EVALUATION OF A SLEEP DISORDERS SCREENING QUESTIONNAIRE FOR PRIMARY CARE OF ADULTS

by

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Table of Contents

Abstract

This dissertation, composed of three manuscripts, provides a foundation for sleep disorders screening in primary care. The first manuscript presents a concept analysis of sleep to guide nurses' understanding of how sleep impacts patients. The first manuscript is currently under review in the *Nursing Forum* journal. A framework for sleep disorders screening in primary care is presented, and followed by a systematic review of the literature to identify questionnaires that might be suitable to screen for sleep disorders in primary care. Several candidate questionnaires are identified, but none of those meet both thoroughness and brevity criteria postulated as necessary for use in primary care practices. The second manuscript is currently under review in *Sleep Medicine Reviews*. The third manuscript introduces the sleep disorders screening checklist (SDS-CL), previously used for research. The SDS-CL meets both thoroughness and brevity criteria but has not yet been validated for primary care application. Psychometric properties of the SDS-CL are evaluated with data from a sample of n=694 adults representative of the primary care population. Psychometric properties of the SDS-CL are favorable for primary care application. The third manuscript is currently being prepared for submission to a journal focusing on primary or preventive care medicine. Finally, future studies are recommended.

Introduction to Manuscript 1

While working as a research assistant on a study to verify the sleep questions of the CDC BRFSS the author became intrigued by the number of healthy study subjects who unknowingly had sleep disorders (30-50%), and wondered about how the disorders had escaped diagnosis and treatment. Sleep carried varying levels of importance to the study participants, from inconveniently necessary to decidedly essential. Manuscript 1 was written, therefore, to aid understanding of sleep as a general concept so that disordered sleep could be better understood, with an eye to how that understanding might guide preventive measures.

Sleep: A Concept Analysis to Guide Nurses' Understanding of their Sleeping Patients

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Abstract

Purpose. The purpose of this paper is to present a concept analysis of sleep to guide nurses' understanding of their sleeping patients.

Conclusions. Sleep is difficult to define or operationalize precisely in terms of easily observable nursing parameters. Patient self-reports of sleep are likely framed in terms of patients' values/expectations. In addition, some patients are unable to perceive their own sleep states.

Practice Implications. Thorough understanding of sleep as a concept enhances the use of already available sleep assessment tools. In addition, health and function outcomes may provide valid measures of effectiveness of patients' sleep. Non-disruptive sleep monitors may provide a solution to the clinical conundrum of needing to wake up sleeping patients to fully assess sleep. And, vigilant attention to sleeping patients is warranted due to patients' vulnerable breathing status and inability to sense surroundings during sleep.

Keywords: sleep, concept analysis, nursing

Almost nine years have elapsed since the Institute of Medicine published its report on the devastating effects of sleep problems (Institute of Medicine, 2006), yet inadequate sleep and sleep disorders continue to plague the health of individuals and society in the United States (American Academy of Sleep Medicine, 2014e; Centers for Disease Control and Prevention, 2014a; U.S. Department of Health and Human Services, 2014). Over the same timeframe, clinicians approaches to sleep disorders have transitioned from being considered secondary symptoms to being recognized as primary disorders requiring appropriate diagnosis and treatment, (American Academy of Sleep Medicine, 2014d; American Psychiatric Association, 2013; Perlis, Kloss, Ellis, & Riemann, In Press). While much is known about sleep cycle physiology (Kryger, Roth, & Dement, 2011) and sequellae of disordered/insufficient sleep (American Academy of Sleep Medicine, 2014e; Centers for Disease Control and Prevention, 2014a; Dinges, 2010; Institute of Medicine Committee on Sleep Medicine and Research, 2006) little has been written about sleep from the human response/nursing point of view. In addition, while one study reports that good sleep equates to sleep continuity (Akerstedt, Hume, Minors, & Waterhouse, 1994), little else is documented regarding what sleep means to people.

Nurses who understand sleep conceptually will recognize normal and disordered or disrupted sleep and respond accordingly. The purpose of this paper is to present a concept analysis of sleep to guide nurses' understanding of their sleeping patients; the method of Walker and Avant (1995) was utilized.

With the concept and purpose of analysis pinpointed, the concept analyses proceeds by: (a) identifying uses of the concept, (b) discerning defining attributes from the uses, (c) describing a model case, (d) describing additional cases (e.g., borderline, related, contrary, etc.), (e) ascertaining antecedents and consequences, and (f) defining empirical referents. The remaining

sections of this paper are organized around these steps, with steps (d) & (e) combined into a single section of example cases.

Usages and Definitions of the Concept of Sleep

Outside the broad base of sciences, sleep takes on a variety of connotations. For instance, in literature, sleep is often associated with dreaming and/or equated to death or escape. Dictionaries primarily define sleep biobehaviorally, e.g., "the unconscious state or condition regularly and naturally assumed by man and animals, during which the activity of the nervous system is almost or entirely suspended, and recuperation of its powers takes place; slumber, repose" (Oxford English Dictionary, 2014). Secondary definitions and synonyms equate"sleep" and "death", e.g. "regretfully put their terminally ill dog to *sleep*" and "a grieving widower longing to join his beloved wife in her eternal *sleep*" (Merriam-Webster Incorporated, 2014).

Within the sciences, sleep has been described as "a universal need of all higher life forms including humans, absence of which has serious physiological consequences" (Institute of Medicine, 2006) (p. 34). However, all people do not experience or contemplate sleep in the same way, nor do all disciplines that study sleep view it from the same vantage point. For example, anthropologists describe the way in which how, where, when, with whom, and how much people sleep are indicators of economic, spiritual, physical, hierarchical and other types of cultural status (Glaskin & Chenhall, 2013). Sociologists discuss sleep in terms of instituionalization/medicalisation and how society as a whole deals with the often inconvenient need of its members to sleep, along with implications of sleep in today's 24/7 society (Williams, 2013). One historian (Ekirch, 2006) chronicles how changes in sleep habits indicate occurance of world events and evolution of technology.

Health Sciences Usages

Various usages of sleep also exist within the medical and health sciences. Sleep is described as a biological process with biobehaviorial, neurological, and functional features. Biobehavioral features incorporate physiological processes (e.g., respiration, muscle tone, metabolism, etc.) as well as outward beahviors (e.g., movement, body postion, etc.)). Neurological features incoroporate senses such as touch, sight, hearing, taste, and smell. And functional features comprise capabilities that are restored during sleep (e.g., memory, focus, psychomotor vigilance, etc. In general, the gold standard for determining whether someone is asleep is the use of elecroencephalograms (EEGs) (American Academy of Sleep Medicine & Iber, 2007).

Health science – biobehavioral and neurological features of sleep. Biobehavioral and neurological definitions are relatively consistent across sources. Biobehavioral definitions generally encompass reversible inactivity. For example, NCBI U.S. National Library of Medicine (2014) defines sleep as "a readily reversible suspension of sensorimotor interaction with the environment, usually associated with recumbency and immobility"; Carskadon and Dement (2011) define sleep as "a reversible behavioral state of perceptual disengagement from and unresponsiveness to the environment" (p. 16); and Shaver (2011) describes sleep as "a neurobehavioral phenomenon in synchrony with wake such that brain functions, either emotional or physical, can disrupt sleep" (p. xv). Typically, when people are asleep they are recumbent with their eyes are closed. They also move very little, have little or no muscle tone, display limited response to sensory stimulations (Carskadon & Dement, 2005, 2011; Landis, 2011), and their breathing appears more restful/slow/rhythmic at sleep onset (Parmeggiani, 2005). Throughout the time asleep, breathing and eye movement patterns can change in association with

the various stages of sleep, generally categorized as REM (rapid eye movement) or NREM (non rapid eye movement) sleep.

Breathing, in particular, changes during sleep (both REM and NREM) in a way that makes respiration vulnerable (Chokroverty & Avidan, 2012). While awake, breathing is controlled both automatically and behaviorally. During wakefulness, there is normal muscle tone in the upper airway, diaphragm and intercostal muscles, and the body automatically responds quickly to increased carbon dioxide or decreased oxygen (hypoxia). However, while asleep, breathing is only controlled automatically (except perhaps during some part of REM sleep). During sleep, there is decreased muscle tone in the upper airway (greatly decreased during REM sleep), diapragm and intercostal muscles, and the body does not automatically respond as readily to changes in carbon dioxide and oxygen. As a result of decreased muscle tone, the upper airway narrows (thus increasing resistance to airflow), which can cause breathing to stop momentarily (apnea), with delay in awakening/breathing to compensate for associated hypoxia because of decreased automatic responsiveness to hypoxia during sleep. Thus, part of normal sleep can include four or fewer of these apneic events per hour, most likely during REM sleep or at sleep initiation.

In addition, sleep is said to comprise cycles and stages that typically repeat during sleep (American Academy of Sleep Medicine & Iber, 2007; Carskadon & Dement, 2005, 2011). Each sleep stage and cycle has characteric EEG wave forms and associated movement and body habitus profiles. Sleep is said to alternate with wake; i.e., being asleep is being not awake. Much of sleep science over the last several decades has focused on elucidating, defining, and refining the chacteristics that define the stages and cycles of sleep.

Sleep scientists have demonstrated that sleep can be objectively measured using a variety of sensors: with appropriate equipment, how long and how deeply people sleep can be ascertained. And, although individuals subjectively express the characteristics of their sleep, they may not always accurately perceive those features. For example, people with insomnia tend to underestimate their time asleep (American Academy of Sleep Medicine, 2014d; American Psychiatric Association, 2013).

Health science – functional features of sleep. The functional definitions remain variable. As Landis (2011) aptly states, "sleep is a biological necessity, but despite decades of research, the functions of sleep remain poorly understood" (p. 1). In general, all sources consulted during the process of writing this concept analysis indicated sleep has restorative functions, which were most often described by results of not-sleep. That is, functions that suffer when individuals do not sleep or sleep improperly were stated as being restored during sleep.

Infection resistance, hunger control, attention span, mood, and memory were among the many functions described in the health science literature as deteriorating without proper sleep. For example, extended sleep loss has been observed to lead to break-down of host defenses and disturbance of metabolic homeostatis, leading to death if left unchecked (Rechtschaffen & Bergmann, 2002; Siegel, 2005; Vassalli & Dijk, 2009). Levels of the appetite-supressant/satiety hormone leptin have been shown to rise during sleep and fall during sleep deprivation (Chaput, Després, Bouchard, & Tremblay, 2007), thus hunger and satiety (and, indirectly, body systems impacted by food intake) are also impacted by sleep. Insufficient sleep also leads to poor motivation, malaise, and decreased ability to perform simple tasks. And, those with severly restricted sleep tend to believe they are not tired and thus are over-confident in their abilities and attempt to peform tasks, such as driving, for which they are not alert enough (Van Dongen,

Maislin, Mullington, & Dinges, 2003). In addition, while the linkage between sleep and memory not yet fully understood, sleep has been shown to be a requirement for certain types of learning and memory formation (Diekelmann & Born, 2010; Peigneux & Smith, 2011).

Defining Attributes

Defining attributes are drawn from among the repeating and/or critical attributes found amongst the concept usages. Examining the usages described above for themes related to guiding nurses' understanding of their sleeping patients, several defining attributes arise. Note that themes associating sleep to death and escape (literary and dictionary usages) are not relevant to the purpose of this concept analysis and are therefore not considered to be defining attributes. First, sleep is temporary, one can awaken or be awoken from sleep. Second, being asleep is being not-awake; however, this attribute may require additional clarification, as the recognition of sleep-wake boundary may be imprecise. People of normal cognitive abilities will know when they have been asleep and subsequently awoken, but they will not realize they are sleeping when they are asleep; some people will not realize how long (or even if) they have been asleep when they awaken. During sleep, people do not interact sensorially with their environment; others should not be able to easily garner the sleeper's attention via visual, auditory, tactile, or olfactory cues. Others should be able to recognize that someone is asleep by observing body position/muscle tone as relaxed and mostly still, eyes as closed, and breathing as if at rest. However, breathing may be erratic if eyes are closed but moving rapidly. Sleeping people are able to breathe without assistance, although can stop breathing momentarily about once every 15 minutes. In addition, all living people sleep sometimes.

In summary, then, defining attributes of sleep are: sleep is temporary, the sleeping person will know that they have been asleep after waking, and the sleeping person does not

readily interact with sensory cues for their surroundings In addition, the sleeping person's body position is generally relaxed, their eyes are closed, and they are alive and breathing automatically.

Additional Defining Features of Sleep

Since part of the usages and definitions included additional features of sleep, those paragraphs can be analyzed as well for additional defining features of sleep.

For instance, it is possible for individuals and outside observers to suspect that sleep has been improper or insufficient when functions that are restored by sleep have deteriorated. Thus, a person who catches colds often, is unable to satisfy their food hunger, cannot focus or complete simple tasks, takes unnecessary risks driving while sleepy, or has difficulty learning or retaining information may be suspected as having problems with their sleep. However, absence of such characteristics does not indicate a person has been asleep. Thus, degradation of functions restored by sleep may be considered in assessing when sleep is disturbed or disordered, but cannot be considered as key attributes of sleep.

Likewise, although some of the contextual usages of sleep alluded to sleep occurring at nighttime or while recumbent, these features also cannot be considered as defining attributes of sleep. The location, position, clock time of sleep and number of intentional sleep sessions per day can depend on a variety of socio-cultural factors, as can be concluded from the anthropological, sociological, and historical resources. These sleep factors can vary according to individual and cultural values, social or economic status, societal and personal demands, and historical/geopolitical situations. While these are not key attributes as defined by Walker and Avant (1995), cultural, sociological and historical factors influence sleep and can therefore be

considered when determining whether sleep is "normal" and what might be manipulated via health-promoting interventions.

Comments on the Nature of Defining Attributes

Note that the defining attributes of sleep selected here are essentially behavioral and do not reference brainwave patterns or other biophysical measurements. This may lead to disfavor among some readers. However, such behavioral cues are observable and could, in general, be utilized by nurses to recognize sleep in a way that enables substandard or disordered sleep to be recognized.

Example Cases

An advantage of concept analyses is the associated translation of defining attributes into distinct practical case scenarios to further clarify the concept. Four case types relevant to this sleep concept analysis are: (a) model cases, which incorporate all key defining attributes, (b) contrary cases, which incorporate many defining attributes but lack at least one key attribute, (c) borderline cases, which may contain all key attributes of a concept but with at least one differing substantially from the norm, and (d) related cases, which contain some but not all of the key attributes and demonstrate how other concepts may overlap with the concept-of-interest (Walker & Avant, 1995). The fictional case scenarios shown in Table 1 illustrate how nurses can use observations of patients and their surroundings to guide assessment, follow-up, and conclusions regarding normal (model case) and disordered sleep (borderline case), along with differentiating between sleep and an overlapping concept such as sedation (related case). In addition, the similarity between sleep and death is illustrated (contrary case).

In the model case, we know the patient was sleeping in his chair because of the following: the condition was temporary - he eventually woke up; his body posture was relaxed

and mostly still and his eyes were closed; he had not been interacting sensorially with the environment (he initially did not respond when the nurse spoke to him); there was a boundary between sleep and wake (he jerked slightly and then spoke to his wife); he was then interacting sensorially with his environment (conversing with the nurse); he knew he had been awake and then fell asleep, and he is alive and breathing automatically.

In the contrary case (death), the patient's condition of being relaxed and unresponsive to the environment not temporary, thus violating one of the key attributes of sleep. In the borderline case (disordered sleep), the attribute of being sensorially detached from the environment is unclear (when the patient's wife first speaks to him, he responds incongruently with the stimulus – it is unclear whether he had been asleep because he may have been interacting with the environment). And, in the related case (sedation), the patient is not breathing automatically.

Antecedents and Consequences

Antecedents must occur before a concept and consequences must occur as outcomes of the concept; neither antecedents nor consequences can be attributes of the concept (Walker & Avant, 1995). For a concept such as sleep that naturally cycles with wake-ness, determination of antecedents and consequences presents particular difficulty: it would seem that the antecedents and consequence are almost identical. That is, the antecedents to sleep include being alive and having been awake, and the consequence of sleep is being alive and able to interact sensorially with one's environment for a finite period of time. In addition, the sleep-wake boundary - the exact moment of falling asleep - is also not readily detectable via current gold standard measurements (Carskadon & Dement, 2011).

