http://dx.doi.org/10.5665/sleep.1410

The Future of Sleep Medicine

Patrick J. Strollo Jr., MD[1]; M. Safwan Badr, MD[2]; Michael P. Coppola, MD[3]; Samuel A. Fleishman, MD[4]; Ofer Jacobowitz, MD, PhD[5]; Clete A. Kushida, MD, PhD, RPSGT[6]

[1]University of Pittsburgh Medical Center, Pittsburgh, PA; [2]Harper University Hospital and Wayne State University School of Medicine, Detroit, MI; [3]Springfield Medical Associates, Springfield, MA; [4]Cape Fear Valley Medical Center, Fayetteville, NC; [5]Hudson Valley Ear, Nose and Throat, Middletown, NY; [6]Stanford University, Stanford, CA

Executive Summary

In July of 2010, at the request of Patrick J Strollo Jr, MD (AASM President 2010-2011), the Board of Directors of the American Academy of Sleep Medicine (AASM) approved a year-long presidential task force designed to examine the future of sleep medicine in the care of adult patients. This initiative was an extension of a workshop convened by Susie Esther, MD (AASM President 2008-2009), in December of 2009 at the request of Clete Kushida, MD, PhD (AASM President 2009-2010). The project was designed to survey current trends, project the ability of sleep medicine specialists to best treat patients with sleep disorders in the future, and identify areas for further exploration. The topics that were identified for further examination included: 1) frameworks for healthcare delivery such as the patient-centered medical home model, 2) patient registries, and 3) new outcomes measures and tools for diagnosis and treatment of sleep disorders.

The Affordable Care Act[1] has put healthcare delivery in a state of flux. Possible future healthcare delivery models were discussed, and the patient-centered medical home was chosen as being the most viable. In this model, the development of "coordinated sleep care centers" acting as good "neighbors" to the primary care physician and others in the medical home appeared to be an effective position for the sleep medicine practitioner in the future. Both patients and their physicians will benefit from the focus on patient-centered care when effective communication, care coordination, and long-term care management, including the integration of electronic health records, are implemented.

Patient registries will also play a part in the future of sleep medicine because of their value in clinical, scientific, and policy domains. Clinical registries in particular can help to describe the natural history of a disease, determine the clinical effectiveness or cost-effectiveness of healthcare products and services, monitor safety, and measure quality of care. Funding is the main barrier to implementation. If they are to be successful, registries should begin on a small, pilot scale to facilitate establishment and manageability. This includes identifying the standard outcomes measures to be collected.

Outcomes-based care is emerging as an effective way to measure value of care as well as treatment efficacy. New polysomnographic and metabolic outcomes measures are currently under investigation, from new measures based on innovative polysomnographic data analysis to novel cardiovascular- and metabolic-related biomarkers. Similarly, well-validated tools to assess behavioral, neurocognitive, and quality of life outcomes such as daytime sleepiness and psychomotor vigilance are available and await validation and incorporation into daily practice. A variety of other tools fall into this category as well, including portable monitoring and transcutaneous CO_2 monitoring.

The exercise of stepping out of everyday practice and considering the future of sleep medicine has been useful, and will continue to bear fruit if it is continued in a periodic manner. Additional items for further consideration of future thought leaders include:

1. The role of telemedicine, including remote monitoring;
2. The impact of health care reform will have on practice;
3. Development of disease management programs for sleep disorders beyond OSA;
4. Strategic research needs in sleep medicine; and
5. Partnership with industry to advance the science and practice of sleep medicine.

There were several steps involved in creating this white paper. In the summer of 2010, the AASM Board of Directors identified the need to host a forum for thought leaders in sleep medicine, sleep research, and allied fields to discuss the future direction of clinical care and scientific investigation. The first meeting of the AASM's Future of Sleep Medicine Task Force was held at the AASM national office in Darien, IL on October 11, 2010; 53 thought leaders attended. The chair of the Task Force, AASM President Patrick J. Strollo Jr., led the discussion, with 16 speakers (including Dr. Strollo) presenting their ideas. Topics were divided into three areas of concentration: Tools, Integrated Care, and Accreditation. The Tools section included presentations on current and emerging technologies in sleep: actigraphy, nasal endoscopy, portable monitoring, high definition EEG, phenotyping of the upper airway, and circadian rhythms testing. The Integrated Care section focused on care delivery models, notably the Patient Centered Medical Home; patient services, including positive airway pressure (PAP) accommodation and behavioral interventions; and data management and clinical registries. The Accreditation section outlined existing and future models for accreditation. These ideas were discussed and key information was identified for further investigation. Based on the discussion, the Steering Committee broadened the areas of concentration and established workgroups to address Tools, the Patient Centered Medical Home, and Patient Registries and Outcomes. Members of the Future of Sleep Medicine Task Force were identified as participants on the workgroups

Submitted for publication September, 2011
Accepted for publication October, 2011

Address correspondence to: Patrick J. Strollo, MD, FAASM, Montefiore University Hospital, 3459 Fifth Avenue, Suite S-643, Pittsburgh, PA 15213; Tel: (412) 692-2880; Fax: (412) 692-2888; E-mail: strollopj@upmc.edu

based on their clinical and research expertise. Each of the three workgroups held several conference calls during the winter of 2011 and wrote draft reports (one from each workgroup), the contents of which were presented to all workgroup members at a second meeting on February 19, 2011, in La Jolla, California. The draft reports were refined subsequent to the presentations and ensuing discussions that resulted in the present report. This report was presented to the membership in June 2011 at the 25th Annual Meeting of the Associated Professional Sleep Societies in Minneapolis, Minnesota.

