Derivation of Research Diagnostic Criteria for Insomnia: Report of an American Academy of Sleep Medicine Work Group

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Summary: Insomnia is a highly prevalent, often debilitating, and economically burdensome form of sleep disturbance caused by various situational, medical, emotional, environmental and behavioral factors. Although several consensually-derived nosologies have described numerous insomnia phenotypes, research concerning these phenotypes has been greatly hampered by a lack of widely accepted operational research diagnostic criteria (RDC) for their definition. The lack of RDC has, in turn, led to inconsistent research findings for most phenotypes largely due to the variable definitions used for their ascertainment. Given this problem, the American Academy of Sleep Medicine (AASM) commissioned a Work Group (WG) to review the literature and identify those insomnia phenotypes that appear most valid and tenable. In addition, this WG was asked to derive standardized RDC for these phenotypes and recommend assessment procedures for their ascertainment. This report outlines the WG's findings, the insomnia RDC derived, and research assessment procedures the WG recommends for identifying study participants who meet these RDC.

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INTRODUCTION

OVER 30 YEARS AGO, THE FIELD OF PSYCHIATRY FOUND ITSELF STRUGGLING WITH AN IMPRECISE DIAGNOSTIC SYSTEM THAT RESULTED IN UNRELIABLE DIAGNOSTIC ASSIGNMENTS ACROSS CLINICAL AND RESEARCH SETTINGS. Largely this was due to the absence of explicit operational criteria in the diagnostic manuals published to aid psychiatric research and practice. As a result, diagnostic practice was a highly subjective and unreliable process that relied as much on psychiatric clinicians' and researchers' conceptions of the diagnoses they assigned as it did on the diagnostic manuals designed to guide their decisions. Fortunately, this problem was effectively addressed by the development of Research Diagnostic Criteria (RDC)[1, 2], a set of operationally defined inclusion and exclusion criteria that standardized the definitions for a majority of the recognized psychiatric conditions. These RDC dramatically improved diagnostic reliability among clinicians and researchers and were quickly incorporated into psychiatry's diagnostic manuals.[3-6]

The field of sleep medicine currently finds itself only slightly ahead of where the field of psychiatry was 30 years ago. For some time now, sleep specialists have had at their disposal diagnostic manuals[6-9] that describe a range of sleep disorders and provide lists of diagnostic criteria for their ascertainment. However, sleep disorder diagnosis has been complicated by the existence of several distinctive nosologies that differ markedly and often produce rather discordant classification results.[6-11] Moreover, many current criteria sets for sleep diagnoses are vague or lack sufficient specificity to assure reliable diagnoses across clinical and research settings.[10-13] Recognizing this problem, work groups have convened to develop RDC-like definitions for selected sleep disorder diagnoses such as sleep apnea[14] and restless legs syndrome.[15] There is little doubt that such efforts will benefit the field greatly by standardizing clinical practice and research with such disorders. Nonetheless, for many sleep disorders, research and practice remains greatly hampered by a lack of universally accepted and precise diagnostic criteria.

Nowhere is this problem more apparent than it is in the basic and clinical research pertaining to insomnia. Although there has been general agreement that insomnia *per se* is a symptom and not necessarily an independent sleep disorder, there has been great variability in how this "symptom" has been defined in the literature. For example, some liberal definitions[16, 17] focus solely on the presence of nocturnal sleep disturbances (e.g., sleep initiation or maintenance difficulties, nonrestorative sleep), whereas other more conservative definitions require additional features such as associated daytime impairment[18, 19], sleep dissatisfaction[20], or meeting all diagnostic criteria for a sleep disorder

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described in one of the available nosologies.[21-25] In addition, insomnia definitions have varied as a function of inconsistent use of frequency, duration, symptom type (e.g., onset problems, maintenance difficulties) and/or severity criteria for case ascertainment.[26] As demonstrated recently by Ohayon[26], use of these varied definitions in epidemiological studies has led to drastically different conclusions regarding insomnia's general prevalence, risk factors, morbidity, and costs to society at large.

Unfortunately, such problems have not been confined to the epidemiological literature. Variable insomnia definitions have encumbered studies concerning the pathophysiology, clinical characteristics, and treatment of this form of sleep disturbance. Admittedly, the advent of consensually-derived insomnia classification schemes[4-9, 27] within the past 25 years has provided some standardization to insomnia research by providing clinical criteria sets for use in research sample characterization. However, both the degree to which researchers have adhered to criteria as well as the methods used for their ascertainment have been highly variable regardless of the specific diagnostic subtype in question. Due to this lack of standardization, synthesizing results of multiple insomnia studies is a difficult if not impossible task.

Given this problem, the American Academy of Sleep Medicine (AASM) commissioned a project designed to develop standard definitions for currently recognized insomnia disorders. This project was devoted to three Major Objectives/Specific Aims. The first aim was to conduct a critical review of the insomnia literature to determine which of the current insomnia diagnoses appear most reliable and valid regardless of the nosological system in which they are defined. The second aim was to derive standard RDC for defining each of the subset of insomnia diagnoses that seem to have the greatest empirical and consensual support. The final aim was to propose specific methods for documenting the presence/absence of the specific RDC among patients and subjects to which they are applied.

In planning this project it was recognized that the status of the available literature would set limits on what could be accomplished. For example, it was anticipated that comparisons and synthesis of results across studies would be difficult because of the historic lack of widely accepted insomnia RDC or methods for defining insomnia samples. As a result, it was expected that the conclusions and recommendations derived from this effort would likely be based, out of necessity, more on consensus than on hard evidence. Nonetheless, attempts were made to consider available evidence in addressing the objectives stated above. The remainder of this report provides a discussion of the methods used and results derived by the group assigned to address these objectives.

METHODOLOGY

Project Planning, Direction, and Execution

In August of 1999, the AASM formed an Insomnia RDC Task Force consisting of two representatives of the AASM Board of Directors as well as four additional at large members with expertise in the fields of insomnia classification and treatment. The Task Force was commissioned to develop the scope, direction and objectives/specific aims of the project and to serve as a liaison to the AASM Board. The Task Force was also charged with the naming of an Insomnia RDC Work Group (WG) to carry out all required tasks to address the three specific aims of this RDC project. In November 1999 a Chair and nine additional WG members (i.e., the coauthors of this report) were named and approved by the AASM Board to conduct the activities leading to the results reported herein.

Literature Review

During the first six months of 2000, a series of conference calls and email communications among WG members were conducted to plan the literature review strategy. Given the aforementioned project aims and the vast insomnia literature, it was decided to focus the literature review on articles that would most likely provide information about the reliability and construct validity of currently recognized insomnia diagnoses. The literature deemed relevant included: (1) articles that reported inter-rater reliability data (e.g., % agreement; kappa values) for one or more insomnia subtypes; (2) studies that compared one or more insomnia subtypes with normal sleepers or controls; (3) studies that compared two or more insomnia subtypes with each other or with other types of sleep disorders; (4) comparisons of one or more insomnia subtypes with historic normative data; (5) comparisons of treatment responsiveness of two or more insomnia subtypes undergoing the same insomnia treatment; and (6) descriptive case series studies of one or more insomnia subtypes that provide information about the defining features of the subtype(s) in question. Excluded from the literature review were treatment studies (randomized trials, case series, within-subject designs) conducted to evaluate one or more forms of insomnia therapy with a single insomnia subtype unless the trial in question provided diagnostic reliability information for the subtype being studied. Also excluded were articles written in a language other than English, single case reports, and all epidemiologic studies except those that reported diagnostic reliability data or examined differences among diagnostic insomnia subtypes. Finally, studies that focused solely on circadian rhythm disorders were excluded since the eventual development of RDC for such conditions, while potentially beneficial to the sleep medicine field, was not a specific aim/objective of this project.

The literature review was conducted by a Duke University Medical Center librarian experienced in computer-assisted library database literature searches under the supervision of the Chair of the WG. Searches were conducted within both the Medline and PSYCINFO databases for the time period between 1966 and June, 2000. Furthermore, searches were conducted for all insomnia diagnostic categories in ICSD (the categories in the 1990 [7] and the 1997[28] versions of the ICSD are identical; therefore, "ICSD" will be used throughout the text to refer to these two versions) and the 1994 version of the DSM-IV.[9] In searching each ICSD diagnosis, the terms insomnia and disorders of initiating and maintaining sleep were cross-referenced with the current name of the diagnosis and the *synonyms and key words* listed with the diagnosis in the ICSD text. In the case of the DSM-IV subtypes, the terms insomnia and disorders of initiating and maintaining sleep were cross-referenced with the current name of the diagnosis and, where indicated, a list of diagnostic subtypes. For example, in the case of Substance-induced Insomnia, such terms as alcohol use/abuse, opiate use/abuse, cocaine use/abuse, etc., were included in the search. Full documentation of the search terms used for all searches is available on request from the first author.

Data Extraction Sheets

To facilitate extraction of relevant information from each arti-

cle reviewed, the WG constructed separate reliability and validity data extraction sheets. Both forms elicited information about the citation (authors, title, journal, year, page numbers), the nature of the study sample (i.e., sample selection, types of subjects, number of subjects, female/male ratio, mean age, etc.), study setting, and study results. The Reliability Data Extraction Sheet also solicited information about the type of reliability assessment conducted and the type of reliability index reported. The Validity Data Extraction Sheet solicited information about the types of group comparisons conducted, the specific measures used, and specific findings (means, standard deviations, statistically significant group differences, etc.) reported in each article. The validity form also solicited a judgment and supporting rationale as to whether the article should be included in an evidence table constructed to assess the validity of the insomnia subtype(s) considered in the article. Finally, both forms also included a check box to indicate that no reliability or validity data were reported in the article listed on the form. Copies of the Reliability and Validity Data Extraction Sheets are shown in Appendix A.

Procedure

To facilitate the final article selection process, the literature search was conducted so that a list of citations and accompanying article abstracts would be produced for each insomnia subtype search conducted. The search results were first divided into the five subsets of articles pertaining to: (1) DSM-IV insomnia subtypes; (2) ICSD intrinsic insomnia subtypes; (3) ICSD extrinsic insomnia subtypes; (4) ICSD insomnia subtypes associated with mental disorders; and (5) ICSD insomnia subtypes associated with medical or neurological disorders. The 10-member WG was subdivided into five dyads, and each dyad was given the search results from one of the five subsets of articles. The WG dyads then reviewed their respective sets of abstracts and eliminated articles that clearly provided no information relevant to the aims of the RDC project (e.g. a randomized clinical trial with one insomnia subtype). When the potential usefulness of an article was in doubt, it was included for an initial review. In addition, dyads were encouraged to select relevant review articles for an initial review inasmuch as such articles provided additional references for consideration.

Once all dyads had completed their initial reviews and submitted their lists of the articles selected for more extensive review, AASM administrative staff obtained copies of the complete articles selected and provided members of each dyad the articles they requested. WG members then carefully reviewed the articles and completed both a Reliability and a Validity Data Extraction Sheet for each one although no such sheets were completed for the review articles. Once this review process was completed, each WG member forwarded the completed data extraction sheets to AASM administrative staff members who entered the data into a database program for subsequent analyses.

In addition to these procedures, a Ph.D. clinical psychologist experienced in sleep medicine was hired to examine each article selected by the WG (excluding review articles) for consideration and extract information about the subject selection criteria and insomnia definitions used. The specific information extracted by the contract reviewer included all self-report (e.g., historic information, presenting complaint, daytime symptoms, description of typical sleep pattern, etc.), self-monitoring data (e.g., sleep diary information), and objective measures (e.g., PSG findings) used as inclusion/exclusion criteria in each of the articles. Also, use of specific diagnostic criteria for subject selection was noted. Findings of this review process were placed into a Microsoft Excel® spreadsheet designed to systematize the database and facilitate the subsequent analyses of information acquired. A copy of the spreadsheet can be obtained from the first author upon request.

Following all data entry procedures, the data extraction sheets were reviewed, and findings supporting the reliability and validity of specific insomnia diagnoses were placed into evidence tables to help identify the most tenable insomnia diagnoses. Subsequently, a series of tabulations were conducted using Version 8.2 of the Statistical Analysis System (SAS Institute, Cary, NC) to determine how frequently various inclusion/exclusion criteria were used for insomnia and normal control sample selection in all articles reviewed. Findings from these tabulations in addition to some additional data (e.g., PSG findings) taken from the completed Validity Data Sheets were then considered in the development of RDC.

RESULTS

Articles Considered for Review and Data Extraction

Following the initial review of a large sample (N=433) of articles requested, a total of 165 articles [10, 12, 13, 20, 23, 29-188] were retained by the WG for data extraction. Table 1 provides categorical breakdowns of the total articles undergoing initial review by the WG as well as those articles selected for data extraction. The 165 articles retained included a total of 176 samples of insomnia sufferers and 83 samples of normal sleepers/controls. The 176 insomnia samples included a total of 9,808 subjects and the 83 control samples included a total of 20,818 subjects. The median size of the insomnia samples was 17.0 (1st quartile = 8; 3rd quartile = 45.5), whereas the median sample size of the normal controls was 20 (1st quartile = 10; third quartile = 42).

