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IMPLEMENTATION RESEARCH

Implementation of Sleep and Circadian Science: Recommendations from the Sleep Research Society and National Institutes of Health Workshop

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EXECUTIVE SUMMARY

A wealth of scientific knowledge is being generated in sleep and circadian science. In order for us to realize the return on investment for such scientific knowledge and to improve the health of the nation, we need to disseminate and implement research findings into practice. An implementation gap—termed a "quality chasm" by the Institutes of Medicine—separates the scientific knowledge we possess and the implementation of such knowledge into preventative interventions or healthcare treatments. It is frequently reported that a time lag of 17 years transpires before medical research reaches clinical practice. The rapid development of new therapies and devices for sleep and circadian disorders, the emergence of wearable devices and mobile health, combined with the mounting interest in sleep from the public and technology industries, present a transformative opportunity for sleep and circadian science researchers. In order to capitalize on this opportunity, the Sleep Research Society and the National Institutes of Health partnered to organize a workshop focused on the translation of evidence-based interventions for sleep and circadian disorders into practice strategies that benefit population health and patient outcomes. The workshop drew on the collective expertise of implementation scientists and sleep scientists in the areas of insomnia, sleep-disordered breathing, and adolescent sleep health. Together, they identified implementation gaps, effective interventions, implementation strategies and relevant outcomes and created a set of recommendations that could accelerate late-stage translation of sleep and circadian rhythms research findings to benefit public health. This white paper represents the proceedings and consensus developed at the workshop. The recommendations for high-priority implementation research are targeted at sleep and implementation researchers, educators, patients, professional societies, industry partners, funding-decision and policy makers. The major recommendations for implementation science in sleep and circadian sciences were to address the following high priority future research needs: (1) Costs and economic benefits associated with screening, diagnosing, treating insomnia across different systems (health care system, employers, etc.). (2) Promoting health literacy and education of patients, providers and community stakeholders regarding obstructive sleep apnea. (3) Increase the proportion of students in grades 9 through 12 who get sufficient sleep and (4) Perform trials aimed at improving adherence to treatments for sleep-disordered breathing (particularly evaluating cognitive therapy approaches). The fourth priority area was identified as an important barrier to implementation science efforts in sleep.

INTRODUCTION AND OVERVIEW

"Knowing is not enough; we must apply. Willing is not enough; we must do."—Goethe

Sleep and circadian disturbances and disorders afflict millions of individuals in the US.[1] Nearly 25% of adults in the US report insufficient sleep which, in turn, is associated with increased risk for heart disease, hypertension, obesity, diabetes mellitus, accidents and all-cause mortality.[2] Adequate sleep is necessary for healthy infant, child, and adolescent development and both physical and mental health in both children and adults.[3] Moreover, sleep and circadian disorders are common with insomnia affecting up to 10% to 15% of adults and sleep-disordered breathing that is conservatively estimated to afflict 7% of adults in the US.[4,5] Both insomnia and sleep-disordered breathing are associated with cardiovascular morbidity and mortality.[6–13] Furthermore, the public health burden of insomnia and sleep-disordered breathing is increasing due to the aging population and the obesity epidemic, respectively.[14] In older adults, the prevalence of sleep-disordered breathing is estimated to be as high as 30% to 40%.[5,6,15] Sleep also has important effects on health and function in younger individuals as well. For instance, cross-sectional data in adolescents consistently link reduced sleep duration and delayed sleep timing to risk behaviors such as substance use, violence-related behaviors, risky sexual practices, suicidality, and driving while impaired from alcohol.[16–22]

In addition to the improved understanding of the public health importance of sleep, circadian rhythms and their disorders on health and safety, there have been major fundamental advances in our understanding of the mechanistic basis for how sleep and circadian rhythms can affect health, disease,