I. HEALTHCARE DELIVERY: THE PATIENT-CENTERED MEDICAL HOME (PCMH)

The Patient Protection and Affordable Care Act (PPACA)[1] was signed into law on March 23, 2010. The PPACA and the Health Care and Education Reconciliation Act of 2010,[2] which were signed into law on March 30, 2010, comprise the health care reform of 2010. Several provisions outlined in the PPACA have been enacted already; additional provisions take effect January 1, of 2012, 2013, 2014, and January 1, 2017 and 2018. Several states have challenged the constitutionality of the law, and these cases might affect implementation. Additionally, efforts are underway in Congress to repeal healthcare reform legislation. These developments may affect implementation of the PPACA and healthcare reform in general. It is uncertain how reform will be implemented fully; the healthcare system is changing with the advent of new technology and introduction of new care delivery models.

Historically, sleep medicine has been practiced as a subspecialty by physicians with backgrounds in internal medicine, family practice, pulmonary, psychiatry, neurology, otolaryngology and pediatrics. With the recognition of sleep as a designated subspecialty, the accreditation of fellowship training programs in sleep medicine, and the certification examination offered by the American Board of Medical Specialties, physicians increasingly designate sleep medicine as their primary practice discipline. Sleep medicine practitioners need to consider how they want to interface with other physician specialties in the healthcare realm.

The concept of the patient-centered medical home (PCMH) represents a useful framework for chronic management of patients with sleep disorders. The PCMH model of care may provide the required transformation of the current, fragmented system of health care delivery. The key feature of the PCMH is an ongoing healing relationship between the physician and the patient rather than an episodic relationship based on illness and complaints. The National Committee on Quality Assurance (NCQA)[3] offers the following background on the PCMH model:

> The American College of Physicians, the American Academy of Family Practice, the American Academy of Pediatrics and the American Osteopathic Association have jointly defined the medical home as a model of care where each patient has an ongoing relationship with a personal physician who leads a team that takes collective responsibility for patient care. The physician-led care team is responsible for providing all the patient's health care needs and, when needed, arranges for appropriate care with other qualified physicians. A medical home also emphasizes enhanced care through open scheduling, expanded hours and communication between patients, physicians and staff.

The PCMH focuses on *care coordination*, where a primary care physician (PCP) generally acts as the center point for all care. In addition to patient care, this responsibility includes relating to institutional providers, acting as a referral source for specialized care with affiliated specialist physicians, and coordinating follow-up care.

Three tracks for specialists in this model were reviewed, including principal provider, selective principal provider, and major provider. It was determined that none of these tracks is ideal for the typical sleep physician. Instead, the sleep physician is best described as a "partner" or "neighbor" in the care process, interfacing and communicating with the PCMH-N,[4,5] and providing specialty sleep care in close collaboration with the patient's designated PCP.

The NCQA has developed standards[6] for certification as a PCMH. Briefly, these standards address the following areas: 1) access and communication; 2) patient tracking and registry functions; 3) care management; 4) patient self-management support; 5) electronic prescribing; 6) test tracking; 7) referral tracking; 8) performance reporting and improvement; and 9) advanced electronic communication. A few of these areas will be highlighted, including communication, long-term care management, electronic health records, and patient registries.

A. PCMH – Communication

Effective communication between the sleep physician, the patient, the PCMH PCP, and other physicians and health care entities is essential for optimal care delivery. Effective communication with patients will facilitate their being able to co-manage their own conditions, but must be done in a manner that is culturally and linguistically appropriate.

The sleep physician needs to communicate with the patient in a variety of ways to improve the self-management of their sleep disorder for attainment of optimal outcomes. Elements of these communications include: 1) participation of patients in decision-making; 2) enhancement of patient education by providing access to educational resources including print and other media; 3) identification of communication needs and barriers; and 4) participation of patients in quality improvement activities. In addition to patient-specific support, the system should facilitate engagement with community resources, such as patient advocacy organizations and tools for community education.

In addition, communications have to be ramped up to coordinate care with the patient's designated PCP and other physicians and health care entities. This necessitates the development of *care coordination agreements*. These care coordination agreements will formalize a relationship between the PCMH-N and the PCMH's PCP, defining the roles and responsibilities of each party. Defined roles and effective coordination should help to eliminate duplication of effort, errors, and deficiencies in performance.