Diagnostic Reliability of Insomnia Subtypes

The review process uncovered a paucity of data concerning the reliability of DSM and ICSD-R insomnia subtypes. In fact, only five published studies[12, 62, 128, 138, 163] reported any reliability data, and these studies collectively included only 440 subjects. Two of these studies[12, 163] were conducted solely or in part to evaluate the diagnostic reliability of the DSM (DSM-III-R or DSM-IV) insomnia classification system. In the earlier of these studies, Schramm et al.[163] examined inter-rater reliability among clinicians using a structured interview to differentiate 3 global DSM-III-R insomnia subtypes. In the latter multi-site study, Buysse et al.[12] examined inter-rater reliability among clinicians using a standard clinical interview to identify DSM-IV insomnia subtypes. Given sample size limitations, only the reliability data for two DSM insomnia subtypes were reported in this latter study. In the third cluster analytic study, Edinger et al.[62] reported reliability data for two independent raters who reviewed archival data from a small insomnia sample (n = 31) and assigned both DSM-III-R and ICSD insomnia diagnoses. In the fourth study, Morin and colleagues[128] assessed reliability for ICSD diagnoses by comparing impressions derived from clinical interviews with diagnoses derived independently from sleep history, psychometric evaluations, and available polysomnographic findings.

Finally, Ohayon et al.[138] compared a computer-assisted structured interview with impressions of clinical interviewers to determine their agreement for detecting the presence or absence of any ICSD insomnia diagnosis.

Table 2 provides summary data taken from these five studies. These data show that the reliability indices for DSM categories derived from structured interviews in the Schramm et al.[163] study are very impressive and suggest highly acceptable reliability of these global diagnoses. In contrast, when such global diagnoses are derived from clinical interviews, as was the case in the Buysse et al.[12] study, reliabilities are less impressive. The remaining studies by Edinger et al.[62], Morin et al.[128], and Ohayon et al.[138] suggest reasonable reliability for ICSD diagnoses, but unfortunately, only the Morin et al. study provides reliability data for individual ICSD categories.

Diagnostic Validity of Insomnia Subtypes

Examination of the Validity Data Extraction Sheets showed that 113 of the 165 articles reviewed included comparisons of insomnia subtypes with each other and/or a normal control sample. However, 85 of these articles were excluded from consideration due to study design limitations that reduced the usefulness of the data reported. Many of these studies focused on samples (e.g., Parkinson's Disease, Alcohol Abusers, etc.) with obvious sleep disturbance but lacked verification that individuals in these samples actually had insomnia complaints. In other cases, insom-

Table 1–Types of Articles Considered and Retained for Data Extraction

Type of Article	# requested for initial review	%	# retained for data extraction	%
Review articles	105	24.2	0	0
Case reports	26	6.0	12	7.3
Case series – descriptive	60	13.9	31	18.8
Group comparisons	129	29.8	107	64.8
Inter-rater reliability studies	3	0.7	3	1.8
Clinical trials	37	8.5	2	1.2
Case series – treatment	29	6.7	1	0.6
Within-subject designs	13	3.0	5	3.0
Survey studies	19	4.4	2	1.2
Other	12	2.8	2	1.2
Total	**433**	**100**	**165**	**100***

*Note: Cumulative percentage actually falls just below 100% due to rounding errors.

Table 2. Studies Reporting Inter-rater Reliability Data (% agreement or Kappa values) for Insomnia Diagnoses

Study	Site(s)	Sample size & characteristics	Diagnostic System & Method Used	Insomnia Subtypes	% Agreement	Kappa
Schramm et al.[163]	Manneheim, Gottingen, & Landeck, Germany	68 sleep center patients	DSM-III-R (Structured interview)	Primary Insomnia Insomnia due to a mental disorder Insomnia due to organic factor	97 91 93	0.86 0.84 0.86
Buysse et al.[12]	Bronx (NY) Detroit (MI) Hershey (PA) Pittsburgh (PA) Rochester (NY)	216 insomnia patients referred to participating sleep centers	DSM-IV (Clinical interview)	Primary Insomnia Insomnia due to a mental disorder	 NR	0.40 0.42
Edinger et al.[62]	Durham (NC)	31 insomnia clinic patients	DSM-III-R & ICSD-90 (Chart review)	Mixed Insomnia (DSM-III-R) Mixed Insomnia (ICSD-90)	81 74	0.71 0.68
Morin et al.[128]	Richmond (VA)	20 insomnia patients	ICSD-90	Psychophysiologic Insomnia Insomnia due to a mental disorder Hypnotic-dependent insomnia Other mixed ICSD subtypes	 NR	0.54 0.64 0.70 0.84
Ohayon et al.[138]	Palo Alto (CA) Regensburg (Germany)	105 sleep center patients	ICSD-90 (Sleep EVAL interview)	Presence vs. absence of ICSD insomnia diagnosis	96.9	0.78

Table Caption: DSM-III-R = the 3rd edition of the American Psychiatric Association's Diagnostic and Statistical Manual; DSM-IV = 4th edition of the American Psychiatric Association's Diagnostic and Statistical Manual; ICSD-90 = The International Classification of Sleep Disorders, 1990 Edition; NR = Not reported

nia samples were described merely as "insomniacs" or were composed of a mixture of insomnia subtypes. Since it was not possible to ascertain much about specific insomnia subtypes from such studies, they were not used for assessing the validity of specific insomnia diagnoses. In a number of studies, results of polysomnographic studies and/or sleep logs were used both to diagnose study subjects and to compare the subtypes derived from the initial diagnostic classification process. Given the obvious confounds affecting such group comparisons, data from studies of this nature were not included in our evidence tables.

A review of the remaining 28 articles provided some evidence for the validity of the DSM[4-6] subtypes of Primary Insomnia and Insomnia due to a Mental Disorder but no group comparisons were found concerning the categories of Insomnia due to a General Medical Condition and Substance-induced Insomnia. Table 3 summarizes the findings from the subset of these studies supporting the former two insomnia diagnoses. This table demonstrates that all studies listed in the table included a Primary Insomnia sample and most included a sample of normal controls. Only three of the studies included a sample of patients with Insomnia due to Another Mental Disorder and one of these three studies subdivided this category into the ICSD Insomnia Due to Depression and Insomnia Due to an Anxiety Disorder subtypes. Most of the findings summarized in the table confirm that Primary Insomnia sufferers differ from normal controls, and the comparisons of the two types of insomnia sufferers suggest consistent differences between them. Although the data are much more limited, the evidence table also suggests differences between individuals who have Insomnia due to Another Mental Disorder and noncomplaining normal sleepers.

Twenty of the 28 articles retained included comparisons among insomnia subtypes listed in the ICSD. Table 4 lists the studies providing validity evidence for the diagnosis Sleep State Misperception (SSM) (in the forthcoming ICSD-2 [189], this diagnosis will be called Paradoxical Insomnia). This evidence table supports the validity of the SSM diagnosis inasmuch as the data listed suggest that individuals with this form of insomnia can be differentiated both from noncomplaining normal controls and from other insomnia subtypes. Several of the studies listed include comparisons of SSM patients with both normal controls and Psychophysiologic Insomnia (PSYI) sufferers. These comparisons suggest that SSM and PSYI sufferers have distinct patterns of differences from normal controls. As preordained by their definition, SSM groups overlap with normal sleepers on PSG measures of sleep time, onset latency, and wakefulness during the night whereas PSYI sufferers differ from normal sleepers on these measures. However, several of the studies suggest some sleep stage architectural differences between SSM sufferers and the other groups. Moreover, as their diagnostic name implies, SSM sufferers are distinguished from normal controls and other insomnia subtypes by an exaggerated propensity to underestimate the sleep they obtain. Finally, the table provides some limited evidence for the distinctiveness of SSM in regard to personality trait measures and indices of daytime functioning.

Since most of the studies cited in Table 4 included a PSYI group, these studies provide evidence for the distinctiveness of this diagnosis as well. Presented in Table 5 are some additional studies supporting PSYI. The studies included in this table provide comparisons of PSYI with normal controls, other insomnia subtypes, and other types of sleep disorders. The findings reported in Table 5 along with relevant data presented in Table 4 suggest that PSYI sufferers have more wakefulness during sleep than do SSM sufferers, normal controls, and groups such as narcoleptics. The two tables also suggest that PSYI subjects differ from normal sleepers and other insomnia subtypes on personality trait measures (e.g., MMPI scales). Considered collectively, these data support the notion that PSYI is a distinctive form of insomnia that differs from normal sleep, other insomnia diagnoses, and other types of sleep disorders not typically associated with insomnia complaints.

Table 6 lists studies concerning other ICSD insomnia subtypes including childhood onset (Idiopathic) Insomnia (COI), Insomnia Related to Sleep Apnea, and Insomnia Related to an Anxiety Disorder. The limited data listed in Table 6 along with the two studies listed in Table 5 suggest that COI may be distinguished from other insomnia subtypes in terms of objective and subjective sleep measures as well as the duration of complaints. Hauri's cluster analytic study[83] cited in Table 5 suggests COI sufferers may be discriminated from normal sleepers on the basis of historic data, presenting information, and sleep lab findings. However, it should be noted that the study by Philip and Guilleminault[146] listed in Table 5 showed few differences between COI and adult-onset insomnia. Considered collectively, these three reports appear to provide some minimal support for the validity of COI although the information about this condition is much more limited than it is for SSM and PSYI.

Similarly, the evidence supporting the diagnosis of Insomnia Related to Sleep Apnea (AI) is very limited. Although the WG encountered many studies that included a sleep apnea sample, in most cases it was not clear that the individuals composing such samples actually had insomnia complaints. The two studies concerning AI cited in Table 6 are the exceptions to this trend. The first study by Roehrs et al.[154] compared an AI sample with another sample of apnea patients who presented mainly with complaints of excessive daytime sleepiness (AS). The second study by Stone et al.[173] compared a sample of AI patients with another mixed insomnia group. The former study found statistically significant differences between AI and AS groups on PSG sleep and MSLT sleep latency whereas the latter study failed to find any differences on measures of daytime cognitive functioning. Thus, experimentally sound studies examining the validity of AI appear to have been so limited that it is difficult to draw conclusions about the validity of this insomnia subtype.

The one remaining study listed in Table 6 involved a comparison of normal controls with a group of individuals with Insomnia Related to an Anxiety Disorder (IAD). This study showed group differences across a range of measures including PSG parameters, ratings of sleep quality, diurnal motor speed and reaction time, and measures derived from EEG mapping studies. It should also be noted that studies [21, 152]cited in Tables 3 and 5 suggest that IAD can be discriminated from other insomnia subtypes on the basis of objective measures of sleep architecture and subjective sleep ratings and self-report measures of daytime functioning. Hence, IAD appears to be a viable diagnosis on the basis of the evidence cited.

In addition, it is noteworthy that individuals with Insomnia Related to a Depressive Disorder (ID) such as Major Depressive Disorder or Dysthymia were included as comparison samples in several studies [13, 21, 29, 86, 152, 176, 180]listed in Tables 3, 4 and 5. Considered collectively, such studies suggest differences between these and other insomnia subtypes on measures of sleep architecture, subjective sleep quality, perceptions of diurnal functioning,

Table 3. Evidence supporting validity of DSM-III-R/DSM-IV diagnoses of Primary Insomnia and Insomnia due to a Mental Disorder

Reference	Samples Compared	Measures Used Mean Age/ Or Range	Polysomnography	Subjective Sleep Estimates & Complaints	Objective/ Subjective Daytime Measures	Clinician Ratings	Other
Frankel et al, [67]	18 (5F) PRI 18 (4F) NC	44.5±16.8 yrs 45.1±16.8 yrs.	PRI > NC on SOL NC > PRI on TST & SE%	PRI overestimated SOL and underestimated TST & SE%; NC estimates not different from their PSG measures.	NR	NR	NR
Gallard[68]	16 (5F) PRI 16 (5F) NC	44±9 yrs. 44±9 yrs.	PRI > NC on SOL, TWT, TIB, NA NC > PRI on TST, SE%, SWS, and mean stage duration	NR	NR	NR	NR
Hajak et al.[79]	10 (3F) PRI 5(0F) NC	41.3± 9.5 yrs. 27.2±0.7 yrs.	PRI > NC on NA, & %TWT NC > PRI on S4% & SE%	NR	NR	NR	PRI < NC on plasma melatonin levels between 3:00 & 8:00 AM
Nowell et al. [13]	48 PRI 99 IMD	14 - 89 yrs.	NR	NR	NR	Negative conditioning & poor sleep hygiene rated more important to PRI diagnosis. The presence of psychiatric disorder rated more important to IMD	NR
Ohayon et al. [21]	73 PRI 81 ID 84 IA	15 - 96 yrs.	NR	PRI < I+D & I+A on ratings of maintenance difficulty, # insomnia sxs, insomnia duration, nightmares, & restlessness upon awakening PRI < I+D on sleep drunkenness, and breathing pauses. PRI < I+A on NA	PRI < I+D & I+A on anxious mood, concentration/attention, problems & psychic irritability. PRI < I+D on difficulty getting started, daytime sleep, depressed mood, memory problems, anxiolytic use & antidepressant use.	NR	Statistical discriminant analyses showed PRI, I+D and I+A could be discriminated from each other and from groups of depressive and anxiety disorders with insomnia symptoms
Rosa & Bonnet[155]	121 (49F) PRI 56 (21F) NC	18 - 50 yrs.	No group differences on PSG	PRI > NC on SOL, NA, & WASO.	PRI > NC on all MMPI scales except L, Mf, & MA and on STAI. PRI > NC on 5/6 POMS negative mood scales PRI > NC on 4PM MSLT PRI < NC on memory test	NR	NR
Stepanski et al.[172]	10M PRI 10M NC	37±7.5 yrs 37.5±8.8 yrs.	NR	NR	PRI > NC on MSLT SOL	NR	NR
Weissman et al.[180]	533 (371F) PRI 408 (300F) IMD 6172 (3627F) NC	51.8± 10.3 yrs 44.9±18.9 yrs. 48.0±20.0 yrs.	NR	NR	IMD > PRI > NC on health care utilization	NR	NR

Figure Caption: PRI = primary insomnia; NC = normal control; ID = insomnia due to depressive disorder; IA = insomnia due to anxiety disorder; IMD = insomnia due to a mental disorder; NR = not reported; PSG = polysomnography; SOL = sleep onset latency; NA = number of awakenings; WASO = wake time after sleep onset; TWT = total wake time; TIB = time in bed; SE% = sleep efficiency percent; SWS = slow wave sleep; S4% = stage 4 percent; MMPI = Minnesota Multiphasic Personality Inventory; STAI = State-Trait Anxiety Inventory; POMS = Profile of Mood States; MSLT = Multiple Sleep Latency Test

Table 4. Evidence supporting validity of ICSD Diagnosis of Sleep State Misperception.

