

Insomnia

Principles and Management

Edited by

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Diagnosis and classification of insomnia disorders

Daniel J. Buysse

Introduction

Clinicians and researchers may underestimate the importance of accurate classification and diagnosis for sleep disorders. In this chapter, we will first examine why classification and diagnosis are important in considerations of insomnia disorders. We will then compare current diagnostic systems in terms of their organization, patterns of use in clinical and research practice, and their more formal properties of reliability and validity. Based on this information, we will then outline a scheme for future research in the area. The basic premise of this chapter is that, although considerable work has been done to define and categorize insomnia disorders, a great deal more work is needed to confirm that these diagnoses are reliable and valid.

Diagnosis and classification: why does it matter?

Consistent diagnosis and classification are important for several reasons in both research and clinical practice. First, accurate diagnoses allow us to identify cases that resemble one another, and to discriminate these cases from others. Such information not only helps us to communicate with our professional colleagues, but also to make decisions regarding treatment, and to evaluate a patient's likely clinical course and outcome. Moreover, diagnoses and classifications of disorders affect the very way in which we conceptualize a disorder; this conceptualization in turn can have a major effect on research into the pathophysiology and treatment of disorders. For instance, if some types of insomnia are conceptualized as including elevated levels of somatized tension, psychophysiological research can be directed at confirming this hypothesis, and treatment research can be aimed at evaluating the effects of tension reduction techniques. Increasingly, diagnosis and classification matter for another

and more prosaic reason: reimbursement and other interactions with managed care companies. In this context, a patient's specific diagnosis may well affect the treatment plan submitted to managed care organizations, their approval of such a plan, and the duration and type of treatment approved. Finally, accurate diagnoses and classification are essential for conducting and interpreting the results of clinical research, both in terms of randomized clinical trials and in terms of broader-based outcomes research. Generalizations regarding treatment efficacy and effectiveness depend on reliable diagnoses.

As an example of the importance of classification, consider the results of an epidemiological study reported by Ohayon.¹ In this study of 5622 individuals in the French population, 18.6% were identified as having an insomnia complaint. However, with the additional criteria of duration greater than 1 month and the presence of distress or impairment, the percentage decreased to 12.7% of the population. Of those meeting criteria for an insomnia disorder, approximately 80% were identified as having a primary or secondary psychiatric diagnosis. By contrast, less than 1% were identified as having a substance-induced insomnia. Clearly, these results influence our expectations of the types of problems patients with chronic insomnia are likely to have. A study of specific insomnia diagnoses in sleep clinics confirms these expectations, but also indicates some important differences. Among 216 patients with chronic insomnia, the largest group again was identified as having insomnia due to a mental disorder. However, the percentage of such patients – 46% – was much lower than that in Ohayon's population study. Moreover, 23% of the clinic patients were identified as having primary insomnia, and less than 5% had substance-induced insomnia.² Thus, epidemiological and clinical studies of specific insomnia diagnoses can be helpful in judging the resources needed to treat patients with chronic insomnia complaints, both in the community and in a specialized clinic setting.

Terms and definitions

Although most people know a disease when they see it, it can actually be quite difficult to define the essential elements of a disease. In most of medicine, a hierarchy can be established that describes the relationship between symptoms and specific diseases. At the most basic clinical level, *symptoms* represent subjective complaints presented by the patient. *Signs* are objective indicators of a specific symptom, e.g., rales or rhonchi on auscultation of the lungs, or a positive drawer sign on examination of the knee. A patient's symptoms and signs can be organized into **syndromes**, which include a characteristic set of signs and symptoms, and which often follow a characteristic clinical course. An **illness** or **disorder** typically includes all of the features of a syndrome, but also includes the connotation of suffering as well as

a deviation from the normal state or abnormality of function. Finally, **diseases** are generally described in terms of the symptoms, signs, course, and derangement of function described above, but are typically understood to involve a particular etiology as well. Medicine offers examples of many different disease models, which differ in terms of the type of etiopathogenesis. For instance, diseases may be defined in terms of morbid anatomy (e.g., mitral stenosis), cellular pathology (e.g., cancer), molecular pathology (e.g., porphyria) or an infectious agent (e.g., tuberculosis).

One other distinction that is important in the consideration of classification and diagnosis is the concept of categorical versus dimensional models. A categorical model assumes that individuals with a disorder/disease differ in some fundamental way from the remainder of the population. On some key element of function or anatomy, affected individuals are assumed to come from a different population than the remainder of the population, allowing a clean distinction between those affected and unaffected. In a dimensional model, however, affected and unaffected individuals are seen as coming from a single population, and affected individuals merely pass some threshold value. In most categorical disease models, a single feature can differentiate those with and without the disease (e.g., in porphyria). In a dimensional model, discrimination of affected and unaffected individuals may again occur along a single feature (e.g., serum cholesterol or diastolic blood pressure). However, in other types of dimensional disease models, features may be defined in several categories, not all of which are essential for a diagnosis. In this instance, individuals with a specific disorder may be heterogeneous with respect to one another, and may overlap substantially with the remainder of the population. Major depressive disorder is an example of this type of diagnosis.

Where does this leave us with insomnia disorders? Most insomnia disorders are disorders rather than true diseases: They involve consistent clinical syndromes that cause suffering or impairment, but for which no clear etiology has been defined. In most cases, insomnia disorders follow more of a dimensional model than a categorical model, which may help to explain why the percentage of affected individuals may vary from study to study, and why there is occasionally confusion as to whether an individual should be considered to have a disorder at all.