B. PCMH – Long-term care management

Another key is moving the field of sleep medicine from one of being lab-based diagnostic testing to being focused on long-term care management of chronic diseases. The NCQA standards identify the PCMH elements that are central *to providing longitudinal, ongoing care for patients with chronic conditions and for optimal coordination of care with the patient's PCP.* Patients with sleep disorders require complex, ongoing and coor-

dinated care that may be unattainable within the constraints of a typical primary care practice. Therefore, the PCMH-N functions as a comprehensive, coordinated sleep care center (CSCC) interfacing with a PCMH hub to ensure delivery of coordinated high-quality care for patients with sleep disorders. *The CSCC will be a sleep care facility that provides patient-centered sleep services including continuous, longitudinal, accessible, comprehensive, coordinated, compassionate, and culturally effective care for patients with sleep disorders in partnership with the PCMH's PCP.* The CSCC has a significant role in facilitating appropriate test tracking and reporting. As part of a care coordination agreement between the PCMH and PCMH-N, the roles of test reporting and tracking should be carefully defined. In addition, sleep centers' capability to establish electronic connectivity between its electronic systems and the electronic systems maintained by the PCMH will be vital to success.

Three examples of coordination relationships are described that address pre-consultation exchange of information, formal consultation requirements, and several forms of patient co-management. Co-management for a disease process might include shared management where the sleep specialist and PCMH's PCP assume ongoing specific responsibilities for a problem, or the sleep specialist may assume principal management for a specific problem indefinitely or for a time-limited basis. Case studies of each form of relationship follow:

Pre-consultation exchange

An 82-year-old female presents to the PCMH having had a fall due to sudden loss of consciousness without any previous sleep issues or problems with syncope. The event was not preceded by any symptoms or aura. The PCP phones the sleep specialist who explains that this does not appear to be a case of cataplexy and a sleep consultation is not necessary. The PCP then orders the appropriate cardiac evaluation.

Formal consultation

A 22-year-old male is referred for poor sleep, mild snoring, and repeated episodes of falling asleep at work and school. He feels weak in his knees when amused or angered. The sleep specialist recommends a polysomnogram, drug testing, and an MSLT. She also recommends that the PCMH approve long term co-management, with the sleep specialist assuming responsibility for the care of this problem.

Co-management

A 53-year-old male with depression has had longstanding problems with insomnia despite good control of depressive symptoms with medication. The sleep specialist has provided cognitive therapy and prescribed a sedative hypnotic, which the patient uses less than 5 times a month. The patient sees his PCP every 8 weeks to monitor his depression and other medical problems. As agreed with the PCMH, the patient sees the sleep specialist yearly and as needed to monitor his sleep patterns and use of hypnotics.

C. PCMH – Electronic Health Records

Essential to effective communication and long-term care management is the integration of electronic health records (EHRs) across the PCMH. This NCQA standard requires the use of an EHR that is compatible with the record-keeping methodology used throughout the PCMH. The CSCC's electronic clinical information system will have many capabilities and purposes, from practice management to patient and community health improvement. A partial list of the elements of the EHR in the PCMH is to: 1) provide decision support, protocols, reminders, and checklists; 2) provide an electronic prescribing program; 3) provide a method for secure communications with the patient as well as other care givers; 4) enable care coordination and maintenance; 5) enable timely reporting of results to the referring physician and the patient; and 6) format pertinent information into a registry based on specific chronic illness and other variables that will facilitate population management reports and quality improvement projects.

It is widely believed that broad adoption of electronic health record (EHR) systems will lead to major healthcare savings, reduce medical errors and improve patient care overall. However, the rate of adoption among U.S. hospital and physicians for these systems has progressed slowly. It is estimated that 20% to 30% of hospitals have adopted such systems. In 2007, 34.8% of office-based physicians reported using any EHR system, which represented a 19.2% increase since 2006.[7]

The American Recovery and Reinvestment Act of 2009 (ARRA)[8] includes the Health Information Technology for Economic and Clinical Health Act (HITECH Act),[9] which incentivizes physicians to adopt EHR systems. According to the Centers for Medicare & Medicaid Services (CMS), eligible professionals can receive up to $44,000 over 5 years through "meaningful use" participation the Medicare EHR Incentive Program. Enrollment in the Medicare EHR Incentive Program opened in 2011, and CMS suggests physicians enroll in the program by 2012 to maximize incentives. Additionally, office-based physicians and hospitals who do not adopt an EHR by 2015 will be penalized 1% of Medicare payments for services provided to beneficiaries, increasing to 3% over 3 years.

Despite incentives, there are numerous barriers to implementation of EHR for both hospital systems and office-based physicians. Prior research has identified 4 major factors that influence the adoption of EHR: high cost, lack of certification and standardization for EHR programs, concerns about privacy, and healthcare regulations and compatibility (e.g., relationship of EHR to payment systems).