Reference	Samples Compared	Measures Used: Mean Age/ Or Range	Polysomnography	Subjective Sleep Estimates & Complaints	Objective/ Subjective Daytime Measures	Other Physiologic Measure	Other Comparisons
Bonnet & Arand[44]	9 (2F) SSM 9 (2F) NC	32±8 yrs. 33±6 yrs.	Used for group identification: therefore group comparisons are confounded.	Used for group identification	NC > SSM on vigilance tests SSM > NC on MMPI scales 1,7 & 8 SSM > NC on POMS Tension, Depression, Anger & Confusion	SSM > NC on measure of 24-hour metabolic rate	NR
Borkovec et al.[47]	17 SSM 12 IP	NR - college students	SSM < IP on SWS time	IP > SSM on measure of pre-sleep body tension during initial nights in the sleep lab	NR	NR	SSM < IP on PGS sleep changes from Tx
Dorsey & Bootzin[56]	9 SSM 9 PSYI 13 NC	18 - 25 yrs.	PSYI > SSM & NC on SOL SSM > PSYI & NC on SWS%	NR	PSYI < SSM & NC on EPI introversion/extroversion scale	NR	NR
Hauri & Wisbey[86]	8 (4F) SSM 10 (8F) PSYI 13 (9F) IMD	43.9±9.4 yrs. 50±11.1 yrs 45.1±11.6 yrs.	For SSM PSG TST > actigraphy TST For PSYI & IMD PSG=actigraphy TST	For SSM PSG TST > STST For PSYI & IMD PSG TST=STST	NR	SSM < PSYI & IMD on actigraphy TST	NR
Kuisk et al.[98]	8 (4F) SSM 8 (6F) PSYI 8 (5F) NC	21 - 60 yrs.	NR	SSM < PSYI on frequency of pre-sleep/sleep onset cognitive activity	NR	NR	NR
Salin-Pascaul et al.[160]	7 (3F) SSM 7 (4F) PSYI 7 (4F) NC	36.4±5.9 yrs 35.4±6.3 yrs. 35.6±5.9 yrs.	SSM > PSYI & < NC o n SWS% SSM > NC & < PSYI on S2% SSM & PSYI > NC on S1% PSYI < SSM & NC on TST PSYI > SSM & NC on SOL, NA, WASO	SSM & PSYI < NC on TST SSM & PSYI > NC on SOL & WASO	SSM & PSYI > NC on MMPI Hy scale PSYI > NC on MMPI Hy & D scales	NR	NR
Sugerman et al.[174]	8 (6F) SSM 8 (6F) PSYI 8 (6F) NC	32.4±10.0 yrs 37.9±9.1 yrs. 32.1±9.4 yrs.	SSM > PSYI & NC on S2%, A/hr & ST/hr PSYI < SSM & NC on TST	NR	SSM > PSYI & NC in AVT errors SSM had flatter MSLT profile than PSYI & NC groups	NR	NR
Vanable et al.[176]	8 SSM 19 PSYI 11 ID 21 IOMD 24 PLMD 21 OAS	45±11.4 yrs for whole sample	NR	SSM < rest of the sample in % TST estimated PSYI > than rest of the sample in % TST estimated	NR	NR	NR

Figure Caption: SSM = sleep state misperception; PSYI = psychophysiologic insomnia, NC = normal control; ID = insomnia due to a depressive disorder; IOMD = insomnia due to a mental disorder other than depression; PLMD = periodic limb movement disorder; OSA = obstructive sleep apnea; IP = other mixed idiopathic insomnia; IMD = insomnia due to a mental disorder; PSG = polysomnography; SOL = sleep onset latency; NA = number of awakenings; WASO = wake time after sleep onset; TWT = total wake time; TIB = time in bed; SE% = sleep efficiency percent; SWS = slow wave sleep; S1% = stage 1 percent; S2% = stage 2 percent; MMPI = Minnesota Multiphasic Personality Inventory; EPI = Eysenck Personality Inventory; POMS = Profile of Mood States; MSLT = Multiple Sleep Latency Test; AVT = auditory vigilance test; NR = not reported.

Table 5. Evidence supporting validity of ICSD Diagnosis of Psychophysiologic Insomnia Excluding Relevant Studies Cited in Table 4

Reference	Samples Compared	Measures Used: Mean Age/ Or Range	Polysomnography	Subjective Sleep Estimates & Complaints	Objective/ Subjective Daytime Measures	Other Physiologic Measure	Otherv Comparisons
Aikens et al.[29]	20 PSYI 30 ID 28 PLMD 30 OAS	47.5 for all groups combined	NR	NR	PSYI, ID, & PLM > OSA on MSLT PSYI < ID & PLMD on MMPI D, Pt & Sc scales	NR	NR
Hauri[83]	89 Mixed Pts. 10 NC	Adults	NR	NR	NR	NR	PSYI & COI separated form other groups in a cluster analysis
Lee et al.[103]	24 (11F) PSYI 16 (8F) NAR	45.1±11.1 yrs. 44.4±14.6 yrs.	PSYI < NAR on SE% PSYI > NAR on SOL & REMLAT PSYI > NAR on length of 1st two REM periods.	PSYI > NAR on frequency of nightmares & recurrent dreams	NR	NR	NR
Lichstein et al.[104]	20 (11) PSYI 20 (12F) HDI	49.6±14.8 yrs. 54.8±16 yrs.	NR	NR	NR	NR	PSYI < HDI on improvement in sleep quality from insomnia treatment
Mercia & Gaillard[122]	12 (7F) PSYI 23 (12F) NC	35.9±12.3 30.0±9.5	PSYI > NC on NA & WLAT PSYI < NC on SE% & TST	NR	NR	NR	Discriminant analysis shows beta & delta differences between PSYI & NC
Philip & Guilleminault[146]	38 (20F) PSYI 27 (14F) COI	51±13 yrs. 43.9±9 yrs.	NR	PSYI < COI on frequency of nightmares PSYI < COI on SOL fear of dark during childhood	NR	NR	NR
Reynolds et al.[152]	10 (8F) PSYI 10 (5F) GAD 20 (13 F) MDD	43.8±13.6 yrs. 36.8±14.5 yrs. 37.2±15.2 yrs.	PSYI <GAD & MDD on REM density PSYI & GAD < MDD on S2%, REM% REMLAT, & Phasic REM activity PSYI FNE > GAD FNE for measures of SE% & REM activity	NR	NR	NR	NR

Figure Caption: PSYI = psychophysiologic insomnia, NC = normal control; ID = insomnia due to a depressive disorder; HDI = hypnotic-dependent insomnia; PLMD = periodic limb movement disorder; OSA = obstructive sleep apnea; COI = childhood onset (idiopathic) insomnia; NAR = narcolepsy; MDD = major depressive disorder; GAD = generalized anxiety disorder; SOL = sleep onset latency; NA = number of awakenings; WLAT = awakening latency; REM = rapid eye movement sleep; REMLAT = REM latency; SE% = sleep efficiency percent; TST = total sleep time; FNE = first night effects; S2% = stage 2 percent; MMPI = Minnesota Multiphasic Personality Inventory; MSLT = Multiple Sleep Latency Test; NR = not reported.

Table 6. Evidence Supporting Validity of Other ICSD Diagnoses

Reference	Samples Compared	Measures Used: Mean Age/ Or Range	Polysomnography	Subjective Sleep Estimates & Complaints	Objective/ Subjective Daytime Measures	Other Physiologic Measure	Other Comparisons
IDIOPATHIC (CHILDHOOD ONSET) INSOMNIA							
Hauri & Olmstead[82]	11 (8F)COI* 11(7F) OMI	42±13 yrs. 43±12 yrs.	COI > OMI on SOL & WASO COI < OMI on TST, Phasic REM%, & mean sleep stage duration	COI > OMI on SOL	Only 1 of 42 questionnaire comparison significant. These results interpreted as a "chance" finding.	NR	COI > OMI in insomnia duration
INSOMNIA ASSOCIATED WITH SLEEP DISORDERED BREATHING							
Roehrs et al.[154]	16 (14F) AI 65 (2F) AS	39±18 yrs. 47±1.4 yrs	AI < AS on TST & S1% AI > AS on SOL, S2%, SWS%, & SE% AI < AS on RDI & several indices of O_2 desaturation	NR	AI > AS o n MSLT latency	NR	NR
Stone et al.[173]	18 (3F) AI 16 (14F) OMI	55 - 84 yrs.	Used for group identification: therefore group comparisons are confounded.	NR	AI differs from OMI at 0.05 level of significance on 2 of 12 cognitive tests, but no differences found using bonferroni corrected p = .004 (.05÷12 tests) level.	NR	NR
INSOMNIA DUE TO GENERALIZED ANXIETY DISORDER							
Saletu et al.[159]	44 (25F) IAD 34 (20F) NC	43.2±11.7 yrs. 41.1±12.3 yrs.	IAD > NC in TWT & T-WASO IAD < NC on TST & SE%	IAD < NC on subjective sleep quality ratings	IAD < NC on subjective waking quality ratings. IAD < NC on diurnal measures of fine motor and reaction time performance	IAD > NC on hypervigilance measure derived from EEG mapping	IAD > NC on sleep pressure detected by late AM EEG mapping

Figure Caption: *These age- and gender-matched samples were taken from larger samples of 20 COI & 39 OMI groups. COI = childhood onset (idiopathic) insomnia; OMI = other mixed insomnia subtypes; AI = sleep apnea with insomnia; AS = sleep apnea with excessive sleepiness; IAD = insomnia due to an anxiety disorder; NC = normal controls; SOL = sleep onset latency; WASO = wake time after onset; TWT = total wake time; TST = total sleep time; T-WASO = total wake time after sleep onset; REM = rapid eye movement sleep; S1% = stage 1 percent; S2% = stage 2 percent; SWS% = slow wave sleep percent; SE% = sleep efficiency percent; MSLT = multiple sleep latency test; O2 = oxygen; RDI = respiratory disturbance index; EEG = electroencephalogram; NR = not reported.

and personality traits. Furthermore, one of these studies[21] showed that ID could be statistically discriminated from IA and Primary Insomnia on the basis of subjective sleep ratings and self-report measures of daytime functioning. As a result, it would appear that ID warrants consideration as a separate insomnia diagnosis as well.

Finally, since two studies[29, 176] listed in the evidence tables included samples of insomnia sufferers with periodic limb movement disorder (PLMD), this diagnosis warrants consideration. Unfortunately, the data supporting the distinctiveness of this condition appears very limited. The studies listed suggest individuals with PLMD differ from some other insomnia subtypes on a limited number of personality trait measures and in regard to how accurately they estimate sleep time. Since there have been few comparisons of PLMD with other insomnia subtypes, there currently is very limited data supporting the validity of this diagnosis.

Consensual Definitions

The evidence tables help delineate the most supportable insomnia diagnoses and provide some guidance as to how these subtypes might be identified in the research subject selection process. In addition, a review of the subject selection criteria used in these studies should help identify consensual research definitions that aid in the development of RDC. However, since most studies reviewed were excluded from the evidence tables, it seemed that much information about consensual research definitions for the various subtypes considered would be ignored if only the selection criteria for studies included in the evidence tables were tabulated. Given this consideration, the WG decided to examine the subject selection criteria for all 165 articles retained for review.

Tabulations of study selection criteria showed marked variability in the types of criteria used for selection of both insomnia and normal control samples. In fact, no single criterion or criteria set was used for selection of as many as 50% of the insomnia or normal control samples described in the articles reviewed. Tabulation results showed that a total of 14 distinctive types of criteria were used for selection of at least 5% of the insomnia samples considered herein. Eight of these were also used with variable frequencies for selection of the normal control samples described in the reviewed studies. Figure 1 shows these criteria sets and the frequency with which they were employed in selecting the insomnia and normal control samples.