Empirical Referents

Empirical referents are phenomena that demonstrate a concept. According to Walker and Avant (1995) "*They are the means by which you can recognize or measure the defining characteristics or attributes*" (p. 168, emphasis theirs) and should give clinical guidance regarding how to recognize the concept in individuals. Empirical referents can also form the basis of developing instruments to measure a concept, such as those mentioned in the introduction (Chasens & Umlauf, 2012; Hoey, Fulbrook, & Douglas, 2014; Richardson, Crow, Coghill, & Turnock, 2007; Ritmala-Castren, Axelin, Kiljunen, Sainio, & Leino-Kilpi, 2014).

Referents can be determined subjectively by soliciting an individual's feelings or objectively through clinicians' observations. For sleep, one challenge in obtaining subjective referents from patients is that they are unable to respond in-the-moment while they are sleeping. After waking, patients may be able to provide information about the quality (though perhaps not quantity) of their sleep. Objective non-patient-provided referents present similar challenges – nurses who have determined that an individual meets most of the key attributes (patient is alive, breathing independently, and not interacting sensorially with the environment) must verify that the condition is temporary by waking them up. Reliance on waking up patients to verify the transitory nature of an apparent sleep state presents a clinical conundrum: patients must be allowed to sleep in order to realize its associated restorative functions.

Clinicians might, however, assess sleep indirectly via its outcomes, for example, per the functional definitions of sleep described above. Another assessment strategy could be to determine how well individuals' sleep meets their own cultural, sociological, and historical expectations.

Conclusions and Implications for Nursing Practice

Sleep is universally experienced yet difficult to define or operationalize. However, the concept analysis presented can guide nurses' understanding of their sleeping patients, and facilitate recognition of normal and disordered or disrupted sleep. For example, although sleep is generally considered a set of biological processes, assessment of its normalcy and "goodness" will likely be influenced by individuals' expectations based on cultural, sociological, and historical perspectives. Self-report after waking may be the only way to obtain individuals' subjective assessment of sleep, since sleeping people are unable to interact with their environment. However, some individuals may be unable to accurately self-report on their sleep as subjectively perceived and objectively measured sleep do not always coincide. In addition, assessment of patient outcomes in areas such as metabolic health or ability to perform while awake wake may be the best way to assess of the effectiveness of sleep. And, finally, solving the conundrum of needing to wake up patients to determine sleep state or assess sleep quality may require technological solutions in the form of non-disruptive sleep monitors; usage of EEGs (the gold standard for measuring sleep states) might also be considered, although benefits of continuous EEG monitoring would need to be weighed against possible sleep disruption or expertise required interpret the signal.

Note also that some attributes of sleep put patients at-risk: decreased airway/diaphragm/intercostal muscle tone with decreased responsiveness to changes in carbon dioxide and oxygen and inability to sense possible dangers in the surroundings make sleeping patients particularly vulnerable. Therefore, vigilant attention to sleeping patients is warranted.

This analysis demonstrated the importance of understanding sleep within context of biophysical, sociological, and historic context, and provides a foundation on which nurses can

build their understanding of sleep in patient care. It has been illustrated that sleep is a physiological state that requires objective and subjective interpretation to determine its effectiveness and state of normalcy. In assessing patients' sleep via self-reports, specific tools or by their own judgment, awareness of the conceptual meaning of sleep will enable a holistic recognition of sleep.

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Table 1: Sleep concept case scenarios with key observations, follow-up, and conclusions

Concept case type with scenario (all cases are fictional)	**Key observations, follow-up, and conclusions**
Model. A homecare nurse enters patient's living room. The patient is relaxed in a reclining chair with eyes closed; the television is on. The nurse calls to the patient and he does not respond. His wife says, "oh, I hope he's ok" and then firmly taps the patient on the arm. The patient jerks slightly, makes a single snoring-like noise and then says "what??" The nurse says, "Hi Mr. Smith, it's the nurse. I'm here to change that dressing." The patient looks at the nurse and says, "Oh, I must have fallen asleep during the morning newscast. Go ahead."	*Observations*: patient looks relaxed, is alive and breathing, not interacting with environment, can be woken up, knew he had been asleep *Follow-up*: no immediate action required *Conclusion*: sleep
Contrary. A homecare nurse enters patient's living room. The patient is relaxed in a reclining chair with eyes closed; the television is on. The nurse calls to the patient and he does not respond. His wife says, "Oh, he was just watching the news and must have dozed off". She then firmly taps the patient on the arm. The patient's head tips to the side and his wife taps his arm harder, but the patient does not respond. The nurse listens to the patient's heart and lungs for two full minutes, finds no heartbeat or breath sounds. The patient has a do-not-resuscitate order, thus the nurse does not perform CPR.	*Observations*: patient looks relaxed, not interacting with environment, cannot be woken up *Follow-up*: assess vital signs *Conclusion*: death
Borderline. A homecare nurse enters patient's living room. The patient is relaxed in a reclining chair with eyes closed; the television is on. She calls to the patient who does not respond. His wife says, "He was just watching the news and must have dozed off". She taps the patient on the shoulder and says, "Honey, the nurse is here." The patient babbles and reaches up as if for a cup of water. His wife says, "Oh dear, he's doing it again." The nurse walks over to the patient and says loudly, "Hi Mr. Smith, it's the nurse. I'm here to change that dressing." The patient says, "Oh, I must have been asleep, the supplies are over there."	*Observations*: patient looks relaxed, is alive and breathing, IS interacting with environment, can be woken up with some difficulty, knew he had been asleep *Follow-up*: assess for sleep disorders *Conclusion:* disordered sleep
Related. Mr. Smith is in surgical recovery. His wife is pleased to see him lying peacefully with his eyes closed and breathing steadily. She is distraught because he doesn't seem to hear her voice and doesn't squeeze back when she squeezes his hand, although he does twitch after she pinches him on the arm. She notices there is a pump labelled "opioid" attached to Mr. Smith's infusion line, and wonders why he has a mouth tube attached to some sort of large machine to which the nurse is paying very careful attention. She is worried and asks the nurse if they think Mr. Smith is going to die. The nurse reassures Mrs. Smith that Mr. Smith is fine and following a normal course of recovery from his surgery.	*Observations*: patient looks relaxed, not interacting with environment, breathing only with ventilator assistance *Follow-up*: monitor ventilator and response to opioids *Conclusion*: sedation

Theoretical Frameworks for the Literature Review

Two theories guided the literature review, one that addresses the workflow in primary care practices and another that emphasizes the outcomes of untreated sleep disorders. In combination, the two theories lend credence to the idea that if adverse outcomes of undetected/untreated sleep disorders are well-documented and well-understood, and a quick, thorough, accurate tool were available for screening, then primary care providers would be more likely to adopt and implement sleep disorder screening.

Primary (Preventive) Care Model

The "Competing Demands Model" presented by Jaen, Stange, and Nutting (1994) illustrates how the provider, the patient, and the practice environment interact to affect a physician's delivery of preventive care services (Figure 1). Physician factors include knowledge, attitudes, and lack of time while practice environment factors include involvement of allied health personnel (such as nurses). In discussing the Competing Demands model, Jaen et al. (1994) also describe how physicians' attitudes about behavior change (i.e., probability of implementing care) are in turn influenced by a combination of expectations that the action will cause a certain outcome and expectations that they can effectively deliver the action, as predicted by Bandura's social learning theory (Bandura, 2004).

Within the realm of sleep disorders screening, then, the Competing Demands Model points to several critical issues. First, physicians (i.e., primary care providers, PCPs) must have knowledge that sleep disorders screening is necessary. Second, they must trust that there is a way to accurately screen for sleep disorders and that they can easily perform that screening. Third, whatever method is used to screen for sleep disorders must not take too much time. In addition, involving non-PCP personnel such as nurses or office staff in delivery of the sleep

disorders screening would facilitate implementation of the screening. While the framework does not illustrate follow-up and treatment, benefits of screening can only be realized if feasible, effective, tolerable treatments/interventions are available. The American Academy of Sleep Medicine (2014) provides standards of care for treatment of sleep disorders.

In addition to explaining the need for sleep disorders screening and availability of guidelines for follow-up to positive screens (affecting the Physician/knowledge component), validity of the screening tool could be described (affecting the Physician/attitude component), and the tool's brevity could also be shown (affecting the Physician/lack of time and Patient/lack of time components). Also, if the tool were a self-report questionnaire, nurses or office staff could facilitate the patients' completion of the questionnaire and provide tallied results to the PCP prior to the encounter (affecting both the Physician/lack of time and Practice Environment/allied personnel factors). Furthermore, getting screened for sleep disorders would likely raise patients' awareness of sleep-related issues, thereby affecting the Patient/knowledge factor and possibly the Patient/new complaints and Patient/demands factors. The combination of these effects would, according to the Competing Demands Model, drive the implementation of sleep disorders screening via the SDS-CL in primary care settings.

Sleep Disorders Framework

The interplay between insufficient sleep and adverse outcomes are well-represented graphically by the Conceptual Model of Impaired Sleep (Lee et al., 2004). The model (Figure 2) could serve as a framework for discussions with primary care providers regarding the impact of sleep disorders on health and safety. Presenting the information graphically as well as verbally would engage multiple senses and therefore facilitate providers' internalization of the effects of undetected/untreated sleep disorders. Knowledge of the potential adverse effects of sleep

disorders (coupled with knowledge of the prevalence of sleep disorders) would likely influence providers' attitudes regarding the need to screen.

Review Strategy Synthesized from Theories

A set of ideal criteria against which candidate tools would be assessed arose from a synthesis of these two theories. First, the ideal tool would be brief and require very little time from the provider. Patient self-report questionnaires were therefore selected as the tool type to be identified. The ideal questionnaire would be brief enough for patients to complete while in a waiting room, without extending normal waiting room time. Ideally, questionnaires would be easily scored and interpreted, so that providers could readily conclude whether follow-up were required.

Next, the questionnaire would need to be thorough and cover a standard set of sleep disorders, which may or may not be symptomatic, so that the myriad of potential adverse outcomes could be addressed. And results of the screening test would concur often enough with diagnostic gold standards to make its use meaningful. Provision of meaningful results would be assessed by psychometric properties of the tools: content validity (agreement with diagnostic criteria), construct validity (item grouping methods, internal consistency of subscales), and criterion-related validity (method used for cut-point determination, sensitivity/specificity).

Finally, the ideal tool would have been developed and tested with the types of individuals expected in adult primary care practices, e.g., the tool targets the general population (as opposed to groups with specific comorbidities), or the tool was tested over a range of age/gender (as opposed to, for example, only in young adults).

These ideal criteria are presented as Table 1 in Manuscript 2.

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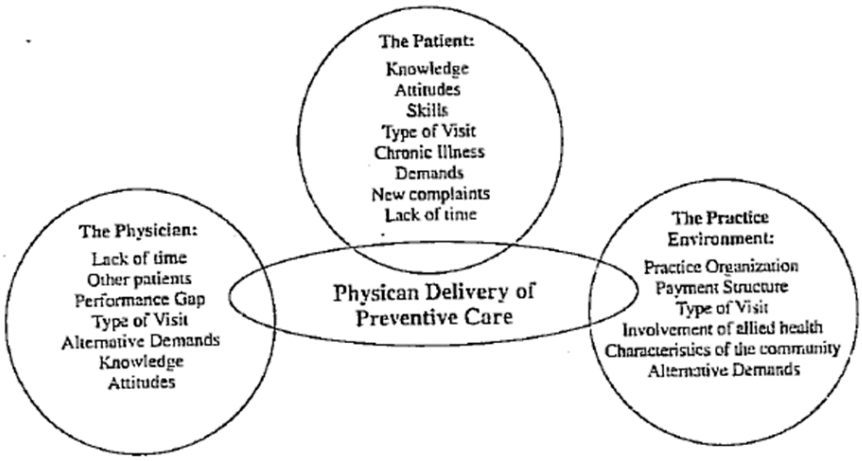

Figure 1: Competing Demands Model for preventive care
From Jaen et al. (1994)
Used with permission of the corresponding author

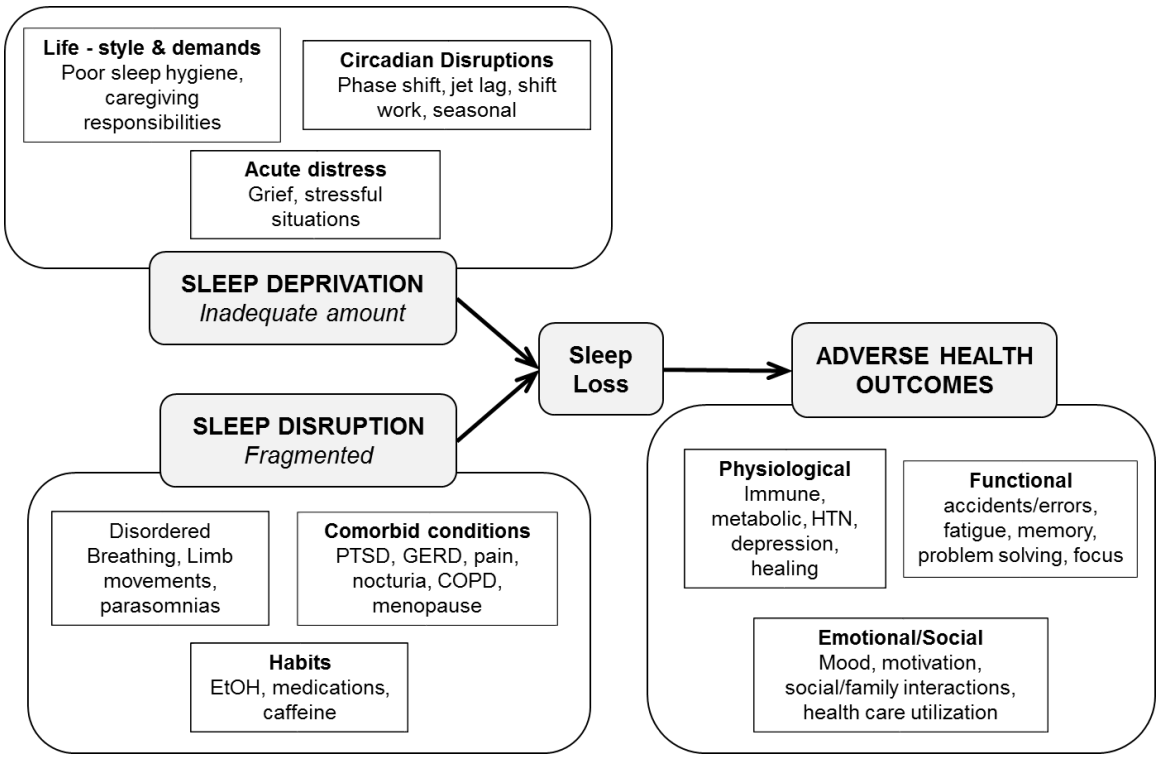

Figure 2: Conceptual Model of Impaired Sleep
Adapted from (Lee et al., 2004)

Introduction to Manuscript 2

With a conceptual understanding of sleep, and a framework for sleep disorders screening in primary care, a literature review was undertaken to identify whether a suitable patient self-report questionnaire to screen for all the intrinsic sleep disorders was available for testing in primary care practices. The version of Manuscript 2 incorporated here has been adapted to APA format from the version that was submitted to the Sleep Medicine Reviews journal.

Questionnaires that Screen for Sleep Disorders in Primary Care: A Qualitative Systematic Review of the Literature

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Abstract

The goal of this review is to identify existing sleep disorders questionnaires that screen for six of the primary sleep disorders (insomnia, sleep apnea, narcolepsy, restless legs syndrome, parasomnias, and circadian rhythm sleep wake disorders) and do so in a manner that is suitable for use in primary care practice. Suitability for primary care is defined by efficiency, thoroughness, and reliability. Efficiency is assessed via number of items and availability of cut-point scores, while thoroughness is assessed by number of sleep disorders covered. Reliability is assessed by features related to concept, construct, and criterion validity along with generalizability from study samples. To address this goal, a systematic review was conducted using both traditional databases and the "grey literature" (academic literature that is not formally published). Search terms were "sleep disorders, screening, questionnaires, and psychometrics". The scope of the search was limited to English language articles for adult age groups from 1989 through March 25, 2015. Articles describing sleep disorders screening questionnaire(s) that evaluate for three or more disorders were considered for the final analysis. Of the n=2756 articles identified, seven of the articles provided details on the development, validation and use of sleep disorders screening instruments. Qualitative and quantitative data are provided on these seven instruments. The evaluative part of this review concluded that three of the questionnaires met some of the criteria with respect to efficiency, thoroughness, and reliability. None met all three criteria. Of the existing instruments the GSAQ appears to be the single most efficient and thorough of the instruments identified. Additional work is required to enable primary care providers to comprehensively but efficiently screen their patients for primary sleep disorders.