II. PATIENT REGISTRIES

A clinical patient registry is an organized system that uses observational study methods to collect uniform data (clinical and other) to evaluate specified outcomes for a population defined by particular disease, condition, or other exposure. It serves one or more predetermined scientific, clinical, or policy purposes.[10] A registry database is a file (or files) derived from the registry. The purposes of clinical registries are to: 1) describe the natural history of a disease, 2) to determine the clinical effectiveness or cost-effectiveness of healthcare products and services (i.e. comparative effectiveness research), 3) to monitor safety, and 4) to measure quality of care. Additionally, data collected in registries will be essential in the future implementation of P4 medicine (predictive, personalized, preventable, and participatory).

There are several issues to consider when planning a clinical registry. First of all, its purpose must be articulated. This will

enable the determination of whether or not it is an appropriate means of addressing a patient care or research question. Next, the scope and target population need to be defined. Articulating these issues early in the planning process enables a course of action for the registry development, including assessing feasibility and estimating costs. Finally, the stakeholders must be identified. This team, selected based on their expertise and experience, should help guide the development of the registry and offer means to secure funding. The plan for registry governance and oversight should clearly address such issues as overall direction and operations, scientific content, ethics, safety, data access, publications, and change management.

Issues related to clinical registry design are similar to those encountered in designing a research study. These issues include formulating the registry question as well as the best location to mine the data. Thoughtful selection of the best study design to address the question, appropriate and measurable exposures and outcomes, and number and type of patients for study (including deciding whether a comparison group) is needed. The choices for these elements should be guided by parsimony, validity, and focus on achieving the registry's purpose.

Determining which elements are absolutely necessary and which are desirable but not essential is critical for clinical registries. Measurement scales that have been appropriately validated should be utilized when such tools exist. A data map should be created, and the data collection tools should be pilot tested. Testing allows assessment of respondent burden, accuracy and completeness of questions, and potential areas of missing data. Rater agreement for data collection instruments can also be assessed, particularly in registries that rely on chart abstraction.

There are several potential topics of interest to the sleep field for which a registry could be considered. The topics range across a variety of sleep disorders, including 1) hypnotics in facilitating positive airway pressure acceptance and adherence, 2) behavioral interventions/CBTI in chronic insomnia, 3) diagnosis and management of restless legs syndrome, 4) diagnosis and management of hypersomnia short sleep/shiftwork, and 5) management of narcolepsy (i.e., stimulant regimens, Xyrem). There are several examples of successful registries upon which to draw experience such as the society of thoracic surgery registry,[11] the national cardiovascular data registry,[12] and the AHA "get with the guidelines" program.[13]

There are some barriers to implementation. There is a substantial cost associated with setting up and maintaining a registry (estimated at approximately $500,000, dependent on the registry duration). Although governmental agencies such as the AHRQ provide grants that could be used for this purpose, the available dollars are limited. Alternatively, a partnership with industry and/or third-party payers could be established to explore areas of common interests that could result in funding opportunities. Lastly, a strategic investment by the American Academy of Sleep Medicine could be considered.

Other issues to be resolved include the participating sites' structure (academic versus community centers), the mechanism of data management (manual data entry or download from an EHR), and the need for an effective long-term commitment (5-10 years) for the maintenance of a registry.

If it is to be successful, the registry should begin on a small, pilot scale to facilitate establishment and manageability. A simple registry could include a small group of standard measures that are currently being collected on a common sleep disorder such as obstructive sleep apnea (OSA). The initial purpose of the registry would primarily be to improve quality of outcomes as well as provide experience with maintenance of the registry itself. Full integration of a pilot OSA registry with the entire EHR at a given site would enable the exploration of complex and multidisciplinary questions such as those regarding the relationship between OSA and cardiovascular disease. At a later time, the registry could be expanded to include additional data on a wider range of sleep disorders.

New Health-Related Outcomes and Tools

Accountable care is on the horizon. The pay structure is changing from fee-for-service to being outcomes-based. With that in mind, attention must be paid to developing new outcome measures and tools that could be used to diagnose patients and assess the effect of treatments. This will ensure that the best care over the long term is provided to the patient. Additionally, new outcome measures development will further the understanding of the relationship between sleep disorders and morbidity, mortality, and quality of life.

Traditional outcome measures are indices derived from polysomnography (PSG) consisting of summary measures made by counting events across the sleep period and expressing the event rate per hour of sleep (e.g., apneas and hypopneas [AHI], desaturations per hour of sleep [ODI], and arousals [arousal index]). These indices have been used for several purposes, such as thresholds above which disease is defined, for characterizing disease severity, and for studying cardiovascular, metabolic, and neuropsychological risk associated with sleep disordered breathing (SDB). These simple measures do not capture or quantify the dynamic patterns of the physiological processes occurring across the sleep period, the interaction between physiological processes (such as sleep stage change and hypoxemia), nor the different dimensions by which a given event can exert physiological stress (e.g., length of an apnea, length between arousals, desaturation-resaturation patterns, the occurrence of events in REM vs. NREM). Many of these summary counts still require manual scoring, potentially reducing reliability while being costly. The rather crude indices used clinically do not optimally exploit the rich temporal and multidimensional data routinely collected during PSG.