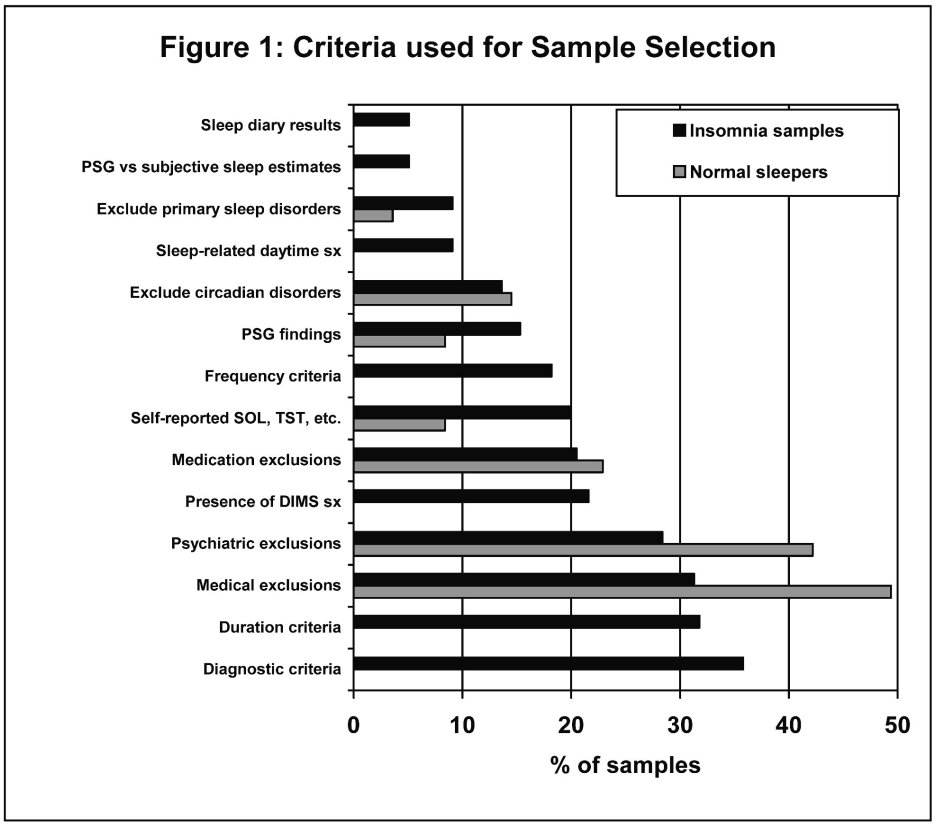


Figure Caption 1–The figure shows the 14 criteria used most frequently for subject selection. Diagnostic criteria = use of published[4-7, 27, 189] diagnostic criteria; Duration criteria = selection on the basis of a minimum insomnia duration; Medical exclusions = subjects excluded for sleep-disrupted medical conditions; Psychiatric exclusions = subjects excluded for the presence of some or any psychiatric conditions; Medication exclusions = subjects excluded for current use of psychoactive medications; Presence of DIMS complaint = subject selection on the basis of specific complaints of sleep onset difficulties, sleep maintenance difficulties, and/or nonrestorative/poor quality sleep; Self-reported SOL, TST, etc. = subjects selected who report certain predetermined mean values of certain sleep parameters such as sleep onset latency, total sleep time, etc.; Frequency criteria = subjects selected on the basis of having insomnia a predetermined minimum number of nights per week; PSG findings = certain polysomnographic findings needed for subject selection; Exclude circadian disorders = subjects who had evidence of unusual sleep/wake schedules (e.g., shift work) or circadian rhythm disorders were excluded; Sleep-related daytime symptoms = subjects were required to have daytime impairment related to sleep difficulties; Exclude primary sleep disorders = subjects who had symptoms/complaints suggestive of certain primary sleep disorders such as sleep apnea, narcolepsy, restless legs syndrome, periodic limb movements, and/or parasomnias were excluded; PSG vs. subjective sleep estimates = subjects selected on the basis of predetermined differences between polysomnographic sleep measures and their coincident subjective sleep estimates; Sleep diary results = sleep diary results were used for subject screening.

As might be expected, most of the selection criteria for the normal samples in the articles reviewed were designed to exclude individuals with evidence of any form of sleep disruption.

Typically such samples were described as individuals either without sleep complaints or without insomnia. Almost 50% of the normal control samples specifically excluded individuals with selected medical disorders that commonly disrupt sleep (e.g., chronic pain conditions). Approximately 42% of the normal samples excluded individuals with histories or symptoms of psychiatric disorders, whereas roughly 23% excluded individuals who reported ongoing use of hypnotics or other psychoactive agents. Roughly 15% of the samples excluded those with unusual sleep/wake schedules or circadian rhythm disorders. Between 8% and 9% of the samples included individuals selected on the basis of "normal values" of sleep onset latency, wake time after sleep onset (WASO) or total sleep time (TST) obtained either from self-report or a screening polysomnogram (PSG). Fewer than 4% of the samples excluded individuals with primary sleep disorders (e.g., sleep apnea, narcolepsy, restless legs syndrome, etc). About 50% of the normal samples included in the articles reviewed met at least two of these selection criteria, but over 85% of these samples were selected using three or fewer of these criteria.

About 55% of the insomnia samples were selected using at least two of the selection criteria listed in Figure 1, but slightly under 30% of these insomnia samples were selected using more than three of these criteria. When the criteria were tabulated individually, it was noted that satisfaction of published diagnostic criteria[4-7, 27] for a particular insomnia subtype was the most frequently used entry requirement in selecting insomnia samples. This requirement was used for slightly over 36% of the insomnia samples considered. For roughly 32% of the insomnia samples, minimal insomnia duration requirements were used for sample selection; the most frequently used criterion in this regard was an insomnia duration of six months or longer. Between 20% and 30% of the insomnia samples excluded individuals with sleep-disruptive medical disorders (29.7% of the samples), histories and/or current symptoms of specified psychiatric disorders (26.7% of the samples), and/or ongoing use of hypnotics or other psychoactive medications (20.9% of the samples). Subject selection for roughly 20% of the insomnia samples was based on the presence of an insomnia complaint (i.e., sleep initiation or maintenance difficulty, poor sleep quality or nonrestorative sleep) or self-reports of an average sleep onset latency (SOL), wake time after sleep onset (WASO), or total sleep time (TST) that surpassed predetermined thresholds for insomnia (e.g., SOL or WASO > 30 minutes; TST < 6 hours). Selection criteria for approximately 18% of the samples included consideration of insomnia frequency. The most commonly used frequency criterion required the occurrence of insomnia three or more nights per week. Slightly fewer than 16% of the insomnia samples were selected on the basis of meeting *a priori* thresholds (i.e., predetermined values for sleep/wake time measures, the RDI, or PLM index) during a screening polysomnogram (PSG), whereas approximately 12% of the samples excluded individuals with variable sleep/wake schedules and/or circadian rhythm disorders. Less frequently used selection criteria included the requirement of self-reported insomnia-related daytime symptoms or impairment (9.3% of the samples), exclusions for the presence of selected primary (e.g., sleep apnea, narcolepsy, etc.) sleep disorders (7% of the samples), predetermined levels of similarity or dissimilarity between subjective sleep estimates and corresponding PSG measures (5.2% of the samples), and *a priori* thresholds for mean values of SOL, WASO, and/or TST derived from screening sleep logs (5.2% of the samples).

To determine how these findings generalized to each of the insomnia subtypes listed in the evidence tables (i.e., Tables 3-6), all of the studies reviewed that contained samples of one or more of these subtypes were first selected. Specifically, studies were retained if they included individuals with DSM[4-6] Primary Insomnia and/or Insomnia due to Another Mental Disorder as well as studies that included samples with PSYI, SSM, COI, Insomnia due to PLMD, AI, IAD, and/or ID as defined by either the ASDC nosology[27] or ICSD-1.[7] Subsequently, tabulations were conducted to ascertain how frequently each of the above-mentioned study selection criteria was used in each of these types of insomnia samples.

A total of 61 articles that included a total of 81 insomnia samples were retained. The numbers of samples for each of the subtypes considered are shown in Table 7 (see table caption for list of references). Relatively few samples with ICSD diagnoses of IAD and ID were found. Since the forthcoming ICSD-2[189] and DSM texts[4-6] combine these categories into a single global insomnia diagnosis, these groups were combined with the samples assigned the DSM diagnosis of Insomnia due to Another Mental Disorder to form one larger set of samples with Insomnia Due to Mental Disorders. Results of the subsequent frequency tabulations of study selection criteria used for each of these subtypes are shown in Figures 2a-2c. Figure 2a shows tabulations for the DSM insomnia supported by the evidence tables whereas Figure 2b shows similar tabulation for the ASDC and ICSD subtypes that appear most tenable. Presented in Figure 2c are the ASDC and ICSD subtypes that received only minimal or incidental support from the evidence tables.

Figure 2a shows that the research criteria most frequently used for selecting samples of Primary Insomnia and Insomnia due to a Mental Disorder closely reflect those features emphasized in the DSM diagnostic criteria sets for these subtypes. In fact, DSM diagnostic criteria were used in subject selection for two thirds of the samples with Insomnias due to a Mental Disorder. Whereas relevant DSM criteria were used for subject selection in slightly under 40% of Primary Insomnia samples, exclusions for sleep-disruptive medical problems, active psychiatric conditions, and psychoactive medications emphasized by these criteria were used

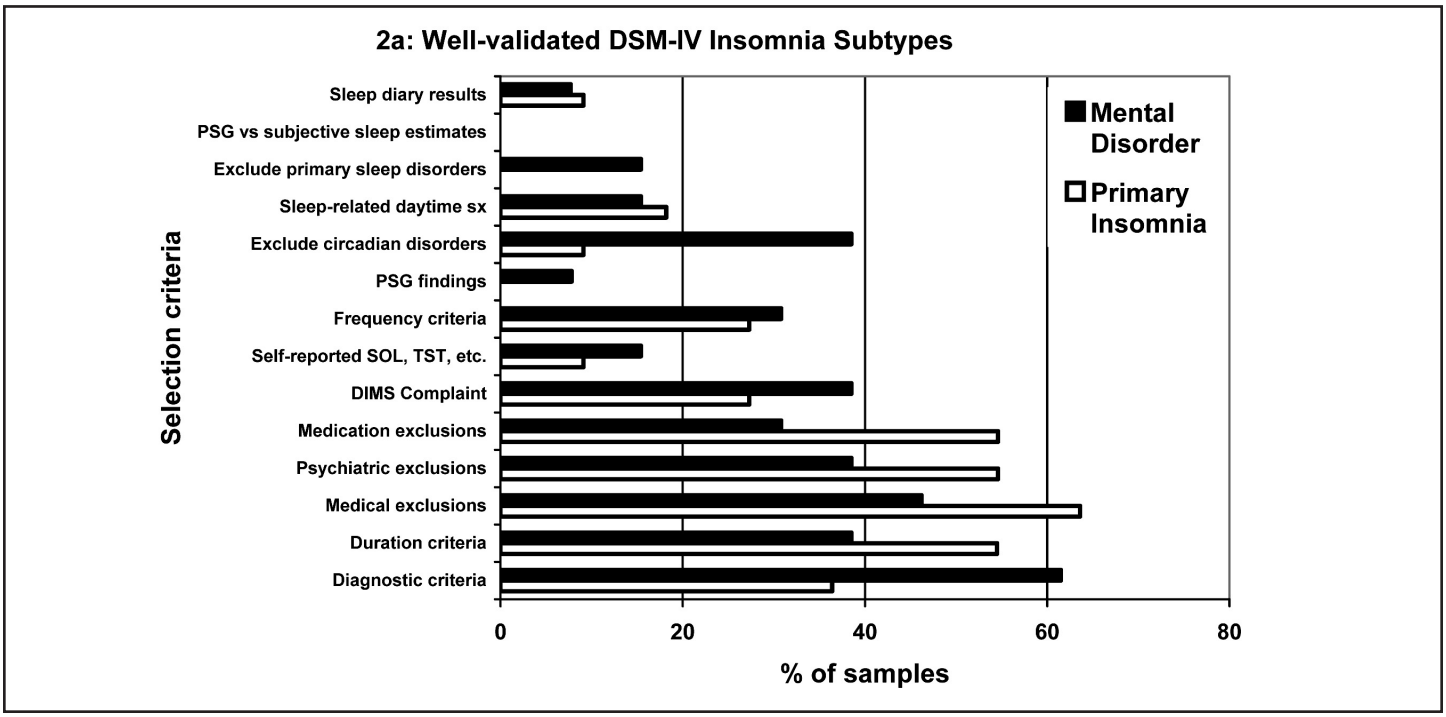
Table 7. Number of Samples of Various Insomnia Subtypes Examined for Consensual Definitions

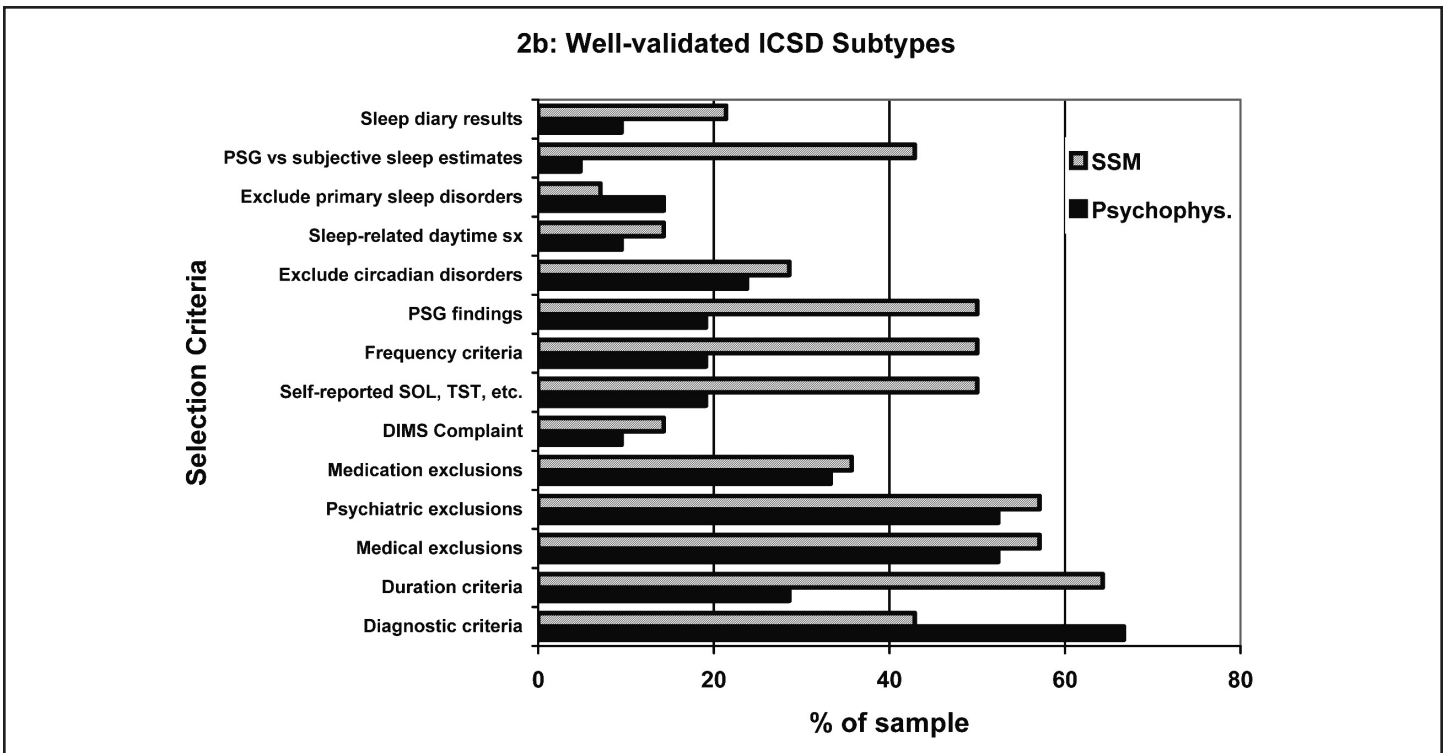
Diagnostic Category	# Samples Considered
Primary Insomnia	11
Insomnia due to Another Mental Disorder	8
Psychophysiologic Insomnia	21
Sleep State Misperception	14
Idiopathic/Childhood Onset Insomnia	3
Insomnia due to Sleep Apnea	5
Insomnia due to Periodic Limb Movement Disorder	14
Insomnia due to an Anxiety Disorder	3
Insomnia due to a Depressive Disorder	2
Total Samples	**81**