Over the course of the last two decades, it has become increasingly clear that undiagnosed and untreated sleep disorders increase the individual's risk for new onset medical and psychiatric illness (American Academy of Sleep Medicine, 2014e; Daniel J. Buysse et al., 2010; Institute of Medicine, 2006; World Health Organization, 2007). This, in combination with the high prevalence of sleep disorders in the population (more than 40% by some estimates, e.g., Institute of Medicine, 2006) underscores the need for increased assessment of sleep disorders at the primary care level. While an increased exposure to sleep medicine during clinical training (both pre-professionally and as part of continuing professional education) would be an ideal way to address this issue, such curricular changes would be difficult to implement and take years, if not decades, to affect clinical practice. One alternative strategy is to provide primary care clinicians with simple screening tools. At present, there are a variety of single condition measures available (e.g., the ISI, the MAPI, the IRLS, etc.) and there are also several comprehensive assessment tools that have been developed (e.g., SDQ, DSISD, etc.). None of these tools, however, are short form self-report instruments that can be used within primary care practice to screen for the core intrinsic sleep disorders (insomnia, sleep apnea, narcolepsy, restless legs syndrome, parasomnias, and circadian rhythm sleep wake disorders). The purpose of this literature review is, therefore, to determine if there are validated instruments available that can be used in the primary care setting to screen adults for sleep/wake disturbances.

Methods

Literature was searched for articles describing questionnaires that screen for multiple sleep disorders in adults who might be seen by primary care providers. Articles that met the search inclusion criteria were then assessed for final analysis according to 15 criteria. The evaluation criteria comprise thoroughness, efficiency, reliability, and validity, as shown in Table

1 (basis and rationale for each of the proposed criteria are discussed later in this methods section). Each of the identified questionnaires was scored for number of criteria met.

Questionnaire / Article Identification Strategy

A review of the literature (Figure 1) was conducted using databases (MEDLINE, CINAHL, and HAPI) and "grey literature" (information presented in academic, government, foundation, and industry reports). The database search terms were: (a) sleep disorder AND diagnosis, (b) sleep disorder AND psychometric*, (c) sleep disorder AND questionnaire, (d) sleep disorder AND screen*, and (e) sleep disorder AND validation (where * indicates a wildcard to allow for multiple word endings). The search was restricted to English language articles for all adult age groups (ages 19+) from 1989 through March 25, 2015. Grey literature was searched for "sleep questionnaire" with both Google and Google Scholar. Additional sources for grey literature were the National Guideline Clearinghouse (search term "sleep disorder") (Agency for Healthcare Research and Quality, 2014), CDC NHANES webpages (question items related to sleep) (Centers for Disease Control and Prevention, 2014b), and the AASM website (search term "sleep disorder") (American Academy of Sleep Medicine, 2014a). Date of last search for grey literature was March 25, 2015.

Articles / questionnaires with studies that met the following criteria were included: (a) community-dwelling adults, (b) self-report questionnaire with responses interpreted numerically, and (d) screening was inclusive of at least four sleep disorders (see also note at bottom of Figure 1). To be considered for final analysis, questionnaires were credited with including restless legs syndrome if they covered any movement disorder, and were credited for including circadian rhythm sleep wake disorders if they covered any type of sleep phase disruption. Articles were excluded if the studies focused primarily on individuals with particular disease processes, or if

they described general guidelines, interview suggestions, or complex diagnostic algorithms without yielding numerical scores. Reference lists from included database articles were also scanned. Following review of this search strategy with a health sciences librarian, MeSH terms "sleep disorders", "sleep disorders, intrinsic", "sleep disorders, circadian rhythm", and "dyssomnias" were also searched using PubMed (Advanced Search Builder).

The resulting list of candidate questionnaires proposed for final analysis was then reviewed by two experts in the field of sleep questionnaires (see acknowledgements) to identify possibly-missed questionnaires.

Questionnaire /Article Assessment Criteria

For each of the final analysis questionnaires, sleep disorders covered, number of items and availability of cut-point scores for each sleep disorder was tabulated (lines 1 and 2 of Table 1). Maximum number of items was set to 25. The 25 item limit is based on two factors: (a) questionnaire completion of no more than 10 minutes based data that about half of the patients in one U.S. study reported waiting 15 minutes or less to see their provider (Anderson, Camacho, & Balkrishnan, 2007) , and (b) one author group's report that their 21 item questionnaire required 10 minutes to complete (Bailes et al., 2008) (and then adding an extra 20% to enable possibly including more questionnaires).

Content validity was assessed by comparison of questionnaires' content to diagnostic criteria as compiled from the "International classification of sleep disorders" (American Academy of Sleep Medicine, 2014d) (ICSD-3) (Table 2) for the six sleep disorders (insomnia, obstructive sleep apnea, narcolepsy, restless legs syndrome, parasomnias, circadian rhythm sleep wake disorders). If ICSD-3 was not in place at time a particular questionnaire was developed, the questionnaire was assessed against whatever diagnostic criteria were in place at time of

development, e.g., as ICSD-1 (Torphy, 1990) or DSM-IV (American Psychiatric Association, 2000). Aspects of content validity include item phrasing, response options, and question stem timespan (i.e., how much recent history respondents are to consider when answering the items) (Table 1, lines 3-6).

Construct validity was assessed by item grouping strategy, sample size utilized to check the item grouping, and use of gold standard diagnoses for determination of item grouping (Table 1, lines 7-9). These criteria were based on recommendations provided by COnsensus-based Standards for the selection of health Measurement Instruments [COSMIN] (COnsensus-based Standards for the selection of health Measurement INstruments, 2011).

Criterion-related validity was assessed by methods used to determine sleep-disorder status during the validation stage, method for determining cut-point scores, and whether sensitivity-specificity values were provided (Table 1, lines 10-13). Again, these criteria are based on COSMIN recommendations (COnsensus-based Standards for the selection of health Measurement INstruments, 2011).

Generalizability was assessed by comparing characteristics and method of selecting the samples utilized in determining cut-point scores (COnsensus-based Standards for the selection of health Measurement INstruments, 2011) (Table 1, lines 14-15). Randomly selected samples with mean age in the mid-40's with approximately equal numbers of males and females were considered to be generalizable.

Results

Questionnaire Identification

Of the n=2812 articles reviewed (n=2398 from databases and n=414 from grey literature), n=2805 were excluded and 7 full-text articles that met the inclusion/exclusion criteria were

analyzed (Figure 1). The expert consultants identified n=2 additional screening tools, but those did not cover 4 or more SDs and so were not considered in the final analysis. Results using the additional librarian-suggested MeSH terms with PubMed (Advanced Search Builder) yielded no new inclusion candidates; however, these numbers are not incorporated into the "n" values shown on Figure 1. Questionnaires that met the inclusion/exclusion criteria described in the search strategy methods section are: (a) Auckland Sleep Questionnaire (ASQ) (Arroll, Fernando, Falloon, Warman, & Goodyear-Smith, 2011), (b) Global Sleep Assessment Questionnaire (GSAQ) (Roth et al., 2002), (c) Holland Sleep Disorders Questionnaire (HSDQ (Kerkhof et al., 2013)) , (d) ISDI (Iowa Sleep Disturbances Inventory (ISDI (Koffel & Watson, 2010)) , (e) Sleep Disorders Questionnaire (SDQ) (Douglass et al., 1994), 6) SLEEP-50 (Spoormaker, Verbeek, van den Bout, & Klip, 2005), and (f) Sleep Symptom Checklist (SSC) (Bailes et al., 2008). Tables 3 - 5 summarize the results, as discussed below.

Thoroughness, Efficiency, Content Validity Results

One of the questionnaires (SLEEP-50 (Spoormaker et al., 2005)) covers all six of the sleep disorders but has more than 25 items, while two questionnaires (GSAQ (Roth et al., 2002) at 11 items and HSDQ (Kerkhof et al., 2013) at 32 items) cover five sleep disorders (Table 3). Three of the questionnaires provide clear cut-points for each subscale (SDQ (Douglass et al., 1994), HSDQ (Kerkhof et al., 2013), GSAQ (Roth et al., 2002)), while two of the questionnaires (ISDI (Koffel & Watson, 2010) & SSC (Bailes et al., 2008)) group sleep disorder symptoms into other factors and do not screen for sleep disorders specifically.

For six of the questionnaires, item content agrees with diagnostic criteria. Only two questionnaires (HSDQ (Kerkhof et al., 2013), SDQ [29]) cover a time span that encompasses at least the entire time span per diagnostic guidelines. The others either do not specify a timeframe

or they query patients about timespans that are shorter than recommended by diagnostic criteria. None of the articles, however, indicate rationale for selecting the time span over which respondents were to base their response choices.

Rationale for wording and number of scale divisions in the response choices was scarce. The yes/no choices for ISDI (Koffel & Watson, 2010) were used for speedy response and certain detection of infrequent symptoms (Koffel & Watson, 2010), the SDQ [29] responses were based on precedent (Douglass et al., 1994), and the SLEEP-50 responses did not specifically include frequencies because of concern for possibly confusing respondents (Spoormaker et al., 2005). None of the others described rationale for response choices or the number of scale divisions.

Methods for Item Grouping & Cut-point Determination and Provision of Sensitivity/Specificity

Factor analysis was utilized by five of the questionnaires (GSAQ) [27], HSDQ (Kerkhof et al., 2013), ISDI (Koffel & Watson, 2010), SLEEP-50 (Spoormaker et al., 2005), SSC (Bailes et al., 2008)) to check grouping of items for each of the subscales (Table 4). The preferred method (receiver operator characteristics curves) of determining cut-points was used by both HSDQ (Kerkhof et al., 2013) and SDQ [29]. All of the studies reported sensitivities and specificities for their covered sleep disorders based on their associated cut-points. Sensitivities for the four studies reporting results for groups with more than n=100 participants ranged from .65 to 1.0. Specificities for those same four studies ranged from .46 to .88. In addition, the GSAQ [27] reported sensitivity and specificity for "no disorder" as .92 and .56, respectively, with n=13 healthy controls (Roth et al., 2002).

Determination of Sleep Disorder Status

In general, sleep clinic protocols were utilized to verify positive screens for sleep disorders (Table 4). Most often, sleep clinic protocols incorporated the gold standard methods per Table 2. However, one study utilized only interviews by skilled practitioners to determine sleep disorder status, and most studies used interview-only to conclude that healthy controls were actually free of sleep disorders. The SDQ [29] study (Douglass et al., 1994) mentions that around 10% of their healthy controls underwent sleep clinic testing, but the rest did not.

Generalizability to Adults in Primary Care

Factors affecting generalizability to the adult primary care population had mixed results. Most of the samples (Table 4) were about half male with average age in the mid-40's. However, some of the sub-groups within the different studies ran on the low end of the adult age range, most likely due to recruitment of college students (Arroll et al., 2011; Koffel & Watson, 2010; Spoormaker et al., 2005). In addition, the sample selection method was most often purposeful. Only the GSAQ [27] study used random sampling for part of its cohort (Roth et al., 2002). The remainder of the samples were all recruited purposefully, from those known or highly suspected to have sleep disorders (sleep clinic patients or new sleep clinic referrals), and those known (or highly suspected) to be without sleep disorders based on researchers' prior experience with those individuals (Arroll et al., 2011; Bailes et al., 2008; Douglass et al., 1994; Kerkhof et al., 2013; Koffel & Watson, 2010; Spoormaker et al., 2005) .

Summary of Results versus Fifteen Assessment Criteria

None of the questionnaires meets all 15 of the assessment criteria (Table 5). (Note that the ISDI (Koffel & Watson, 2010) and SSC (Bailes et al., 2008) are absent from Table 5 - they were not specifically tested against sleep disorder diagnoses, as they were developed to

characterize individuals and not screen for sleep disorders. For this reason, the remainder of this paper focuses only on the ASQ (Arroll et al., 2011), GSAQ [27], HSDQ (Kerkhof et al., 2013), SDQ (Douglass et al., 1994), and SLEEP-50 (Spoormaker et al., 2005)).

Two questionnaires, HSDQ (Kerkhof et al., 2013) and SLEEP-50 (Spoormaker et al., 2005), meet about half of the ideal criteria but are deficient in two key features: number of items at 25 or fewer and generalizability to the adult primary care setting. In addition, they (along with the other questionnaires) lack validation in randomly-selected healthy adults and verification of controls' sleep health status with gold standard testing – casting doubt regarding applicability of these tools to detection of sleep disorders in adult primary care settings.

Failure to meet the other ideal criteria are less specifically related to the use in primary care of adults and more generally associated with content and criterion validity issues, as indicated in Table 5.

Discussion

Seven self-report questionnaires were identified as potential screening instruments for primary care practice. While none of these instruments were found to be efficient, thorough, and reliable, three of the questionnaires were relatively thorough and one was efficient. With respect to thoroughness, the SLEEP-50 (Spoormaker et al., 2005) covered all six intrinsic sleep disorders and the HSDQ (Kerkhof et al., 2013) and GSAQ (Roth et al., 2002) and covered five. With respect to efficiency, the SLEEP-50 (as the name denotes) was comprised of 50 items, the HSDQ was comprised of 32 items, and the GSAQ was comprised of 11 items. Thus, on balance, the GSAQ appears to be the single most thorough and efficient of the instruments identified.

Strengths and Limitations of the GSAQ

The primary strengths of the GSAQ, in addition to efficiency and thoroughness, is its physical layout and the effort to embrace factors that may predispose, precipitate, or perpetuate sleep disturbance (i.e., pain, medications, mood disturbance, etc.). The physical layout of the GSAQ is in many ways ideal because it: 1) is presented on a single page; 2) has a header that contains pertinent information regarding patient characteristics (e.g., age, sex, height and weight), work status, and work shift; 3) lays out symptom complaints within a grid that allows for easy patient response and clinician interpretation (i.e., the more check boxes on the right the more sleep disorders morbidity); and 4) arrays relevant symptomatology by row where each row corresponds to either a specific sleep disorder or the report of impaired daytime function. Finally, while the GSAQ does not cover all six of the intrinsic sleep disorders (narcolepsy is not assessed), it does evaluate (as noted above) for the existence of daytime impairment and insufficient sleep disorder (items 3 and 4).

The primary limitations of the GSAQ [27], given the present review criteria, are that 1) it does not allow for the detection of narcolepsy and 2) its reliability (content and construct validity) is less well developed than most of the other instruments (See table 5). With respect to narcolepsy, the omission of this sleep disorder from a primary care screener may have been (and may still be) viewed as less problematic based on the fact that narcolepsy is a rare disorder (estimated prevalence of 1/3000 (National Institute of Neurological Disorders and Stroke, 2015)). Thus, it need not be assessed by primary care practitioners. This said, the ramifications of not screening for an infrequently occurring disorder needs to be considered. Narcolepsy, while admittedly rare, has a profound impact on the health and wellbeing of the affected individual. The disease is associated with substantially altered daytime function (National Institute of

Neurological Disorders and Stroke, 2015; National Sleep Foundation, 2014b) and increased morbidity and mortality (National Institute of Neurological Disorders and Stroke, 2015; National Sleep Foundation, 2014b; M. M. Ohayon et al., 2014). Given that narcolepsy has significant consequences, the addition of two to four questions to screen for this disorder seems warranted.

Extending beyond the present criteria, the GSAQ has some significant untapped potential. First, the 4 item response selection is arrayed qualitatively (never, sometimes, usually, and always). While this has the advantage of having general universal meaning, the variance in interpretation between individuals may be problematic. More important than this, if the response selection were set to frequencies of clinical relevance, this would greatly aid in the determination of the clinical significance of the endorsement and provide one way to assess severity. For example if "never" was changed to "rarely", then each anchor could be defined semi-quantitatively where: "Rarely" refers to less than once a month, "Sometimes" refers to once every 2-4 weeks, "Usually" refers to weekly, and "Always" refers to more than 3 times per week. Extending the scale to a 5 item response could provide for the differentiation between 3 to 5 times per week and more than 5 times per week, allowing for a reasonable way of scaling symptom severity. Second. The item responses are not assigned numeric values. If zero to five numbering was used for each of the 4 responses, this would allow for a cumulative morbidity index. Third, the instrument was designed to take into account "the past four weeks". While this provides a very reasonable time frame for the estimation of what constitutes persistent symptomatology, it does not allow for the distinction between acute and chronic forms of the various sleep disorders. While not easily done within the given format, an additional check box per symptom regarding chronicity would allow clinicians to make judgments about whether recent life/health changes precipitated the observed sleep disorders symptom and/or about

whether or not to initiate, or to make a referral for, treatment (e.g., "This has been true for the last 3 or more months").