A **classification system** refers to the organizational structure that comprises a set of specific diagnoses. A **diagnosis** is the determination of the nature of a case of illness or disorder. The term is derived from Latin, meaning “to recognize.” More commonly, “diagnosis” also refers to the label placed on a specific case of disease, illness, or disorder. A diagnosis can have several elements. First, the diagnosis must include **essential features**, comprising the symptoms or signs that distinguish this condition from others. Such symptoms and/or signs are necessary to make the diagnosis. Precise, behaviorally or objectively verifiable symptoms and signs are

desirable. The essential features for a diagnosis may be part of a monothetic or polythetic set of diagnostic criteria. Monothetic criteria imply that each and every symptom is required to establish a diagnosis. Polythetic criteria address several constructs, not each of which must be present in order to establish a diagnosis. Categorical diagnoses often have monothetic diagnostic criteria (e.g., the presence of abnormal enzyme levels in porphyria). Dimensional illness types often have polythetic diagnostic criteria. Major depressive disorder is again a useful example. This disorder requires the presence of depressed mood *and/or* pervasive loss of interest, plus any *combination* of four out of seven other possible symptoms. In addition to essential features, diagnostic criteria often specify **exclusionary features**. Exclusionary features are used to avoid the concurrent diagnosis of two disorders that may cause very similar symptoms. For instance, major depressive disorder cannot be diagnosed if the individual has a medical illness or substance intoxication that could cause the same symptoms. **Associated features** are often described for specific disorders. These are features that frequently, but not invariably, accompany a particular disorder and are not necessary to establish the diagnosis. They are assumed to be less specific in regard to differential diagnosis and may or may not be related to the underlying pathophysiology. **Predisposing factors** refer to antecedent factors, assumed to be present before the condition was manifest, and which increase the likelihood of a disorder. Such predisposing factors may be alterable (e.g., cigarette smoking) or unalterable (e.g., sex or race). Diagnoses may have specific features related to the patient's age, sex, or family history. Finally, the longitudinal course of illness may sometimes be an essential feature of diagnosis (e.g., in chronic active hepatitis, schizophrenia, or dementia), but is usually a descriptive feature.

Attributes of classification systems

A reasonable classification system and set of insomnia diagnoses should have several attributes. First, the system should be reasonably easy to use. A complex diagnosis is unlikely to be widely used, even if it accurately describes a syndrome. Second, reasonable classifications and diagnoses must have acceptable reliability. Reliability is the extent to which diagnoses are reproducible either among multiple raters (inter-rater reliability) or across time (test–retest reliability). Reliability varies as a function of several factors, discussed in greater detail below. Third, classifications and diagnoses should have acceptable measures of validity – the extent to which a diagnosis serves its purpose of case identification, clinical prediction, or communication. Validity is also discussed in greater detail below (see p. 17).

It is important to note that the goals of classification and diagnosis may occasionally differ for clinical and research applications. In clinical applications, the

goal is usually to have diagnostic and descriptive coverage for all or most cases. This would mean that it is desirable to have very few cases that cannot be classified. As a result, optimal clinical categories are often fairly broad. On the other hand, research applications often benefit from narrower diagnostic categories. This ensures homogenous samples for pathophysiological and treatment research. Whereas the goal of clinical classification is to be able to diagnose and treat **patients**, the goal in research is often to study a specific **disease** or **disorder**. Outcomes research often attempts to bridge the gap between clinical and research applications.

Classification systems for insomnia

It is a commonplace to state that insomnia is a symptom, not a diagnosis or disease. In this sense, it is often compared with other nonspecific symptoms such as headache or abdominal pain. For insomnia, as for headache or abdominal pain, the real challenge is to determine a likely etiology for the complaint. But in research and clinical practice, this determination is often not done in a rigorous and systematic way. For instance, many studies on the efficacy of drug treatments for insomnia disorders simply describe patients as having chronic insomnia, or meeting a certain criterion for sleep latency or number of awakenings. The analogous situation – treating patients with headache of a certain intensity with a particular drug – would clearly be viewed as unsatisfactory.

One common method of classifying insomnia complaints is by their duration: transient, defined as less than 2 weeks; short term, lasting for 2–4 weeks; and chronic, lasting for more than 4 weeks.³ Such a scheme, however, is only an intermediate step. The duration of the insomnia complaint is significant only insofar as it is related to a set of likely etiologies. Thus, transient insomnia complaints are likely related to situational or medical stresses, and chronic insomnia to psychiatric disorders or circadian rhythm disturbances. A duration-based classification in itself is not very satisfactory for other reasons. First, few patients with truly transient insomnia problems present for treatment. Second, even chronic insomnia starts as a transient or short-term problem. Third, longitudinal studies have shown that some patients have a pattern of recurrent brief insomnia, and that this pattern frequently alternates with more persistent sleep complaints.⁴

For these reasons, a more etiologically based classification of insomnia disorders makes intuitive sense. Insomnia complaints can be related to a number of broadly defined etiologies, as depicted in Figure 1.1. As the figure suggests, the causes of insomnia can act singly or in combination. However, virtually all forms of insomnia appear to involve some type of increased arousal as a final common pathway. Furthermore, insomnia that arises from one source may often acquire an overlay of behavioral factors which perpetuate the problem even after the primary