Figure Caption: Samples were derived from articles with the following reference numbers in the reference list: (13, 29, 43, 44, 46, 47, 51, 56-58, 63, 67, 68, 73, 75-77, 79, 80, 84, 86, 98, 103-105, 112, 113, 119-122, 128, 133, 135, 143, 145, 146, 148, 151-154, 156, 158-162, 166, 168, 170, 172-178, 180, 183, 188)

in selecting over 50% of these samples. The figure shows that ascertainment of an insomnia (DIMS) complaint, as well as use of duration and frequency criteria were commonly employed in subject selection of both insomnia subtypes. Exclusion of circadian rhythm disorders was mentioned in selecting one third of the insomnia samples with mental disorders but this criterion was seldom specifically mentioned in the selection of the Primary Insomnia samples. However, since this exclusion is incorporated into DSM criteria for Primary Insomnia, it can be assumed that such samples selected on the bases of these criteria excluded individuals with circadian disturbances. A similar assumption can be made about the limited consideration of daytime impairment as a selection criterion for either type of sample since the diagnostic criteria for both subtypes require evidence of such impairment. In contrast, PSG findings and subjective sleep estimate via self-report or sleep diary seem less essential since they were infrequently used as selection criteria for these subtypes.

Figure 2b shows tabulation results concerning criteria used for selection of the two most strongly supported ICSD insomnia subtypes, PSYI and SSM. These data suggest some overlap and





Figures 2a-2b–Research Selection Criteria used for Defining Insomnia Subtypes. The definitions provided in the caption for Figure 1 apply to Figures 2a, 2b, & 2c.

some notable differences in the research selection criteria used for these subtypes. Specific diagnostic criteria as well as exclusions for sleep-disruptive medical problems, active psychiatric conditions, psychoactive medications, and circadian disorders were frequently employed for the selection of both subtypes in the studies considered. Another common finding was that insomnia complaints, daytime symptoms or impairment, and exclusions for primary sleep disorders were seldom considered in sample selection for both subtypes, perhaps because diagnostic criteria that include these considerations were used with relative frequency. In contrast, the figure shows that subjective sleep impressions (i.e., self-reports, diary results), PSG findings, and comparisons of PSG and subjective sleep measures were much more common selection factors for the SSM groups than for the psychophysiologic samples. Given the nature of SSM, these latter findings admittedly are not surprising. Nonetheless, these consensual data imply the potential importance of such factors in developing RDC for this condition.

Figure 2c provides findings concerning the typical research selection/definition criteria used for the remaining ICSD diagnoses considered in the evidence tables. As was the case for the above two diagnoses, these data suggest some marked differences among these subtypes in regard to the relative importance of the selection criteria listed. PSG findings (either apneic/hypopneic events or counts of PLMs) coupled with DIMS complaints were used very frequently for selection of AI and PLMD patients, whereas specific diagnostic criteria were employed somewhat less frequently. The remaining selection criteria were used much more rarely for selecting and defining these subtypes in the studies reviewed. In contrast, insomnia complaints coupled with duration criteria were used universally to select idiopathic insomnia samples. Diagnostic criteria and exclusions for medical and sleep disorders seemed of moderate importance for sample selection/definition of this subtype. PSG data were also frequently considered in defining idiopathic samples, but mainly as a means of ruling out occult primary sleep disorders such as sleep apnea and PLMD. The remaining criteria sets were used infrequently or not at all for selecting idiopathic samples.

Derivation of Insomnia RDC

The findings derived from the literature search provide guidance in the development of a standardized definition for chronic insomnia per se as well as RDC for specific diagnostic subtypes and normal control samples. Since the literature review showed frequent use of published diagnostic criteria for insomnia subject selection, it seemed useful to begin by considering commonalities in insomnia definitions contained in the most recent of these nosologies. Both the latest DSM[6] and most recent versions of the ICSD[7, 28] systems agree that complaints of difficulty initiating sleep, difficulty maintaining sleep, and/or sleep that is nonrestorative or poor in quality constitute the sleep-related symptoms of insomnia. Furthermore, both systems require associated daytime impairment that is perceived to be the result of the nocturnal sleep symptoms. These two requirements, nocturnal sleep disturbance and associated daytime impairment, appear to repre-

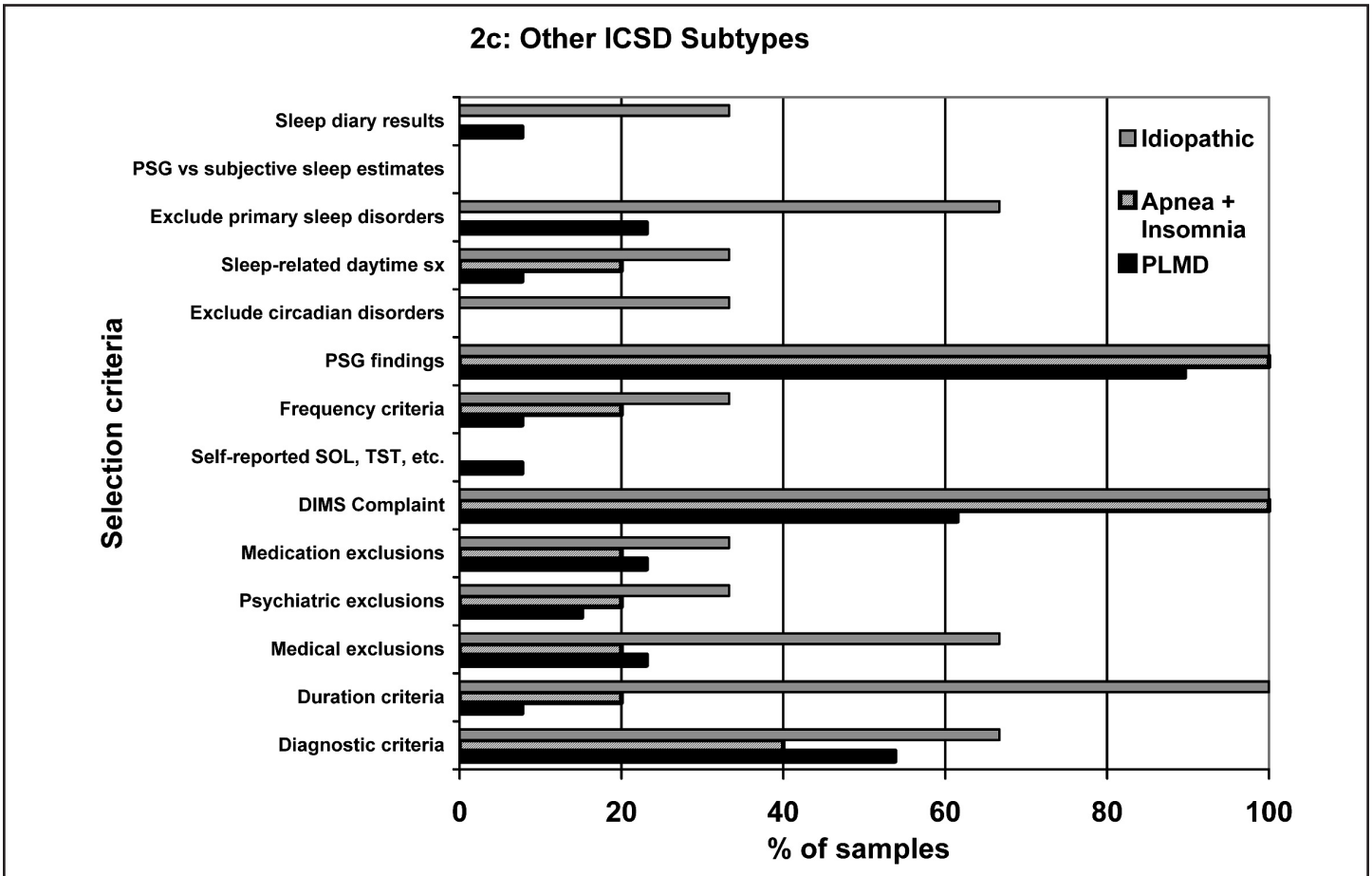


Figure 2c–Research Selection Criteria used for Defining Insomnia Subtypes. The definitions provided in the caption for Figure 1 apply to Figures 2a, 2b, & 2c.

sent universal definitional criteria that "fit" within extant insomnia nosologies and apply equally well to the various subtypes highlighted by the WG literature review.

In contrast, other frequently used definitional criteria examined do not appear of equal importance to a global insomnia definition. For example, the tabulations conducted suggest that insomnia duration may be important to the definitions of various subtypes but not for insomnia associated with PLMD or sleep apnea. Likewise, frequency criteria appear relatively important to some subtypes (e.g., SSM) but not to others. Similar statements can be made about the remaining definitional criteria examined. Hence, none of these can be applied to a universally applicable insomnia definition.

A final consideration relates to the context in which the nocturnal and diurnal insomnia symptoms occur. Although typically not stated, implicit to the term insomnia is the assumption that its associated nocturnal and diurnal symptoms arise despite a consistently adequate opportunity for sleep. That is to say, nocturnal sleep difficulties occur despite the allocation of adequate time periods and circumstances (e.g., a quiet and dark bedroom) for sleep. In this vein, the ICSD-2[189] will specifically mention this requirement in its generic insomnia definition. Given these considerations, the criteria shown are offered as universal RDC for insomnia. These criteria have been included in the ICSD-2, and the WG recommends their use for selection of adult insomnia samples by all researchers regardless of the insomnia subtype in question.

In addition to these universal criteria, additional criteria seem appropriate for the distinctive insomnia subtypes previously discussed. Results of the literature review suggest the RDC criteria sets should vary across the subtypes considered. The specific criteria sets and their justifications are provided for each subtype in the following discussion.

Research Diagnostic Criteria for Insomnia Disorder

A. The individual reports one or more of the following sleep related complaints:
   1. difficulty initiating sleep,
   2. difficulty maintaining sleep,
   3. waking up too early, or
4. sleep that is chronically nonrestorative or poor in quality.

B. The above sleep difficulty occurs despite adequate opportunity and circumstances for sleep.

C. At least one of the following forms of daytime impairment related to the nighttime sleep difficulty is reported by the individual:
   1. fatigue/malaise;
   2. attention, concentration, or memory impairment;
   3. social/vocational dysfunction or poor school performance;
   4. mood disturbance/irritability;
   5. daytime sleepiness;
   6. motivation/energy/initiative reduction;
   7. proneness for errors/accidents at work or while driving;
   8. tension headaches, and/or GI symptoms in response to sleep loss; and
   9. concerns or worries about sleep.

Primary Insomnia: This diagnosis is specific to the DSM [4-6] sleep disorders nosology. It is a fairly global diagnosis established primarily by the exclusion of other primary sleep disorders, psychiatric conditions, medical factors, and substance use/abuse as causes to the reported sleep difficulty. Given its global nature, primary insomnia subsumes several of the subtypes (e.g., PSYI, idiopathic insomnia, SSM) listed in the ICSD. These ICSD-2 subtypes are more specific and are defined by positive symptoms as well as by exclusionary criteria. As such, the utility of RDC for both primary insomnia and these more specific ICSD-2 subtypes could be questioned. However, as demonstrated by previous studies[10, 11] there is not perfect concordance between the more global primary insomnia diagnosis and the more specific ICSD-2 subtypes. For example, some patients who fail to meet criteria for any of the more specific ICSD-2 subtypes may meet criteria for primary insomnia whereas some patients who meet criteria for one of the ICSD-2 subtypes may not meet criteria for primary insomnia. In addition, there is a formidable treatment literature devoted to primary insomnia. Given these considerations, it seems reasonable to provide RDC for primary insomnia as well as for the several overlapping ICSD-2 subtypes described later.