Given that the GSAQ represents the best possible screener available, dissemination of this instrument to primary care practice will likely provide clinicians the ability to engage in early detection and the initiation of treatment and intervention to prevent the adverse effects of untreated sleep disorders. Wide spread dissemination of the GSAQ, however, will need to be supplemented with the provision of treatment and/or specialist referral guidelines. Several resources for this purpose are readily available. The American Academy of Sleep Medicine (AASM) maintains an on-line "resource library" (American Academy of Sleep Medicine, 2014b), a PDF archive of practice guidelines regarding diagnosis, treatment, and follow-up for sleep disorders (American Academy of Sleep Medicine, 2014f), and dedicated search engine for the location of sleep centers (American Academy of Sleep Medicine, 2014c). Additionally, the Society of Behavioral Sleep Medicine maintains an on-line provider directory for individuals with insomnia or individuals who require or prefer behavioral interventions (Society of Behavioral Sleep Medicine, n.d.). Additional educational materials (patient information) may be found at web sites for the National Center on Sleep Disorders Research (NCSDR) (National Heart Lung and Blood Institue, n.d.), the National Sleep Foundation (NSF) (National Sleep Foundation, 2014c, n.d.) and National Institute of Neurological Disorders and Stroke (NINDS) (National Institute of Neurological Disorders and Stroke, 2014).

Limitations of this Review

The search strategy for identifying questionnaires may have limited scope of the results. Key items may have been missed by including only those articles written in English using three medical/nursing databases; grey literature items may also have been missed, e.g., by not

purposefully searching websites others may consider promising. Conclusions regarding validity may be limited by having only examined introductory articles, i.e., by not searching for all subsequent articles citing the introduction to determine whether subsequent studies had validated questionnaires for adult primary care populations.

Conclusion

While the GSAQ represents the best available screening tool for primary care practice, further development is needed to optimally meet the need for an efficient, thorough, and reliable screening instrument. Development should take into account the need for such an instrument (or instruments) to assess for the full complement of intrinsic sleep disorders (including insufficient sleep disorder), to provide scales that are anchored to clinically relevant frequencies, to allow for the temporal course of the presenting symptoms (i.e. at least the distinction between acute and chronic forms of the various sleep disorders), and to potentially allow for the quantification of cumulative sleep disorders morbidity.

Acknowledgments

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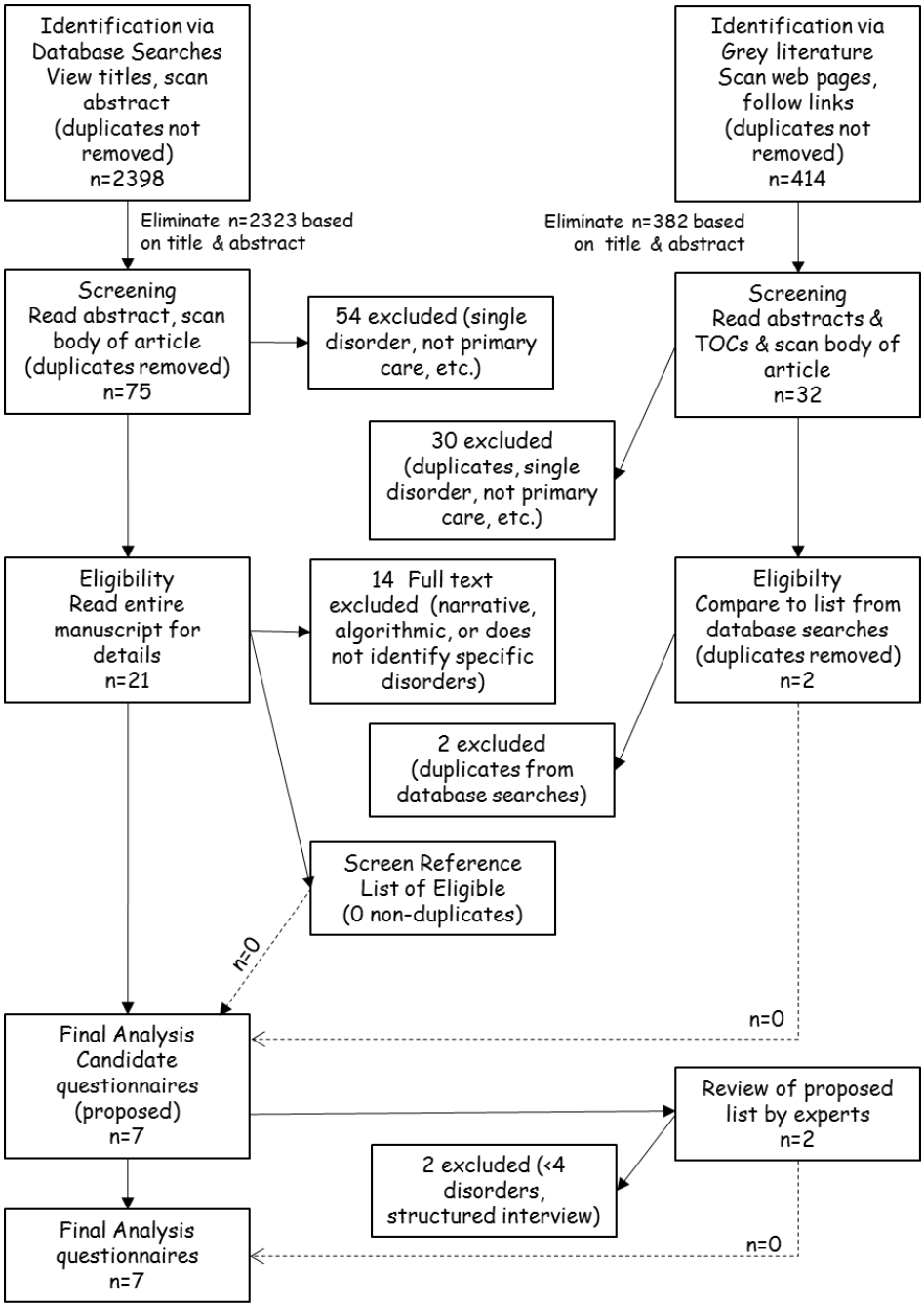
Figure 1: Sleep disorders screening questionnaire literature review strategy



Note: "articles" were counted according to the number of tools on which they reported (e.g., a reference that reported on three screening tools was tabulated as 3 "articles"). Grey literature sources were identified via Google Scholar, and (Agency for Healthcare Research and Quality, 2014; American Academy of Sleep Medicine, 2014a; Centers for Disease Control and Prevention, 2014b)

Table 1: Criteria and evaluation methods for assessing sleep disorders screening questionnaires

Criterion	Evaluation Method Each criterion scored as 1 if met, 0 if not met, for a total possible score is 15
Thorough	Covers 6 SDs (insomnia, obstructive sleep apnea, narcolepsy, restless legs syndrome, parasomnias, and CRSDs)
Efficient	No more than 25 items
Reliable (content and construct validity)	Item content corresponds to diagnostic criteria (for standards in place at time of questionnaire development)
	Response choices based on diagnostic criteria
	Time period covered encompasses diagnostic criteria
	Response choices justified diagnostically or statistically
	Item grouping verified by factor analysis (or multivariable regression) in sample with known SD diagnoses
	Known diagnoses based on gold standards
	Sample size at least 5/item for factor analysis (or multivariable regression)
Valid (criterion-related validity)	SD status verified against gold standard
	SD-free status verified by gold standard
	Cut-points based on receiver-operator curve
	Sensitivity and specificity given
Generalizable (to adult primary care patients)	Content validation sample demographics and non-SD health representative of primary care population
	Control sample of sufficient n randomly selected from target population

Abbreviations:
CRSDs - circadian rhythm sleep wake disorders; I - insomnia; N – narcolepsy; O – OSA; P – parasomnias; R – restless legs syndrome;
QoL – quality of life; SD – sleep disorder

Table 2: Sleep disorder diagnostic criteria compiled from (American Academy of Sleep Medicine, 2014d)

Sleep Disorder	Key Features	Timeframe	Methods
Insomnia (chronic insomnia disorder) (INS)	• Adequate opportunity & conditions for sleep; AND • At least one of: difficulty falling asleep, difficulty staying asleep, waking up earlier than would like; AND • Daytime impairment	• 3+ times per week; AND • 3+ months duration	Actigraphy compared to self-report sleep logs
Obstructive Sleep Apnea (OSA)	• AHI or resp event[a] = 15 or greater; AND/OR • AHI or resp event = 5 or greater; AND • At least one of: c/o insomnia, fatigue, daytime symptoms or sleep that is not refreshing; wakes holding breath, gasping, or choking; observer reports routine snoring and/or interrupted breathing; has dx of HTN, CAD, type 2 DM, or other from the list[b]	Not specified	PSG or OCST, observer interview
Narcolepsy Type 1 (NAR)	• Unable to prevent falling asleep during the daytime; AND • Cataplexy cluster[c] and/or bioassay (CSF hypocretin-1)	3+ months duration	PSG, CSF testing
Restless Legs Syndrome (RLS)	• Urge to move limbs (legs or arms, usually accompanied by unpleasant sensations) that is worse when inactive, is alleviated during intentional movement (e.g., walking), AND occurs almost exclusively in evening/night; AND • Movement urge not due to another known condition; AND • Movement urge causes sleep disturbance or other distress	Not specified	Self-report
Parasomnias (PAR)	• Episodes of incomplete awakening • Does not respond properly during episode • Does not remember episode • No other condition explains the episodes	Not specified	Observation, PSG to rule-out other disorders
Circadian Rhythm Sleep Disorders (CRSD)	• Body's sleep drive not aligned with required schedule • Insomnia symptoms and/or excessive sleepiness • Impairment	3+ months duration	Sleep log, actigraphy; PSG to rule-out other disorders

c/o - complains of; dx - diagnosis; AHI- apnea hypopnea index; CSF - cerebral spinal fluid; CAD - coronary artery disease; DM - diabetes mellitus; EEG - electroencephalography; HTN - hypertension; OCST - out of center sleep testing (usually without EEG); PSG - full channel polysomnographic sleep study; REM - rapid eye movement sleep

Notes:

a. resp event - obstructive respiratory events per hour, as measured by sleep study
b. mood disorder, cognitive dysfunction, stroke, congestive heart failure, atrial fibrillation
c. cataplexy - more than one two-minute or shorter period of sudden loss of muscle tone while remaining conscious that follow strong emotions; cataplexy cluster includes criteria regarding short sleep latency and immediate entry into REM sleep as determined from sleep studies

Table 3: Number of items, response options, covered sleep disorders, scoring methods, item basis and response timeframe for sleep disorders screening questionnaires identified by literature review

Questionnaire - Reference	# of Items: Responses	#SDs: SDs Covered	Scoring	Item Content Basis	Response Timeframe
ASQ (Auckland Sleep Questionnaire) - (Arroll et al., 2011)	30: yes/no	3: I, O, C	Algorithm based on pattern of yes/no	ICSD-1 (Torphy, 1990)	Last 2 weeks
GSAQ (Global Sleep Assessment Questionnaire) - (Roth et al., 2002)	11: 4[a]	5: I, O, R, P, C	Cutpoints provided for each SD	Expert opinion	Last 4 weeks
HSDQ (Holland Sleep Disorders Questionnaire) - (Kerkhof et al., 2013)	32: 5[b]	5: I, O, R, P, C	Cutpoints provided for each SD	ICSD-2 (American Academy of Sleep Medicine, 2005) six categories	Past 3 months
ISDI (Iowa Sleep Disturbances Inventory) - (Koffel & Watson, 2010)	86: yes/no	6[f]	Characterize patients on lassitude and insomnia	Review of previous sleep questionnaires, DSM-IV (American Psychiatric Association, 1994), ICSD-2 (American Academy of Sleep Medicine, 2005)	Not specified
SDQ (Sleep Disorders Questionnaire) - (Douglass et al., 1994)	175: 5[c]	3: O, N, R	Cutpoints provided for each SD	Expert opinion	Past 6 months
SLEEP-50 - (Spoormaker et al., 2005)	50: 4[d]	6: I, O, N, R, P, C	SD subscale and impact subscale above cutpoints	DSM-IV (American Psychiatric Association, 1994)	Last 4 weeks
SSC (Sleep Symptom Checklist) - (Bailes et al., 2008)	21: 3[e]	4[g]	Calculate total score	Authors' other SD and QoL questionnaires	Last 1 month

Abbreviations: C - circadian rhythm sleep wake disorders; I - insomnia; N – narcolepsy; O – OSA; P – parasomnias; R – restless legs syndrome; QoL – quality of life; SD – sleep disorder;

Footnotes: [a]never, sometimes, usually, always; [b]not at all, usually not, sometimes, usually, completely; [c]not at all, somewhat, rather much, very much; [d]never (strongly disagree), rarely (disagree), sometimes (not sure), usually (agree), always (agree strongly); [e]severity 0-3; [f]4 SDs covered (I, N, R, P) but grouped into non-SD- specific factors; [g]6 SDs covered (I, O, N, R, P, C) but grouped into non-SD-specific factor

Table 4: Development reasons, study sample, diagnostic criteria, item grouping method, cutpoint determination and resulting sensitivity & specificity ranges for sleep disorders questionnaires identified by literature review

Questionnaire (Reference)	Reasons for Development	Study Sample (ages are average)	Diagnostic criteria	Grouping Method (n/item)	Cutpoint Method	Sensitivity Range for Subscales	Specificity Range for Subscales
ASQ (Arroll et al., 2011)	Identify primary insomnia by eliminating other SDs	n=121, primary care & psych pts, ~30%M, mid-30's age	Interview by SD psychiatrist	ICSD-1 (Torphy, 1990) (n/a)	Not specified	.78-.80	.77-.97
GSAQ (Roth et al., 2002)	Screen for indiv SDs for referral and/or testing	n=212, primary care & sleep clinic referrals, ~48%M, mid-40's age	Table 2 methods in clinic, exc. interview only for healthy controls	MVR (19.3)	Average score for all participants	.77-1	.49-.88
HSDQ (Kerkhof et al., 2013)	Screen for SDs based on ICSD-2 (American Academy of Sleep Medicine, 2005), discriminate SDs	n=1269, SD pts & partners, college stu, ~50%M, mid-40's	Table 2 methods ambulatory exc interview only for healthy controls	FA (24.7)	ROC	.81-.9	.51-.9
ISDI (Koffel & Watson, 2010)	Explore overlap of SD symptoms and psychiatric diagnoses	n=1291, college stu, psych pts, SD pts, ~40%M, high-20's age	n/a	FA (23.6)	n/a	n/a	n/a
SDQ (Douglass et al., 1994)	Chance that pt on sleep clinic waitlist will have SD	n=649, sleep cinic referrals, SD pts, normal controls, ~65%M, mid-40's age	Table 2 methods for OSA & narcolepsy, interview only for nightmare & healthy controls	Expert opinion (n/a)	ROC	.65-.88	.46-.81
SLEEP-50 (Spoormaker et al., 2005)	Screen for indiv SDs in general population	n=699, college stu, SD pts, healthy volunteers, ~45%M, mid-30's age	Table 2 methods exc interview only for healthy controls	PCA (6.4)	Manual tradeoffs	.71-.85	.69-.88
SSC (Bailes et al., 2008)	Find symptom profile for primary care to refer pt to sleep clinic	n=243, older adults in primary care, ~40%M, 70's age	n/a	PCA (1.23)	n/a	n/a	n/a

Abbreviations: FA – factor analysis; MVR – multivariable regression; PCA – principle components analysis; pt – patient; ROC – receiver operator characteristic curve; SD – sleep disorder; stu – students

Table 5: Assessment of sleep disorders screening questionnaires identified by literature review