It is likely that the mechanisms linking SDB to adverse cardiovascular, metabolic, and neurocognitive outcomes include hypoxemic stress, oxidative stress, baroreceptor and sympathovagal activation, alterations in cardiopulmonary hemodynamics due to intrathoracic pressure swings, and sleep fragmentation. High density EEG can be particularly useful for analyzing sleep-related oscillatory rhythms, such as slow waves and spindles, as well as for measuring brain connectivity during NREM and REM sleep. It may be combined with other techniques to further probe brain function in sleep, such as transcranial magnetic stimulation. Quantitative assessments of airflow limitation, electrocardiogram (ECG) patterns of arousal, and respiratory disturbances across the night (including quantifying their durations and inter-event intervals) and linkage and interactions among physiological signals could provide novel information on pathophysiological stresses relevant to SDB

and better delineate the heterogeneity among patients with similar AHI levels but different cardiovascular risk profiles. Such measures could be amenable to objective, reproducible automatic analyses. There have been a number of studies which have reported a variety of such novel quantitative measurements.[14-22] To date, limitations include development and testing of algorithms in small samples, lack of cross-validation in new samples, and lack of systematic comparison to traditional or to other new techniques.

In addition to PSG-related outcomes, sleep physicians urgently need the discovery of an inexpensive, easily obtained biomarker that correlates with time-dependent sleep apnea treatment efficacy. An ideal biomarker would have sensitivity and specificity for disease detection, would have prognostic utility, would be modifiable with disease treatment, and thus could serve as a reasonable surrogate outcome measure in interventional studies. If the biomarker were known to be on a causal pathway important in the pathogenesis of disease complications, interventional studies would be considered more compelling. Evaluating the molecular signatures of OSA is an approach that may lead to the understanding of the subject-specific clinical variability in the consequences of OSA.[23]

Arnardottir et al.,[23] as well as other investigators, have examined the evidence for cardiovascular-related molecular domains affected by OSA such as increased sympathetic activity (e.g., microneurography of muscle sympathetic nerve activity, plasma and urine norepinephrine levels, elevated free fatty acids), oxidative stress (e.g., 8-isoprostane), inflammatory state (e.g., TNF-α, IL-6, soluble IL6 [slL6R]), adhesion molecules (ICAM-1, VCAM-1), changes in adipokines (e.g., leptin, adiponectin, resistin), and activation of transcription factors (e.g., NF-κB, HIF-1α). Newer approaches such as gene expression, metabolic profiling, and proteomics (the simultaneous examining expression of proteins and post-translational modifications of thousands of proteins) may show greater promise than these existing approaches.[23]

Metabolic assessments that dynamically characterize glucose and insulin kinetics (e.g., oral and intravenous glucose tolerance, insulin suppression test) rather than simply assessing static metrics such as fasting glucose and insulin, should be employed in future studies. In addition, while quantifying insulin sensitivity is important, it is equally imperative that alterations in insulin secretion be examined. Such measurements are necessary given that it is the combination of insulin resistance and pancreatic βcell dysfunction that is central to the development and progression of type 2 diabetes. Perhaps most importantly, future studies need to consider how a particular sleep disorder alters adipocyte function. Adipocytes express and secrete numerous pro-inflammatory cytokines (e.g., TNF-α, IL-6) and peptides (e.g., leptin, adiponectin, and resistin).[23]

There are two major obstacles in establishing a molecular signature for OSA. The most significant obstacle is that the current biomarkers studied in the OSA field lack the sensitivity and specificity to be a molecular signature for OSA, since the levels of these biomarkers are confounded by the comorbidities of OSA. The second is that obesity leads to activation of the same pathways as does OSA. Since obesity is commonly associated with OSA, there is a need to separate the effects of OSA from those of obesity. The optimal approach may be examining the overnight change in relevant biomarkers across the sleep period.[23] There is a crucial need both to search for more relevant biomarkers and to explore more critically the association between existing biomarkers and their specific association with OSA.