DSM criteria for this condition include an insomnia complaint as well as a number of the exclusionary criteria highlighted by the findings shown in Figure 2a. Both the figure and the DSM texts advocate excluding medical, psychiatric, and medicinal causes of sleep disturbance. In addition, the diagnostic criteria require exclusions for other primary sleep disorders (e.g., sleep apnea, parasomnias, etc.), sleep disturbances due to unusual sleep/wake schedules or circadian rhythm disorders, and sleep difficulties arising from substance abuse. Along with these criteria, both the DSM texts and the data summarized in Figure 2a highlight the importance of duration criteria. The DSM system requires an insomnia duration of one month or longer. All six reviewed articles that used a duration criterion for primary insomnia required at least one-month duration although five of these six articles required longer durations. Nonetheless, these articles provide consensus that an insomnia duration of at least one-month is needed for this diagnosis. The following criteria incorporate these considerations in RDC for Primary Insomnia.

Research Diagnostic Criteria for Primary Insomnia

A. The individual meets the criteria for insomnia disorder.

B. The insomnia noted in A has been present for at least one month.

C. One of the following two conditions applies:
   1. There is no current or past mental or psychiatric disorder.
   2. There is a current or past mental or psychiatric disorder, but the temporal course of the insomnia shows some independence from the temporal course of the mental or psychiatric condition.

D. One of the following two conditions applies:
   1. There is no current or past sleep-disruptive medical condition.
   2. There is a current or past sleep-disruptive medical condition, but the temporal course of the insomnia shows some independence from the temporal course of the medical condition.

E. The insomnia cannot be attributed exclusively to another primary sleep disorder (e.g., sleep apnea, narcolepsy, or parasomnia) or to an unusual sleep/wake schedule or circadian rhythm disorder.

F. The insomnia cannot be attributed to a pattern of substance abuse or to use or withdrawal of psychoactive medications.

Insomnia due to a Mental Disorder: This diagnosis has been included in several editions of the DSM sleep disorders nosology. A variety of mental disorders have insomnia as a symptom, but this diagnosis is applied when insomnia arises from a mental disorder and is of sufficient severity or concern to the patient as to require separate attention in treatment. Traditionally, the ICSD system has included several subtypes of insomnias that can be subsumed within this more global DSM category. However, the ICSD-2 has adopted the DSM approach and includes the global category of Insomnia due to a Mental Disorder rather than several specific mental disorder subtypes described in the previous ICSD. As such, development of RDC for insomnia due to a mental disorder has applicability to both DSM and the current ICSD-2 classification systems.

Figure 2a suggests strong adherence to published diagnostic criteria for this insomnia subtype by previous researchers. The condition's DSM criteria include a complaint of insomnia. The criteria and Figure 2a also highlight the importance of exclusions for sleep-disruptive medical conditions and medications that disrupt sleep. In addition, the DSM criteria emphasize the relationship between the insomnia and the comorbid mental disorder and include exclusions for substance abuse and such sleep disorders as narcolepsy, breathing-related sleep disorders and parasomnias as causative factors. In regard to this latter set of exclusions, Figure 2a suggests that sleep schedule and circadian disorders may warrant exclusionary attention as well. Furthermore, the criteria emphasize the relative prominence and importance of the insomnia to distinguish this subtype from mental disorders wherein insomnia is a common albeit less central symptom.

Along with these considerations, both the DSM texts and Figure 2a suggest the importance of duration criteria for this subtype. DSM-IV criteria require a minimum insomnia duration of one month. The findings presented in Figure 2a represent five instances in which a minimum duration criterion was used, and in none of these cases was a duration of less than one month used. As such, a duration of one-month seems appropriate as a minimum criterion for this condition although longer time periods may be helpful in ascertaining the association/co-variation of insomnia and its causative mental disorder. Given these considerations the criteria shown are offered as RDC for Insomnia due to a Mental Disorder.

Psychophysiologic Insomnia: This diagnosis is specific to the ICSD system [7, 28, 189] and is one of the subtypes that may be subsumed within the more global DSM diagnosis of primary insomnia. Unlike primary insomnia, PSYI is defined by positive symptoms reflective of somatized tension and conditioned arousal as well as by several exclusionary criteria. Admittedly, there is debate[190, 191] about the utility of subdividing primary insomnia into this and other subtypes, and there is a need for much more diagnostic reliability and validity studies to settle this controversy. However, the evidence tables discussed previously provide some limited support for subdividing primary insomnia into a number of ICSD subtypes. As such, RDC for PSYI and other selected ICSD subtypes seem needed to systematize study of these subtypes so that their utility vis a vis the DSM global diagnosis of primary insomnia can be ascertained.

As suggested by Figure 2b, published diagnostic criteria frequently have been used to identify or select individuals for studies of PSYI. Central to the ICSD criteria[7, 189] for this condition are evidence of sleep-preventing associations and somatized tension/arousal that disrupt sleep. The ICSD criteria for PSYI also incorporate the above-mentioned insomnia definition and, along with the findings shown in Figure 2b, highlight the importance of exclusions for sleep-disruptive medical and psychiatric conditions as the sole cause of the insomnia. Not mentioned in the criteria for this condition are exclusions for sleep-disruptive medications, yet Figure 2b suggests such exclusions have been used with relative frequency in previous studies of this subtype. Neither the ICSD criteria nor the findings summarized in Figure 2b argue for the exclusion of co-morbid sleep disorders with the possible exception of circadian rhythm disorders. In fact, the diagnostic criteria allow for coexisting sleep disorders such as obstructive sleep apnea presumably if the observed sleep problem cannot be explained solely by this coexisting condition.

In regard to duration, Figure 2b suggests that duration criteria have been used with relative frequency in research studies concerning this subtype. In fact, duration criteria were used for the selection of 8 of the 21 psychophysiologic samples identified in the articles reviewed. Minimum insomnia duration required for these samples was variable and included three months, six months and twelve months. Despite these findings, ICSD allowed for the diagnosis of *acute* PSYI in cases where the insomnia is present for less than four weeks. Nonetheless, it seems that some period of time would be required to allow for the development of the conditioned arousal that defines this condition. Hence, as a compromise between research practice and ICSD, the WG proposes requiring a minimum insomnia duration of one-month for clear identification of established cases of this

Research Diagnostic Criteria for Insomnia due to a Mental Disorder

A. The individual meets the criteria for insomnia disorder.
B. The insomnia noted in A has been present for at least one month.
C. There is an association between the insomnia and a co-existing DSM-IV-TR-defined mental disorder as reflected by both of the following:
   1. The onset of the insomnia coincides with the onset of the associated mental disorder.
   2. The temporal course of the insomnia coincides with the temporal course of the mental disorder.
D. The insomnia is either the sole complaint or is sufficiently severe to warrant separate clinical attention.
E. One of the following two conditions applies:
   1. There is no current or past sleep-disruptive medical condition.
   2. There is a current or past sleep-disruptive medical condition, but the temporal course of the insomnia shows some independence from the temporal course of the medical condition.
F. The insomnia cannot be attributed exclusively to another primary sleep disorder (e.g., sleep apnea, narcolepsy or parasomnia) or to an unusual sleep/wake schedule or circadian rhythm disorder.
G. The insomnia cannot be attributed to a pattern of substance abuse nor to use or withdrawal of psychoactive medications.

Research Diagnostic Criteria for Psychophysiological Insomnia

A. The individual meets the criteria for insomnia disorder.
B. The insomnia noted in A has been present for at least one month.
C. The patient has evidence of conditioned sleep difficulty and/or heightened arousal in bed as indicated by one or more of the following:
   1. Excessive focus on and heightened anxiety about sleep.
   2. An inability to fall asleep in bed at the desired bedtime or during planned naps but relative ease falling asleep during other relatively monotonous activities (e.g., watching TV, reading, etc.) when not intending to sleep.
   3. Being able to sleep better away from home than at home.
   4. Mental arousal in bed characterized either by intrusive thoughts or a perceived inability to volitionally cease sleep-preventing mental activity.
   5. Heightened somatic tension in bed reflected by a perceived inability to relax the body sufficiently to allow the onset of sleep.
D. One of the following two conditions applies:
   1. There is no current or past mental disorder.
   2. There is a current or past mental disorder, but the temporal course of the insomnia shows some independence from the temporal course of the mental disorder.
E. One of the following two conditions applies:
   1. There is no current or past sleep-disruptive medical condition.
   2. There is a current or past sleep-disruptive medical condition, but the temporal course of the insomnia shows some independence from the temporal course of the medical condition.
F. The insomnia cannot be attributed solely to another primary sleep disorder (e.g., sleep apnea, narcolepsy, or parasomnia) or to an unusual sleep/wake schedule or circadian rhythm disorder.
G. The insomnia cannot be attributed to a pattern of substance abuse or to use or withdrawal of psychoactive medications.

condition. This duration criterion appears in ICSD-2 criteria for Psychophysiologic Insomnia and has been integrated into the following RDC for this condition.

Paradoxical Insomnia (*Sleep State Misperception)*: This condition represents another ICSD subtype that can be subsumed within the global DSM diagnosis of primary insomnia. It has been assigned various names including *insomnia complaint without objective findings*, *pseudo-insomnia*, *subjective insomnia*, and most recently, *sleep state misperception*. Each of these terms connotes an absence of actual sleep pathology despite the presence of an insomnia complaint. However, the origins of sleep complaints in patients with this condition remain poorly understood, although some recent studies[192, 193] suggest that excessive high frequency activity in patients' sleep EEGs may relate to their subjective sleep dissatisfaction. Accordingly, this condition has been renamed Paradoxical Insomnia in the ICSD-2 to avoid the negative connotations of its previous names. As the evidence tables provide some support for this subtype, RDC are offered to systematize future study of this condition.

As reflected by Figure 2b, the types of criteria required for this condition are qualitatively different from those required for the other subtypes considered thus far. Published diagnostic criteria[7] have been used less frequently for sample definition/selection for this subtype than for PSYI. However, duration criteria, as well as exclusions for medication, medical disorders, and psychiatric conditions have figured very prominently in sample definition. In addition, the studies reviewed show frequent use of frequency criteria, self-reports of sleep/wake measures, PSG findings, and comparisons of subjective sleep estimates with PSG data to define research participants with this condition.

In the studies reviewed, duration criteria were used for selection/definition of 9 of 14 samples, and in all of these cases, a minimum insomnia duration of six months was used. However, ICSD allows diagnosis of acute versions of this disorder in cases having insomnia complaints for less than one month. Nonetheless, the WG surmised it would be difficult to be certain about this diagnosis in the acute phase. As such, a minimum duration of one month was selected as a criterion so as to compromise between ICSD criteria and previous research practice.

Criteria related to the frequency (number of nights per week) of insomnia were used as selection criteria for 7 of the 14 samples with this condition. When frequency criteria were used, an insomnia occurring > 3 nights per week was required. However, it should be noted that the ICSD and ICSD-2 require no specific minimum frequency of sleep difficulties for diagnosis of this condition. Furthermore, frequency criteria were generally not viewed as important for the other ICSD primary insomnia subtypes (i.e., PSYI, & COI). As a consequence, frequency criteria were not included in the proposed RDC for this condition, although it is recognized that future research may show that these RDC can be improved by the addition of such criteria.

In regard to PSG criteria, both the ICSD and a review of relevant studies suggest that sleep recordings show no evidence of other sleep disorders that may account for the insomnia complaint. The original ICSD system [7]suggests "sleep latencies of less than 15 to 20 minutes and sleep durations in excess of 6fi hours" are characteristic PSG findings among patients with this condition. To corroborate this statement, PSG findings were extracted from all reviewed studies that included SSM samples. PSG values of SOL were reported for seven samples totaling 73 subjects, whereas values of TST were available for five samples totaling 48 patients. These data were used to compute weighted averages of SOL and TST by multiplying the mean values reported for each sample by the sample size, summing the results of these calculations, and then dividing the result by the total number of subjects included in the samples considered. Results of these calculations produced a weighted mean SOL of 22.8 minutes and a weighted mean TST of 415.5 minutes. These findings suggest that a minimum TST requirement of 6fi hours may be reasonable for definition of paradoxical insomnia, but a 20-minute SOL may be an overly strict requirement.

In addition to these measures, several articles used a minimum sleep efficiency value as a defining feature of this diagnosis. Sleep efficiencies of ≥ 85% or 90% were most commonly used for selection of subjects with this condition. A review of relevant articles produced mean values of sleep efficiency for four separate samples totaling 33 subjects. Computation of a weighted average produced a mean sleep efficiency value of 92.2% for these samples. Whereas these findings suggest either efficiency requirement could be employed, it should be noted that the value of 85% has commonly been regarded as normal in the insomnia literature.[194] Therefore, use of this more lenient cutoff may represent a more practical requirement for defining paradoxical insomnia.

A final consideration regarding definition of this insomnia subtype pertains to the observed mismatch between the patient's reported and recorded sleep. The studies reviewed used several different strategies to attempt to operationalize this discrepancy. One strategy required pathologically high values of SOL or WASO derived from self-report or sleep logs in subjects who show "normal" PSG measures of these parameters. Another strategy required subjects to overestimate SOL or underestimate TST by a pre-determined degree. For example, Dorsey and Bootzin[56] assigned SSM diagnoses to those who overestimated PSG determined SOL by 150% or more. However, the articles reviewed showed no consistent strategy for operationalizing this mismatch. As such, ascertaining complaints of insomnia and/or pathologic values of SOL or WASO on sleep logs in individuals who meet the above described PSG criteria may represent the most pragmatic approach for identification of paradoxical insomnia at this juncture. The RDC shown for this condition assimilate these various considerations.

