insomnia, without

Table 3
Disease burden of insomnia.

Insomnia and risk of psychiatric disorders				
References	Main Conclusions	Source of evidence	Insomnia definition	Comments
Hertenstein et al. [35,36]	Insomnia is a significant predictor for the onset of Depression (10 studies, OR 2.83, CI 1.55–5.17), Anxiety (6 studies, OR 3.23, CI 1.52–6.85), Alcohol abuse (2 studies, OR 1.35, CI 1.08–1.67, Psychosis (1 study, OR 1.28, CI 1.03–1.59)	Longitudinal studies investigated insomnia at baseline vs no insomnia, as a predictor of the later onset of psychopathology within a follow-up of at least 12 mo.	Insomnia diagnosis made according to different criteria, mainly ICD9 and DSM-III and DSM-IV	Overall risk of bias in the primary studies was moderate
Grandner et al. [37]	Patients with untreated insomnia disorder (ID) had an increased likelihood of depression and anxiety, compared with individuals with no record of insomnia (NID). Annualized prevalence per 100 patient-years: Depression: ID 33.7 vs NI 6.8, Mean difference (95 % CI) 26.89 (26.56, 27.22), $p < 0.01$ Anxiety: D 43.1 vs NI 7.7, Mean difference (95 % CI) 35.38 (34.99, 35.80), $p < 0.01$	Large scale study using a US medical claims database 139,959 individuals with untreated insomnia disorder and 836,975 without insomnia	The 'untreated insomnia' cohort comprised patients with diagnosed insomnia disorder and no record of receiving any insomnia medication. The 'non-insomnia' cohort comprised patients without a diagnosis of insomnia disorder or circadian rhythm sleep disorder, and no record of receiving any of the insomnia medications as for the first cohort	The increased risk of depression and anxiety among individuals with Insomnia disorder was found irrespective of the age (i.e. both in adults younger than 40, and adults older than 65)

Insomnia and risk for dementia and stroke				
References	Main Conclusions	Source of evidence	Insomnia definition	Comments
Dementia				
de Almondes et al. [40]	The results showed that Insomnia was associated with a significant risk of all-cause dementia (RR = 1.53 CI95 % (1.07–2.18), z = 2.36, p = 0.02).	meta-analysis population-based prospective cohort studies,5 studies	Self-reported insomnia	
Grandner et al. [37]	Patients with untreated insomnia disorder (ID) had an increased likelihood of dementia, including Alzheimer's disease. Annualized prevalence per 100 patient-years: Overall population 1 vs NI 0.5, Mean difference (95 % CI) 0.49 (0.46, 0.51), $p < 0.01$ Older than 65 yrs: ID 7.7 vs NI 4.2, Mean difference (95 % CI) 3.48 (3.33, 3.62). $p < 0.01$	Large scale study using a US medical claims database, 139,959 individuals with untreated insomnia disorder and 836,975 without insomnia	The 'untreated insomnia' cohort comprised patients with diagnosed insomnia disorder and no record of receiving any insomnia medication. The 'non-insomnia' cohort comprised patients without a diagnosis of insomnia disorder or circadian rhythm sleep disorder, and no record of receiving any of the insomnia medications as for the first cohort	The increased risk of dementia is significantly higher in older adults.
Meng et al. [41]	Analyses revealed a significant association between insomnia and dementia risk (OR = 1.36; 95 % CI: 1.01–1.84), with increased risks for Alzheimer Dementia (OR = 1.52; 95 % CI: 1.19–1.93) and Vascular Dementia (OR = 2.10; 95 % CI = 2.06–2.14). Subgroup analyses showed no evidence of associations between initial insomnia (OR = 1.01; 95 % CI = 0.71–1.31), sleep-maintenance insomnia (OR = 0.88; 95 % CI = 0.66–1.17), and early morning awakening (OR = 0.94; 95 % CI = 0.83–1.07) with dementia risk. Insomnia patients from Europe (OR = 1.24; 95 % CI = 1.14–1.35), Asia (OR = 2.19; 95 % CI = 2.06–2.32), and the Americas (OR = 1.05; 95 % CI = 1.04–1.07) had varying risks of dementia.	meta-analysis included 16 studies with a combined sample size of over 9 million individuals.		
Ungvari et al. [42]	Significant associations between all-cause dementia and insomnia (HR 1.36, 95 % CI 1.19–1.55), obstructive sleep apnea (HR 1.33, 95 % CI 1.09–1.61), and other sleep disorders (HR 1.33, 95 % CI 1.24–1.43). Insomnia was significantly associated with increased risk for both vascular dementia (HR 1.59, 95 % CI 1.01–2.51) and Alzheimer Disease (HR 1.49, 95 % CI 1.27–1.74). Obstructive sleep apnea increased the risk for Alzheimer Disease (HR 1.45, 95 % CI 1.24–1.69) but not vascular dementia.	Thirty-nine cohort studies were included		Among sleep disorders insomnia had the higher risk for all causes of dementia