In addition to cardiovascular and metabolic outcomes, critical behavioral and neurocognitive outcomes include sleepiness, attention-related performance, memory and executive function, and quality of life and mood. Identification of a readily measureable biomarker or endophenotype for sleepiness is crucial[24] because of well-demonstrated links to safety, health, and mortality. The psychomotor vigilance test (PVT) provides a relatively straightforward and well-validated measure (more than 100 peer-reviewed publications on the sensitivity of this test to sleep loss, sleep disorders, and treatment) of attention-related performance (alertness, attention, psychomotor speed and impulsivity). Research has consistently shown that tracking slow eyelid closures (PERCLOS) while performing the PVT and related vigilance tasks, is highly correlated with sleepiness-related performance lapses—much more so than EEG and other biobehavioral measures, including subjective reports of sleepiness.[25]

Two tests of neurocognitive functions include 1) the Digit Symbol Substitution Test (DSST), which is an extensively validated, reliable, brief (1.5 minutes) neuropsychological measure of cognitive speed that has proven to be very sensitive to sleep loss and adequate recovery sleep,[26] and 2) the Digit Span (DS) test, which is a reliable, brief (3 minutes) neuropsychological measure of working memory capacity that has proven to be sensitive to sleep loss and sleep apnea.[27] These tests have extensive validation relative to sleep loss/disorders, have established neural correlates (via imaging), can be measured with a high degree of precision using a notebook computer, and have extensive normative data for age groups. A number of other validated brief neuropsychological tests[28] could be included in a neurobehavioral test battery for patients.

A large number of valid, practical, and scalable self-report instruments are available for the measurement of health-related quality of life and mood. One example is the Patient-Recorded Outcomes Measurement Information System (PROMIS), which is a series of web based dynamic tools developed by NIH investigators with the goal of providing clinicians and researchers access to efficient, precise, valid, and responsive adult- and child-reported measures of health and well-being.[29] Other quality-of-life instruments, ranging from more general measures (e.g., SF-12, SF-36, Functional Outcomes of Sleep Questionnaire [FOSQ]) to more disease-specific instruments (e.g., Sleep Apnea Quality of Life Index [SAQLI], Pittsburgh Insomnia Rating Scale [PIRS]), also exist. Mood can be assessed with easily administered and scalable tools such as the Patient Health Questionnaire-9 and Beck depression inventory.

There is clearly a need for more socioeconomic and quality-of-life data for the major sleep disorders; in particular, cost-effectiveness of the therapies used to treat these disorders are lacking. Barriers for cost-effectiveness and quality-of-life studies include the complexities and gaps in available data and short treatment duration in many of the clinical studies.[30] Another major gap is that studies are not consistent in their use of the various quality-of-life instruments, which makes comparisons across studies difficult. Nevertheless, health-economic assessment of sleep disorders and their treatment is an emerging field,

and health-economic models that incorporate relevant economic costs (both direct and indirect), clinical consequences, and the costs and consequences of the disorders plus related comorbidities, such as the one proposed by Botteman for insomnia,[30] should be developed in the future.

The sleep physician relies on well-validated and informative tools to diagnose sleep disorders. Several tools that are underutilized or that need some investment for development exist. For example, portable monitoring is currently being used by many in the field, but not in a consistent manner. Nasal endoscopy may be beneficial in identifying airway abnormalities for surgical treatment, as well as for assessing patients with CPAP adherence problems for nasal treatment, but requires evidence for clinical utility. Transcutaneous CO_2 ($PtcCO_2$), although not the gold standard, is noninvasive and offers advantages over arterial or capillary blood gas measurement. Having widespread availability of CO_2 levels in the sleep clinic and during polysomnography offers potential advantages in better tailoring diagnostic evaluations and mode of PAP therapy to specific patient needs, as well as improving patient safety and monitoring treatment response. Ambulatory blood pressure monitoring (ABPM), consisting of repeated measurements of blood pressure and heart rate over 24 hours during wakefulness and sleep, is potentially an important complement to PSG. Nocturnal BP monitoring identifies non-dippers (patients with blood pressures whose nocturnal physiologic decrease in blood pressure is blunted or absent) who have an increased cardiovascular risk. The interaction between sleep abnormalities (whether it is insomnia, restless legs, OSA, CSA, etc.) and BP can be better understood from these measurements.

Phenotyping of individual patients has the promise of facilitating personalized care. One potential tool is the ability to phenotype OSA based on four traits, including: 1) upper airway anatomy/collapsibility; 2) upper airway response to a collapsing pressure; 3) respiratory arousal threshold; and 4) loop gain (a measure of ventilator control stability).[31] Several lines of investigation in this area are currently underway. First, the normal variability in these four traits in patients with OSA and how the traits can be used to predict the presence and severity of OSA needs to be determined. Second, the influence of surgeries, devices, and medications on the phenotyped traits and apnea severity in a given individual needs to be addressed. Last, an automated device that can determine the four traits in a sleeping patient during a single night in a sleep lab needs to be developed.