Idiopathic Insomnia: This condition represents a third ICSD subtype that generally may be subsumed within the global DSM category of primary insomnia. Whereas the WG found few articles that included samples of COI, these articles provided some guidance in the development of RDC. Figure 2c shows that use of published diagnostic criteria, duration criteria, ascertainment of specific insomnia symptoms (e.g., onset, maintenance, or quality complaint), and PSG findings appear to be the most prominent selection criteria used. Included among the published criteria set is the requirement of childhood onset. The articles reviewed all included adult samples. As such, the duration criteria used in this limited number of studies appeared designed to assure a childhood onset, and one[82] of these articles specifically required an insomnia onset before age 10. Although ICSD criteria allowed the presence of comorbid sleep disorders, the few articles reviewed used PSG to exclude patients with sleep disorders such as sleep apnea and periodic limb movements.

Figure 2c shows exclusions for medications and psychiatric conditions were infrequently employed, but more attention was given to exclusions for medical conditions. ICSD criteria allow for coexisting medical and psychiatric conditions and provide no exclusionary criteria for current medication use or use/abuse of substances. However, these criteria state, " No medical or mental disease can explain the early onset of insomnia." On the basis of WG findings and published criteria the RDC shown here are offered for COI.

Research Diagnostic Criteria for Paradoxical Insomnia

A. The individual meets criteria for insomnia disorder.
B. The insomnia noted in A has been present for at least one month.
C. Nocturnal polysomnography shows a sleep time ≥ 6fi hours and a sleep efficiency ≥ 85%.
D. One or more of the following applies:
   1. The individual reports a chronic pattern of little or no sleep most nights with rare nights during which relatively normal amounts of sleep are obtained.
   2. Sleep log data during one or more weeks of monitoring show an average sleep time well below published age-adjusted normative values, often with no sleep at all indicated for several nights per week. Typically there is an absence of daytime naps following such nights.
   3. The individual shows a consistent, marked mismatch between objective findings from polysomnography and subjective sleep estimates.
E. The daytime impairment reported is consistent with that reported by other insomnia subtypes, but it is much less severe than expected given the extreme level of sleep deprivation reported. There is no report of intrusive daytime sleep episodes, disorientation, or serious mishaps due to marked loss of alertness/vigilance.
F. One of the following applies:
   1. There is no current or past mental disorder.
   2. There is a current or past mental disorder, but the temporal course of the insomnia shows some independence from the temporal course of the mental condition.
G. One of the following applies:
   1. There is no current or past sleep-disruptive medical condition.
   2. There is a current or past sleep-disruptive medical condition, but the temporal course of the insomnia shows some independence from the temporal course of the medical condition.
H. The insomnia cannot be attributed solely to another primary sleep disorder (e.g., sleep apnea, narcolepsy, or parasomnia) or to an unusual sleep/wake schedule or circadian rhythm disorder.
I. The insomnia cannot be attributed to a pattern of substance abuse or to use or withdrawal of psychoactive medications.

Insomnia Related to PLMD: This condition is specific to the ICSD system; no specific analogous diagnosis is included in the DSM system. The WG found a number of studies containing individuals whose insomnia was attributed to PLMD. It is recognized that there is an unresolved debate[120] as to whether periodic limb movements are a cause of insomnia or merely an epiphenomenon of sleep disruption or insomnia *per se*. Since further research to clarify the clinical usefulness of this diagnosis is needed to resolve this controversy, RDC for this condition would currently seem useful.

Figure 2c shows that PSG findings and a specific insomnia complaint were the two most common definitional criteria in the articles reviewed. In fact, these two selection criteria were cited more commonly for subject selection than were specific diagnos-

tic criteria. Admittedly this finding is, in part, artifactual because only articles that specifically linked a finding of PLMD and insomnia were selected for review. Nonetheless, these two components may indicate the most salient features of this condition in that Figure 2c shows relative infrequent use of the remaining selection criteria. However, it should be noted that the ICSD criteria exclude medical disorders, mental conditions and coexisting sleep disorders as explanations for presenting complaint.

Research Diagnostic Criteria for Idiopathic (Childhood Onset) Insomnia

A. The individual meets the criteria for insomnia disorder.
B. The insomnia noted in A began during childhood (i.e., before age 10) without an identifiable precipitant.
C. The insomnia has been persistent and unrelenting since its onset.
D. One of the following applies:
   1. There is no current or past mental disorder.
   2. There is a current or past mental disorder, but the temporal course of the insomnia shows some independence from the temporal course of the mental condition.
E. One of the following applies:
   1. There is no current or past sleep-disruptive medical condition.
   2. There is a current or past sleep-disruptive medical condition, but the temporal course of the insomnia shows some independence from the temporal course of the medical condition.
F. The insomnia cannot be attributed solely to another primary sleep disorder (e.g., sleep apnea, narcolepsy, or parasomnia) or to an unusual sleep/wake schedule or circadian rhythm disorder.
G. The insomnia cannot be attributed to a pattern of substance abuse or to use or withdrawal of psychoactive medications.

PLMD should be clearly distinguished from restless legs syndrome (RLS), which is itself a very common cause of insomnia. Periodic limb movements of sleep (PLMS) accompany RLS in the majority of patients, but by definition the term PLMD is only used in ICSD-2 when RLS is not present. In the past, confusion between RLS, PLMS and PLMD have led to difficulty in assessing the inclusion criteria of many research studies.

Individuals with Insomnia Related to PLMD have been identified primarily by specific PSG indices of periodic limb movement activity. Methods for quantifying this activity in the articles reviewed typically refer to the method originally suggested by Coleman.[52] The ICSD requires a rate of 5 PLMs per hour of sleep for a diagnosis of PLMD. The updated ICSD-2 requires a rate of 5 PLMs per hour in children and, in most adult cases, a rate of 15 per hour, but cautions that the PLMS rate must be interpreted in the context of a patient's sleep-related complaint. A review of the 14 articles that included PLMD samples showed specific mention of a 5 PLMs per hour cutoff in four articles, whereas no specific PLM criterion was reported in the remaining articles. Recognizing that there is not adequate data to establish any absolute cut-off for PLMS rate, and in order to assure some consistency in future PLMD studies, a minimum of 5 PLMS per hour in children and 15 PLMS per hour in adults has been included as a minimum criterion in the following RDC for insomnia related to PLMD.

Research Diagnostic Criteria for Insomnia Related to Periodic Limb Movement Disorder

A. The individual meets criteria for insomnia disorder.
B. Polysomnographic monitoring shows stereotyped limb movements that:
   1. are one half second to 5 seconds in duration,
   2. are of amplitude greater than or equal to 25% of toe dorsiflexion during calibration,
   3. occur in a sequence of four or more movements, and
   4. are separated by more than five seconds and less than 90 seconds.
C. The PLMS Index based on the scoring criteria in B exceeds five per hour in children and 15 per hour in most adult cases.
D. Other coexisting sleep disorders, including RLS, cannot account either for the insomnia noted in A or the PLM activity.

Insomnia Related to Sleep Apnea: Both the DSM and ICSD systems suggest insomnia may be attributable to sleep disordered breathing. However, the extent to which IA represents a useful clinical diagnosis has been debated. Some[105] have argued that sleep apnea is a common occult cause of insomnia complaints, whereas others[195] report that insomnia arising from sleep apnea is relatively uncommon. Since this controversy remains unresolved, RDC to allow further study the utility of this diagnosis seem warranted.

As was the case for PLMD-related insomnia, articles selected for review concerning this condition were chosen because they specified a presence of both insomnia and sleep apnea in the subjects described. Many articles included samples of apnea sufferers, but these had to be excluded because they were composed primarily of hypersomnolent individuals. As a result of our selection process, Figure 2c shows that PSG findings and insomnia symptoms were the two universally used criteria for the few samples representing this subtype considered. However, the published DSM and ICSD criteria and the findings shown in Figure 2c suggest that other selection criteria are important in defining this subtype.

Unfortunately the PSG definitional criteria for IA were not consistently defined in the studies considered. Only five articles specifically examined insomnia in the context of sleep apnea, and several of these were case reports published prior to 1980. One such paper[77] suggests the use of a minimum of "30 apneic episodes per recording night"; this index appears very crude by the recent consensus apnea definition.[14] A more recent paper[173] used a respiratory disturbance index (RDI) of $\geq$10 apneas + hypopneas per hour of sleep in selected apnea sufferers from a group of individuals with insomnia complaints, but required an RDI < 5 to identify insomnia sufferers with no apnea. It seems noteworthy that an RDI = 5 is the minimum RDI listed in the ICSD and updated ICSD-2 diagnostic criteria for sleep apnea. Given the limited articles devoted to this insomnia subtype and the lack of consensus regarding an RDI cutoff, this currently may represent the best consensual criterion to use for identifying Insomnia Related to Sleep Apnea. Hence, this RDI criterion is included in the following RDC set proposed.

Research Diagnostic Criteria for Insomnia Related to Sleep Apnea.

A. The individual meets criteria for insomnia disorder.
B. Nocturnal polysomnographic recording shows ≥ 5 respiratory events that meet current definitional criteria for apneas, hypopneas or respiratory effort-related arousals per hour of sleep.
C. Sleep-disruptive medical conditions, mental disorders, and any coexisting sleep disorders can not totally account for the insomnia noted in A.

Other insomnia subtypes: The literature provided little information about other specific insomnia subtypes. Both the DSM-IV and ICSD texts provide diagnoses for insomnias resulting from a medical disorder and insomnias related to substance use/abuse. The more recent DSM and ICSD-2 texts delineate global diagnoses for labeling these two conditions. Hence, additional RDC appear warranted for these global insomnia diagnoses.

Although WG members reviewed many articles concerning the study of sleep in various medical conditions (e.g., Parkinson's Disease, chronic pain), these studies characteristically failed to confirm the presence of insomnia complaints in the samples examined. Similarly, many studies of sleep disturbance related to substance abuse/exposure were found but, once again, these studies failed to document coincident insomnia complaints. Nonetheless, the WG consensus supports the notion that both medical conditions and use of or exposure to certain substances may give rise to insomnia. To encourage studies of the reliability, validity, course, and treatment requirements of these conditions, the criteria sets shown here are offered as provisional RDC for these disorders.

Insomnia due to Medical Condition

A. The individual meets criteria for insomnia disorder.
B. The insomnia is present for at least one month.
C. There is an association between the insomnia and a co-existing medical disorder as reflected by both of the following:
   1 The onset of the insomnia coincides with the onset of the associated medical disorder.
   2 The temporal course of the insomnia coincides with the temporal course of the medical disorder.
   (Note: Researchers should identify the specific medical disorder(s) causing the insomnia)
D. The insomnia is either the sole complaint or is sufficiently severe to warrant separate clinical attention.
E. One of the following two conditions applies:
   1. There is no current or past sleep-disruptive mental condition.
   2. There is a current or past sleep-disruptive mental condition, but the temporal course of the insomnia shows some independence from the temporal course of this mental condition.
F. The insomnia cannot be attributed exclusively to another primary sleep disorder (e.g., sleep apnea, narcolepsy, or parasomnia) or to an unusual sleep/wake schedule or circadian rhythm disorder.
G. The insomnia cannot be attributed to substance abuse or to use or withdrawal of psychoactive medications.

Insomnia due to Drug or Substance

A. The individual meets criteria for insomnia disorder.
B. The insomnia is present for at least one month.
C. One of the following applies:
   1. There is current ongoing dependence on or abuse of a drug or substance known to have sleep-disruptive properties either during periods of use/intoxication or during periods of withdrawal; or

   2. The patient has current ongoing use of or exposure to a medication, food, or toxin known to have sleep-disruptive properties in susceptible individuals.
D. There is an association between the insomnia and substance use/abuse/exposure as reflected by both of the following:
   1. The onset of the insomnia coincides with the onset of the substance use/abuse/exposure or withdrawal.
   2. The temporal course of the insomnia coincides with the exposure to, use of, or withdrawal from the substance.
   (Note: Researchers should specify the substance and whether the insomnia occurs during intoxication, chronic use, or substance withdrawal.)
E. One of the following two conditions applies:
   1. There is no current or past sleep-disruptive mental condition.
   2. There is a current or past sleep-disruptive mental condition, but the temporal course of the insomnia shows some independence from the temporal course of this mental condition.
F. One of the following two conditions applies:
   1. There is no current or past sleep-disruptive medical disorder.
   2. There is a current or past sleep-disruptive medical disorder, but the temporal course of the insomnia shows some independence from the temporal course of the comorbid medical condition.
G. The insomnia cannot be attributed exclusively to another primary sleep disorder (e.g. sleep apnea, narcolepsy, or parasomnia) or to an unusual sleep/wake schedule or circadian rhythm disorder.

Normal Sleepers: Current diagnostic manuals provide no guidance for definition of normal sleeper controls. Nonetheless, normal controls are an essential part of research concerning insomnia subtypes. The data presented in Figure 1 highlight common research practice in regard to characterization of these individuals. These data show that exclusions for sleep-disruptive medical conditions, mental disorders, and psychoactive medications were used more frequently than other criteria. Less frequently, PSG findings, self-reported sleep estimates, and exclusions for specific sleep disorders or unusual sleep wake schedules/circadian disturbances, were considered in selecting normal samples. In addition, anecdotal information from a majority of the articles suggested that a lack of any current sleep complaint represents a defining criterion for such samples. Based on these observations the RDC shown are offered as universal criteria for identifying normal sleepers for insomnia research.