(continued on next page)

Table 3 (*continued*)

Insomnia and risk for dementia and stroke				
References	Main Conclusions	Source of evidence	Insomnia definition	Comments
Tan X et al. [43]	Individuals with insomnia symptoms at baseline experience a higher risk of dementia. HR = 1.08, 95 %CI: 1.03,1.35	22,078 individuals prospectively followed for 19.2 years	Insomnia symptoms assessed through the Karolinska Sleep questionnaire, referring to the past 12 months.	Only sleep initiation, not sleep maintenance insomnia, was associated with higher risk of dementia
Stroke	Main Conclusions	Source of evidence	Insomnia definition	Comments
Wu et al. [44]	The incidence rate of stroke was significantly higher (IRR 1.85) in individuals with insomnia than without insomnia. The distributions of stroke subtypes were ischemic stroke (IRR 1.79) and hemorrhagic stroke (IRR 1.32). Those with insomnia were at increased risk of stroke by a magnitude of 54 % (HR 1.54).	85742 adults without a previous diagnosis of stroke or sleep apnea	Difficulties in initiating or maintaining sleep, according to the ICD-9	
Hsu et al. [45]	Individuals suffering from insomnia exhibited a greater occurrence of stroke (8.01 compared to 3.69 per 1000 individuals per year; $p < 0.001$). Insomnia was found to be independently linked to a heightened risk of stroke development (HR 1.85; $p < 0.001$).	44.080 adults without a previous diagnosis of stroke, coronary heart disease, or sleep apnea	Difficulties in initiating or maintaining sleep, according to the ICD-9	
Zheng et al. [46]	All three symptoms (DIMS, EMA, and DDF) were associated with slightly increased risks of total stroke incidence (HR 1.05, 1.05, and 1.08; $p < 0.05$) and ischemic stroke incidence (HR 1.06, 1.07, and 1.09; $p < 0.05$). No associations were observed between the 3 symptoms and hemorrhagic stroke incidence. Compared with those with no insomnia symptoms, 1, 2, or 3 symptoms increases the risk of stroke by 7, 10, and 18 %, respectively.	487.200 adults (30–79 years old), without a previous diagnosis of stroke, coronary heart disease, or cancer	Difficulties in initiating or maintaining sleep (DIMS), early morning awakening (EMA), and daytime dysfunction (DDF) for at least 3 days/week in the past month.	
Sawadogo et al. [47]	Compared with those with no insomnia symptoms, an increased risk of stroke was observed for those with insomnia symptom scores ranging from 1 to 4 and 5 to 8 (hazard ratio (HR) = 1.16, 95 % confidence interval (CI) 1.02–1.33) and (HR = 1.51, 95 % CI 1.29–1.77. The association was stronger in participants younger than 50 years (HR = 3.84, 95 % CI 1.50–9.85) than in those aged 50 years and older (HR = 1.38, 95 % CI 1.18–1.62), comparing those with insomnia symptoms ranging from 5 to 8 with those with no insomnia symptoms.	The Health and Retirement Study, a survey of Americans older than 50 years and their spouses. Only those who were stroke-free at baseline were included in this study. A total of 31,126 participants were included with a mean follow-up of 9 years. The mean age was 61 years (SD = 11.1) and 57 % were females.	The exposure variable was insomnia symptoms and was derived from self-reported sleep-related factors including difficulty initiating sleep, difficulty maintaining sleep, waking up too early, and nonrestorative sleep.	Insomnia symptoms were associated with an increased risk of stroke, especially in adults younger than 50 years,