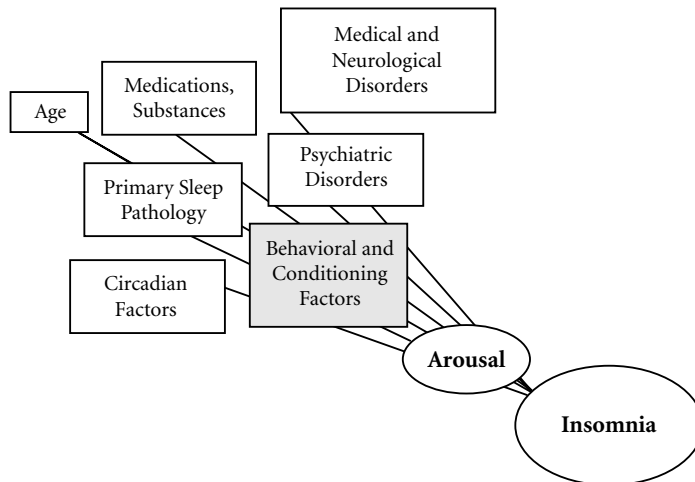


Figure 1.1. Multiple factors may act singly or in combination to cause a complaint of insomnia. Many of these primary causes lead to secondary behavioral and conditioning factors that reinforce insomnia. Physiological and cognitive arousal constitute a “final common pathway” for insomnia.

cause resolves. For instance, a patient may develop insomnia in association with a psychosocial stressor, and in an attempt to deal with the problem, may begin to spend more time in bed. This increased time in bed may contribute to poor sleep efficiency and increased frustration that persist well beyond the original stressor. Spielman and Glovinsky had used the concepts of “predisposing factors,” “precipitating factors,” and “perpetuating factors” to describe this phenomenon.⁵

Diagnostic classifications for sleep disorders ultimately attempt to define the major etiology for a particular patient’s complaints, including complaints of insomnia. Table 1.1 outlines the major diagnostic classification systems available for sleep disorders. The four systems most recently in use are: (1) the Diagnostic Classification of Sleep and Arousal Disorders (Association of Sleep Disorders Centers),⁶ (2) the International Classification of Sleep Disorders (American Sleep Disorders Association),^{7,8} (3) the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition (American Psychiatric Association),⁹ and (4) the International Classification of Diseases (World Health Organization).^{10,11} These classification systems differ in terms of their organizational schemes, the number of specific diagnoses, and their reliance on specific criteria. A comparison of these features is included in Table 1.2. In addition to these four established systems, many published studies of insomnia have established their own clinically based criteria. The most common clinical research definition includes

Table 1.1. Diagnostic classifications for sleep disorders

DCSAD	ICSD	DSM-IV	ICD-9CM
<ul style="list-style-type: none"> • Disorders of initiating and maintaining sleep (DIMS) • Disorders of excessive sleep (DOES) • Disorders of the sleep–wake schedule • Parasomnias 	<ul style="list-style-type: none"> • <i>Dyssomnias:</i> <ul style="list-style-type: none"> ○ Intrinsic ○ Extrinsic ○ Circadian rhythm sleep disorders • Parasomnias • Sleep disorders associated with mental, neurological, or medical disorders 	<ul style="list-style-type: none"> • <i>Primary sleep disorders:</i> <ul style="list-style-type: none"> ○ dyssomnias ○ parasomnias • Sleep disorders related to another mental disorder • Sleep disorders due to medical disorder • Substance-induced sleep disorder 	<ul style="list-style-type: none"> • <i>Sleep disorders:</i> <ul style="list-style-type: none"> ○ Disorders of initiating and maintaining sleep, disorders of excessive sleep, disorders of the sleep–wake schedule, sleep apnea, narcolepsy • <i>Non-organic sleep disorders:</i> <ul style="list-style-type: none"> ○ Insomnia, hypersomnia, disorders of the sleep–wake schedule, sleepwalking, sleep terrors, nightmares

Table 1.2. A comparison of the diagnostic classifications for sleep disorders

	DCSAD	ICSD	DSM-IV	ICD-9
Derivation	Expert opinion	Expert opinion, literature reviews		Expert opinion
Organizing feature	Symptoms	Presumed pathophysiology, etiology		
Breadth of categories	Narrow	Narrow	Intermediate	Broad
Number of disorders	68	84	23	18
PSG criteria	No	Yes	No	No

subjective and polysomnographic evidence of a sleep latency greater than 30 minutes, sleep duration of less than 6 hours, and/or more than three awakenings per night.

Diagnostic classification of sleep and arousal disorders (DCSAD)

The DCSAD system was the first widely used classification of sleep disorders and included four major categories of disorders: (1) disorders of initiating and maintaining sleep (DIMS or “insomnias”), (2) disorders of excessive sleepiness (DOES or “hypersomnias”), (3) disorders of the sleep/wake schedule, and (4) parasomnias. This classification is easy to use, given its symptom-based organization. The number of categories is fairly large and approximately 29 of these diagnoses could

conceivably lead to a complaint of insomnia. The DCSAD provides useful clinical descriptions of each disorder. However, it also has some important limitations. First, specific clinical or polysomnographic criteria were not included. This necessitates considerable clinical judgement in establishing a diagnosis and is likely to decrease reliability. Second, the symptom-based approach makes sense clinically but leads to duplicate listings of a single diagnosis. For instance, periodic limb movement disorder can produce either insomnia or hypersomnia, so the diagnosis was listed twice in the classification.