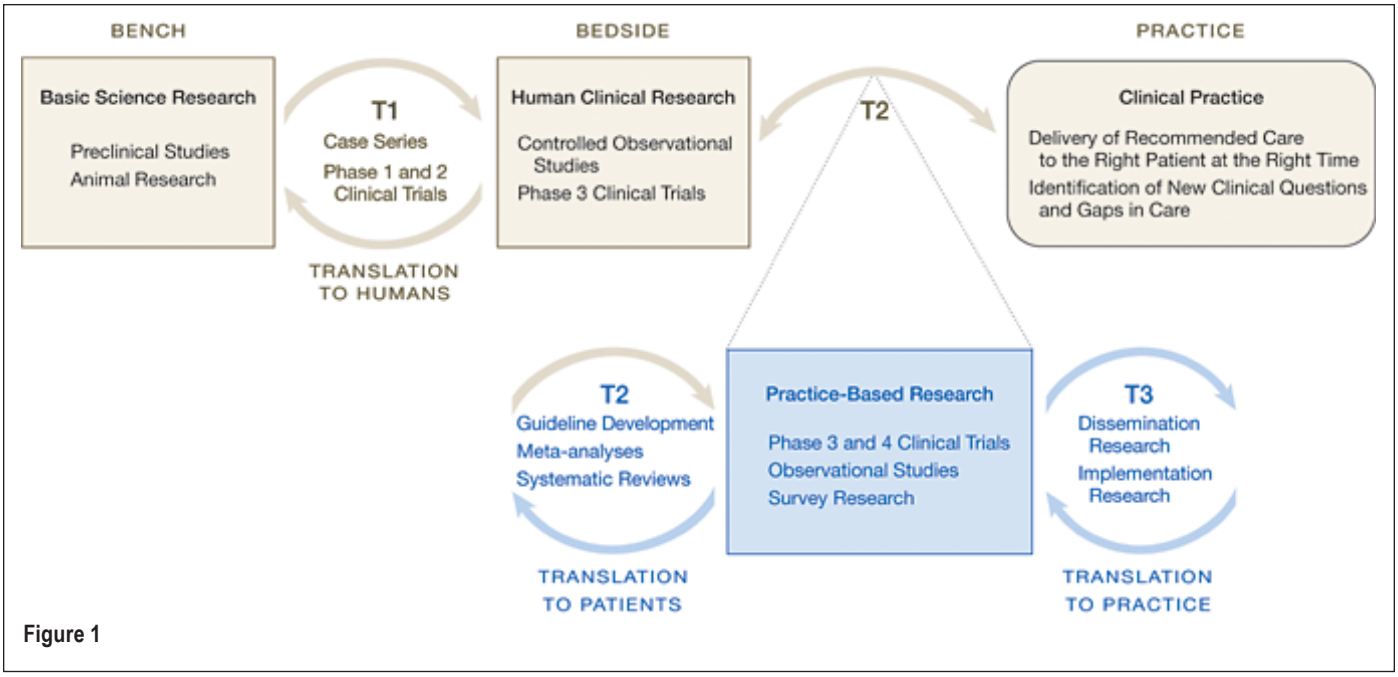

Figure 1

and safety.[23–28] The wealth of scientific knowledge that is being generated in the fields of sleep and circadian sciences needs to translated to the bedside and communities to benefit the patients and the public.[29] An implementation gap—termed a "quality chasm" by the Institutes of Medicine—separates the scientific knowledge we possess and the implementation of such knowledge into preventative interventions or healthcare treatments.[30] In all of medicine, not just sleep medicine, it is frequently reported that a time lag of 17 years transpires before research evidence reaches clinical practice.[31,32] Moreover, at present, Americans receive only half of recommended preventative, acute and long term healthcare.[33] Such sobering statistics have led some critics to assert that the translation of basic discoveries and evidence-based clinical interventions, to advance the health and well-being of patients and communities is agonizingly slow.[34] The problem is multifaceted and due to lack of access to affordable healthcare resources; patient, provider and healthcare knowledge regarding guidelines; patient-level care seeking behaviors and other factors. However, part of the failure is due to incomplete understanding of how to effectively deliver healthcare guidelines in real-world settings.

Even if such translation of knowledge to the bedside were to occur, patients and clinicians often face complex and confusing choices when it comes to addressing healthcare concerns. Traditional medical research has not always addressed the questions that patients, families, and their clinicians face daily. Such barriers to dissemination and implementation (D&I) may be overcome only by the full participation of patients in the research process in ways that can make them understand their health and use the available health information more effectively.[35] The creation of the Center for Translation Research and Implementation Science (CTRIS) within the National Institutes of Health, the Patient-Centered Outcomes Research Institute (PCORI), and their research networks are meant to tackle these issues head-on to improve the health of the nation.[35–37] The ultimate goal of D&I research is to identify ways to extend and adapt generally accepted and effective interventions that have previously been carried out in well-controlled settings to broader populations or settings (i.e., real-world settings like the workplace, schools, community centers and clinics, neighborhoods). D&I research bridges research and practice in real-world settings and strike a balance between rigor and relevance in study designs, methods and outcomes (Figure 1).

The rapid development of new therapies and devices for sleep and circadian disorders, the emergence of wearable devices and mobile health, and the mounting interest in sleep from the public and technology industries present a transformative opportunity for sleep and circadian science researchers. Recognizing this opportunity, the Sleep Research Society in conjunction with the National Heart Lung Blood Institute organized a workshop in Seattle, Washington, in June 2015 focused on the translation of evidence-based interventions for sleep and circadian disorders to benefit population health. Specifically, the objectives were to set a research agenda for sleep and circadian sciences in the area of implementation science and to enable collaborations between sleep, circadian, and implementation scientists. The workshop drew on the collective expertise of both sleep and implementation scientists who identified implementation gaps, effective interventions, implementation strategies, and relevant outcomes and created a set of recommendations that could accelerate translation of sleep and circadian rhythms research into benefitting the American people. In addition to harnessing the interest of implementation scientists from outside of the sleep field, over 20 young investigators with aspirations in sleep and implementation science were selected through a competitive application process to participate in the workshop. The young investigators culled and weighed the scientific evidence prior to the workshop with the guidance from leaders in the sleep field; presented their synthesized reports at the workshop; and contributed substantially to writing this white paper. This white paper represents

Table 1—Objectives of the sleep and circadian science implementation workshop.

- Review the state of the science in the specific group domain
- Identify what interventions are at the right point for implementation efforts
- Identify the most critical implementation barriers, questions, and gaps
- Develop a set of concrete sleep health research recommendations for implementation science
- Advance active community-engagement, research networks, and team science
- Support and promote research training in implementation science as it pertains to sleep and circadian sciences
- Sleep Research Society to provide and campaign for more funding opportunities for investigator-initiated implementation research applications