Insomnia and risk for cardiovascular diseases				
References	Main Conclusions	Source of evidence	Insomnia definition	Comments
Sofi et al. [48]	Insomnia determines an increased risk of developing or dying from cardiovascular disease during the follow-up (RR 1.45, 95 % confidence interval 1.29–1.62; $p < 0.00001$)	Meta-analysis of prospective studies: 13 studies with a follow up between 3 and 20 yrs	Insomnia assessed through questionnaire and defined as either difficulty of initiating or maintaining sleep or presence of restless, disturbed nights122,501 individuals free from CV diseases at baseline	
Ali et al. [49]	Individuals with chronic insomnia experience a higher risk of long-term mortality, MI, and incidence of CV disease. Incidence of cardiovascular disease. (RR 1.31, 1.14–1.51 < 0.01) and Myocardial infarction (RR 1.48, 1.03–2.12 $p < 0.03$)	Extensive systematic review and meta-analysis: 21 studies included	Insomnia disorder or associated four major symptoms: difficulty in initiating sleep (DIS), difficulty in maintaining sleep (DIMS), nonrestorative sleep (NRS), and early morning awakening (EMA); 388,906 insomnia patients, and 2,194,211 healthy subjects	The increased risk of cardiovascular disease was the highest in the subgroup with 10–20 years of follow up
Grandner et al. [37]	Patients with untreated insomnia disorder (ID) had an increased likelihood of hypertension, ischemic heart disease and heart failure, compared with individuals with no record of insomnia (NID). Annualized prevalence per 100 patient-years: Hypertension:ID 60.1 vs NI 15.9, $p < 0.01$	Large scale study using a US medical claims database 139,959 individuals with untreated insomnia disorder and 836,975 without insomnia	The 'untreated insomnia' cohort comprised patients with diagnosed insomnia disorder (ICD code: F51.0X, G47.0X, G47.8, or G47.9) and no record of receiving any insomnia medication. The 'non-insomnia' cohort comprised patients without a diagnosis of insomnia disorder or circadian rhythm sleep disorder, and no record of receiving any	The increased risk of CV diseases associated with insomnia is maximum in the older adults, although it's present in adults younger than 40 for hypertension and ischemic heart disease.

(*continued on next page*)

Table 3 (*continued*)

Insomnia and risk for cardiovascular diseases

References	Main Conclusions	Source of evidence	Insomnia definition	Comments
	Ischemic heart disease: ID 9.0 vs NI 3.5, p < 0.01 Heart failure: ID 4.1 vs NI 1.6, p < 0.01		of the insomnia medications as for the first cohort	

Insomnia and risk for metabolic disorders

References	Main Conclusions	Source of evidence	Insomnia definition	Comments
Zhang et al. [51]	The risk of insomnia patients suffering from hypertension, hyperglycaemia, hyperlipidaemia and obesity in metabolic syndrome was 1.41 times, 1.29 times and 1.31 times than people without insomnia respectively	Meta-analysis of prospective studies 12 studies	Insomnia assessed through questionnaire and defined as either difficulty of initiating or maintaining sleep or presence of restless, disturbed nights	

Insomnia and risk for cancer

References	Main Conclusions	Source of evidence	Insomnia definition	Comments
Shi et al. [52]	The results demonstrate a 24 % overall increased risk of cancer for individuals with insomnia in comparison to those without insomnia. Subgroup analyses show that the risk of developing cancer was significantly higher in studies conducted in women (HR = 1.24; 95 % CI, 1.01–1.53), but not in men (HR = 1.28; 95 % CI, 0.90–1.80).	Meta-analysis of 8 studies, seven prospective and 1 retrospective involving 578,809 participants and 7451 cancer events	Insomnia assessed through questionnaire and defined as either difficulty of initiating or maintaining sleep or presence of restless, disturbed nights	