Criterion	**Evaluation method**	**Criterion Met – Y (yes) or N (no) Questionnaire / Reference / # Items**				
		ASQ (Arroll et al., 2011) 30	GSAQ (Roth et al., 2002) 11	HSDQ (Kerkhof et al., 2013) 32	SDQ (Douglass et al., 1994) 175	SLEEP-50 (Spoormaker et al., 2005) 50
Thorough	SDs: INS, OSA, NAR, RLS, PAR, and CRSD	N	N	N	N	**Y**
Efficient	≤ 25 items	N	**Y**	N	N	N
Reliable (content and construct validity)	Item content corresponds to diagnostic criteria (for standards in place at time of questionnaire development)	**Y**	**Y**	**Y**	**Y**	**Y**
	Response choices based on diagnostic criteria	N	N	N	N	N
	Time period covered encompasses diagnostic criteria	N	N	**Y**	**Y**	N
	Response choices justified diagnostically or statistically	N	N	N	N	N
	Item grouping verified by factor analysis (or multivariable regression) in sample with known SD diagnoses	N	N	**Y**	N	**Y**
	Known diagnoses based on gold standards	N	N	**Y**	N	**Y**
	Sample size at least 5/item for factor analysis (or multivariable regression)	N	N	**Y**	N	**Y**
Valid (criterion validity)	SD status verified against gold standard	N	N	**Y**	N	**Y**
	SD-free status verified by gold standard	N	N	N	N	N
	Cut-points based on receiver-operator curve	N	N	**Y**	**Y**	N
	Sensitivity and specificity given	**Y**	**Y**	**Y**	**Y**	**Y**
Generalizable (to adult primary care patients)	Content validation sample demographics and non-SD health representative of primary care population	N	**Y**	N	N	N
	Control sample of sufficient n randomly selected from target population	N	N	N	N	N
Total number of criteria fully met		**2**	**4**	**8**	**4**	**7**

Note: a "Y" score indicates all aspects of the feature adhere to criterion; an "N" score indicates not all aspects met
Abbreviations: SD – sleep disorder, INS - insomnia; OSA - obstructive sleep apnea; NAR – narcolepsy; RLS - restless legs syndrome; PAR –parasomnias; CRSD - circadian rhythm sleep wake disorders

Introduction to Manuscript 3

No brief questionnaire that screens for all six of the intrinsic sleep disorders was identified by the literature review. A questionnaire that has been used in sleep research settings is sufficiently brief and thorough, but has not yet been validated for use in primary care setting. Manuscript 3 describes the dissertation study aimed at evaluating the research tool to screen for sleep disorders in primary care.

Evaluation of a Sleep Disorders Screening Questionnaire for Primary Care of Adults

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Abstract

Psychometric properties of the Sleep Disorders Screening Checklist (SDS-CL), were evaluated for potential use in primary care. Previously collected data from two studies was combined for this analysis. Subjects (n=694, 56% female, average age 45 years) were patients referred to a sleep disorders center with suspected sleep disorders (n=395) and community volunteers without known sleep disorders (n=299). The SDS-CL is a 17-item questionnaire that screens for six sleep disorders: obstructive sleep apnea, chronic insomnia disorder, circadian rhythm sleep wake disorders, restless legs syndrome, narcolepsy and parasomnias. As the two samples did not include any subjects with parasomnias and circadian rhythm sleep wake disorders, those two disorders were not included in all the analysis procedures. The remaining four subscales (obstructive sleep apnea, insomnia, restless legs syndrome, and narcolepsy) were evaluated for construct, and criterion-related validity (including cut-point determination and associated sensitivity/specificity). All six subscales underwent evaluation of content validity and understandability of instructions. Results of cognitive interviews indicate the instrument structure is understandable and written at the fifth grade reading level. Experts in the area of sleep disorders were surveyed (n=3) to assess content validity. Construct validity was demonstrated by significant t-tests with Cohen's d values ranging from 0.82-1.58. Internal consistency reliability was demonstrated via Cronbach's alpha of >.6 for the obstructive sleep apnea and insomnia subscales. Sensitivity and specificity ranged from .70-.88 and .64-.80, respectively, based on ROC curve analyses with areas under the curve of >.7. The SDS-CL shows promise as a brief sleep disorders screening tool for use in primary care. The recommendation to add questions regarding insufficient sleep

was made. Partnering with primary care providers and patients for implementation of routine sleep disorders screening via SDS-CL is recommended.

Evaluation of a Sleep Disorders Screening Questionnaire for Primary Care of Adults

Untreated sleep disorders lead to increased medical and psychiatric illness (American Academy of Sleep Medicine, 2014e; Daniel J. Buysse et al., 2010; Institute of Medicine, 2006; World Health Organization, 2007). Until recently, sleep disorders were considered to be secondary to other conditions; however, sleep disorders are currently considered to be primary disorders in need of differential diagnosis (American Academy of Sleep Medicine, 2014d; American Psychiatric Association, 2013). The prevalence of sleep disorders in the population is more than 40% by some estimates (Institute of Medicine, 2006). The high prevalence and known negative impact on health highlights a need to screen for sleep disorders within primary care. However, busy primary care practices may be unable to add sleep disorders screening to their long lists of competing demands. A quick tool, such as a brief self-report questionnaire that screens patients for the core intrinsic sleep disorders (insomnia, sleep apnea, narcolepsy, restless legs syndrome, parasomnias, and circadian rhythm sleep wake disorders) could facilitate sleep disorders screening within the primary care practices. The purpose of this study was to evaluate the psychometric properties of a brief sleep disorders questionnaire to determine its applicability for use as a screening tool in primary care practice.

In particular, understandability of the questionnaire instructions and response options, content validity, internal consistency reliability, construct validity, criterion-related validity were assessed. Sensitivity and specificity were determined, along with cut-point scores for individual sleep disorder subscales. The ultimate goal was to provide clinical cut-point scores for the SDS-CL subscales to indicate when providers could conclude that a patient has screened positive for the associated sleep disorder: obstructive sleep apnea, chronic insomnia disorder, circadian rhythm sleep wake disorders, restless legs syndrome, narcolepsy, or parasomnias.

Methods

Study Design and Data Collection

This was a cross-sectional study of adults from two samples of subjects from previous unpublished sleep related research studies. The aim of this study was to evaluate the validity and reliability of the Sleep Disorders Screening Checklist (SDS-CL) questionnaire (see description below) as a quick screen for sleep disorders in primary care practices. The two samples were comprised of adult subjects referred by primary care providers to a sleep disorders clinic for confirmatory sleep disorder diagnoses (n=395) and subjects from the general community who had volunteered to participate in sleep research study (n=299). Inclusion/Exclusion criteria for the community volunteer sample included adults over the age of 18 years and did not wear continuous positive airway pressure (CPAP) devices, or use supplementary oxygen while sleeping. Measures of subject characteristics, sleep disorder diagnoses, and SDS-CL responses had already been collected, coded, cleaned, de-identified and stored as SPSS (IBM Corp., 2013) data files prior to the initiation of this study. This study analyzed combined information from the previously created data files as described below.

For analysis purposes, diagnostic status for each sleep disorder was coded as "missing" if a subject's respective study did not address that disorder; for example, the community volunteer subjects all had diagnosis coded as missing for restless legs syndrome, circadian rhythm disorders, narcolepsy, and parasomnias. Other diagnostic status data had already been coded as "missing" in the data files from their respective research studies.

The Institutional Review Board from the first author's university affiliation approved use of the de-identified data, classifying this as non-human-subjects research.

The Sleep Disorders Symptom Checklist (SDS-CL)

The Sleep Disorders Symptom Checklist (SDS-CL) (Figure 1) is a seventeen item questionnaire originally developed as a recruitment tool for research studies. The intent was for the SDS-CL to be a fast and comprehensive screen for all of the intrinsic sleep disorders, i.e., obstructive sleep apnea, chronic insomnia disorder, circadian rhythm sleep wake disorders, restless legs syndrome, narcolepsy and parasomnias. The seventeen items written at a fifth grade Flesh-Kincaid reading level create a one-page grid with five response options, and a single instruction at the top ("over the past year… place an X in the box"). Response options are never, seldom (1 x yr), sometimes (1-3 x mo), often (1-3 x week) or frequently (>3 x wk). Item stems and response options were developed to correspond with diagnostic criteria using the International Classification for Sleep Disorders (American Academy of Sleep Medicine, 2014d) and the DSM-V (American Psychiatric Association, 2013). The timeframe of "over the last year" was intended to capture chronicity. The number of items per subscale is: obstructive sleep apnea – 4 (items 4, 8, 9 & 10), insomnia – 4 (items 1, 2, 3, & 4), circadian rhythm – 2 (items 5 & 6), restless legs syndrome – 3 (items 11, 12 & 13), narcolepsy – 2 (items 7 & 14), and parasomnias – 3 (items 15, 16 & 17). As one of the items (#4) is included in both the obstructive sleep apnea and insomnia subscales, adding up items per subscale yields 18, but the total number of items completed by patients is only 17.

The form of SDS-CL shown in Figure 1 is for illustrative purposes; however, a format of the SDS-CL that can be given directly to subjects, clients, or patients is provided in Appendix A along with a clinical scoring guide based on results of this study.

Measures

Subject characteristics. Measures collected in both samples were age, sex, height and weight; body mass index (BMI) was calculated from height and weight. The community based population demographics also included race, ethnicity, and educational level. In addition, subjects were characterized in terms of daytime sleepiness according to the Epworth sleepiness scale (ESS). The ESS (Johns, 1992) is an eight-item questionnaire that reflects the subjective report of likelihood of falling to sleep in 8 situations. The range of scores is 0-24 with 24 the most severe of excessive daytime sleepiness. A score of greater than ten is considered clinically relevant sleepiness. ESS was included as a descriptive to assess whether there was a range of daytime sleepiness amongst the study subjects.

Gold standard sleep disorder diagnoses. All subjects had undergone a diagnostic sleep study that was interpreted according to American Academy of Sleep Medicine diagnostic criteria (American Academy of Sleep Medicine, 2005). The sleep clinic sample was evaluated by a physician boarded in sleep medicine and an in-lab diagnostic sleep study; diagnostic status for each sleep disorder was provided in physician notes. The community volunteer sample was evaluated according to out of center sleep testing protocol: they wore wrist actigraphs for two weeks and wore home respiratory sleep test equipment for one night. Sleep medicine specialists interpreted the out of center sleep test data to provide a diagnosis for obstructive sleep apnea and a diagnosis for chronic insomnia disorder. Out of center sleep test interpretations were: 1) insomnia severity index (ISI) score (Morin, Belleville, Bélanger, & Ivers, 2011) of ten or greater for positive insomnia diagnosis, and 2) apnea hypopnea index (AHI) of five or greater for positive obstructive sleep apnea diagnosis. The ISI (Morin, Belleville, Bélanger, & Ivers, 2011) is a seven-item subjective measure of sleep quality, sleep disruption, satisfaction and worry

about sleep and how sleep interferes with daytime function, with each item rated from 0-4 (no symptom – very much symptom); with an ISI score of 10 or greater indicating clinically significant insomnia in the general population (Morin, Belleville, Bélanger, & Ivers, 2011).

SDS-CL subscale scores. For this study, SDS-CL subscale scores were determined by summing the responses to items associated with each subscale. In the data files, items had been assigned scores of 0, 1, 2, 3, or 4 corresponding to never, seldom (1 x yr), sometimes (1-3 x mo), often (1-3 x week) or frequently (>3 x wk), respectively. With different number of items (as shown in Figure 1), the six subscales had different possible score ranges: 1) 0-16 for obstructive sleep apnea, 2) 0-16 for insomnia, 3) 0-8 for circadian rhythm sleep wake disorders, 4) 0-12 for restless legs syndrome, 5) 0-8 for narcolepsy, and 6) 0-12 for parasomnias.

Qualitative Assessment Procedures

Understandability assessment. Cognitive interviews regarding the SDS-CL introductory stem ("over the past year. . .") and response options - never, seldom (1 x yr), sometimes (1-3 x mo.), often (1-3 x wk), and frequently (>3 x wk.) - were performed with a subset of the community volunteers. The specific question approach to assess the cognitive domain of understanding per methods of Beatty and Willis (2007) was used, with additional probing as needed for researchers to understand participants' answers.

Expert opinion assessment. A fillable form / survey was created for this study, and comprised seven sections: one section for each SDS-CL subscale/sleep disorder and another section for the introductory stem and response options. Surveys were e-mailed to experts, who then filled out the forms and e-mailed them back to the primary author. For each survey section, experts responded via yes/no checkbox if key content were missing. For each item within a

survey section, experts responded via yes/no checkbox if the item was relevant and clear/concise. Also for each survey section, experts had the ability to enter unlimited free text feedback.

Analysis Procedures

SPSS version 22 (IBM Corp., 2013) was utilized for all statistical analyses.

Sample characteristics. Descriptive statistics of the sample age, sex, race, education, body mass index (BMI), smoking status, Epworth sleepiness scale (ESS), sleep study diagnoses, and SDS-CL subscale scores were determined.

Understandability of instructions and response options. To assess understandability of the introductory stem ("over the past year. . .") and response options, researchers' notes from the cognitive interviews were examined for themes to indicate subjects' preferences or possible confusion regarding the instructions and response options.

Content validity. Content validity was assessed by examining experts' opinions (via surveys described above) regarding relevancy, clarity/conciseness, and potential key features that may be missing from the SDS-CL. Survey responses were analyzed for frequencies of yes/no answers and comments were summarized. The number of "no" responses was tallied for clarity/conciseness and relevancy; while the number of "yes" responses was tallied for missing key content. These rules were utilized: 1) for clear/concise – response was counted as "no" if an expert checked the "no" box or commented that an item should be reworded, 2) for relevant – the response was counted as "no" if an expert checked the "no" box or commented that an item might not be relevant, and 3) for missing content – the response was counted as "yes" if an expert checked the "yes" box or commented that key content might be missing.

Construct validity. Construct validity was assessed by comparing mean subscale scores for individuals with and without positive diagnoses for each of the sleep disorders via t-tests, to

assess whether groups with known differences had significantly different measures at $p<.05$. For each sleep disorder / SDS-CL subscale, only data for subjects with valid (non-missing) gold standard diagnoses were utilized.

Internal consistency reliability. Cronbach's coefficient alpha was used to characterize internal consistency reliability of the six SDS-CL subscales. Cronbach's alpha was obtained from inter-item correlation coefficients for each subscale according to the Spearman-Brown prophecy formula (Streiner & Norman, 2008) from the individual item by item correlation coefficients. The 17 x 17 matrix of item by item correlation coefficients was obtained using bivariate statistics.

Cut-point determination and sensitivity/specificity. To determine cut-point scores, diagnoses provided by sleep specialists were used as the criterion standard for receiver operator characteristics (ROC) curve analyses (Hanley & McNeil, 1982; Streiner & Cairney, 2007). One ROC analysis was performed for each subscale. For each sleep disorder / SDS-CL subscale, only data for subjects with valid (non-missing) gold standard diagnoses were utilized. Cut-points were selected to be at the ROC curve inflection point, as determined visually from the ROC curve plot and by examination of values in the SPSS output table for sensitivity vs. (1-specificity). The ROC analyses were performed with diagnosis as the state variable and subscale score as the test variable.

For each ROC curve, area under the curve (AUC) with 95% confidence intervals was also obtained as an assessment of accuracy of conclusions based on ROC curves. Sensitivity-specificities were then converted to positive and negative predictive values based on a range of prevalence.

Criterion-related Validity. With cut-points available, the proportion of subjects who screened positive for each sleep disorder was determined and compared with the proportion of subjects who were diagnosed positive for that same sleep disorder. For each sleep disorder / SDS-CL subscale, only data for subjects with valid (non-missing) gold standard diagnoses were utilized. Chi-squared tests with McNemar significance (Polit, 2010) were used to make the comparison; a non-significant chi-squared was interpreted to mean the proportion who screened positive is not different from the proportion who were diagnosed positive. McNemar significance was utilized to account for the lack of independence of the two proportions (diagnostic and screening) having been generated from the same sets of subjects. Chi-squared analyses with McNemar significance were performed.