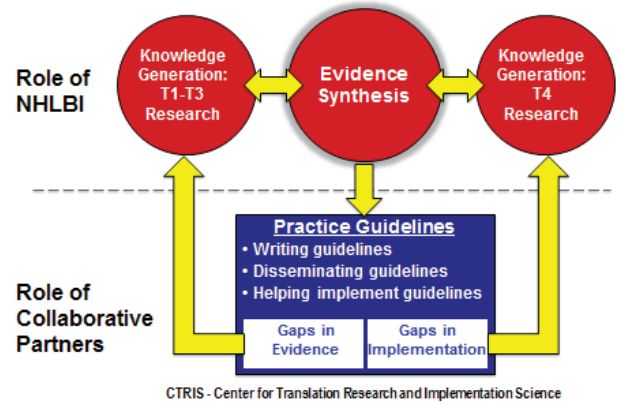

Figure 2

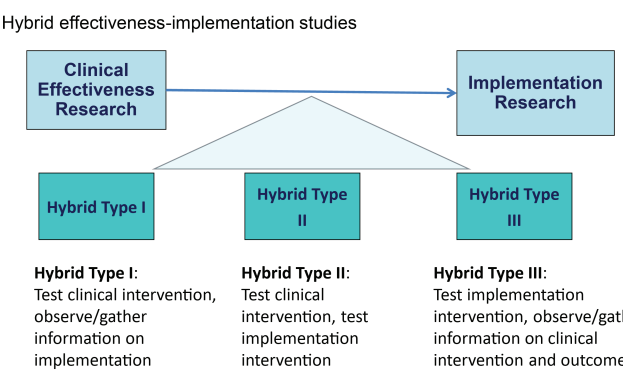

Figure 3

the proceedings and consensus development from the workshop. The recommendations for high-priority research were derived from a ranking of future research needs that emerged from the workshop. Such high priority future research needs in this implementation arena will be of substantial interest to sleep and implementation researchers, educators, patients, professional societies, industry partners, funding-decision and policy makers.

Prior to the workshop, the organizers established major questions that should be addressed by each group domain (Table 1). Each group was tasked with (a) reviewing the state of the science in the specific group domain; (b) identifying interventions that are ready for implementation; (c) clarifying the most critical implementation barriers, questions, gaps; and (d) developing a set of concrete recommendations. When evidence gaps were identified, groups were asked to identify research needed at an earlier phase of translation, such as efficacy utilizing a hybrid design (Figure 2 and Figure 3). For evidence- or guideline-based care delivery, the implementation agenda could include advancing active community-engagement, research networks, and team science; development and promotion of research training in implementation science as it pertains to sleep and circadian sciences; and investigator-initiated implementation research.

The following sections review the state of science, deliberations, and recommendations of the three pre-identified tracks on insomnia, sleep-disordered breathing, and adolescent sleep health that were chosen. The workshop focused on three targeted aspects of sleep and circadian science to begin the process towards implementation science considering the large public health burden that they impose. This document can serve as an exemplar for future sleep implementation efforts for other sleep and circadian disorders and sleep duration.

INSOMNIA

Overview

Insomnia disorder is characterized by disturbed sleep and associated impairments during wakefulness. Sleep symptoms may include sleep-onset difficulties, sleep-maintenance problems, or waking up earlier than desired, and must occur at least three nights a week for three months or longer to warrant a diagnosis.[38,39] These sleep symptoms must be accompanied by a daytime complaint, such as fatigue, cognitive impairment, or mood disturbance. In the US, prevalence estimates of insomnia range from 10% to 15% in the general population, with significantly higher rates in women, patients with comorbid medical and psychiatric disorders, and first-degree family members of individuals with insomnia.[40] Other proposed risk factors, such as old age, low socioeconomic status, and African American race, have less consistent empirical support.[41] Insomnia is associated with significant health care costs, as well as occupational impairment in the form of workplace absenteeism, reduced productivity, and health-related quality of life.[42,43] It is also a reliable risk factor for various psychiatric and medical conditions, especially depression[44] and hypertension.[45] A growing body of evidence demonstrates that insomnia is associated with cardiovascular and all-cause mortality.[7,9,13,46–55]

Promising Interventions: Cognitive Behavioral Therapy for Insomnia (CBT-I)

CBT-I, the most widely studied intervention for insomnia, combines treatment components including stimulus control,

Table 2—Evidence-based interventions ready for implementation.

Insomnia

Psychological and behavioral treatment types
- Cognitive behavioral therapy for insomnia (CBT-I)
- Brief behavioral treatments
- Mindfulness

Psychological and behavioral treatment modalities
- Group based CBT-I
- Internet based CBT-I
- Mobile App-based CBT-I

Medications
- Benzodiazepine receptor agonists
- Sedating antidepressants

Obstructive Sleep Apnea
- CPAP in adults with obstructive sleep apnea
- Adeno-tonsillectomy in children with sleep apnea
- Mandibular advancement devices ("oral appliances")

Adolescent Sleep Health
- Increase sleep duration in children and adolescents
- Implementation of sleep apnea screening tools in pediatric practices
- Delayed school start times

CPAP, continuous positive airway pressure therapy.

sleep restriction, cognitive therapy, relaxation, and sleep hygiene education. Meta-analyses support the efficacy of CBT-I for primary insomnia,[56–58] insomnia among older adults,[59,60] and insomnia comorbid with medical and/or psychiatric conditions.[61–63] CBT-I's positive treatment effects are durable over 12-month follow-up.[57] Comparative meta-analyses also suggest CBT-I is superior to benzodiazepine receptor agonist medications for reducing sleep onset latency[64,65] and that the effects of CBT-I are more durable over the long term.[65] Adverse effects of CBT-I appear to be mild, but have not been investigated as systematically as adverse effects of medications. However, access to CBT-I remains limited due to availability of qualified therapists. Recent research efforts have focused on alternative delivery methods that may increase access to care.[66] Compared to control conditions, meta-analyses support the efficacy of group CBT-I,[67] self-help modalities (e.g., booklets, videotapes, audiotapes, internet),[68] and interactive web programs.[69] While each mode of delivery has its limitations, these alternatives are most likely to be viable options for widespread dissemination of CBT-I and increased access to care especially considering recent recommendations that CBT-I is the preferred initial treatment for insomnia.[70]

