

North Carolina Academy of Sleep Medicine Virtual Conference Feb 26-27, 2021 Speaker and Planner Disclosures and Resolutions

Statement of Need

The need for these activities has been determined based on identifying professional practice gaps, as well as review of previous course evaluations and member surveys. The educational content was developed based on current issues and topic trends provided by the North Carolina Academy of Sleep Medicine (NCASM) leadership and membership.

Accreditation Statement

This activity has been planned and implemented in accordance with the accreditation requirements and policies of the Accreditation Council for Continuing Medical Education (ACCME) through the joint providership of The American Academy of Sleep Medicine and The North Carolina Academy of Sleep Medicine. The American Academy of Sleep Medicine is accredited by the ACCME to provide continuing medical education for physicians.

Disclosure Statement

As an education provider accredited by the Accreditation Council for Continuing Medical Education (ACCME), the American Academy of Sleep Medicine must ensure balance, independence, objectivity, and scientific rigor in all its sponsored educational activities. All product developers, planners, and speakers are expected to disclose any relevant financial interest or other relationships held by the individual, or members of their family, that are relevant to the presentation over the preceding twelve months with (1) manufacturers of any commercial products and/or providers of commercial services, (2) any commercial supporters, (3) any off-label or investigational uses of products. The individual is also required to disclose if he/she has no relationships with any manufacturers, products or services that are relevant to the presentation. The ACCME Standards for Commercial Support require accredited CME providers to resolve all identified potential conflicts of interest with any individual in a position to influence and/or control the content of CME activities prior to the education activity being delivered to learners.

Resolution of Conflicts of Interest

AASM has implemented mechanisms to identify and mitigate conflicts of interest for all individuals in a position to control content, prior to the planning and implementation of these CME activities. **Course Chair(s) review the COI declarations to satisfy no commercial bias exists.** All Conflict of Interest Disclosures are provided to participants prior to start of the activity.

Faculty Disclosures:

The following North Carolina Academy of Sleep Medicine faculty member has no relevant relationships with any commercial interests to disclose:

Carol Rosen, MD

The following North Carolina Academy of Sleep Medicine faculty members disclosed the following relationships:

Beth Malow, MD, MS disclosed: Grant/Research Support : Neurim Pharmaceuticals and Autism Speaks Autism Treatment Network

Citations:

1. Malow BA, Findling RL, Schroder CM, Maras A, Breddy J, Nir T, Zisapel N, Gringras P. (in press). Sleep, Growth and Puberty after Two Years of Prolonged-Release Melatonin in Children with ASD. JAACAP. 2020 Jan 23:S0890-8567(20)30034-4. doi: 10.1016/j.jaac.2019.12.007.

2. Malow BA, Byars K, Johnson K, Weiss S, Bernal P, Goldman SE, Panzer R, Coury D, Glaze DG. A practice pathway for the identification, evaluation and management of insomnia in children and adolescents with autism spectrum disorders. *Pediatrics*. 130 Suppl 2 (2012):S106-24.

Joyce Lee-Iannotti, MD disclosed Speakers' bureau: Jazz Pharmaceuticals Health and Wellness Partners/Eisai Neurology Harmony Biosciences.

Michael H. Silber, M.B.Ch.B. disclosed Other financial/material support: Honoraria from the American Academy of Neurology, the American Academy of Sleep Medicine, UpToDate and Oakstone Publishing. Salary: Salary from full-time employment as neurologist and sleep specialist by Mayo Clinic, and Royalties: Royalties from publication of "Sleep Medicine in Clinical Practice, 2nd edition" and "Atlas of Sleep Medicine", both published by Informa Healthcare, 2010.

John Winkelman, MD, PhD disclosed Consultant : Eisai, OrbiMed, Avadel, Grant Research Support: Luitpold Pharma, Merck, RLS Foundation Other, Financial Material: UpToDate.

Citations:

1. Winkelman JW. "Insomnia Disorder". *New England Journal of Medicine*. 373(2015):1437-1444.
2. Winkelman JW, Armstrong MJ, Allen RP, Chaudhuri KR, Ondo W, Trenkwalder C, Zee PC, Gronseth GS, Gloss D, Zesiewicz T. Practice guideline summary: Treatment of restless legs syndrome in adults: Report of the Guideline Development, Dissemination, and Implementation Subcommittee of the American Academy of Neurology. *Neurology*. 2016;87:2585-2593.
3. Mackie SE, Winkelman JW. Long-term treatment of RLS: An approach to management of worsening symptoms, loss of efficacy, and augmentation. *CNS Drugs* 2015;29:351-7. - Remove

Sujay Kansagra, MD disclosed Consultant: Sleep Health Consultant for Mattress Firm, Royalties: Book royalties from: My Child Won't Sleep.