The diagnosis of a circadian rhythm disorders in clinical practice has primarily relied on subjective assessments of patients' sleep wake patterns with sleep diaries/logs; however, actigraphy, which is an objective measure of rest-activity patterns, has been underutilized.[32] Direct measurement of the biomarker melatonin via blood plasma or salivary testing is a research tool that is on the horizon for clinical application. Circadian phase misalignment can be determined from the relationship between the dim light melatonin onset (DLMO) and the desired sleep/wake cycle. This type of direct testing is essential for several reasons, including 1) differential diagnosis between circadian rhythm sleep disorder and chronic insomnia, since it has been estimated that 10% of patients diagnosed with chronic insomnia actually have delayed sleep phase disorder[33]; and 2) melatonin therapy has only been shown to be effective if the time of administration is prior to DLMO.[34,35] Barriers to transitioning the technology from research to the clinic include the fact that, at present, sampling is time-consuming, and only a few labs have the capability to analyze the samples, leading to long time lags for results. Work is underway to include a melatonin assay in the primary care and sleep physicians' standard diagnostic toolkit such that results can be returned in a day; however, currently the technology is not FDA-approved and utilized primarily in a research setting. It appears that within 5 years, this "point of care" technology may allow physicians to correctly diagnose a large population of undiagnosed or misdiagnosed people and also effectively treat their disorder with the appropriate type and timing of therapy (bright light, exogenous melatonin) to shift or entrain their circadian rhythms.

SUMMARY AND CONCLUSIONS

In defining a strategy and vision for the field of sleep medicine for the future, a concerted effort has been made over the past year to determine trends likely to impact sleep medicine practitioners and their ability to care for patients with sleep disorders. Emerging changes in the healthcare system will undoubtedly have a large, but unfortunately unknown, impact on our field. One model that has emerged is the patient-centered medical home (PCMH). As a specialty, the best place for sleep medicine in the PCMH framework is as a good neighbor. Being a good neighbor requires enhancements in multiple forms of communications and demonstrating value with measurable long-term outcomes.

Longitudinal value based care as opposed to a focus on in laboratory diagnostic testing will be essential for the survival of sleep medicine as a field. The glue that will hold together the variety of relationships in play between the coordinated sleep care center and the primary care physician caring for patients with a variety of sleep-related conditions is the integrated electronic medical record.

Clinical registries will undoubtedly play a critical role in assessing the effect of coordinated longitudinal care as well as providing a basis for better understanding sleep disorders and their impact on a range of chronic diseases and treatment efficacy of these disorders.

Many biomarkers related to cardiovascular and metabolic health are in various forms of development. Several well-validated tools for neurocognitive assessment are available to the sleep practitioner, but barriers must be overcome for implementation. Other tools such as portable monitoring, transcutaneous CO_2, and actigraphy are also available, but their use is not widespread. A concerted effort to mandate the standardized use of many already-available or nearly-available tools could greatly enhance the diagnostic ability and treatment options available to sleep physicians and their patients.

To continue the momentum and further enhance sleep medicine, this initiative needs to continue. Other items for further consideration include 1) Development of robust integrated care programs that focus on patient and economic outcomes 2) Incorporating telemedicine and remote monitoring in future healthcare delivery; 3) Adapting current sleep medicine practice to align with health care reform such as capitated systems; 4) Strategic planning for the future of sleep research to include research

training and the design of research networks; and 5) Partnering with industry for new tools development and deployment that bring value to the care of patients with sleep disorders.

CITATION

Strollo PJ; Badr MS; Coppola MP; Fleishman SA; Jacobowitz O; Kushida CA. The future of sleep medicine. *SLEEP* 2011;34(12):1613-1619.

DISCLOSURE STATEMENT

Dr. Strollo has received research support from ResMed. Dr. Kushida has received research support from Philips-Respironics and ResMed via grants to Stanford and royalties from patent licensed to Philips-Respironics. The other authors have indicated no financial conflicts of interest.