International classification of sleep disorders (ICSD)

The ICSD was the successor to the DCSAD and was first introduced in 1990. It differs from the DCSAD classification in two major ways. First, the organization of disorders is by presumed etiology rather than symptom presentation. Second, the ICSD includes specific clinical and polysomnographic criteria for each disorder. In addition, the ICSD includes severity readings for each disorder as well as “minimal” and “complete” diagnostic criteria. The three major categories of sleep disorders in ICSD are dyssomnias, parasomnias, and secondary sleep disorders. **Dyssomnias** are disorders in which the primary complaint relates to sleep and/or wakefulness; without these symptoms, no disorder would be identified. The dyssomnias are further subdivided into *intrinsic dyssomnias*, in which some abnormality of brain function is thought to underlie the symptoms and signs, *extrinsic dyssomnias*, in which some external factor leads to the sleep complaint, and *circadian rhythm sleep disorders*, which are thought to result from abnormal entrainment or misalignment of the circadian system with external time cues. **Parasomnias** are disorders that are characterized by abnormal behavioral or physiological events during sleep, rather than by changes in amount or timing of sleep. Common examples include sleep walking and nightmares. In most cases parasomnias do not cause prominent insomnia. However, some patients may develop a fear or aversion to sleep because of their unusual behaviors. **Secondary sleep disorders** are those associated with mental, neurological, and medical disorders. In contrast to dyssomnias, secondary sleep disorders occur with a broader set of symptoms and signs beyond those pertaining to sleep. For example, a patient with insomnia secondary to rheumatoid arthritis has many symptoms and signs beyond insomnia, and would still have a disorder (rheumatoid arthritis) even in the absence of sleep complaints. Of the 84 diagnoses in ICSD, approximately 43 could lead to insomnia complaints. These disorders are divided among the dyssomnias and the secondary sleep disorders.

Although the ICSD has several advantages over the older DCSAD, it also has some potential weaknesses. First, diagnoses were based largely upon expert opinion, although literature reviews were also used. Second, for most sleep disorders, the

exact pathophysiology remains unknown, despite the broad assumed pathophysiology that drives the ICSD classification. Third, most specific diagnostic criteria in the ICSD have not been rigorously tested against alternatives. In other words, the criteria for specific disorders have not been empirically selected from a larger set of possible items, but were based largely upon expert opinion. Fourth, there is some concern that the ICSD's large number of categories may represent a form of pseudo-precision. For instance, Reynolds and colleagues¹² argue that subtyping chronic insomnia may be premature, given the uncertain validity of concepts such as sleep state misperception, environmental sleep disorder, and inadequate sleep hygiene. Finally, the specific diagnostic criteria for certain disorders have been questioned by expert interest groups within those areas. For instance, alternative criteria had been proposed for the diagnosis of restless leg syndrome and periodic limb movements,¹³ sleep apnea syndromes,¹⁴ and narcolepsy.^{15,16} A revision of the ICSD was initiated in 2002 by the American Academy of Sleep Medicine.

Diagnostic and statistical manual of mental disorders, 4th edn (DSM-IV)

The DSM-IV is designed primarily as a classification of mental disorders but also includes a sleep disorders section. It includes a section of **primary sleep disorders**, which present with prominent sleep symptoms. Primary sleep disorders include *dyssomnias* and *parasomnias*. Other broad classes with DSM-IV classification are **sleep disorders related to another mental disorder or medical disorder**, and **substance-induced sleep disorder**. Thus, there is some homology between DSM-IV and ICSD. The main difference between the two classifications is in the number of specific categories and the breadth of these diagnoses. DSM-IV includes only one diagnosis for chronic insomnia unrelated to mental, medical, or substance-induced sleep disorders (primary insomnia). This category subsumes ICSD categories of psychophysiological insomnia, inadequate sleep hygiene, idiopathic hypersomnia, adjustment sleep disorder, and environmental sleep disorder, both in theory and in practice.¹⁷ Like the ICSD, DSM-IV was derived from expert opinion and literature reviews, and the organization is based broadly on presumed pathophysiology. Also like the ICSD, it includes clinical criteria, but unlike ICSD, it does not include specific polysomnographic criteria or severity descriptors. Although DSM-IV is appropriate for, and appears to be well accepted by, the psychiatric community, it is not widely used by sleep disorders specialists.

International classification of diseases (ICD)

The ICD includes two broad categories of sleep disorders: (1) **organic**, including insomnia, hypersomnia, circadian disorders, sleep apnea, and narcolepsy, and (2) **Non-organic**, including insomnia, hypersomnia, circadian rhythm disorders, sleep walking, sleep terrors, and nightmares. Specific diagnostic descriptions are provided only for the non-organic sleep disorders in ICD-9. The distinction between organic

and non-organic is largely arbitrary and may be difficult to operationalize in clinical practice. Therefore, ICD-9 is not widely used clinically. However, the diagnosis codes from ICD-9 have been cross-referenced to ICSD and DSM-IV, and these codes are widely used for billing and record-keeping purposes.

Summary of classification systems

The existing classifications show similarities and differences, and have their own strengths and weaknesses. The ICSD is most widely used by sleep disorders specialists. With regard to insomnia, the major issue regarding ICSD relates to the “lumping vs. splitting” debate. Simply stated, the question is whether chronic insomnia is best “lumped” into a single category or “split” into distinct subtypes. This issue in turn relates to whether there is adequate validation of the various subtypes of insomnia. This issue is further discussed below.