Research Diagnostic Criteria for Normal Sleepers (Controls)

A. The individual has no complaints of sleep disturbance or daytime symptoms attributable to unsatisfactory sleep.
B. The individual has a routine standard sleep/wake schedule characterized by regular bedtimes and rising times.
C. There is no evidence of a sleep-disruptive medical or mental disorder.
D. There is no evidence of sleep disruption due to a substance exposure, use, abuse, or withdrawal.
E. There is no evidence of a primary sleep disorder.

Methods of Assessment

The final aim of this project was to propose specific methods for documenting the presence/absence of the RDC among patients/subjects to which they are applied. The findings summarized in Figures 1 and 2 as well as procedural information provided in the articles reviewed provide ample guidance for addressing this aim. Considering this information along with the precision required by the internal and external validity demands of the research venue, the WG offers the following methodological guidelines for insomnia RDC ascertainment.

Interview Assessment: Use of the clinical interview to ascertain insomnia symptoms and specific diagnoses was found to be a ubiquitous practice in the articles reviewed. In most instances, it appeared that findings and resulting opinions derived from a single interviewer using a standard clinic interview served as the basis of diagnostic ascertainment. Given the very modest inter-rater agreement found by Buysse et al.[12] (Table 2) for discerning global insomnia diagnoses by this method, it is clear that more reliable interview methods are desirable for the research setting. Specifically, reliable interview methods that assure consistent RDC ascertainment across clinicians and settings are needed to standardize insomnia research.

In this regard, the WG was able to identify two promising approaches. The first method, derived from those studies listed in Table 2, is that of using independent interviewers to ascertain the presence of insomnia RDC in prospective research candidates. One manner of applying this approach would be to select only those study subjects who, in the mutual opinion of independent interviewers, meet RDC for the insomnia diagnosis of interest. Alternately, a researcher could choose to demonstrate high inter-rater reliability between two or more interviewers during subject screening for the insomnia RDC in question. Use of this latter alternative would require that only a randomly selected subset of study enrollees are used to test reliability for RDC. A second method would involve the use of structured interview methodology to assure that standardized interview questions targeting essential diagnostic information are administered consistently across research candidates. Examples of this methodology are the Structured Interview for Sleep Disorders described by Schramm et al.[163] and the computer-driven Sleep Eval system described by Ohayon et al.[138] Although neither of these instruments is specifically structured to ascertain the RDC provided herein, they serve as models for the development of an instrument for reliable assessment of these criteria sets.

Polysomnography: The RDC for such subtypes as SSM, IA and PLMD require specific information from polysomnographic (PSG) recording. The WG found that PSG was often used in studies of other insomnia subtypes to rule out the presence of occult primary sleep disorders. Although PSG is not considered essential for the clinical assessment of insomnia[196], its use in establishing the insomnia RDC presented herein seems desirable. Thus, the WG recommends incorporating at least a single night of PSG into the screening process to ascertain insomnia RDC using established methods for sleep staging and event scoring.[197-200]

Sleep Diaries/Logs: Sleep diaries or logs were used sparingly in the studies reviewed for this project. In fact, only in the case of paradoxical insomnia/sleep state misperception were sleep diaries/logs used commonly, most often to assess the degree of mismatch between subjective and objective sleep measures. In such comparisons, there appeared to be no well accepted standard for confirming the diagnosis, but there seems to be some consensus that ascertaining markedly inaccurate estimates of sleep through logs or diaries is useful. The WG also recognizes the reputed[201] usefulness of sleep logs or diaries for the assessment of insomnia complaints *per se*. As such, they are considered useful in helping to establish the presence of an insomnia disorder in general. However, their usefulness for ascertaining RDC for many of the subtypes discussed will require further exploration.

Other Assessment Procedures: The WG review identified a number of additional objective and subjective measures used to assess and compare insomnia subtypes. Among the objective measures were assessments of sleep/wake motor activity (actigraphy), heart-rate variability, metabolic rate, and melatonin levels. Subjective measures were derived from both widely used and relatively obscure personality/mood questionnaires. Whereas all of these measures may provide useful information about insomnia subtypes, their utility for differentiation of insomnia subtypes has yet to be established. Thus, such additional instruments have not been included as requirements for RDC assessment.

DISCUSSION

The scientific literature includes thousands of articles concerning insomnia. Nonetheless, results of the WG's targeted literature review showed a paltry amount of research providing support of the insomnia diagnoses included in past and current sleep disorders nosologies.[4-7, 27, 29, 189] There have been astonishingly few studies designed to assess the reliability of any of these diagnostic categories, and no reliability information is available for many of the insomnia subtypes delineated in the most recent DSM[6] and ICSD[28, 189] manuals. The number of studies supporting the validity of such subtypes is, at best, only slightly more encouraging. Such findings not only make the development of research diagnostic criteria difficult, but also call into question much of the body of literature devoted to insomnia in general. Clearly, much more attention needs to be devoted to confirming the reliability and validity of the insomnia subtypes our nosologies describe if the field is to move forward.

The RDC proposed are not intended to limit the clinical assessment of insomnia patients, and we acknowledge that alternative approaches may be preferable to the RDC in non-research settings. However, the insomnia RDC should be regarded as a starting point for improving insomnia research and documenting

whether currently recognized methods of insomnia classification are optimal or need change. These RDC hopefully will discourage additional studies of poorly characterized insomnia samples that provide us little insight into the pathology and specific treatment needs of the distinctive subtypes commonly encountered in clinical venues. Furthermore, these RDC should help standardize insomnia research and facilitate the reliability and validity studies that are so sorely needed to determine if an alternate insomnia classification system may be desirable. However, the RDC should not be regarded as eternally fixed definitions. They represent initial efforts toward standardizing insomnia research, but they may undergo refinements as a function of both the degree to which they prove useful and the findings of future insomnia research.

To assist with future revisions/improvements in these preliminary RDC, it is recommended that insomnia researchers consistently report the following information in their published studies:

- The methods of recruitment (media announcements vs. clinical contacts) and types of individuals (research volunteers vs. clinical patients) enrolled in the study.
- Means, standard deviations, and ranges of common sleep measures such as total sleep time (TST), sleep onset latency (SOL), wake time after sleep onset (WASO), and sleep efficiency for each diagnostic group included in the study sample as well as any quantitative cutoffs (e.g., onset latency > 30 minutes) in such measures used for sample selection. When subjective sleep measures are reported, the source (e.g., sleep diary, questionnaire, clinical interview) of these data should be specified.
- The mean, standard deviation, and distribution of insomnia duration for each diagnostic group included in the study sample.
- The mean and distribution of insomnia frequency (number of nights per week of insomnia) for each diagnostic group in the study sample.
- Means and standard deviations of the discrepancies between subjective estimates and objective measures of TST, SOL, and WASO for samples of SSM and other diagnostic groups included in the study.
- Means and standard deviations of leg movement and respiratory disturbance indices for insomnia samples meeting RDC for insomnia related to PLMD or sleep apnea.

Researchers also are encouraged to assign applicable ICSD diagnoses (i.e., psychophysiologic, paradoxical, idiopathic insomnia subtypes) to study participants who meet RDC for primary insomnia and report frequency, duration, and quantitative sleep measures for each subtype separately. This information will help determine the utility of the ICSD subtypes over the more global primary insomnia diagnosis.

Admittedly, there are several limitations of the methodology used herein that should be considered. The literature reviewed excluded most insomnia treatment studies in which the efficacy of one or more insomnia therapies was evaluated with single insomnia subtypes. Such studies were excluded since they provided no useful empirical information (reliability/validity data) for addressing the aims of this RDC project. Nonetheless, the usefulness of the RDC proposed will need to be established for such studies if these criteria sets are to prove viable. It is also recognized that the literature review did not include relevant studies published after June 2000. Although the original time line for this project would have resulted in publication of this report at a time more proximal to that date, the complexity of the data collection and entry process delayed this final report. Since the WG considered insomnia literature published over a period exceeding 35 years, it is not likely that the most recent publications would have significantly altered the trends noted. Nevertheless, the findings reported should be considered in the context of the most recent insomnia literature. Finally, it should be noted that the proposed RDC are, in part, based on published evidence but also reflect consensus opinion of the WG panel of insomnia "experts." Whereas the limited informative literature obviated a purely evidence-based set of RDC, future refinements of these criteria sets hopefully will be made largely on empirical grounds.

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APPENDIX A: RDC WORKGROUP DATA EXTRACTION SHEET

RDC WORKGROUP DATA EXTRACTION SHEET: DIAGNOSTIC RELIABILITY

Citation	**Authors:**	
	Article Title:	
	Journal:	
	Year/Volume/Page #s	
Sample Selection	**Check the method(s) used in the column to the right**	
	Randomly selected community sample (e.g., random digit dialing method)	
	Series of consecutive clinic patients	
	Prospectively selected clinic patients (not necessarily all consecutive)	
	Physician (or other health provider) Referrals	
	Archival data such as a clinic data base	
	Solicited research volunteers	
	Other/specify:	
Inclusion Criteria Used in Addition to Specified Diagnostic Criteria	**List additional criteria here:**	
Study Setting (Circle)	Sleep Disorders Center/Clinic; Medical Center; Nursing Home; Mental Health Center; Private Medical Clinic; Univ. Psychology Clinic; Other/Specify:	
Types of Subjects (Circle)	Inpatients; Outpatients; Long-term Care; Other/specify; Research Volunteers	
Method of Reliability Assessment	**Check the method(s) used in the column to the right**	
	Independent blinded interviewers using structured interview	
	Independent blinded interviewers without structured interview	
	Independent judges viewing video interviews of patients	
	Independent judges reviewing audio recordings of patient interviews	
	Independent judges reviewing archival data (e.g. chart reviews)	
	Other/specify: None - Reliability was not assessed in this article	
Reliability Index Used	**Check those that apply** ___% agreement between/among raters ___Reliability Coefficient (correlation between/among raters) ___Kappa values ___Other/specify: None-Reliability not assessed	

Sample Characteristics: numbers and types of diagnoses / age, gender information	Number of subjects			Age	
Diagnostic Groups: List each separately	**Women**	**Men**	**Total**	**Mean**	**S.D.**
Totals:					

Study Results: Reliability Indices	**Insomnia Diagnostic Subtype**	**Reliability Index***

* Note: It is assumed that the reliability index value shown is this column is of the type indicated on the previous page. If not, please explain here.

RDC WORKGROUP DATA EXTRACTION SHEET: DIAGNOSTIC VALIDITY

Citation	**Authors:**	
	Article Title:	
	Journal:	
	Year/Volume/Page #s	
Sample Selection	**Check the method(s) used in the column to the right**	
	Randomly selected community sample (e.g., random digit dialing method)	
	Series of consecutive clinic patients	
	Prospectively selected clinic patients (not necessarily all consecutive)	
	Physician (or other health provider) Referrals	
	Archival data such as a clinic data base	
	Solicited research volunteers	
	Other/specify:	
Inclusion Criteria Used in Addition to Specified Diagnostic Criteria	**List additional criteria here:**	
Study Setting (Circle)	Sleep Disorders Center/Clinic; Mental Health Center; Other/Specify:	
	Medical Center; Private Medical Clinic	
	Nursing Home; Univ. Psychology Clinic	
Types of Subjects (Circle)	Inpatients; Long-term Care; Research Volunteers	
	Outpatients; Other/specify	
Types of Comparisons Conducted	**Check the types of comparisons in the column to the right**	
	Single Diagnostic Subtype with Normal Controls	
	Multiple Diagnostic Subtype with Normal Controls	
	Multiple Diagnostic Subtype with each other	
	Multiple Diagnostic Subtype with each other & with Normal Controls	
	Comparison of one or more subgroup with historic normative data	
	Other/specify:	
	None Conducted	
Measures Used in Making Comparisons	**Check those that apply**	
	Polysomnography R & K Measures	
	Polysomnography Spectral Measures	
	Actigraphy	
	Sleep Logs	
	Heart Rate Variability	
	MSLT Latencies	
	MMPI	
	Beck Depression Inventory	
	State Trait Anxiety Inventory	
	Gobal or Retrospective Questionaire: Specify	
	Other Psychometircs (specify):	
	Other – Specify	

Sample Characteristics: numbers and types of diagnoses / age, gender information		Number of subjects			**Age**	
	Diagnostic Groups: List each separately	**Women**	**Men**	**Total**	**Mean**	**S.D.**
	Totals:					

Results of Comparisons: Group Means, SD's and statistical differences

RDC WORKGROUP DATA EXTRACTION SHEET: DIAGNOSTIC VALIDITY *continued on next page.*

Comparative Measure	Diagnostic Groups and DSM-IV/ICSD Code #'s							
	(1)		(2)		(3)		(4)	
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
PSG/R&K								
SOL								
WASO								
TWT								
SE%								
TST								
TIB								
other								
PSG Spectral								
Actigraphy								
SOL								
WASO								
TWT								
SE%								
TST								
TIB								
other								
	Mean	SD	Mean	SD	Mean	SD	Mean	SD
Sleep Logs								
SOL								
WASO								
TWT								
SE%								
TST								
TIB								
quality								
Heart Rate Variability								
MSLT								
MMPI								
L								
F								
K								
1								
2								
3								
4								
5								
6								
7								
8								
9								
0								
Beck Depression COG/AFF Somatic Total								
State-Trait								
Anxiety								
State								
Trait								
Other Measures								
(List)								

In a few sentences, please provide a brief narrative summary of the study findings here.		
Bias to Internal Validity	**Check all that apply**	
	None - there are no biases	
	Patient/subject selection	
	Confounding factors	
	Measurement errors	
	Drop-outs	
	Non-Standardized Conditions of Measurement	
	Improper statistics	
	Insufficient power - n too small	
	Other - specify	
Bias to External Validity	Population and other issues - specify	
Should this study be included in our final diagnostic validity evidence table? Give reasons.		