REFERENCES

1. Patient Protection and Affordable Care Act. In, March 23 2010.
2. Health Care and Education Reconciliation Act of 2010. In, March 30 2010.
3. National Committee for Quality Assurance. Physician Practice Connections®– Patient-Centered Medical Home (PPC-PCMHTM). *cited 2011 June 27+; Available from: http://www.ncqa.org/LinkClick.aspx?fileticket = tAzezm7UpMo%3D&tabid = 631&mid = 2435
4. Yee HF Jr. The patient-centered medical home neighbor: a subspecialty physician's view. Ann Intern Med 2011;154:63-4.
5. American College of Physicians. The Patient-Centered Medical Home Neighbor: The Interface of the Patient-Centered Medical Home with Specialty/Subspecialty Practices. Policy Paper. Philadelphia: American College of Physicians, 2010.
6. National Committee for Quality Assurance. Standards and Guidelines for Physician Practice Connections—Patient-Centered Medical Home (PPC-PCMHTM). Washington, DC, 2008.
7. Hing E, Hsiao CJ. Electronic medical record use by office-based physicians and their practices: United States, 2007. Natl Health Stat Report 2010:1-11.
8. American Recovery and Reinvestment Act of 2009. In, February 17 2009.
9. American Recovery and Reinvestment Act of 2009/Division B/Title IV Health Information Technology for Economic and Clinical Health Act. In, February 17 2009.
10. Gliklich R, Dreyer N. Registries for Evaluating Patient Outcomes: A User's Guide. Rockville, MD, 2010. Report No.: Report No.: No. 10-EHC-49.
11. The Society of Thoracic Surgeons. Adult Cardiac Surgery Database. [cited 2011 June 27]; Available from: http://www.sts.org/national-database/database-managers/adult-cardiacsurgery-database.
12. American College of Cardiology Foundation. National Cardiovascular Data Registry. [cited 2011 June 27]; Available from: http://www.ncdr.com.
13. American College of Cardiology Foundation, American Heart Association. ACTION Registry®– GWTGTM. *cited 2011 June 27+; Available from: http://www.ncdr.com/WebNCDR/Action/default.aspx.
14. Chervin RD, Burns JW, Ruzicka DL. Electroencephalographic changes during respiratory cycles predict sleepiness in sleep apnea. Am J Respir Crit Care Med 2005;171:652-8.
15. Chervin RD, Burns JW, Subotic NS, Roussi C, Thelen B, Ruzicka DL. Correlates of respiratory cycle-related EEG changes in children with sleep-disordered breathing. Sleep 2004;27:116-21.
16. Jamasebi R, Redline S, Patel SR, Loparo KA. Entropy-based measures of EEG arousals as biomarkers for sleep dynamics: applications to hypertension. Sleep 2008;31:935-43.
17. Thomas RJ, Mietus JE, Peng CK, et al. Differentiating obstructive from central and complex sleep apnea using an automated electrocardiogram-based method. Sleep 2007;30:1756-69.
18. Thomas RJ, Mietus JE, Peng CK, Goldberger AL. An electrocardiogram-based technique to assess cardiopulmonary coupling during sleep. Sleep 2005;28:1151-61.
19. Tretriluxana S, Khoo MC, Redline S, Surovec SA, Gottlieb DJ. Cardiac autonomic function in older adults with sleep-disordered breathing. Conf Proc IEEE Eng Med Biol Soc 2005;2:1103-5.
20. Wang W, Tretriluxana S, Redline S, Surovec S, Gottlieb DJ, Khoo MC. Association of cardiac autonomic function measures with severity of sleep-disordered breathing in a community-based sample. J Sleep Res 2008;17:251-62.
21. Pitson DJ, Stradling JR. Value of beat-to-beat blood pressure changes, detected by pulse transit time, in the management of the obstructive sleep apnoea/hypopnoea syndrome. Eur Respir J 1998;12:685-92.
22. Pitson DJ, Stradling JR. Autonomic markers of arousal during sleep in patients undergoing investigation for obstructive sleep apnoea, their relationship to EEG arousals, respiratory events and subjective sleepiness. J Sleep Res 1998;7:53-9.
23. Arnardottir ES, Mackiewicz M, Gislason T, Teff KL, Pack AI. Molecular signatures of obstructive sleep apnea in adults: a review and perspective. Sleep 2009;32:447-70.
24. Seugnet L, Boero J, Gottschalk L, Duntley SP, Shaw PJ. Identification of a biomarker for sleep drive in flies and humans. Proc Natl Acad Sci U S A 2006;103:19913-8.
25. Dinges DF, United States. National Highway Traffic Safety A. Evaluation of techniques for ocular measurement as an index of fatigue and as the basis for alertness management. Washington, DC: National Highway Traffic Safety Administration, 1998.
26. Banks S, Van Dongen HP, Maislin G, Dinges DF. Neurobehavioral dynamics following chronic sleep restriction: dose-response effects of one night for recovery. Sleep 2010;33:1013-26.
27. Verstraeten E, Cluydts R, Pevernagie D, Hoffmann G. Executive function in sleep apnea: controlling for attentional capacity in assessing executive attention. Sleep 2004;27:685-93.
28. Gur RC, Richard J, Hughett P, et al. A cognitive neuroscience-based computerized battery for efficient measurement of individual differences: standardization and initial construct validation. J Neurosci Methods 2010;187:254-62.
29. Buysse DJ, Moul DE, Germain A, et al. Development and validation of patient–reported outcome measures for sleep disturbance and sleep–related impairments. Sleep 2010; 33:781-92.
30. Botteman M. Health economics of insomnia therapy: implications for policy. Sleep Med 2009;10 Suppl 1:S22-5.
31. White DP. Sleep Apnea. Poc Am Thorac Soc 2006;3:124-8.
32. Morgenthaler T, Alessi C, Friedman L, et al. Standards of Practice Committee, American Academy of Sleep Medicine. Practice parameters for the use of actigraphy in the assessment of sleep and sleep disorders: an update for 2007. Sleep 2007; 30:519-29.
33. Regestein QR, Monk TH. Delayed sleep phase syndrome: a review of its clinical aspects. Am J Psychiatry 1995;152:602-8.
34. van Geijlswijk IM, Korzilius HP, Smits MG. The use of exogenous melatonin in delayed sleep phase disorder: a meta-analysis. Sleep 2010;33:1605-14.
35. Mundey K, Benloucif S, Harsanyi K, Dubocovich ML, Zee PC. Phase-dependent treatment of delayed sleep phase syndrome with melatonin. Sleep 2005;28:1271-8.