Insomnia and risk for mortality

References	Main Conclusions	Source of evidence	Insomnia definition	Comments
Li et al. [53]	Men with difficulty initiating sleep (DIF) and non-restorative sleep (NRS) most of the time had a 55 % and 32 % increased risk of cardiovascular disease mortality, respectively, relative to men without those symptoms: DIF: HR 1.55 (95 % CI, 1.19–2.04; *p* = 0.01) NRS: HR 1.32; 95 % CI, 1.02–1.72; *p* = 0.002	Prospective cohort study of 23,447 US men participating in the Health Professionals Follow-Up Study and free of cancer, follow up of 6 years	How often (rarely/never, sometimes, or most of the time) is the presence of nocturnal insomnia symptoms with difficulty initiating sleep, difficulty maintaining sleep, and early-morning awakenings, accompanied by nonrestorative sleep and excessive daytime sleepiness.	This large prospective cohort study (n = 23,447) indicates that difficulty initiating sleep and non-restorative sleep are associated with a modestly higher risk of total and CVD specific mortality, and these associations persisted even after exclusion of participants with CVDs and depression.
Parthasarathy et al. [54]	Patients with persistent chronic insomnia, but not intermittent insomnia, were more likely to die than participants without insomnia. All-cause mortality HR = 1.58; 95 % confidence interval [CI], 1.02–2.45) with persistent insomnia. HR = 1.22; 95 % CI, 0.86–1.74) with intermittent insomnia	Community cohort of 1409 adults: 249 (18 %) had intermittent and 128 (9 %) had persistence (persistence of symptoms over a 6-year period)	International Classification of Sleep Disorders criteria	Representative cohort of patients with chronic insomnia and with an adequate follow up period (20 years) to assess the impact on all-cause mortality
Ge et al. [55]	Patients with chronic insomnia - i.e. with non-restorative sleep (NRS) – had the highest increased risk of both all-cause and CV disease mortality. All-cause mortality: HR = 1.23, 95 %CI 1.07 to 1.42, p = 0.003, high certainty) CV disease mortality: NRS: HR = 1.48, 95 %CI 1.06 to 2.06, p = 0.02, moderate certainty)	Twenty-nine cohorts including 1,598,628 individuals (55.3 % men; mean age 63.7 yrs old), with a median follow-up duration of 10.5 yrs	Insomnia disorder or individual insomnia symptoms	The highest increased mortality was therefore reported in those patients with chronic insomnia
Lovato et al. [57]	Increased risk of mortality when the presence of daytime impairment was considered (chronic insomnia). All-cause mortality in patients with daytime impairment HR 1.25 (1.05–1.48) p = 0.03	Seventeen studies, including a total of 36,938,981 individuals followed up for a mean of 11.6 years	Symptoms present >3 nights/week, for >1 month.	
Ali et al. [49]	Individuals with chronic insomnia experience a higher risk of long-term mortality, MI, and incidence of CV disease. All-cause mortality: RR 1.14 (95 % CI 1.01–1.29), p = 0.03	Extensive systematic review and meta-analysis: 21 studies included, with a study population representative of chronic insomnia	Insomnia disorder 388,906 insomnia patients, and 2,194,211 healthy subjects	The increased risk of all-cause mortality was the highest in the subgroup with 10–20 years of follow up (RR: 1.23, 95 % CI [1.05–1.43], p-value = 0.01

Legend ID= Insomnia disorder, NID= Non-Insomnia Disorder OR: Odd ratio, RR= Relative Risk, HR: Hazard ratio**,** RR= Relative Risk, CV = cardiovascular.

imposing any restrictions on the duration of their use even if no more than 4 weeks are reccomended. In particularly, Italy does not support any of pharmacological and non-pharmacological treatment recomended for chronic insomnia.

As a result, patients often engage in complicated processes primarily involving self-medication. This can result in the utilization of over-the-counter remedies which have limited evidence of efficacy, extended consumption of sedative hypnotic medications beyond the approved duration, or utilizing off-label medications that are typically available at low prices or reimbursed for other mental health issues [15,16].

Table 4
Public reimbursement status by evidence-based insomnia treatment (YES/NO).

	CBT-I	DORA	Z-DRUGS	BZ for insomnia	PR Melatonin	Any other off label compounds	Comments
Austria	YES	Daridorexant YES	YES	YES	NO	YES, Off-label antidepressant, antipsychotics	
Canada	YES, Digital CBT-I reimbursed by some private insurance	Daridorexant under revision Lemborexant is also available and both Lemborexant and Daridorexant are reimbursed by private insurance	YES	YES	NO, only over the counter products	YES, Off label antidepressants, antipsychotics	
Denmark	Subsidised within public health care	NOT AVAILABLE	YES	YES	YES	YES, Off-label sedative anti-histamines	
Finland	Subsidised within public health care	Daridorexant under submission	YES	YES	NO	YES, Off label antidepressants	
France	NO	Daridorexant YES	YES	YES	NO	YES, Off label antidepressants	No eCBT-I reimbursed
Germany	YES (incl. Digital CBT-I)	Daridorexant YES	YES (reimb. max. 28 days) Eszopiclone (max. 28 days)	YES (max. 28 days)	YES Melatonin PR (Circadin >55years, max. 28 days)	YES, Doxepin, Off-label anti-depressants	ALL EVIDENCE BASED TREATMENT REINBOURSED
Italy	NO	Daridorexant NO REIMBOURSMENT DENIED	NO	NO	NO	YES, Off label antidepressants, antipsychotics	NO EVIDENCE BASED TREATMENT REINBOURSED only Off-label compounds
Norway	Subsidised within public health care	NOT AVAILABLE	YES (Only end of life palliative care)	YES (Only end of life palliative care)	NO	YES, promethazine (Only end of life palliative care)	
Spain	NO	Daridorexant UNDER REVISION	YES	YES	NO	YES, Off-label anti-histamines	NO eCBT-I reimbursed
Sweden	Subsidised within public health care	Daridorexant NO REIMBOURSMENT DENIED	YES	YES	NO	YES,Off-Label sedative anti-histamines	
Switzerland	YES, Digital CBT-I reimbursed by some private insurance providers	Daridorexant UNDER REVISION	YES	YES	YES Melatonin PR (Circadin >55years)	YES Off-label Off label antidepressants, antipsychotics	
The UK	NO, Digital in some cases	Daridorexant YES	YES	YES	YES		Majority of these therapies are centrally (NICE)