One measure of the acceptability of specific insomnia diagnoses is how often those diagnoses are used in research or clinical practice. In order to address this issue, the author conducted a search of Medline from 1993 through March 1998. Under the medical subject heading “insomnia,” 571 citations were identified. In order to identify specific diagnoses in any of the major classification systems, the terms “primary insomnia,” “psychophysiological insomnia,” “sleep state misperception,” “idiopathic insomnia,” “adjustment sleep disorder,” and “insomnia ‘cross-referenced with’ depression” were used as keywords. These specific insomnia diagnoses were identified in only 99 citations or 17.3% of all insomnia citations. As a comparison, the author also assessed the medical subject heading for “depression” during the same time interval. A total of 5598 citations were identified. When the more specific diagnoses of major depression, major depressive disorder, or bipolar depression were then assessed, a total of 2586 citations, or 46.2% of total “depression” citations, were identified. Thus, it would appear that clinical researchers in the area of insomnia do not use the diagnoses available to them, in contrast to researchers in the area of depression.

The above literature search may underestimate the use of diagnoses even in clinical research. Authors may not have included these specific names of diagnoses in their abstracts or may have used diagnostic classifications without mentioning them by name. However, a more qualitative review of the literature would suggest that this is not the case. Although quantitative measures of subjective or objective sleep disturbance are typically included in insomnia studies, specific syndrome definitions are usually not used. Moreover, even when specific diagnoses are mentioned, the methods for determining these diagnoses are often not stated in detail. Specifically, methods for identifying subjective impairment or distress, and methods for excluding medical and substance-related disorders from consideration of “primary” forms of insomnia, are often not stated. In conclusion, although several

sleep disorders classifications are available, they do not appear to be widely used in research practice.

In order to examine use of various sleep disorders classifications in clinical practice, the Nosology Committee of the American Sleep Disorders Association conducted a survey in the Fall of 1996.¹⁸ This survey indicated that 91.7% of the sleep disorders centers that participated in the survey used the ICSD for establishing clinical diagnoses. This was far more than used the DCSAD (18.5%), DSM-IV (12.1%), or ICD (30.6%). However, when clinicians were asked to rate different features of each classification system, a somewhat different picture emerged. Specifically, the organizational structure of ICSD and DCSAD was rated significantly more highly than that of ICD-9 or DSM-IV, and DCSAD was ranked more highly than ICSD. The “fit” of each classification to patients was also rated more highly for ICSD and DCSAD. In terms of “ease of use,” clinicians rated the DCSAD as being simpler than ICSD; both of these were rated as easier to use than ICD-9 or DSM-IV and DCSAD was ranked more highly than ICSD. These data indicate that, in contrast to research practice, clinicians actually do use the diagnostic classification systems available. However, there is some perception among clinicians that the organization and ease of use of these classification systems may not be optimal.

Reliability

Reliability is a measure of the extent to which diagnoses are reproducible across time (test–retest reliability) and among different raters (inter-rater reliability). Obviously, most clinical diagnoses will not have perfect test–retest or inter-rater reliability. Several sources of variance contribute to reduced reliability. First, test–retest reliability may be low because patients’ actual clinical state may change from one time to another. Inter-rater reliability may be imperfect because the judgements of one clinician will not perfectly match those of another. In addition, both types of reliability may suffer from measurement error, either in the sensitivity of particular questions asked of a patient, or of physiological measures such as EEG sleep studies. Similarly, the interpretation of specific measurements will vary across raters and over time. Finally, the specific criteria used to establish a diagnosis may be imprecise. Table 1.3 summarizes data on inter-rater and test–retest reliability for insomnia diagnoses using DSM and ICSD criteria. The table illustrates that the total number of reliability studies and the total number of insomnia patients assessed has been small.

One way of examining reliability is to determine whether various sleep disorders centers make similar types of diagnoses among their insomnia patients. A study examining this question investigated diagnostic patterns in five sleep disorders centers.² As Figure 1.2 indicates, the five sites had similar overall patterns of

Table 1.3. Inter-rater reliability for insomnia diagnoses (kappa)

	DSM-III-R/ DSM-IV	ICSD	Total no.	Insomnia n
Schramm, 1993	0.91	—	68	54
Buysse, 1994	0.35–0.56	—	216	216
Buysse, 1997	0.25	0.22	41	41
Edinger, 1996	0.71	0.68	31	31