Promising Interventions: Pharmacologic Treatments

Benzodiazepine receptor agonists (BzRA), which include benzodiazepine and non-benzodiazepine compounds, are the most widely-used medications for insomnia treatment. Meta-analyses demonstrate their efficacy compared to placebo for subjective (sleep diary) and objective (polysomnography) sleep onset- and sleep maintenance insomnia symptoms.[71] BzRA were formerly recommended only for the short-term management of insomnia (≤ 4 weeks), but several double-blind RCTs support their efficacy for up to six months.[72,73] Adverse effects include somnolence, headache, cognitive and psychomotor impairment, and abnormal sleep-related behaviors.[71,74] In adults > 60 years of age, the small therapeutic effects may not outweigh the relatively high risk of adverse effects.[74] Furthermore, BzRA carry risks of tolerance, dependence, rebound insomnia, and abuse.[75] Some evidence suggests increased mortality associated with BzRA use.[76] Low-dose sedating antidepressants, which are increasingly prescribed in clinical practice,[77] appear to be relatively safe and efficacious in a relatively small number of clinical trials.[71,78] However, the risk-benefit ratio of these medications requires further evaluation. The paucity of evidence supporting the efficacy, effectiveness, and safety of the many other medications used to treat insomnia renders them inappropriate for D&I research at this time.

Outcome Measures and Implementation Methods

Numerous psychometrically sound measures are available to assess insomnia treatment outcomes. Objective measures include polysomnography, although not typically recommended outside of clinical research, and actigraphy.[79] More common in clinical settings are self-report measures of sleep behaviors,[80] insomnia symptoms,[81,82] sleep quality,[83–85] and sleep-related cognitions.[86] An American Academy of Sleep Medicine (AASM) commissioned workgroup recently developed consensus insomnia quality metrics considered vital to a desirable treatment outcome: improved sleep satisfaction/quality (SSQ) and improved daytime functioning.[87] Assessment of SSQ is accomplished using self-report measures[81–87] and prospective sleep diaries.[80] Assessment of daytime functioning can be measured across multiple domains: sleepiness; fatigue, energy, and motivation; family, social, educational, and occupational function; mood; and cognitive function.[88] Insomnia treatment outcomes should also be measured at the systemic/organization and the provider level in addition to patient-level outcomes. Measures of successful insomnia treatment *implementation* include the rate of adoption, penetration of treatment services, patient and provider adherence, sustainability, and cost effectiveness.[58] To implement best treatment practices for insomnia all levels of care must be measured with continuous assessment and quality improvement efforts taking place.

Recommendations for Implementation Studies in Insomnia

A large body of evidence describes the diagnosis, health correlates, and treatment of insomnia, and important strides have been made toward implementation of these strategies in specific health care settings. However, a number of barriers and unanswered questions also remain in these areas, creating opportunities for implementation science to bridge existing gaps in insomnia care. Promising interventions ready for implementation are listed in Table 2 and the recommendations for implementation in insomnia are provided in Table 3.

OBSTRUCTIVE SLEEP APNEA

Obstructive sleep apnea (OSA) is a serious condition which involves the cardiovascular, pulmonary and metabolic systems and is associated with increased risk of ischemic stroke and myocardial infarction, particularly in younger individuals.[89]

Research on OSA has progressed over the last two decades, yet, there are major inadequacies. Overall, positive airway pressure (PAP) therapy appears to be more effective than oral devices such as mandibular advancement devices or oral surgery. However, the benefits with PAP therapy are only realized when such therapy is worn for at least 4–5 hours every night.[11,90] Continuous positive airway pressure (CPAP) therapy is generally poorly tolerated,[91] although strategies to improve patient adherence such as mask optimization, heated humidification, topical nasal therapy, sleep apnea education, and automatic PAP as compared to continuous PAP therapy may be helpful.[92–94] PAP therapy is effective in reducing subjective symptoms of sleepiness, apnea-hypopnea index, and cardiovascular and metabolic health.[95,96] Generally, PAP therapy is effective in reducing arterial blood pressure and the benefits are dependent on the population group; and results are better with increasing time of use per night.[97,98] In some instances, alternative oral devices also show improved quality of life equivalent to PAP therapy.[99] Oral devices including mandibular advancement devices are recommended to be considered as alternatives for PAP treatment only in patients with mild OSA[100] and for those who do not tolerate PAP therapy.[101] Short-term PAP therapy withdrawal accentuates subjective sleepiness and cardiovascular symptoms thus confirming its use in treating OSA.[102] However, over the long term, data on the efficacy of PAP therapy are still forthcoming.[103–106] Newer treatment modalities such as hypoglossal nerve stimulation appear to have an advantage over PAP therapy, but the invasive nature, high costs, and the need for more long-term data need to be considered.[107] Moreover, such therapies may not work in certain subset of patients with OSA and appropriate selection of treatment responsive individuals remains a challenge.

Health Disparities in OSA

Although men and women are affected by OSA in a ratio of about 2:1,[108] very few studies include 33% of women in their sample. Similarly, most studies are performed on obese middle-aged individuals and there is poor representation of races other than Whites, when disease prevalence and severity is greater in minorities.[108,109] Therefore, more long-term real-world clinical trials need to be conducted in different populations with adequate representation of women and minorities using different treatment devices. Finally, implementing successful strategies in minority communities in order to increase awareness about OSA and improve adherence to treatment needs action. There are a few ongoing trials which focus on such implementation research in patients with OSA, but more work needs to be done in this area. Moreover, there is a paucity of data on racial or socioeconomic differences or rural versus urban differences in diagnostic and therapy services for OSA.[110]

Adherence to PAP therapy

While PAP therapy has been shown to be a highly efficacious treatment of OSA in clinical trials, adherence to PAP therapy has been identified as a significant factor limiting real-world effectiveness.[111] There are racial differences in PAP adherence.[112,113] One study found that PAP users who are black have an average of one hour less use per night than PAP users who are white, with no difference between PAP users who are white and Hispanic.[114] Lower socioeconomic status also negatively affects adherence to PAP therapy.[115] Additionally, psychological characteristics such as posttraumatic stress disorder, insomnia, and depression reduce PAP adherence.[116,117]

Given that adherence is a major hurdle to effectiveness of PAP therapy, there have been multiple investigations of interventions to improve patient adherence. Interventions have primarily focused on device or interface factors or educational, supportive, and behavioral interventions. A recent Cochrane review[93] showed that automatic PAP therapy appeared to increase

Table 3—Results of workshop: opportunities for sleep and circadian sciences implementation research for insomnia.