Results

Sample Characteristics

The sample comprised 56% females, with average age 45 years, average body mass index (BMI) of 31.7, 14% of whom were smokers (Table 1). Subjects exhibited a range between non-significant to clinically significant daytime sleepiness as indicated by Epworth sleepiness scale (ESS). Obstructive sleep apnea was the most prevalent sleep disorder in the study sample (61%), followed by chronic insomnia disorder (37%). About 37% of the healthy volunteer community cohort with valid data had either obstructive sleep apnea, chronic insomnia disorder, or both (Table 1), in line with the 40% population prevalence estimate reported earlier. The rank ordering of sleep disorders prevalence in the study sample align with the rank ordering of sleep disorders prevalence estimates in the general adult population (Table 2). Mean SDS-CL subscale scores were lowest for narcolepsy and parasomnias in both community volunteers and sleep clinic patients. Among the community volunteers, mean SDS-CL subscale scores seem to be

ranked in order of prevalence of the sleep disorders in the general, i.e., with chronic insomnia disorder and obstructive sleep apnea being the highest, followed by restless legs syndrome and circadian rhythm sleep wake disorders, then by narcolepsy and parasomnias. None of the study subjects received diagnoses of either circadian rhythm sleep wake disorders or parasomnias.

Understandability of Instructions and Response Options

Instructions were reported to be easily understood and readable by the cognitive interview participants (Table 3). Although only the community volunteers participated in cognitive interviews, the subjects were diagnosed with either insomnia or obstructive sleep apnea, and therefore, there is no expectation that their responses would not be representative of the subjects from the sleep clinic referral group. About three-fourths of the interviewees commented that remembering the past year was difficult, while the others commented that they liked the idea of reporting symptoms over the last year because it was "a leveler" and allowed them to report how they usually were, without having to worry about a recent week or month being abnormal. In addition, those who reported the last year was difficult to remember, also stated that they answered whatever timeframe they could remember, or "whatever I'm usually like".

Everyone interviewed stated they liked having the frequencies or timeframes along with the descriptive words for response options, and that the choices seemed clear. They all stated that the frequencies helped them choose where to mark their answers. One, however, also stated that he interpreted the "1-3 x week" as asking if he'd had the symptom over the last one to three weeks. In addition, one person commented on the once a year option, "why bother, it's so close to never is it worth mentioning?".

Content Validity

Responses were received from three of the eleven experts queried: one practicing sleep medicine physician, one practicing sleep medicine physician/medical school faculty (Professor & Head, Section Of Pulmonary, Critical Care & Sleep Medicine), and one sleep disorders researcher/nurse faculty (Associate Professor). In general, most areas of the SDS-CL were deemed appropriate, although a few areas were suggested for modification (Table 4).

Construct Validity

Results (Table 5) indicate support for construct validity of the SDS-CL subscales for construct obstructive sleep apnea, insomnia, restless legs syndrome, and narcolepsy, as indicated by the significant ($p<.01$) mean differences between those diagnosed with and without the sleep disorder and associated large effect sizes. As can be seen from the results in Table 5, the mean difference of 4.78 for restless legs syndrome is about 40% of the possible SDS-CL subscale score range (0-12); for OSA (mean difference 3.19, range 0-16), insomnia (mean difference 2.65, range 0-16) and narcolepsy (mean difference 1.76, range 0-8), the mean differences are about 20% of their respective score ranges.

Internal Consistency Reliability

For obstructive sleep apnea and insomnia, Cronbach's coefficient alpha (.67 and .66, respectively) further indicates acceptable construct validity (internal consistency), although for restless legs syndrome and narcolepsy internal consistency is less desirable (Table 5).

As none of the participants had diagnoses of either circadian rhythm sleep wake disorders or parasomnias, construct validity results cannot be reported here regarding either of these subscales.

Cut-point Scores, Sensitivity-Specificities, and Criterion-related validity

Obstructive sleep apnea, chronic insomnia disorder, restless legs syndrome, and narcolepsy subscales could be evaluated against gold-standard diagnoses. In general, their SDS-CL subscale sensitivities and specificities were around 0.7, based on ROC curve analyses with moderate ratings for areas under the curve (AUCs) (Table 5). (ROC curves are shown in figure form in Appendix B.) The subscale cut-point scores (Table 5) above which subjects can be considered as screening positive for the associated sleep disorders are: 1) obstructive sleep apnea at 6 (maximum possible score 16), 2) chronic insomnia disorder at 8 (maximum possible score 16), 3) restless legs syndrome at 7 (maximum possible score 12), and narcolepsy at 2 (maximum possible score 8).

In comparing prevalence of sleep disorders based on screening (using cut-points described above), it can be seen that the prevalence of subjects who screen positive for obstructive sleep apnea based on SDS-CL subscale score is congruent with the prevalence of subjects who were diagnosed with obstructive sleep apnea. The McNemar significance for the chi-squared test of obstructive sleep apnea (Table 5) is $p=.13$ (i.e., $p>.05$ and therefore not significant), indicating that there is no reason to reject the hypothesis that the prevalence of obstructive sleep apnea based on screening (SDS-CL score) is statistically significantly different than the prevalence based on gold standard diagnosis (n=596 with valid data, n=351 screen positive, n=372 diagnosed positive). For insomnia, restless legs syndrome, and narcolepsy, however, the McNemar p values ($p<.01$) indicate there is a statistically significant difference in the proportions who screen positive based on the SDS-CL scores and the proportions who were diagnosed positive by gold standard, i.e., those proportions are not congruent. Examination of the frequency data reveals that the SDS-CL subscales with cutpoints derived as described above

tend to over-predict the proportions of individuals who screen positive for insomnia (n=674 with valid data, n=331 screen positive, n=255 diagnosed positive), narcolepsy (n=385 with valid data, n=129 screen positive, n=8 diagnosed positive), and restless legs syndrome (n=383 with valid data, n=29 screen positive, n=28 diagnosed positive). Thus, the results of this study support criterion related validity is the SDS-CL obstructive sleep apnea subscale but do not support criterion related validity of the SDS-CL subscales for chronic insomnia disorder, restless legs syndrome and narcolepsy. It may be possible to move the proportions screened and diagnosed closer together for insomnia, narcolepsy and restless legs syndrome by raising their SDS-CL subscale cutpoints. However, this would move cut-points away from the inflection points of the ROC curves, and decrease sensitivity while increasing specificity.

Sensitivity-specificity pairs translate to positive predictive value (the probability that someone who screens positive actually has the disease) and negative predictive value (the probability that someone who screens negative is actually free of the disease) if disease prevalence is known. For example, a screening test with sensitivity-specificity of .7-.7 has a positive predictive value of 21% (with negative predictive value 96%) for a disease with 10% prevalence, but a positive predictive value of 50% (with negative predictive value of 85%) for a disease with 30% prevalence. The range of predictive values that could be achieved with the sensitivity-specificity pairs of the SDS-CL subscales over a range of prevalence is illustrated in Figure 2.

As noted for construct validity, no results can be reported for criterion-related validity for circadian rhythm sleep wake disorders or parasomnias due to absence of study sample participants diagnosed with either disorder.

Discussion

The results of this study support that the SDS-CL may screen with diagnostic accuracy for obstructive sleep apnea in adults, based on a non-significant difference in proportion of individuals who screened positive by the SDS-CL and were diagnosed positive by gold standards (chi-squared test with McNemar $p=0.13$). For chronic insomnia disorder, narcolepsy and restless legs syndrome in adults, proportions who screened positive by the SDS-CL were significantly higher than proportions who were diagnosed positive by gold standards (chi-squared test with McNemar $p<.01$). However, the SDS-CL is intended for use as a screening instrument, to refer for additional testing, and therefore, over-detection indicates an error on the side of caution. For all four of the sleep disorders which presented in the study sample – obstructive sleep apnea, chronic insomnia disorder, narcolepsy, and restless legs syndrome, the concordance between SDS-CL screening status and sleep specialist diagnosis (sensitivity) ranged from 68% - 87%, with SDS-CL cut-point scores based on accurate ROC curves (AUCs above 0.7).

Two of the SDS-CL subscales (circadian rhythm sleep wake disorders, parasomnias) could not be evaluated using subject data, since no subjects included in the dataset were positively diagnosed for them. The prevalence estimates for these disorders (Table 2) indicate that at least as many people should have presented with circadian rhythm sleep wake disorders as did with narcolepsy, and about half as many people should have presented with parasomnias as presented with restless legs syndrome. The results of this study may, therefore, be somehow biased by absence of individuals with circadian rhythm sleep wake disorders and parasomnias. Absence of circadian rhythm sleep wake disorders and parsomnias from the study sample may be an indication that individuals who have them do not seek treatment or diagnosis from sleep clinics. Or, the disorders may have been present in the community volunteer cohort but missed

because their assessment was not part of that study's protocol. It may also be that the prevalences reported in Table 2 are over-estimates, although that seems unlikely since there is a general consensus among sleep scientists that sleep disorders are under-reported and therefore under-estimated.

Clinical Cut-off Scores

To use the SDS-CL in practice, patients' responses to the SDS-CL items would need to be scored, then summed and interpreted as shown in Table 6. Individuals whose subscale scores fall above the cut-point scores shown in Table 6 could, based on results of this study, be said to screen positive for the associated sleep disorder. A clinically friendly format of the SDS-CL and the scoring guide are provided in Appendix A of this dissertation.

Positive Predictive Values

For obstructive sleep apnea, at prevalence of around 30%, the positive predictive value of SDS-CL is around 40% (Figure 2). As a comparison, this falls below the positive predictive value of 75% for the PHQ-2 depression screen (which may be familiar to primary care providers) when used for any depressive disorder in primary care settings, if scores of 3 or greater indicate depression. For the lower prevalence sleep disorders, the SDS-CL positive predictive values are even lower, on the order of 10-20%. Additional risk-cost-benefit analysis would likely contribute to decisions regarding need for further testing based on positive SDS-CL screening results.

However, negative predictive values of the SDS-CL subscales are around 99% for low prevalence sleep disorders, e.g. restless legs syndrome at 5% or narcolepsy at less than 1% (Figure 2). For the higher-prevalence disorders such as obstructive sleep apnea and chronic

insomnia disorder, negative predictive value of SDS-CL is around 85%. Therefore, the SDS-CL would be accurate at ruling-out sleep disorders.

Criterion-related Validity

Criterion-related validity for obstructive sleep apnea is supported by the concordance between proportions of subjects with positive SDS-CL screening results and positive sleep specialist diagnoses. Results of this study do not support criterion-related validity for chronic insomnia disorder, restless legs syndrome or narcolepsy, with a lack of concordance between proportions in the direction of over-detection, i.e., proportions screened as positive are higher than proportions diagnosed as positive. Given the intent of using the SDS-CL as a screening tool to recommend additional testing with a long-term goal of preventing adverse outcomes associated with undetected/untreated sleep disorders, over-detection may be beneficial; the economical and emotional risks of additional testing for some would need to be weighed against the possible prevention of future chronic health issues for others. However, area under the curve (AUC values shown in Table 5) of the receiver operator characteristics (ROC) curve analyses used for cut-point determination, indicate valid and accurate cut points were obtained from the ROC curve analyses that utilized diagnostic status as the criterion reference. In addition, the sensitivity and specificity values yield promising predictive values as discussed earlier.

Construct Validity

Construct validity of the SDS-CL is evidenced by the four represented subscales' ability to differentiate individuals diagnosed with sleep disorders (large Cohen's d). Internal consistency of the subscales with four items (obstructive sleep apnea, chronic insomnia disorder) with Cronbach's alpha of ~.66 further supports construct validity of the subscales. For scales with only four items, Cronbach alpha of 0.66 likely indicates high internal consistency; anything

higher might indicate an inter-item correlation indicative of redundancy. Although low values of Cronbach's alpha for the subscales with fewer than four items (restless legs syndrome, narcolepsy) appear to indicate poor construct validity, such conclusions may not be valid for subscales with so few items. Furthermore, the mean differences between groups are not only significant in terms of Cohen's d, but also in terms of the response options: all of the mean differences indicate that individuals with sleep disorders endorse at least one of the items higher on the response option scale than their non-diagnosed counterparts; none of the mean differences are less than 1 (Table 5).

Content Validity

In general, experts' endorsements of SDS-CL content indicates that minor changes to the instrument may be required, for example, by clarifying the difference between the terms tired, fatigued, and sleepy or by eliminating one or two of the items. However, additional expert opinion might be warranted before extensive changes are made to the SDS-CL, in light of the promising results in both construct validity and sensitivity/specificity values. Efforts to improve response to expert opinion queries might also prove beneficial.

Understandability

The SDS-CL appears to be well-suited to adults in primary care. The instructions ("over the last year…") and response options (descriptive words with clarifying frequencies) were deemed clear and understandable via cognitive interviews. While the yearlong timeframe was often considered too long to remember, participants stated they responded based on their typical patterns. Thus, all participants seemed to endorse the idea that the SDS-CL is looking for chronic conditions.

However, while educational level and age of the cognitive interview group varied, no individuals for whom English is a second language, with vision limitations, or other specific issues that might preclude ability to read and understand a questionnaire such as the SDS-CL participated in the cognitive interviews. Adapting SDS-CL may be possible, although any change in format of delivery (other than on a single sheet of paper, as for this study) would require re-evaluation of psychometric properties.

Recommended SDS-CL Modifications

Based on results of this study, no changes to the SDS-CL are recommended at this time. Although the proportion of individuals who screened positive vis SDS-CL for insomnia, narcolepsy, and restless legs syndrome did not match (according to chi-squared tests) the proportion of individuals who were diagnosed positive for those disorders, the the proportion of individuals screening positive via SDS-CL did not differ (per chi-squared testing) from the proportion of individuals diagnosed positive for obstructive sleep apnea. Results of this study support internal consistency reliability of the SDS-CL obstructive sleep apnea and insomnia subscales. And, clinical cut-point scores for the obstructive sleep apnea, insomnia, narcolepsy, and restless legs syndrome subscales were indicated to be of at least moderate accuracy by the ROC curve analyses. In addition, sensitivities of the SDS-CL subscales ranged from .70 - .88, indicating that the SDS-CL can detect 70% or greater of the true positives for the four sleep disorders presenting in this study. Furthermore, construct validity of the tool was well-supported by large differences in average subscale scores (Cohen's d from .82 – 1.58) between groups known to have the sleep disorders and those ruled-out for sleep disorders.

However, although the SDS-CL was designed to screen for diagnosable sleep disorders, lack of sleep due to insufficient opportunity is also a national health concern (Centers for Disease

Control and Prevention, 2014a; National Sleep Foundation, 2014a; U.S. Department of Health and Human Services, 2014). Insufficient sleep is associated with poor cardiovascular and metabolic health, increased mental and physical distress, and worse general health (Strine & Chapman, 2005), while sleep restriction leads to decreases in functionality equivalent to drunkenness (Roehrs, Burduvali, Bonahoom, Drake, & Roth, 2003). Therefore, addition of one or two items addressing number of hours slept per night and frequency of sleep insufficiency would enhance the ability of SDS-CL to assess for sleep-related health and safety. For example, the question, "During the past 30 days, for about how many days have you felt you did not get enough rest or sleep? (number of days)" as used in correlations by Strine & Chapman (2005) is a possible addition. And, another question regarding the number of hours an individual typically sleeps in a 24-hour period could be another key indicator of safety issues related to insufficient sleep (National Sleep Foundation, 2014a; Roehrs, et al., 2003).

Alternative Approaches to Sleep Disorder Screening

Flow charts, as for example in Malow (2011) or structured interviews, e.g., (Bloom et al., 2009; D. J. Buysse et al., 1994; Edinger et al., 2009; Merikangas et al., 2014; Schramm et al., 1993), could also be used to assess and/or diagnose for sleep disorders. However diagnostic assessments are not necessarily quick screens. With office visits of around twenty minutes (Chen, Farwell, & Jha, 2009), use of interviews to routinely screen for sleep disorders would seem prohibitive. General history and physical approaches are also possible, however, sleep disorders can be easily missed with these approaches (Senthilvel, Auckley, & Dasarathy, 2011).

Packets of questionnaires – one or more for each sleep disorder - may also be an option. However, completion time and survey fatigue would need to be considered. And, multiple questionnaires would require additional information management when compared to, say, one

short questionnaire. In addition, questionnaire completion time that takes longer than the typical 15 minutes spent in primary care waiting rooms (Anderson et al., 2007) might also deter utilization.