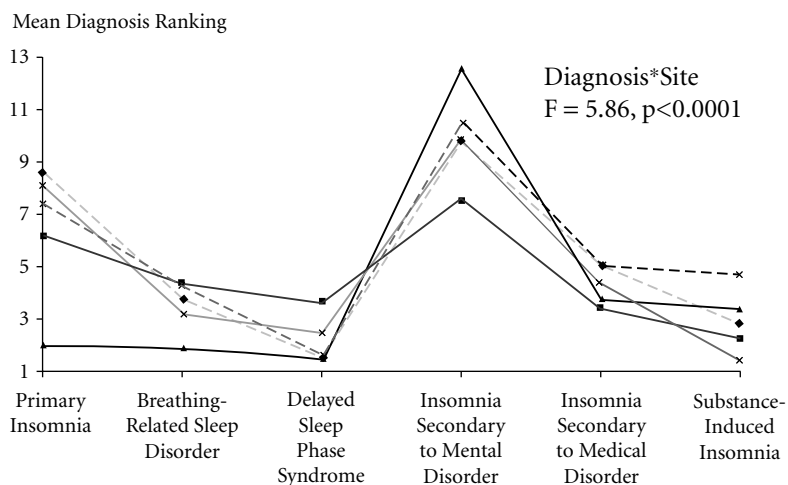


Figure 1.2. Mean rankings for DSM-IV insomnia diagnoses among clinically referred patients at five different sites. Higher numbers on the y axis indicate stronger rankings. Although “insomnia secondary to a mental disorder” was the most highly ranked diagnosis and “primary insomnia” the second, the specific pattern of diagnoses varied significantly across sites, as indicated by the significant “diagnosis*site” interaction effect. Data are adapted from reference2.

diagnoses, but the specific ranks assigned to different diagnoses differed according to site (diagnosis by site interaction, $P \leq 0.0001$). In other words, some sites made a large majority of diagnoses in the “insomnia related to another mental disorder” category, and very few diagnoses in the “primary insomnia” category. At other sites, the frequency of primary insomnia was generally higher, and that of insomnia related to another mental disorder was generally lower. This study also included diagnostic rankings of two different interviewers. At each site, one of the interviewers was a sleep specialist and one was a non-specialist sleep clinician. As indicated in Figure 1.3, the specialist and non-specialist again had fairly similar patterns of diagnoses overall. Nevertheless, a significant diagnosis – interviewer interaction was observed, indicating that non-specialists tended to make

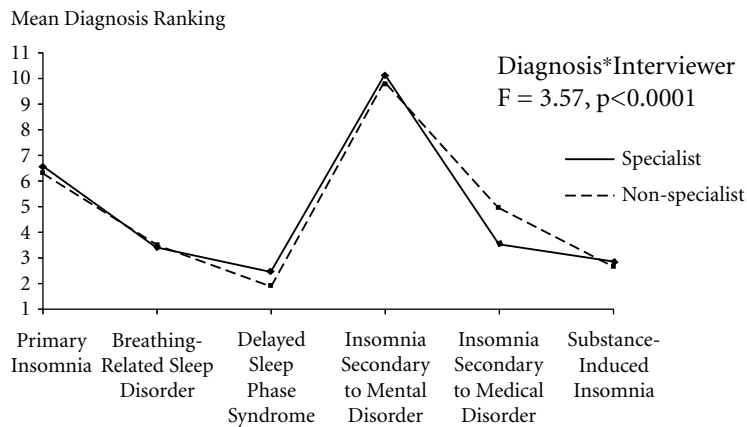


Figure 1.3. Mean ranks for DSM-IV insomnia diagnoses among sleep specialist and non-specialist interviews. Data are adapted from reference 2. Each of 216 patients with chronic insomnia was seen by two interviewers [one specialist and one non-specialist], each of whom assigned ranks for the various diagnoses. Although the general pattern of diagnoses was similar, the two types of raters differed significantly in their pattern of rankings [significant “diagnosis*interviewer” interaction].

more diagnoses of insomnia related to a medical condition, whereas sleep specialists tended to make more diagnoses of delayed sleep phase syndrome in the DSM-IV classification.

Other studies have examined more traditional measures of inter-rater reliability. Schramm et al.¹⁹ used a structured diagnostic interview to establish DSM-III-R insomnia diagnoses in a sample of 68 patients with complaints of sleep disturbances. Of these patients, 39 were referred to the sleep laboratory for evaluation of a sleep disorder, and 29 were psychiatric inpatients complaining of sleep disturbance as one of their major symptoms. Polysomnography was also performed on each patient. The overall kappa value for insomnia disorders was 0.91, indicating excellent inter-rater agreement. The kappa value for hypersomnias was 0.90, again indicating excellent agreement; agreement rates for other categories of diagnoses were based on very small numbers of patients and, although high, may be less reliable. With regard to specific types of insomnia, kappa values ranged from 0.84 to 0.86 for insomnia related to a mental disorder, insomnia related to a known organic factor, and primary insomnia. Of note, the kappa value for primary insomnia was derived from a total of only 10 cases, which again makes the reliability of this estimate uncertain.

The DSM-IV field trials mentioned above used a different methodology to evaluate inter-rater agreement. In this study, 216 patients who were clinically referred for a sleep disorder were seen by two interviewers – one an experienced sleep specialist

and one a non-sleep specialist clinician in psychiatry, psychology, or neurology. The two raters were permitted to use their “usual clinical interview” to assess patients rather than a structured sleep interview. Kappa values for the primary diagnosis ranged from 0.35 to 0.56 across the five sites, indicating moderate levels of diagnostic agreement. Kappa values for specific diagnoses were somewhat worse, ranging from 0.28 to 0.59 for primary insomnia and from 0.34 to 0.60 for insomnia related to another mental disorder. As noted above, significant differences between sites were noted in the range of diagnoses assigned to patients, although kappa values for primary diagnosis did not significantly differ among sites. The most plausible reason for the lower degree of inter-rater reliability in this study compared with that by Schramm and colleagues was the use of clinical interviews, rather than structured interviews. In addition, half of the interviewers were not trained sleep specialists. The finding of site-related differences in diagnoses also raises the question of whether different patients were seen at different sites or whether the raters at different sites vary in their specific approach to patients.