Insomnia

High Priority Future Research Needs

1. Costs and economic benefits associated with screening, diagnosing, treating insomnia across different systems (health care system, employers, etc.).
2. Disseminate simple screening tools for insomnia that can be incorporated into routine practice.
3. Comparative effectiveness studies within and across treatment classes, modalities, and patient groups.

Other Future Research Needs

4. Systematically assess knowledge, attitudes, and behaviors regarding insomnia diagnosis among key stakeholders including patients, providers, payers, and health systems.
5. Increase promising educational interventions aimed at promoting awareness in providers/communities of the adverse health, functional outcomes, and costs associated with insomnia among various stakeholders.
6. Incorporate insomnia recognition and insomnia care into wellness programs as well as medical care.
7. Conduct pragmatic, patient-centered, and comparative effectiveness trials within and between the major treatment modalities for insomnia: Cognitive-behavioral interventions and medications.
8. Investigate strategies for developing a trained work force sufficient to manage insomnia and other behavioral sleep health problems in routine care settings.
9. Identify simple measures and metrics for the health and adverse outcomes associated with insomnia.
10. Investigate barriers and facilitators of reimbursement for insomnia management.
11. Assess perceived and actual barriers regarding insomnia treatment delivery, and incentives and disincentives for using various treatment modalities.
12. Investigate implementation frameworks, models, and study designs to use in the conduct of hybrid clinical-effectiveness and implementation trials, to measure the uptake and sustainability of integrating treatments for insomnia into routine care settings.
13. Investigate the utility and value of objective monitoring devices (e.g., wearable personal monitors) in insomnia recognition and diagnosis.
14. Systematically investigate adverse effects of all treatment modalities for insomnia (cognitive-behavioral as well as pharmacologic).
15. Investigate the utility and value of objective monitoring devices (e.g., wearable personal monitors) in insomnia treatment.

PAP use compared to CPAP therapy, but only by 12 minutes per night. In another review which analyzed the impact of educational, behavioral, and supportive interventions on CPAP adherence,[94] supportive and educational therapies modestly improved CPAP adherence,while behavioral therapies—such as motivational interviewing and cognitive behavioral therapy—resulted in large improvements in CPAP adherence. There is a clear need for high-quality adequately powered behavioral, educational and supportive interventions, or combinations thereof, on adherence to PAP therapy. Further research in this field is needed to better clarify the efficacy and real-world effectiveness of different interventions, as well as determine the cost-effectiveness and effective implementation strategies for such interventions. The rapid development of mobile health applications, secure messaging, and telemedicine platforms along with patient-centered and patient-navigator strategies are attractive and efficient options for delivering behavioral, educational, and supportive interventions to improve PAP adherence.[118–120]

Home-Based versus Laboratory-Based Testing

In two large randomized controlled trials, home-based diagnostic testing and PAP titration were comparable to laboratory-based diagnosis and manual PAP titrations in the management of OSA[121–123] and may be cost effective alternatives to full night polysomnography.[124] However, real-world Markov modelling suggest that laboratory polysomnography may be more cost-effective.[125,126] Furthermore, in randomized controlled studies, the effects of treatment on variables such as sleep quality, quality of life, blood pressure, and sleepiness did not differ based on whether the diagnosis for OSA was made in the lab or at-home.[127] In terms of acceptance, adherence, time to treatment, and functional improvements, home sleep testing was equivalent to in-laboratory testing.[123] Further, ambulatory testing improved test accessibility and reduced waiting times and the total direct cost of OSA management was also reduced.[128] However, there is a need for real-world studies without the strict selection criteria that assesses service-related outcomes such as cost-effectiveness, equity, and timeliness when comparing conventional laboratory versus home-based management of OSA.[129,130]

Impact of Managed Care on OSA Treatment

There are very little data examining the impact of managed care on OSA treatment. In a American Academy of Sleep Medicine (AASM) survey of 245 respondents sleep laboratory staff spent 41–185 minutes per sleep study in order to obtain prior authorization.[131] Denial of a laboratory sleep study occurred 21% to 44% of the time, and denial of both in-lab and out of sleep center testing occurred 6% to 15% of the time. These data suggest that there are significant inefficiencies related to management of patients with OSA that would negatively impact the generalizability of cost-effectiveness analysis performed in controlled trials. There is scant literature related to the impact of managed care on patients with OSA. Possible negative impacts of managed care on patients may include the high co-pays associated with sleep diagnostic testing, as well as high payments related to PAP therapy. Additionally, specific hurdles related to Medicare may include the strictly enforced loss of PAP coverage benefits when an arbitrary PAP adherence threshold is not accomplished in a narrow time window. Future research is needed to better identify and overcome barriers to treatment for OSA patients.

Health Services Research, Access to Care, and Health Literacy

Currently there are a paucity of data on issues related to access to care for individuals with OSA. Additionally, little is known about utilization of health services including primary care vs. Sleep specialist for management of OSA, certified sleep clinics vs. non-certified sleep clinics, interventions to promote screening in primary care clinics, and interventions to promote sleep testing.[132] There are barriers to care at an individual level, provider level, and at a system level.[133,134] Individuals at risk for sleep and circadian disorders including OSA may not be knowledgeable about the symptoms, risk factors as well as diagnosis and treatment regimens. Focus groups have revealed that Blacks often described OSA as being similar to acid reflux or other conditions such as primary cardiac or pulmonary disease.[135] It is plausible that such false beliefs and limited knowledge may exist with regards to other sleep and circadian disorders and general sleep hygiene practices.