Joseph Anderson disclosed Speakers' bureau: MEDBRIDGE, Stock/Stockholder (excluding diversified mutual funds): PRIORITY HEALTH EDUCATION.

Donald Bliwise, PhD disclosed Consultant: Merck, Ferring, Eisai, Huxley, Speakers' bureau: Merck.

Citations:

1. Herring WJ, Ceesay P, Snyder E, Bliwise D, Budd K, Hutzelmann J, Stevens J, Lines C, Michelson D. Polysomnographic assessment of suvorexant in patients with probable Alzheimer's disease dementia and insomnia: a randomized trial. *Alzheimer's Dement*. 2020 Mar;16(3):541-551.
2. Bliwise DL, Foley DJ, Vitiello MV et al. Nocturia and sleep disturbance in the elderly. *Sleep Medicine* 10: 2009: 540-8.

Massimiliano Di Giosia, DDS disclosed Royalties: Coeditor of the textbook: Dental Management of Obstructive Sleep Apnea. EDRA Publishing. 2020.

Ann Augustine, MD disclosed Consulting: One-time consulting for S2N Health in Oct 2020. We are a small Boston-based consulting firm that works with healthcare technology innovators. For a current client, we are hoping to better understand the potential market for a novel Type II, unattended study technology, specifically relating to its reimbursement.

Terri E. Weaver, PhD, RN, FAAN, ATSF disclosed Royalties: FOSQ License Agreements-Unless otherwise indicated, less than \$10,000/year: Philips Respironics (more than \$10,000 per year); ResMed; ResMed Germany; Nyxoah; Jazz Pharmaceuticals; Merck & Co., Inc., Bayer, AG; Cook Medical, RWS, Verily Life Sciences, Stratevi, WCG MedAvante Prophase, LivaNova, Evidation Health

Consultant: Advisory Board Jazz Pharmaceuticals, Inc.

Citations:

1. Weaver, Terri. "An Instrument To Measure Functional Status Outcomes For Disorders of Excessive Sleepiness." *SLEEP*. 20. (1997):835-843.

2. Weaver, Terri. "Night-To-Night Variability in CPAP Use Over First Three Months of Treatment". SLEEP. 20:(1997):278 – 283.
3. Massie, Clifford. "Clinical Outcomes Related to Interface Type in Patients with Obstructive Sleep Apnea/Hypopnea Syndrome Who Are Using Continuous Positive Airway Pressure." Chest.123.04 (2003):1112-1118.
4. Drake, Christopher. "Sleep During Titration Predicts Continuous Positive Airway Pressure Compliance." SLEEP.26.03(2003):308-11.
5. Carson, Shannon S; Malhotra, Atul; Mularski, Richard A; Riekert, Kristin A; Rubenfeld, Gordon D; Weaver, Terri E , et al. An official American Thoracic Society research statement: comparative effectiveness research in pulmonary, critical care, and sleep medicine American journal of respiratory and critical care medicine. 188.10 (2015):1253-1261
6. Almeida, Fernanda R and Bansback, Nick.Long-term effectiveness of oral appliance versus CPAP therapy and the emerging importance of understanding patient preferences Sleep. 36.09 (2013), p. 1271
7. Colvin, Loretta; Cartwright, Ann; Collop, Nancy; et al. Advanced Practice Registered Nurses and Physician Assistants in Sleep Centers and Clinics: A Survey of Current Roles and Educational Background. JOURNAL OF CLINICAL SLEEP MED. 10.05 (2014): 581-587
8. Weaver, TE, Mancini C, Maislin G, Cater, J, Staley B, Landis JR, Ferguson KA, George CFP, Schulman DA, Greenberg H, Rapoport DM, Walsleben JA, Lee-Chiong T, Gurubhagavatula I, Kuna ST. Continuous positive airway pressure treatment of sleepy patients with milder obstructive sleep apnea. Results of the CPAP Apnea Trial North American Program (CATNAP) Randomized Clinical Trial. American Journal of Respiratory and Critical Care Medicine, 186(7):677-683, 2012.

Nancy Collop, MD disclosed Investigational Device/Drug: Unfunded study on device testing speaker on PAP mask (Ataia), Royalties: I receive royalties from Up-To-Date, Other financial/material support: Editor for JCSM (receive stipend from AASM, beginning 1/15).

Citations:

1. Adenuga O, Attarian H.Treatment of disorders of hypersomnolence. Curr Treat Options Neurol. 2014 Sep;16(9):302
2. Khan Z, Trotti LM.Central Disorders of Hypersomnolence: Focus on the Narcolepsies and Idiopathic Hypersomnia. Chest. 2015 Jul;148(1):262-73
3. American Academy of Sleep Medicine. International classification of sleep disorders, 3rd ed. Darien, IL: American Academy of Sleep Medicine, 2014.