In order to address this last question, interviews were taped for a subset of 41 patients in the DSM-IV field trial and the videotapes were reviewed by sleep specialists at each of the five sites. The overall kappa value for DSM-IV primary diagnosis was 0.25, in the fair-to-poor range. The kappa value for ICSD diagnoses was 0.22, in the same range.²⁰ Thus, it would appear that different raters, even among sleep specialists, make use of clinical information in different ways as they establish their diagnoses.

Finally, a study by Edinger and colleagues²¹ examined inter-rater agreement in 31 clinically referred patients with insomnia. Diagnoses were based on clinical and polysomnographic information rather than a direct interview with the patients. Using these methods, Edinger et al. found a kappa value of 0.71 for DSM-III-R diagnoses, and 0.68 for ICSD diagnoses. Both of these are within the moderate-to-very-good range of reliability. However, these diagnoses were based on a review of written clinical information rather than direct patient interview, and the sample size was fairly small.

No published studies have formally assessed the test–retest reliability of insomnia diagnoses. The study by Schramm et al. described above indicates that test–retest reliability was assessed, but the interval between interviews was only 1–3 days. In addition, this study combined elements of both a test–retest and inter-rater reliability study. A study by Hohagen and colleagues²² did examine test–retest reliability of clinical criteria for insomnia. Specifically, these investigators examined whether subtyping insomnia as “sleep onset,” “sleep maintenance,” “early morning awakening,” or some combination of these would be stable across time. Patients were assessed at an initial timepoint and then again 4 months later. Treatment was not

controlled during this interval. The stability of subtypes was greatest for sleep-onset insomnia, but even this subtype was concordant in only 50% of cases over the follow-up interval. For sleep maintenance insomnia, the concordance was only 17%, and for other combinations of onset, maintenance, and early morning awakenings, values were in between. Thus, clinical criteria do not appear to remain very stable over time.

In summary, available data suggest moderate inter-rater reliability for insomnia diagnoses using DSM-IV or ICSD criteria. Test-retest reliability has yet to be adequately assessed. The finding of significant differences among sleep disorders centers and the diagnoses they establish, and the low rates of inter-rater agreement among sleep specialists at different sites, suggests that different investigators apply the diagnostic criteria for insomnia disorders in very different ways.

Validity

Validity is a measure of the extent to which a diagnosis serves its purposes of case identification, clinical prediction, or communication. Several types of validity are commonly investigated. **Face validity** or **ecological validity** describes how reasonable a diagnosis is based on clinical experience; in other words, does the diagnosis make sense? **Descriptive validity** determines whether the defining features of a diagnosis are unique to that diagnosis or whether they are shared by other diagnoses. In a sense, this type of validity measures the extent to which a specific diagnosis can be differentiated from its “nearest neighbors.” **Predictive validity** assesses the degree to which a diagnosis corresponds with a particular natural history or treatment response. Finally, **construct validity** measures the extent to which a diagnosis corresponds to a proposed etiological or pathological process. In the case of sleep disorders, construct validity might assess the degree to which a specific diagnosis differs, in terms of polysomnographic measures, from other diagnoses.

A large number of studies have been reported that describe distinctive clinical features or polysomnographic features of one type of insomnia diagnosis compared with other insomnia diagnoses. For instance, polysomnographic and clinical characteristics that distinguish “chronic insomnia” from the insomnia of depression^{23,24} or “objective insomnia” from “subjective insomnia”^{25,26} have been evaluated. However, what has generally been lacking among these types of studies are confirmatory analyses, i.e., replications of the original finding that confirm the hypothesis raised in the first study. Likewise, the sensitivity, specificity, or receiver-operating characteristic curves of specific polysomnographic or clinical features have not been described for one subtype of insomnia versus another. By contrast, such studies

have been conducted for measures such as reduced REM latency in depression.^{27,28} Perhaps partly as a result of insufficient research on validity, current recommendations do not support the use of polysomnography for diagnosis in most patients with insomnia.^{29,30}

Another method of assessing validity is to determine the extent to which clinical and polysomnographic features empirically cluster together, and then to determine how well such empirical clusters correspond to clinical diagnoses. Hauri³¹ reported this type of cluster analysis of insomnia compared with DCSAD diagnoses. This analysis included 89 patients with insomnia and 10 controls. Data included psychological tests, results of a clinical interview, and three nights of polysomnography. A factor analysis was used to derive 26 factors from the polysomnographic test and interview data. A cluster analysis was then performed on the 26 factors. A nine-cluster solution provided empirical validation for the category of persistent psychophysiological insomnia, insomnia associated with affective disorder, and childhood-onset (idiopathic) insomnia. However, six other clusters did not readily correspond to DCSAD diagnoses. A similar study using ICSD and DSM-III-R diagnoses was reported by Edinger and colleagues.²¹ A total of 113 patients with insomnia and 39 healthy controls were used in the analyses. Questionnaire data, polysomnographic data, and interview data were used to derive 15 factors. A subsequent cluster analysis identified a 14-cluster solution as optimal from a statistical point of view. However, the empirically identified clusters did not correspond strongly to either DSM-III-R or ICSD diagnoses (Figure 1.4). Thus, the construct validity of DSM-III-R and ICSD insomnia diagnoses was not well supported in these analyses.