Health literacy defined as "the degree to which individuals have the capacity to obtain, process, and understand basic health information and services needed to make appropriate health decisions"[136] impacts health status and disease morbidity. There are very few studies that have examined the association between health literacy and sleep and circadian disorders. Nevertheless, the existing studies provide important information, which suggests that patients with sleep and circadian disorders have limited health literacy and that available patient education materials are not easy to understand for most patients.[137,138] Moreover, providers may not communicate with their patients about sleep because they may not fully appreciate sleep in the context of the overall health of their patients or be knowledgeable about sleep and circadian disorders such as OSA.[139,140] Such lack of knowledge may translate to reduced adherence to treatment such as PAP therapy for OSA, greater discontinuation rates, and consequently greater patient dissatisfaction.[132,141] Kramer et al. demonstrated that only 0.13% of primary care physicians referred their patients for OSA screening.[142] In cases where a referral was made, patients were more likely to be obese and reported severe obesity.[143] Lack of physician referrals is not entirely understood, but may be related to the patient requesting a referral rather than the physician generating the referral based upon a sleep assessment.[144] In the US, more health services research aimed at promoting case identification, disease management, and health promotion as it pertains to sleep and circadian disorders needs to be performed.

Data from the National Ambulatory Care Medical Survey (1999–2010) showed that the number of physician office visits for a diagnosis of sleep apnea rose from 1.1 million in 1999 to 8.4 million visits in 2009.[145] During the same study period the number of polysomnography and multiple sleep latency testing increased from 500,000 to over 2 million.[145] There were significant findings by race for some years and significant differences by gender and age for all years. The sample was primarily white. It is plausible that African Americans and other racial and ethnic

groups were not receiving such care in these settings. Lack of geographic distribution of available accredited screening centers poses a barrier and may contribute to health disparities.[146]

Multi-Level Interventions

Utilizing Brofenbrenner's Ecological Model, multi-level interventions at the individual, provider, community, and health system or national level are needed to improve healthcare delivery to patients with OSA. Interventions targeting individual behavior should include educational interventions that impart knowledge about sleep and circadian disorders. For individuals diagnosed with a disorder such as OSA, interventions should focus on treatment adherence, and education, behavior, motivation and social support.[147] There are no known published reports of community level interventions to encourage screening of OSA or other circadian rhythm disorders. Community-level interventions have been effective in addressing hypertension. For example, Victor et al. conducted a study in barbershops to increase hypertension screening among African American men.[148] Barbershop owners were trained as lay health educators and conducted blood pressure screening. This approach improved hypertension control and marginally decreased systolic blood pressure.[148] Currently there are two ongoing studies to address barriers to OSA screening and adherence to treatment for OSA among African Americans.[149]

Several interventions are currently underway to raise awareness around the importance of sleep and circadian disorders. For example, the Center for Disease Control and Prevention, the American Academy of Medicine and the Sleep Research Society have developed a partnership to increase knowledge about the importance of adequate sleep.[150]

Gaps and Future Directions

The review of the literature above highlights the fact there is an abundance of early stage efficacy research, but less later-stage implementation research. Some of the barriers and facilitators to disease detection and treatment have been identified for OSA. However, much less work has been done to translate and implement these findings into real-life settings and systems of care. Most of the translational and implementation work done serve as repositories of information, either in the form of a website with OSA information, support networks for individuals with OSA, patient advocacy, or research databases that scientists tap for more exploratory studies. However, hard to reach groups and underserved communities, who are most at risk for OSA and its medical comorbidities, seldom benefit from the above-mentioned translation and implementation efforts because they do not fully engage the population. In conclusion, the areas identified as important for implementation science in the area of sleep-disordered breathing including important barriers that need to be addressed are rank-ordered and listed in Table 4.

Table 4—Results of workshop: opportunities for sleep and circadian sciences implementation research for sleep-disordered breathing.

Obstructive Sleep Apnea

High Priority Future Research Needs

1. Promoting health literacy and education of patients, providers and community stakeholders regarding OSA.
2. Perform trials aimed at improving adherence to treatments for sleep-disordered breathing (particularly evaluating cognitive therapy approaches). [BARRIER]
3. Training of nurses and community lay health workers in the case identification and treatment of OSA (task shifting)

Other Future Research Needs

4. Greater community engagement to ensure acceptability and sustainability of sleep-based health education and awareness campaigns and programs.
5. Generate data to help help understand health impact of sleep healthcare in real-world settings.
6. Make sleep-health information highly-scalable in diverse communities.
7. Hybrid effectiveness-implementation trials that perform comparative-effectiveness of various treatments for sleep-disordered breathing in special populations (peri-operative care, hospitalized patients, major medical comorbidities such as resistant hypertension, COPD, and heart failure).
8. Address the barrier to care delivery that is imposed by the uncertainty of management of central sleep apnea and complex sleep apnea in the presence of heart failure with reduced ejection fraction. [BARRIER].
9. Models of care delivery that compare specialists versus non-specialists.
10. Influence community leaders to engage hard-to-reach communities.