Stefan Cemens, PhD, HdR disclosed Grant/Research Support : Bioprojet Pharma (Paris, France), Industry grant; North Carolina Biotechnology Center, Business Innovation Grant; National Science Foundation

Intellectual Property Rights: U.S. patent 10,751,327, Treatment and Management of Augmentation in Restless Legs Syndrome, published Aug 25, 2020; U.S. Provisional Application No. 62/577,443, Maintaining opioid efficacy over time in the treatment of chronic pain by adjuvant use of dopamine receptor compounds, filed Oct 26, 2017

Citation:

U.S. patent 10,751,327, Treatment and Management of Augmentation in Restless Legs Syndrome, published Aug 25, 2020;

Lynn Marie Trotti, MD, MSc disclosed Other financial/material support : Funds to my institution (none to me) for the pitolisant EAP; Investigational Device/Drug : IND for flumazenil for hypersomnia; Consultant : none

1. Thorpy MJ, Shapiro C, Mayer G, Corser BC, Emsellem H, Plazzi G, et al. A Randomized Study of Solriamfetol for Excessive Sleepiness in Narcolepsy. Ann Neurol. 2019;85(3):359-70.
2. Dauvilliers Y, Bassetti C, Lammers GJ, Arnulf I, Mayer G, Rodenbeck A, et al. Pitolisant versus placebo or modafinil in patients with narcolepsy: a double-blind, randomised trial. The Lancet Neurology. 2013;12(11):1068-75.

Judith Owens, MD, MPH disclosed Consultant: Jazz, Sleep Number, Citrine, Indorsia, Harmony Biosciences, Royalties: Wolters Kluwer WebMD Taylor and Francis (journal Editor stipend).

Grant/Research Support: Jazz

Citations:

1. Maski K, Owens JA. Insomnia, parasomnias, and narcolepsy in children: clinical features, diagnosis, and management. *Lancet Neurol*. 2016 Oct;15(11):1170-81. doi: 10.1016/S1474-4422(16)30204-6.
2. Fiks AG, Mayne SL, Song L, Steffes J, Liu W, McCarn B, Margolis B, Grimes A, Gottlieb E, Localio R, Ross ME, Grundmeier RW, Wasserman R, Leslie LK. "Changing patterns of alpha agonist medication use in children and adolescents 2009-2011". *J Child Adolesc Psychopharmacol*. 2015 May;25(4):362-7
3. Malow BA, Katz T, Reynolds AM, Shui A, Carno M, Connolly HV, Coury D, Bennett AE. "Sleep Difficulties and Medications in Children With Autism Spectrum Disorders: A Registry Study". *Pediatrics*. 2016 Feb;137 Suppl 2:S98-S104.
4. Bock DE, Roach-Fox E, Seabrook JA, Rieder MJ, Matsui D. "Sleep-promoting medications in children: physician prescribing habits in Southwestern Ontario, Canada". *Sleep Med*. 2016 Jan;17:52-6.
5. Lecendreux M; Poli F; Oudiette D; Benazzouz F; Donjacour CEHM; Franceschini C; Finotti E; Pizza F; Bruni O; Plazzi G. Tolerance and efficacy of sodium oxybate in childhood narcolepsy with cataplexy: a retrospective study. *SLEEP* 2012;35(5):709-711. Aran A; Einen M; Lin L; Plazzi G; Nishino S; Mignot E. Clinical and therapeutic aspects of childhood narcolepsy-cataplexy: a retrospective study of 51 children. *SLEEP* 2010;33(11):1457-1464.

Richard Kravitz, MD disclosed Consultant: I have consulted for Biogen, Santhera, and AveXis. Speakers' bureau: I am on the Speaker's Bureau for Biogen, Santhera, and AveXis.

Planner Disclosures:

The following North Carolina Academy of Sleep Medicine planners have no relevant relationships with any commercial interests to disclose:

Mary Ellen Wells, PhD, RPSGT, R. EEG T., R. NCS T (Chair)

The following North Carolina Academy of Sleep Medicine planners disclosed the following relationships:

Brad Vaughn, MD disclosed Other financial/material support: Former Chair of the Sleep Medicine Board Exam and Policy Committee, Associate Editor for Sleep Multimedia, author on Medlink Neurobase and Up to Date, I am on the Editorial Board for the AASM Scoring Manual. Interpret sleep studies as part of my occupation. Salary: Director of Sleep Medicine Program at University of North Carolina

Citation:

The AASM Manual for the Scoring of Sleep and Associated Events Rule, Terminology and Technical Specifications version 2.3 – AASM

Tom Perkins, MD, PhD disclosed Speakers' bureau: Eisai.