Implications

Although subjects in the community volunteer cohort were not previously diagnosed with sleep disorders, about 37% of them had at least one (obstructive sleep apnea, chronic insomnia disorder, or both) according to sleep specialist diagnosis. Yet, these same individuals had not sought treatment for their conditions - they did not realize they had a sleep disorder, possibly because of being accustomed to their own levels of general well-being. The assessment algorithms mentioned above most often rely on patient complaint to trigger their use (a sensible approach considering the limited time primary care providers have for face-to-face patient contact) and therefore could not have detected sleep disorders without a patient complaint. However, the SDS-CL accurately detected over 70% of the subsequently diagnosed sleep disorder cases, and would have required only a few minutes of patient time to complete and perhaps a few minutes more of clarifying questions from a provider to determine whether additional testing and/or treatment was required.

Patients may not realize they have sleep disorders, yet that does not prevent the adverse outcomes of untreated sleep disorders. While screening for disorders is typically only recommended in high risk populations, everyone is at high risk for sleep disorders: more than one out of every three of us likely has one, and routine screening seems warranted. With a tool such as the SDS-CL which can quickly screen for multiple sleep disorders, providers could easily begin the road to prevention of sleep-disorder associated cardiovascular, metabolic, psychiatric, and quality-of-life issues.

Conclusion

The SDS-CL shows promise as a brief sleep disorders screening tool for use in primary care. Although two of the subscales could not be fully tested as part of this study, the overall ease of use and promising predictive values of the four subscales that were fully evaluated warrant testing the SDS-CL in a primary care setting. Addition of items related to insufficient sleep opportunity would enhance utility of the SDS-CL. A logical next step is to partner with providers and patients to develop and implement routine screening for sleep disorders and insufficient sleep via the SDS-CL.

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Table 1: Study Sample Characteristics

Characteristic	Community Volunteers (n=299)	Sleep Clinic Patients (n=395)	Total (n=694)
Age – mean (s.d.)	40 (17)	48 (13)	45 (16)
Sex (proportion female)	68%	48%	56%
Race proportions Caucasian African American Other	 83.9% 9.5% 6.6%	n/a	--
Ethnicity proportions Hispanic or Latino Non-Hispanic or Latino	 8.7% 91.3%	n/a	--
Education level proportions < High school High school 2 yr college 4 yr college >4 yr college	 1.0% 16.0% 23.2% 26.3% 33.4%	n/a	--
Cigarette smoker proportion	10%	17%	14%
Body mass index (BMI) – mean (s.d.)	27 (6.0)	35 (8.5)	31.7 (8.5)
Epworth sleepiness scale – mean (s.d.)	6.9 (4.8)	11.2 (5.3)	9.3 (5.5)
Diagnosed with obstructive sleep apnea – proportion (numbers)	27% (n=77 dx, 283 valid)	85% (n=334 dx, 395 valid)	61%
Diagnosed with chronic insomnia disorder – proportion (numbers)	24% (n=163 dx, 298 valid)	55% (n=299 dx, 395 valid)	37%
Dual dx obstructive sleep apnea and insomnia – proportion (numbers)	14% (n=39 dx, 283 valid)	14% (n=56 dx, 395 valid)	14%
Diagnosed with circadian rhythm sleep wake disorder – proportion (numbers)	n/a	0%	--
Diagnosed with restless legs syndrome – proportion (numbers)	n/a	7% (n=28, 395 valid)	--
Diagnosed with narcolepsy – proportion (numbers)	n/a	2% (n=8, 395 valid)	--
Diagnosed with parasomnias – proportion (numbers)	n/a	0%	--
SDS-CL subscale scores – mean (s.d.):			
Obstructive sleep apnea	5.5 (2.6)	9.3 (3.5)	7.8 (3.7)
Insomnia	7.5 (3.1)	9.3 (3.5)	8.5 (3.5)
Circadian rhythm disorder	2.2 (1.6)	2.3 (1.7)	2.2 (1.6)
Restless legs syndrome	3.3 (2.3)	4.9 (3.3)	4.2 (3.0)
Narcolepsy	.9 (1.3)	2.0 (1.7)	1.5 (1.6)
Parasomnias	2.0 (2.0)	2.8 (2.6)	2.5 (2.4)

Key: dx- diagnosed, n/a – not available or not assessed, s.d. – standard deviation

Table 2: Sleep disorder prevalences in adult populations

	Estimated Prevalence	Reference
Obstructive sleep apnea	9-28%	Young, Peppard, and Gottlieb (2002)
Chronic insomnia disorder	8-33%	M. Ohayon (2002)
Circadian rhythm sleep wake disorders	.13-.17%	Schrader, Bovim, and Sand (1993) Yazaki, Shirakawa, Okawa, and Takahashi (1999)
Restless legs syndrome	5.5%	M. Ohayon and Roth (2002)
Narcolepsy	.047 - .056%	M. Ohayon, Priest, Zulley, Smirne, and Paiva (2002) Silber, Krahn, Olson, and Pankratz (2002)
Parasomnias	2-4%	M. Ohayon et al. (1999)

Table 3: Cognitive interviewee characteristics

Characteristic	Value
Sex	
Male	n=4
Female	n=4
Age range (yr)	33 – 73
Education	
High school	n=1
2 yr college	n=2
4 yr college	n=2
>4 yr college	n=3
Race	
Caucasian	n=6
African American	n=1
Other	n=1
Sleep disorder diagnoses	
Obstructive sleep apnea	n=4
Chronic insomnia disorder	n=4

Table 4: Proportion of experts indicating need to change parts of the SDS-CL

SDS-CL part	**Clear & Concise** (#no/total)	**Relevant** (#no/total)	**Missing content** (#yes/total)	**Suggested Modifications**
Introductory stem	0	0	0	none
Response options	0	0	0	none
Obstructive sleep apnea subscale	1/3	0	1/3	Item 4 – differentiate between tired, fatigued, sleepy Item 9 - should be "I wake up during the night choking or gasping or from snoring"
Insomnia subscale	1/3	0	0	Item 4 – differentiate between tired, fatigued, sleepy
Circadian rhythm disorders subscale	0		0	none
Restless legs syndrome subscale	0	1/3	0	Item 13 not relevant ("I wake up frequently during the night for no reason")
Narcolepsy subscale	0	0	2/3	Need additional item regarding dreaming at night Need something regarding sleep paralysis
Parasomnias subscale	0	1/3	0	Item 17 not relevant ("For no reason, I awaken suddenly, startled and feeling afraid")

Table 5: Results of statistical analyses for construct validity, cut-point scores, and criterion-related validity of the SDS-CL

Subscale # Items / Score Range	**Mean (s.d., n)** without dx / with dx	**Mean Difference**[a] (pooled s.d.)	**Cohen's d** Effect Size[b]	**Cronbach α**	**Cut-point Score**[c]	**AUC (95% C.I.)** AUC Rating[d]	**Sensitivity /Specificity**	**Chi-Squared w/Continuity Correction** (McNemar p)
Obstructive sleep apnea 4 / 0-16	5.86 (2.83, 224) 9.04 (3.63, 372)	3.19 ** (3.37)	.95 large	.67	6	.76 (.72 - .80) moderate	.74 / .67	94.0 (.13)†
Chronic insomnia disorder 4 / 0-16	7.52 (3.38, 419) 10.17 (3.00, 255)	2.65 ** (3.23)	.82 large	.66	8	.72 (.69 - .76)	.70 / .64	73.0 (<.01)
Circadian rhythm sleep wake disorders 2 / 0-8	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a
Restless legs syndrome 3 / 0-12	4.54 (3.08, 355) 9.32 (2.36, 28)	4.78 ** (3.03)	1.58 large	.45	7	.88 (.83 - .93) moderate	.75 / .80	39.3 (<.01)
Narcolepsy 2 / 0-8	1.99 (1.66, 377) 3.75 (1.49, 8)	1.76 ** (1.65)	1.06 large	.24 (Pearson's r for 2 items)	2	.79 (.65 - .93) moderate	.88 / .68	8.4 (<.01)
Parasomnias 3 / 0-12	n/a	n/a	n/a	n/a	n/a	n/a	n/a	n/a

** p< .01

† by McNemar test, chi-squared is not significant, thus proportions screened positive and diagnosed positive are not different

Key: dx – diagnosis, n/a – not applicable, s.d. – standard deviation

Notes

a) higher subscale scores indicate more frequent sleep disorder symptoms; **b)** .2-.5 small, 5-.8 medium, >.8 large; **c)** scores greater than cut-point indicate positive screen, with cut points chosen from inflection points of ROC curves; **d)** <0.5 useless, .5-.7 low, .7-.9 moderate, >.9 high

Table 6: SDS-CL scoring and screening guide

SDS-CL SCORING GUIDE – FOR PROVIDER					
Item choice	**Item score**	**Subscale**	**Items to sum for subscale score**	**Subscale score range**	**Subscale clinical cut-off score**
Never	0	Insomnia	1, 2, 3, 4	0-16	8
Seldom	1	Circadian rhythm	5, 6	0-8	n/a
Sometimes	2	Narcolepsy	7, 14	0-8	2
Often	3	Obstructive sleep apnea	4, 8, 9, 10	0-16	6
Frequently	4	Restless legs syndrome	11, 12, 13	0-12	7
		Parasomnias	15, 16, 17	0-12	n/a
Subscale clinical cut-off scores: if client scores above this value for a subscale, they have screened positive for the sleep disorder associated with that subscale.					

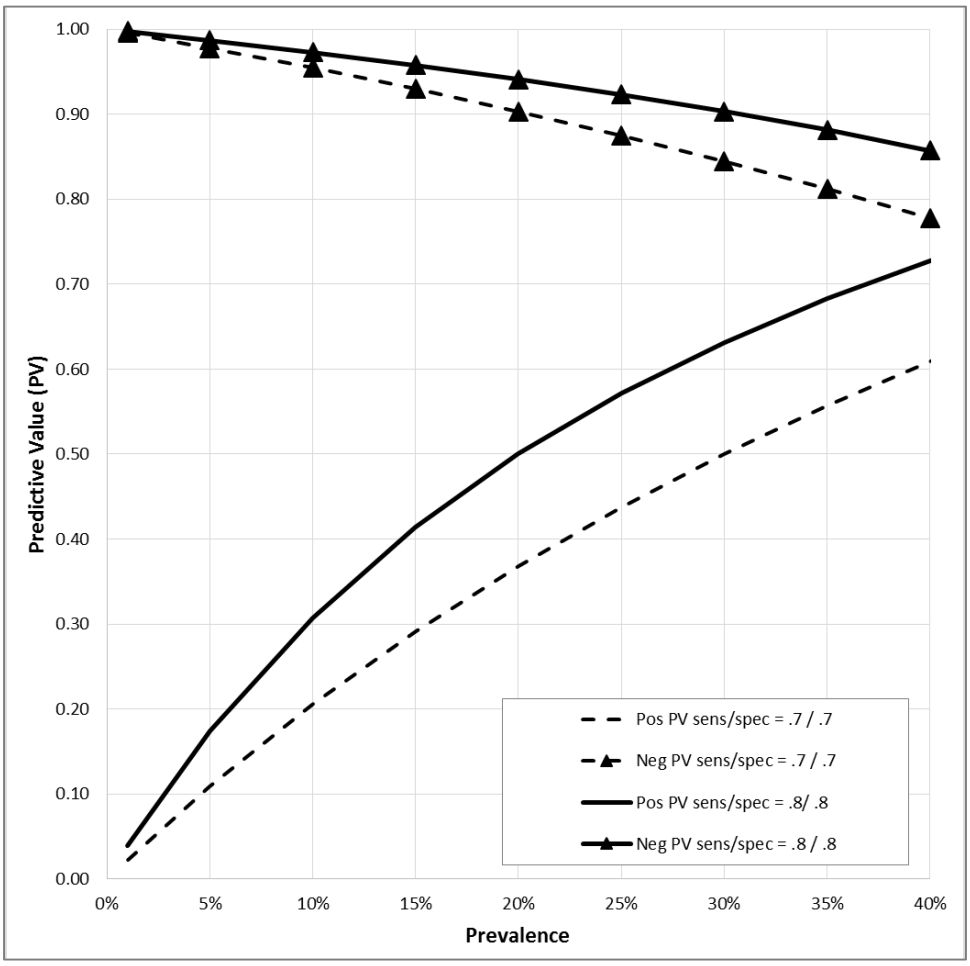
Figure 1: The Sleep Disorders Symptom Checklist (SDS-CL)

	Over the past year: (place an X in the box)	**Never**	**Seldom (1 x yr.)**	**Sometimes (1-3 x mo.)**	**Often (1-3 x wk.)**	**Frequently (> 3 x wk.)**
1	It takes me 30 minutes or more to fall asleep.					
2	I am awake 30 minutes or more during the night.					
3	I am awake 30 minutes or more prior to my scheduled wake time or alarm.					
4	I am tired, fatigued or sleepy during the day.					
5	I sleep better if I go to bed before 9 pm and wake up before 5:30 am.					
6	I sleep better if I go to bed late (after 1 am) and wake up late (after 9 am).					
7	I fall asleep at inappropriate times or places.					
8	I have been told that I snore.					
9	I wake up during the night choking or gasping.					
10	I have been told I stop breathing when I sleep.					
11	I feel uncomfortable sensations in my legs, especially when sitting or lying down that are relieved by moving them.					
12	I have an urge to move my legs that is worse in the evenings and nights.					
13	I wake up frequently during the night for no reason.					
14	I have experienced sudden muscle weakness when laughing, joking, angry or during other intense emotions.					
15	I have been told that I walk, talk, eat or act strange or violent while sleeping.					
16	I have nightmares.					
17	For no reason, I awaken suddenly, startled, and feeling afraid.					

Item choice	**Item score**	**Subscale**	**Items to sum for subscale score**	**Subscale score range**
Never	0	Insomnia	1, 2, 3, 4	0-16
Seldom	1	Circadian rhythm	5, 6	0-8
Sometimes	2	Narcolepsy	7, 14	0-8
Often	3	Obstructive sleep apnea	4, 8, 9, 10	0-16
Frequently	4	Restless legs syndrome	11, 12, 13	0-12
		Parasomnias	15, 16, 17	0-12

Note: clients receive only the 17 items for completion (i.e., portion of figure enclosed in heavy bolded lines); format for use with client and full scoring guide with clinical cut-off scores is given in Appendix.

Figure 2: Range of predictive values as function of prevalence for sensitivity-specificity pairs near the SDS-CL subscale results



Overall Dissertation Conclusions

This manuscript format dissertation demonstrated, through a concept analysis, the importance of understanding sleep within biophysical, sociological, and historic contexts as a foundation on which nurses can build an understanding of sleep in patient care (manuscript one). Sleep requires objective and subjective interpretation to determine its state of normalcy, and conversely, whether sleep might be disordered.

Although the meaning of sleep is individualized, sleep is a physiological process which, if disordered, leads to poor medical and psychiatric health outcomes. As discussed in manuscript two, sleep disorders were historically considered to be secondary to other conditions; however, sleep disorders are currently considered to be primary disorders with well-defined diagnostic criteria (American Academy of Sleep Medicine, 2014a; American Psychiatric Association, 2013b). Primary care providers would be well-positioned to prevent the adverse outcomes of undetected sleep disorders if a suitable sleep disorders screening tool, such as a brief questionnaire for patients to complete in the waiting room, were available. An ideal screening tool would comprise at most 25 items and cover the six intrinsic sleep disorders (obstructive sleep apnea, chronic insomnia disorder, circadian rhythm sleep wake disorders, restless legs syndrome, narcolepsy, and parasomnias). Yet, no suitably brief and thorough questionnaire currently exists.

A brief questionnaire developed to screen potential research subjects, the sleep disorders screening checklist (SDS-CL), was evaluated psychometrically for potential use in primary care (manuscript three). The SDS-CL covers the six intrinsic sleep disorders with 17 items. The validation sample (n=694) comprising sleep clinic patients and healthy community volunteers

was representative of the adult primary care population. Psychometric properties indicate the SDS-CL shows promise for use in primary care.

Based on this dissertation work, several recommendations for future nursing research are made.

Follow-up Evaluation of SDS-CL

Two of the SDS-CL subscales could not be validated in this dissertation study: parasomnias and circadian rhythm sleep wake disorders (CRSD). Additional work, perhaps with purposeful sampling for these two disorders at sleep clinics, seems warranted.