ADOLESCENT SLEEP HEALTH

Risk Behavior, Obesity Risk, E-Media Use, and the Role of Primary Care

The recommendations summarized below follow the reviews and workshop discussions of four important components of sleep and health in adolescents: risk behavior, obesity risk, e-media use, and the role of primary care. One promising area for eventual implementation science efforts is the reduction of adolescent risk behaviors through improvements in adolescent sleep health. Adolescence is a uniquely vulnerable period for the development of risk-taking behaviors due to the concurrent structural and functional maturation of relevant brain centers.[151,153] Risk behaviors include, but are not limited to, substance use, violence-related behaviors, risky sexual practices, suicidality, and driving while impaired (e.g., by sleepiness or alcohol).[154,155] The latter two are perennial top causes of teen death.[156] Abundant cross-sectional data consistently link sleep duration and timing to risk behaviors.[16,22,157] More limited longitudinal data suggest that sleep loss and sleep and circadian disorders predict later risk behavior, particularly substance involvement, and vice versa.[17,158–160] However, with the possible exception of one RCT in progress,[161] there are essentially no published experimental or treatment studies that have targeted the sleep-risk behavior pathways in this age group. Such a paucity of scientific data precludes any statements of causality and places constraints on implementation.

Despite this lack of intervention studies, one adolescent risk behavior area identified as promising stems from a small literature suggesting that delaying school start times reduces teen vehicular crashes. Limited experimental evidence has

demonstrated a relationship between sleep manipulation and simulated driving in adolescents.[162] Moreover, communities with later school start times show fewer teen auto crashes than similar districts with earlier school start times,[163,164] and school districts that have enforced delayed school start times have observed concurrent reductions in automobile crashes by as much as 65% to 70%.[165,166]

While later school start times for middle and high school students that are commensurate with adolescent sleep and circadian biology represent a promising policy-based strategy,[167] the need for additional effective interventions that can reduce chronic sleep loss and circadian misalignment in adolescents was identified as an important next step for early stage implementation research.

Obesity Risk

A major clinical concern in adolescence is obesity and downstream medical and psychosocial consequences such as increased cardiovascular morbidity, type 2 diabetes, and decreased quality of life.[168] Both cross-sectional and prospective observational studies have linked shorter sleep duration with increased obesity risk in children and adolescents in a dose-dependent fashion.[169,170] A smaller body of evidence suggests that sleep timing (e.g., evening chronotype) may also contribute to obesity risk.[171–173] Recent experimental studies examining potential mechanisms has pointed to alterations in metabolic regulation (e.g., insulin resistance), and eating behaviors (e.g., calorie consumption and food preference) in sleep restricted teens.[174–177] Overall, this research provides a strong theoretical foundation for the development of interventions that target sleep to reduce obesity risk in teens[178]; however, currently there is no evidence that experimental sleep manipulation results in changes in obesity-related behaviors, metabolic regulation or reduced BMI in normal weight or overweight/obese adolescents.[175] Moreover, while there are a handful of RCTs in progress targeting sleep health interventions in younger (i.e., school-aged) obese/overweight children, there are currently no published RCTs in adolescents, nor are there published prospective studies examining the impact of sleep health education in early adolescence on later development of obesity. Therefore, the improvement of sleep health aimed at reducing obesity risk in adolescents is not ready for implementation efforts.

E-Media Use

Electronic media (e-media) may account for a significant amount of adolescents' daily activities, with youth spending > 7 hours/day in front of a screen.[179,180] Two recent reviews of this topic have shown a significant adverse association between e-media use and various sleep parameters such as delayed bedtime, longer sleep onset latency, and reduced total sleep time.[181,182] Additionally, experimental work has shown the deleterious impact of e-media such as extended video game use on adolescent sleep.[183,184] However, the relationship between e-media use, especially in adolescents, is complex and likely bi-directional; for example, studies found that sleep problems in adolescents/young adults is predictive of greater e-media use (not vice versa),[185] and screen time is often used as a "sleep-aid."[186]

While a number of studies have assessed the impact of interventions to reduce screen time in children,[187] and several studies have included limiting screen time as part of recommendations to improve sleep hygiene in general,[188] there have been virtually no sleep interventions specifically targeting e-media use in adolescents. Thus, additional studies are needed to further support the causal effect of e-media use on sleep, and to develop and test e-media interventions to improve sleep and associated health outcomes.

The Role of Primary Care in Adolescent Sleep Health

The primary care office represents an important setting for implementation efforts around the identification and management of sleep and circadian disorders and the provision of sleep health education.[189,190] While the need to identify and treat sleep and circadian disorders in both children and adolescents is clear,[191,192] studies have found low rates of screening, diagnosis, and management of sleep and circadian disorders in youth of all ages in primary care settings.[193,194] Moreover, a review of the literature did not identify any implementation studies examining strategies to improve evidence-based identification and management of adolescent sleep and circadian disorders in primary care, highlighting an important gap in the field. OSA identification and treatment in adolescents may be an area that is particularly ripe for implementation, given the body of evidence supporting negative outcomes associated with untreated OSA.[192] There are few published guidelines on diagnosis and management of adolescent sleep and circadian disorders for primary care providers and in issued recommendations for OSA diagnosis and management in the primary care setting. Guidelines for evaluation and management of sleep and circadian disorders in adolescents such as those published by the American Academy of Pediatrics (AAP) on OSA,[195] should be developed for other disorders (e.g., insomnia, circadian-based disorders, and narcolepsy).[196,197]

Besides early identification of sleep and circadian disorders, it is critically important for PCPs to provide sleep health education[167] and anticipatory guidance to adolescents and their families.[197,198] Sleep education programs targeting adolescents in other settings (e.g., schools) have shown promise in improving sleep knowledge, but have not consistently yielded improvements in sleep patterns and behaviors.[199] Thus, more work is needed to determine ideal settings and formats to provide sleep guidance resulting in meaningful sleep behavior change. Moreover, recent studies have suggested that there are important racial, ethnic, and socioeconomic factors which increase the risk of unhealthy sleep practices and contribute to sleep health disparities.[200–203] Potential topics for sleep health educational interventions in adolescents include drowsy driving, caffeine and stimulant use, irregular sleep-wake patterns, strategic napping, and sleep needs.