Nowell and colleagues³² also addressed the issue of construct validity, focusing on distinctions between primary insomnia and insomnia related to another mental disorder in the DSM-IV classification. This analysis used data from the DSM-IV field trial reported above. Before assigning diagnoses for each specific patient, clinicians were asked to rate a number of factors that they thought might contribute to the individual patient's insomnia complaint, regardless of diagnosis. These contributing factors included items such as breathing disturbances, use of medications, conditioning factors and poor sleep hygiene. Clinicians then assigned a primary diagnosis and up to three secondary diagnoses. These combinations of diagnoses were used to identify groups of "pure" primary insomnia and insomnia related to a mental disorder, as well as groups with less certain diagnoses. When contributing factors were contrasted across these diagnostic groups, three variables were found to differ. First, patients with insomnia related to a mental disorder were identified as having less evidence of poor sleep hygiene and negative conditioning than patients in the other three groups. Conversely, patients with pure primary insomnia were felt

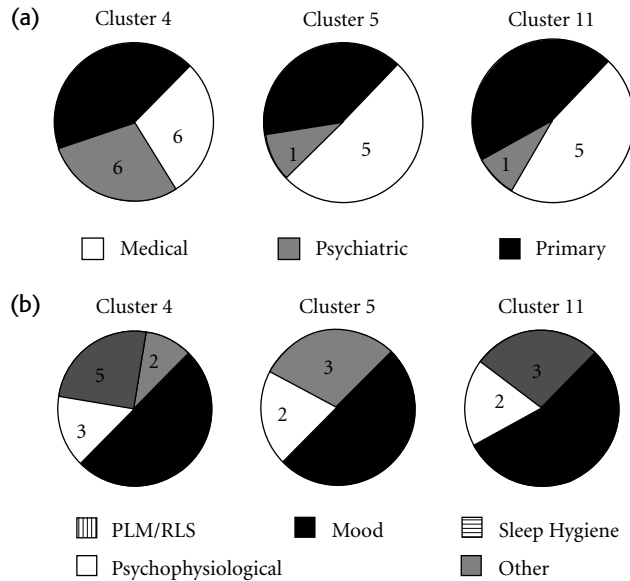


Figure 1.4. Validity of DSM-IIIR (a) and ICSD (b) insomnia diagnoses using cluster analysis of clinical and polysomnographic variables. Empirically determined clusters of clinical and polysomnographic variables did not correspond well with categories from either diagnostic system. Data are adapted from reference 21.

to have significantly less psychiatric etiology for their insomnia. Thus, clinicians do identify important etiological differences in patients with different insomnia diagnoses. These data not only support the distinction between the insomnia subtypes of primary and psychiatric insomnia, but further suggest that additional criteria reflecting sleep hygiene and conditioning factors may help to improve the reliability of these diagnoses.

Clinicians also use diagnostic judgements to make treatment decisions. Further data from the DSM-IV field trial²⁰ showed that the pattern of diagnostic recommendations for different specific insomnia diagnoses does in fact differ in significant ways. Specifically, treatment recommendations for psychophysiological insomnia, delayed sleep phase syndrome, inadequate sleep hygiene, insomnia related to mood disorder, and obstructive sleep apnea syndrome have very distinct patterns of treatment recommendations. A similar finding was noted for DSM-IV diagnoses: clinicians made different treatment recommendations for patients in whom they assigned different diagnoses. Clearly, treatment recommendations are not equivalent to actual treatment results. However, these data do provide some support for the notion that clinicians believe their diagnoses have predictive validity in the clinical setting.

Summary and future needs

Classification and diagnosis of disorders serve important functions in clinical and research practice. Several classification systems are currently available for describing patients with insomnia disorders. Progress has been made regarding the reliability and validity of these diagnoses, but major gaps are also evident.

There is a pressing need for more data regarding the reliability of clinical insomnia diagnoses. Such studies should ideally include multiple study sites, because available evidence suggests that diagnoses may vary systematically as a function of where those diagnoses are being made.

A second pressing need is for more data on construct validity of specific insomnia diagnoses and specific criteria. As noted above, numerous studies have contrasted patients with different subtypes of insomnia, but confirmatory analyses have been far fewer. Once again, multicenter studies using similar diagnostic criteria are necessary to acquire the large number of patients necessary for hypothesis-testing studies to examine construct validity. Such validity studies apply equally to clinically based and widely used criteria, such as the 30-minute sleep latency criterion for inclusion of patients in pharmacological studies. It would be helpful to know how well this 30-minute criterion separates those patients with insomnia and those without, and to what extent such a criterion bears any relationship to long-term course or treatment response. Future reliability and validity studies would both benefit by the use of structured diagnostic interviews. This refers simply to a standard, printed list of questions that can be administered to each patient in a prospective study. Such instruments have been used for many years in psychiatric research, and serve to minimize variance among raters in the determination of specific diagnoses. Along with structured diagnostic interviews, specific diagnostic criteria must be based on behavioral or reasonably objective indicators rather than introspective patient reports. Such criteria would again serve to minimize inter-rater variance.

The reliability and validity of insomnia diagnoses would also be assisted by the consistent publication of studies using diagnostic categories. It will be difficult to advance the field of insomnia research and to compare results across studies if each uses different inclusion criteria among its patients. Finally, if investigators and clinicians consistently use the available diagnoses and report their results using these diagnoses, we will be able to revise and refine both diagnostic categories and diagnostic criteria in the future. Such data-based revisions would improve the quality of research and clinical care for patients with insomnia.

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