Develop an Implementation Plan

If plans to test sleep disorders screening via the SDS-CL in primary care practices are developed in partnership with providers and patients, the results will most likely translate smoothly into practice. The goal of this planning phase would be to determine types of information providers and patients might require, such as teaching materials, algorithms for follow-up depending on screening status, outcome variables that researchers may not have considered, and so on.

Operationalize and Assess Feasibility of Outcome Variables

While the long-term goal of screening for sleep disorders is prevention of adverse health outcomes, short-term variables would be required for initial assessment of a screening program. One possibility is to assess the effect of sleep disorders screening on health care usage, for example, by measuring how often patients seek medical care (primary care, specialist, urgent care, etc.). More investigation regarding measurement of health care usage is required. Implementation of treatments for sleep disorders could be another outcome variable. Other possible outcomes might be biophysical, e.g., blood pressure, body weight, or hemoglobin A1c.

Develop Follow-up Protocol for Positive Screens

Follow-up protocols could be developed by summarizing AASM guidelines (American Academy of Sleep Medicine, 2014b) or by consultation with sleep medicine specialists. Follow-up might include referral for additional testing, initiation of treatment by the primary care provider or referral to specialists for treatment, for example. Cost-benefit analyses may be required.

Pilot Test SDS-CL in Primary Care

For a small sample of patients, on the order of n=30, the influence of screening for sleep disorders in a primary care practice could be tested. The subjects would be individuals who are being seen for routine office visits (e.g., annual check-ups) or new intake patients.

Test Long-term Impact of Using SDS-CL in Primary Care

Billing codes in a primary care practice might be an indication of whether sleep disorders screening decreases health care usage. For example, if a primary care practice implemented sleep disorders screening on routine visits, then the types of codes for which the practice bills over the next year, for example, might change favorably as patients are diagnosed and then treated for sleep disorders. Historical data for billing codes could be used for comparison.

Pilot Test SDS-CL in Psychiatric Practice (for Ruling-out Sleep Disorders)

Differential diagnosis for some psychiatric disorders can include ruling-out of sleep disorders (American Psychiatric Association, 2013a). The SDS-CL, with negative predictive values of 99% on some of the sleep disorders, might be an efficient tool for psychiatric providers to utilize.

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Appendix A: Clinically-friendly format of SDS-CL

Figure A1 is a single-page format of the SDS-CL that could be utilized with patients. The scoring guide is provided as Table A1. (The remainder of this page is left blank to enable the SDS-CL and scoring guide to be printed out in practice-friendly format.)

Figure A1: **SLEEP DISORDERS SYMPTOM CHECKLIST (SDS-CL) for clients**

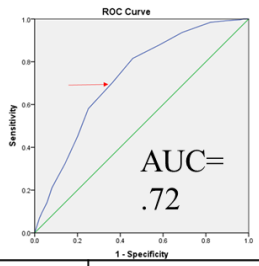
Name/Subject #_____ **Date:**_____

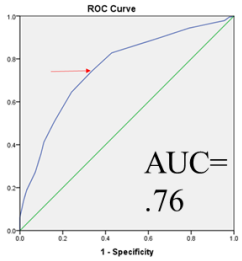
	Over the past year: (place an X in the box)	**Never**	**Seldom (1 x yr.)**	**Sometimes (1-3 x mo.)**	**Often (1-3 x wk.)**	**Frequently (> 3 x wk.)**
1	It takes me 30 minutes or more to fall asleep.					
2	I am awake 30 minutes or more during the night.					
3	I am awake 30 minutes or more prior to my scheduled wake time or alarm.					
4	I am tired, fatigued or sleepy during the day.					
5	I sleep better if I go to bed before 9 pm and wake up before 5:30 am.					
6	I sleep better if I go to bed late (after 1 am) and wake up late (after 9 am).					
7	I fall asleep at inappropriate times or places.					
8	I have been told that I snore.					
9	I wake up during the night choking or gasping.					
10	I have been told I stop breathing when I sleep.					
11	I feel uncomfortable sensations in my legs, especially when sitting or lying down that are relieved by moving them.					
12	I have an urge to move my legs that is worse in the evenings and nights.					
13	I wake up frequently during the night for no reason.					
14	I have experienced sudden muscle weakness when laughing, joking, angry or during other intense emotions.					
15	I have been told that I walk, talk, eat or act strange or violent while sleeping.					
16	I have nightmares.					
17	For no reason, I awaken suddenly, startled, and feeling afraid.					

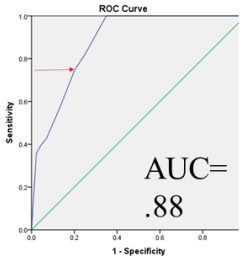
Table A1: SDS-CL scoring guide

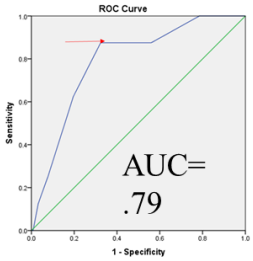
SDS-CL SCORING GUIDE – FOR PROVIDER					
Item choice	**Item score**	**Subscale**	**Items to sum for subscale score**	**Subscale score range**	**Subscale clinical cut-off score**
Never	0	Insomnia	1, 2, 3, 4	0-16	8
Seldom	1	Circadian rhythm	5, 6	0-8	n/a
Sometimes	2	Narcolepsy	7, 14	0-8	2
Often	3	Obstructive sleep apnea	4, 8, 9, 10	0-16	6
Frequently	4	Restless legs syndrome	11, 12, 13	0-12	7
		Parasomnias	15, 16, 17	0-12	n/a
Subscale clinical cut-off scores: if client scores above this value for a subscale, they have screened positive for the sleep disorder associated with that subscale.					

Appendix B: ROC Curves for determining cutpoints of SDS-CL subscales for insomnia, obstructive sleep apnea, narcolepsy, and restless legs syndrome









Disorder (# dx)	Insomnia (n=462)	Obstructive Sleep Apnea (n=411)	Restless Legs Syndrome (n=28)	Narcolepsy (n=8)
Cutpt (max score)	**8** (16)	**6** (16)	**7** (12)	**2** (8)
AUC (95% C.I.)	.72 (.69 - .76)	76 (.72 - .80)	.88 (.83 - .92)	.79 (.65 - .93)
Sensitivity/ specificity	.70 / .64	.74 / .66	.75 / .800	.87 / .68

dx – number of subjects diagnosed with the sleep disorder

Clinical relevance: pts score above cut-points screen positive for disorder

Appendix C: Competing Demands Model– Permission to Use

Below is a copy of the e-mails exchanged with Dr. Jaen regarding permission to use the competing demands model in this dissertation (Figure 1 of the "Theoretical Frameworks for the Literature Review" section).

Karen Klingman <karenkli@buffalo.edu> Wed, Mar 25, 2015 at 10:22 PM
To: jaen@uthscsa.edu

Dear Dr. Jaen,

I am writing to request permission to include the Figure from your publication:
Jaen, C. R., Stange, K. C., & Nutting, P. A. (1994). Competing demands of primary care: A model for the delivery of clinical preventive services. The Journal of Family Practice., 38, 166-171.

in my dissertation entitlted "Evaluation of a Sleep Disorders Screening Questionnaire for Primary Care of Adults". I have used your model to illustrate why provision of an efficient tool (questionnaire) to screen for multiple sleep disorders would facilitate sleep disorders screening as a form of preventive care, and would like to include it in my dissertation. I expect to receive my doctorate in nursing from your alma mater UB this coming June.

Thank you for your kind consideration.

Sincerely,

Karen Klingman, RN
--
Karen Klingman, RN
SUNY Buffalo SON, PhD student

Jaen, Carlos R <JAEN@uthscsa.edu> Thu, Mar 26, 2015 at 6:41 AM
To: Karen Klingman <karenkli@buffalo.edu>

Dear Ms. Klingman,
Congratulations on getting this far in your studies. I'm delighted to find out that our paper is useful to you. You have my permission to use the figure. Your study sounds very practical and potentially useful. Please send me a copy of your paper once it gets published in a journal.

All the best,
Carlos Roberto Jaén, MD, PhD

Sent from my iPhone

Appendix D: IRB Document- Not Human Subjects Research

University at Buffalo
The State University of New York

University at Buffalo Institutional Review Board (UBIRB)

Office of Research Compliance | Clinical and Translational Research Center Room 5018
875 Ellicott St. | Buffalo, NY 14203

UB Federalwide Assurance ID#: FWA00008824

DATE:	April 8, 2015
TO:	Karen Klingman
FROM:	SUNY University at Buffalo Institutional Review Board
PROJECT TITLE:	[733351-1] Evaluation of a Sleep Disorders Screening Questionnaire for Primary Care of Adults
SUBMISSION TYPE:	New Project
ACTION:	DETERMINATION OF RESEARCH NOT INVLOVING HUMAN SUBJECTS
DECISION DATE:	April 8, 2015

Dear Karen Klingman:

The SUNY University at Buffalo IRB (UBIRB) has reviewed the above referenced project.

The following is a list of the documents reviewed in this package:

- Application Form - HRP-211-FORM-Initial Review Klingman 3-16-15.docx (UPDATED: 03/17/2015)
- Protocol - HRP-503-Template Protocol Klingman 3-17-15.docx (UPDATED: 03/17/2015)
- Questionnaire/Survey - Expert Opinion SDS-CL Content Validity Survey - fillable form (UPDATED: 03/17/2015)
- SUNY Buffalo - Core Data Form - SUNY Buffalo - Core Data Form (UPDATED: 03/25/2015)

The IRB determined that the proposed activity is not research involving human subjects as defined by DHHS and FDA regulations.

The IRB determined that the proposed activity is research involving human subjects as defined by regulations but that this organization is not engaged in the research.

IRB review and approval by this organization is not required. This determination applies only to the activities described in the IRB submission and does not apply should any changes be made. If changes are made and there are questions about whether these activities are research involving human in which the organization is engaged, please submit a new request to the IRB for a determination.

If you have any questions, please contact the UBIRB. Please include your project title and IRBNet Project Number in all correspondence with the IRB.

Appendix E: CITI Certificates

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Karen Klingman (ID: 2980332)
- **Email:** karenkli@buffalo.edu
- **Institution Affiliation:** SUNY - Buffalo (University at Buffalo) (ID: 479)
- **Institution Unit:** Nursing
- **Phone:** 585-465-2701

- **Curriculum Group:** Human Research
- **Course Learner Group:** Social & Behavioral Research Investigators
- **Stage:** Stage 1 - Basic Course

- **Report ID:** 8450915
- **Completion Date:** 08/26/2012
- **Expiration Date:** 08/26/2015
- **Minimum Passing:** 80
- **Reported Score*:** 91

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Introduction (ID:757)	08/26/12	No Quiz
History and Ethical Principles - SBE (ID:490)	08/26/12	5/5 (100%)
Defining Research with Human Subjects - SBE (ID:491)	08/26/12	4/5 (80%)
The Federal Regulations - SBE (ID:502)	08/26/12	5/5 (100%)
Assessing Risk - SBE (ID:503)	08/26/12	5/5 (100%)
Informed Consent - SBE (ID:504)	08/26/12	5/5 (100%)
Privacy and Confidentiality - SBE (ID:505)	08/26/12	4/5 (80%)
Research with Prisoners - SBE (ID:506)	08/26/12	4/4 (100%)
Research with Children - SBE (ID:507)	08/26/12	3/4 (75%)
Research in Public Elementary and Secondary Schools - SBE (ID:508)	08/26/12	4/4 (100%)
International Research - SBE (ID:509)	08/26/12	3/3 (100%)
Internet-Based Research - SBE (ID:510)	08/26/12	5/5 (100%)
Research and HIPAA Privacy Protections (ID:14)	08/26/12	3/5 (60%)
Vulnerable Subjects - Research Involving Workers/Employees (ID:483)	08/26/12	4/4 (100%)
Conflicts of Interest in Research Involving Human Subjects (ID:488)	08/26/12	4/5 (80%)
SUNY at Buffalo (ID:756)	08/26/12	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

CITI Program
Email: citisupport@miami.edu
Phone: 305-243-7970
Web: https://www.citiprogram.org

COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Karen Klingman (ID: 2980332)
- **Email:** karenkli@buffalo.edu
- **Institution Affiliation:** SUNY - Buffalo (University at Buffalo) (ID: 479)
- **Institution Unit:** Nursing
- **Phone:** 585-465-2701

- **Curriculum Group:** Responsible Conduct of Research
- **Course Learner Group:** Social and Behavioral Responsible Conduct of Research Course
- **Stage:** Stage 1 - Basic Course
- **Description:** This course is for investigators, staff and students with an interest or focus in Social and Behavioral research. This course contains text, embedded case studies AND quizzes.

- **Report ID:** 15079283
- **Completion Date:** 01/28/2015
- **Expiration Date:** N/A
- **Minimum Passing:** 80
- **Reported Score*:** 97

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
Responsible Conduct of Research (RCR) Course Introduction (ID:1522)	08/26/12	No Quiz
Research Misconduct (RCR-Basic) (ID:16604)	01/28/15	5/5 (100%)
Data Management (RCR-Basic) (ID:16600)	01/28/15	4/5 (80%)
Authorship (RCR-Basic) (ID:16597)	01/28/15	5/5 (100%)
Peer Review (RCR-Basic) (ID:16603)	01/28/15	5/5 (100%)
Conflicts of Interest (RCR-Basic) (ID:16599)	01/28/15	5/5 (100%)
Collaborative Research (RCR-Basic) (ID:16598)	01/28/15	5/5 (100%)
Responsible Conduct of Research (RCR) Course Conclusion (ID:1043)	01/28/15	No Quiz
SUNY at Buffalo (ID:756)	08/26/12	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid independent Learner.

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COLLABORATIVE INSTITUTIONAL TRAINING INITIATIVE (CITI PROGRAM)

COURSEWORK REQUIREMENTS REPORT*

* NOTE: Scores on this Requirements Report reflect quiz completions at the time all requirements for the course were met. See list below for details. See separate Transcript Report for more recent quiz scores, including those on optional (supplemental) course elements.

- **Name:** Karen Klingman (ID: 2980332)
- **Email:** karenkli@buffalo.edu
- **Institution Affiliation:** SUNY - Buffalo (University at Buffalo) (ID: 479)
- **Institution Unit:** Nursing
- **Phone:** 585-465-2701

- **Curriculum Group:** CITI Good Clinical Practice
- **Course Learner Group:** CITI Good Clinical Practice Course
- **Stage:** Stage 1 - GCP
- **Description:** This course is for investigators and staff who conduct FDA regulated research or international research with investigational drugs and devices according to ICH Gidelines.

- **Report ID:** 15079284
- **Completion Date:** 01/28/2015
- **Expiration Date:** 01/27/2019
- **Minimum Passing:** 80
- **Reported Score*:** 98

REQUIRED AND ELECTIVE MODULES ONLY	DATE COMPLETED	SCORE
The CITI Good Clinical Practice Course for Clinical Trials Involving Drugs and Devices (ID:1350)	01/28/15	3/3 (100%)
Overview of New Drug Development (ID:1351)	01/28/15	5/5 (100%)
Overview of ICH GCP (ID:1352)	01/28/15	4/4 (100%)
ICH - Comparison Between ICH GCP E6 and U.S. FDA Regulations (ID:1354)	01/28/15	4/4 (100%)
Conducting Investigator-Initiated Studies According to FDA Regulations and GCP (ID:1355)	01/28/15	3/3 (100%)
Investigator Obligations in FDA-Regulated Research (ID:1356)	01/28/15	5/5 (100%)
Managing Investigational Agents According to GCP Requirements (ID:1357)	01/28/15	5/5 (100%)
Overview of U.S. FDA Regulations for Medical Devices (ID:1358)	01/28/15	3/3 (100%)
Informed Consent in Clinical Trials of Drugs, Biologics, and Devices (ID:1359)	01/28/15	4/4 (100%)
Detecting and Evaluating Adverse Events (ID:1360)	01/28/15	4/4 (100%)
Reporting Serious Adverse Events (ID:1361)	01/28/15	4/4 (100%)
Audits and Inspections of Clinical Trials (ID:1363)	01/28/15	5/5 (100%)
Monitoring of Clinical Trials by Industry Sponsors (ID:1362)	01/28/15	7/8 (88%)
Completing the CITI GCP Course (ID:1364)	01/28/15	No Quiz

For this Report to be valid, the learner identified above must have had a valid affiliation with the CITI Program subscribing institution identified above or have been a paid Independent Learner.

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