In addition, sleep health education interventions would ideally address two critical gaps, improving not only healthy sleep behaviors in families but also sleep health knowledge among pediatric medical care providers. Primary care setting-based interventions must take into consideration barriers identified by primary care providers regarding implementation of sleep health education interventions, including limited time, lack of

training in sleep medicine, knowledge gaps and the dearth of published guidelines and practice parameters.[198,204–206]

While more studies are needed to demonstrate a clear relationship of school start time change (SSTC) to a reduction in health risk behaviors mediated by increased sleep duration and/or reduction in circadian misalignment, healthy school start times (e.g., 08:30 or later[167]) for middle and high school students as a strategy to improve sleep and health and safety outcomes was identified as a systemic intervention for which a significant amount of empirical evidence is currently available. In addition to improvements in sleep and alertness parameters, a number of positive student outcomes have been identified, including increased academic achievement and engagement, lower depression scores, and decreased rates of health facilities usage.

Research Priorities, Gaps and Future Directions

With these points in mind, a number of priority areas in adolescent sleep health that represent key research gaps and thus provide opportunities for sleep and circadian sciences implementation research were discussed and ranked (Table 5). These research areas were considered to have promise for eventual implementation and dissemination once key gaps are addressed.

In addition, the group discussed adolescent sleep health research areas that were deemed to have enough empirical evidence to support implementation and dissemination in the near future. Despite the relative paucity of studies documenting the effectiveness of interventions, including RCTs, targeting the key adolescent sleep health issues discussed above, the group was able to identify two major areas. The first was healthy school start times for middle and high school students as a potential means of improving sleep, mood, academic achievement and engagement, and safety, and reducing risk behaviors and cardiovascular and metabolic morbidity in adolescents. The second was application of screening tools and existing guidelines for evidence-based assessment and management of obstructive sleep apnea in primary care settings. Finally, in regards to both of these topics, a number of key remaining research questions critical to address in future research were identified and are summarized below.

For healthy school start times for middle and high school students aimed at reducing proportion of students with insufficient sleep more needs to be done with regards to effective engagement of schools and community stakeholders; identifying tools and strategies (such as effective sleep health education) that could be best adapted to meet the needs of individual communities; derive consensus on the outcome measures that all communities should consider in assessing the impact of SSTC (driving accidents, health and other safety measures such as lower rates of pedestrian accidents and sports and work-related injuries). Moreover, the sustainability of such interventions over time needs to be assessed. Additionally, insight into specific sub-populations of students who may benefit preferentially from SSTC (e.g., high-achieving students, academically and socioeconomically disadvantaged students, racial and ethnic minority students); assessing the impact of SSTC on faculty and other school personnel (e.g., custodial and transportation workers) and other groups of students in the district (e.g., preschool/kindergarten, elementary school, students in special education and vocational programs) needs to be better understood.

Implementation of screening tools and guidelines that would enable identification and treatment of sleep apnea in children and adolescents in primary care settings requires better understanding of the perceived barriers to diagnosing and treating adolescent patients with sleep apnea (e.g., insurance considerations, community availability of and access to appropriate diagnostic and treatment facilities, lack of caregiver knowledge and patient engagement). A critical assessment of current guidelines such as those published by the AAP and whether they are being adequately utilized in primary care as well as an assessment of the optimal methods for assessing the outcomes

Table 5—Results of workshop: opportunities for sleep and circadian sciences implementation research for adolescent sleep health.

Adolescent Sleep Health

High Priority Future Research Needs

1. Increase the proportion of students in grades 9 through 12 who get sufficient sleep.
2. Build more scientific evidence for the efficacy and effectiveness of sleep and circadian interventions that can improve adolescent sleep health as it relates to obesity, risk-taking behaviors, and mental health.
3. Identification and treatment of sleep apnea in children and adolescents.

Other Future Research Needs

4. Identify & engage stakeholders who are relevant to children and adolescents -- Peers, parents, families, physicians, principals, sports, etc.
5. Effectiveness of approaches to improve sleep health, e.g., remotely delivered interventions (i.e., E-health), school-based education, popular media, teacher education, and other stakeholders.
6. Experimental evidence for changes in sleep impacting cardiometabolic health of adolescents, substance use risk, functional and structural neurobiology, memory, and learning.
7. Identification of best practices for implementing guidance on sleep health in primary care settings.
8. Epidemiology of sleep health and outcomes such as BMI, suicidality, depression, social/life success, and risk of other mental illnesses that emerge in adolescence (substance abuse, schizophrenia).
9. RCTs of intervention identified strategies used elsewhere as applied to sleep health, comparing strategies for different stakeholders and sources of influence (e.g., parents, principals, coaches, teachers, peers, etc.).
10. Systematic review of interventions targeting improvements in other core behaviors (e.g., diet and exercise) of adolescents to identify barriers and successful strategies applicable to sleep.
11. Build links to other adolescent interventions touching all the co-morbid areas.
12. Inclusion of vulnerable adolescent populations into intervention efforts, such as youth with chronic health conditions who are at-risk for sleep disturbances and poor neurological and psychosocial outcomes.

of enhanced screening, diagnosis and treatment of adolescents with sleep apnea need to be performed.

CONCLUSIONS

Many critical issues confront the future of sleep medicine. Simultaneously, there are many strengths and opportunities that have become available to us. As a community of scientists, clinicians, industry, and policy makers we need to strive to advance the recommendations stemming from this workshop. A complete list of the recommendations are rank-ordered by priority in Tables 3–5. We recognize that there are many topical areas in sleep and circadian sciences that were not comprehensively addressed by this initial endeavor. We need to advance the implementation efforts in these and other areas of sleep and circadian sciences to translate our investments in sleep and circadian research to directly benefit the health of the nation.

CITATION

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