Legend. CBT-I = Cognitive Behavioral Therapy for Insomnia, DORA: Dual Orexin Rceptor Antagnists, BZ=Benzodiazepines, PR= Prolonged Release.

4. Conclusions

This document serves as a position paper from sleep medicine and mental health experts across Europe, Switzerland, the UK, and Canada, emphasizing the critical need for public health systems to recognize chronic insomnia as a disorder in order to enhance support for patients during their treatment journeys.

In fact, insomnia disorder is a very common sleep disorder affecting a large population in Canada, UK, Switzerland and Europe. The economic impact of chronic insomnia is considerable, as demonstrated by the direct costs of treatment and, more critically, the indirect costs arising from personal and societal burdens, reduced quality of life, increased absenteeism and lower productivity related to the disorder, and potential negative effects on physical and mental health [75]. Chronic insomnia represents a serious public health challenge that requires attention through individualized clinical care and widespread sleep health programs at the community level. Conversely, therapies based on evidence for chronic insomnia disorder can improve quality of life, enhance overall well-being, and increase work productivity, which may subsequently lead to positive effects on both direct and indirect costs. Evidence-based therapies for chronic insomnia treatment may also help in preventing and enhancing other mental and medical conditions.

While some nations offer reimbursement or financial aid for evidence-based treatments, others do not recognize insomnia disorder as a chronic condition hindering a consistent approach to chronic insomnia therapy. This paper acts as a crucial reminder for public health systems to prioritize the acknowledgment of chronic insomnia as a disorder to reduce stigma from both patients and clinicians as well as better support patients throughout their treatment processes. It is crucial to ensure that at least the recommended treatments would be accessible to all patients suffering from chronic insomnia. Similar to other prevalent mental health issues, a stepped-care model should be implemented for insomnia disorder [17,18,76].

CRediT authorship contribution statement

Laura Palagini: Writing – original draft, Validation, Data curation, Conceptualization. **Celso Arango:** Writing – review & editing, Validation, Supervision. **Claudio Lino Alberto Bassetti:** Writing – review & editing, Validation, Supervision. **Celyne Bastien:** Writing – review & editing, Validation, Supervision. **Pierre, A. Geoffroy:** Writing – review & editing, Resources, Methodology. **Greg Elder:** Writing – review & editing, Supervision. **Jason Ellis:** Writing – review & editing, Validation, Supervision. **Jan Hedner:** Supervision. **Atul Khullar:** Validation. **Lino Nobili:** Validation, Supervision. **Markku Partinen:** Validation. **Michael Saletu:** Validation, Supervision. **Eduard Vieta:** Visualization, Validation, Supervision. **Charles M. Morin:** Validation, Supervision. **Dieter Riemann:** Visualization, Validation, Supervision. **Luigi Ferini Strambi:** Writing – review & editing, Visualization, Validation, Supervision. **Andrea Fiorillo:** Writing – review & editing, Visualization, Validation, Supervision, Software.

Position

Sleep is crucial for overall health, whereas chronic insomnia is a common mental and sleep disorder that adversely affects health, economy and society. Patients suffering from chronic insomnia should receive treatment similar to that of other mental disorders, following evidence-based approaches. A stepped-care model, akin to those used for other mental health disorders, ought to be applied to insomnia disorder. This approach would help mitigate disparities in access to evidence-based treatments, yielding benefits for sleep health, mental well-being, physical health, and societal welfare. Chronic insomnia should be acknowledged as 'Insomnia disorder' and included in public health initiatives. It should be important to integrate sleep health into mental health services and to formulate policies that advocate for sleep health. Prioritizing these initiatives, along with the implementation of prevention and treatment strategies for this mental health disorder, would be essential for individuals and societies.

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LP served as consultant, advisor or CME speaker for the following entities: Bruno, Fidia, Idorsia, Italfarmaco, Neopharmed Gentili, Pfizer, Pharmanutra, Sanofi-Aventis, Viatris, outside the submitted work.

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