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<b>Activity description</b>	Practicing evidence-based medicine (EBM) is important in today's health care environment because this model of care offers clinicians a way to enrich quality, provide patient satisfaction, reduce costs and improve outcomes. A common implementation of EBM involves the use of clinical practice algorithms during medical decision-making to encourage optimal care. This widely recognized practice is designed to address the persistent problem of clinical practice variation with the help of actionable information at the point of care. These E-newsletters will enable health care professionals (HCPs) to put new EBM into practice.
<b>Target audience</b>	This activity is designed to meet the educational needs of physicians, PAs, nurses, nurse practitioners and other HCPs who have an interest in EBM.
<b>Learning objectives</b>	At the end of this educational activity, participants should be able to: <ul style="list-style-type: none"> <li>• Explore the educational content surrounding obstructive sleep apnea as a means to advance optimal care outcomes.</li> <li>• Recall pharmaceutical recommendations for the management of mild persistent asthma and review the Global Initiative for Asthma (GINA) updated guidelines for 2019.</li> <li>• Apply medical management principles grounded in evidence-based medicine that could help modify and expand shared decision making in regards to newer technologies for monitoring occult atrial fibrillation, surveillance of prostate cancer in young men, and total shoulder arthroplasty.</li> </ul>

### Accreditation statement



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#### Nurse practitioners

The American Academy of Nurse Practitioners Certification Program (AANPCP) accepts credit from organizations accredited by the ACCME and ANCC.

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# Obstructive Sleep Apnea – Evidence Based Management



Let's begin by examining the incidence of apneas and hypopneas in a normal population. A recent meta-analysis in *Lancet Respiratory Medicine*<sup>1</sup> looked at over 5200 healthy individuals who served as controls in sleep research studies and reported the sleep parameters derived from overnight polysomnography. The AHI (apnea hypopnea index expressed as events per hour) is our most frequently used measure to determine the need for therapy. At the age range from 18-64 years, the average AHI remained below 5 per hour, which is consistent with our definition of a normal AHI on our sleep study reports. However in the age range of 65-80 years, the average AHI was 15, and over age 80, the average AHI was 30. Physicians and patients alike tend to overestimate the benefits and underestimate the harms of medical and surgical interventions. This observation, coupled with the high prevalence of abnormal sleep study results in older individuals who do not report symptoms of OSA, suggest that it is important to understand the evidence in support of the evaluation and treatment of OSA.

The predominant symptom of OSA is excessive daytime sleepiness. Other important symptoms include loud snoring, a decrease in psychomotor function, a decrease in quality of life measures and a threefold increased risk of motor vehicle accidents. There are good data that treatment improves daytime sleepiness and fatigue, snoring, and quality of life. There are limited data that treatment reduces the risk of future MVA's. There are not clear data that treatment improves cognitive function. Given the above, treating symptomatic patients to reduce daytime sleepiness and possibly reduce the risk of MVA's, has a strong evidence base of support.

The other significant risks associated with OSA include an increased incidence of hypertension, and associated risks of cardiovascular disease and sleep related dysrhythmias. It is important to recognize however, that the data demonstrating a reduction of these risks through treatment of OSA is far more limited. There are data looking at hypertension control, and treatment of OSA has been associated with a small 4 mm<sup>Hg</sup> improvement in systolic BP. However there are not data showing reductions in cardiovascular risk with OSA treatment. Two important studies have looked at this.

- The first was a randomized trial of 4 years duration in 725 non-sleepy individuals with an AHI>20 and showed no reduction in the incidence of hypertension or cardiovascular events<sup>2</sup>.
- The second study was more compelling. It looked at a group of 2700 patients with known CAD or stroke and moderate to severe OSA. The primary composite end point was death from cardiovascular causes, myocardial infarction, stroke, or hospitalization for unstable angina, heart failure, or transient ischemic attack. Patients were randomized to usual care or CPAP therapy and after 3.7 years, there was no reduction in CV events or improvement in mortality in the CPAP group<sup>3</sup>.

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# Obstructive Sleep Apnea – Evidence Based Management

(continued from page 1)

At the referral desk, we also frequently see requests for sleep studies in asymptomatic individuals with CHF. Both OSA and central sleep apnea are associated with CHF and the SERVE-HF trial looked to see if there was any clinical benefit to adaptive servo-ventilation, which can be used for central sleep apnea. When this was studied in the setting of CHF, looking at over 1300 individuals, cardiovascular outcomes worsened with treatment. The updated 2017 AHA/ACC CHF guidelines are consistent with the results of the above studies and recommend testing and treatment in the subset of patients with symptoms of OSA<sup>4</sup>. Examining this data in its totality suggests that treatment of OSA should be based upon symptoms and not coexistent disease. [The USPSTF recently recognized this when it recommended against population screening for OSA in asymptomatic individuals.](#)

Testing for OSA should predominantly be limited to those patients with typical symptoms of daytime sleepiness, fatigue and snoring, who are willing to consider treatment for OSA. Unexplained polycythemia may be related to undiagnosed OSA and may be an indication for testing. Testing and treatment for the purpose of reducing cardiovascular risk is not indicated based on the current literature. The small average reduction in systolic BP seen with treatment might occasionally warrant investigation. Home sleep study is the preferred diagnostic test when patients have a moderate to high pretest probability of OSA, and no comorbidities which would affect the interpretation of a home sleep study (significant CHF or COPD, chronic hypoventilation from pulmonary or neuromuscular disease, or nocturnal oxygen use). A recent study comparing the management of OSA by sleep specialists using data derived either from a facility study or a home study showed equivalent clinical outcomes when either test was used to direct therapy<sup>5</sup>. The main indication for treatment is an elevated AHI >15. AHI readings between 5 and 15 are considered to be borderline abnormal and may be treated when patients are symptomatic and highly motivated to be compliant with CPAP. Alternatively, mild symptomatic OSA can be treated with a mandibular advancement device or positional therapy (techniques to avoid the supine position) although the AHI reduction is less than that

seen with CPAP therapy. Unless there are significant craniofacial abnormalities present, the data on improvement with surgical procedures is unclear and this should not be a preferred modality. Weight loss continues to be the most successful modality to resolve or improve OSA. When OSA is severe and associated with refractory obesity, pharmacotherapy and bariatric surgery should both be considered, particularly when multiple comorbidities are present.

Treatment with an auto-titrating CPAP unit avoids the need for a CPAP titration at a facility and markedly decreases the cost of the evaluation. These units also have an internal chip which can periodically be interrogated to obtain both compliance data and an AHI on treatment. Compliance with CPAP overall is suboptimal and even in the research setting typically averages only about 4 hours nightly. Patients who are not significantly symptomatic and therefore don't feel improved with CPAP, can be expected to have even worse compliance with a high rate of CPAP discontinuation. The availability of respiratory therapists skilled in the selection and fitting of CPAP masks can markedly improve patient tolerance of CPAP and therefore compliance with treatment. If there are concerns about persistent nocturnal hypoxemia after the AHI has been successfully reduced with CPAP treatment, this can be evaluated with overnight oximetry. Nocturnal oxygen can be bled into the CPAP system when indicated. Following the above recommendations will allow for the appropriate cost effective, evidence based management of OSA in the majority of patients. Consultation can be obtained for patients falling outside of the above parameters or responding poorly to treatment.

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2. Barbe, F., Duran-Cantolla, J., & Sanchez-de-la-Torre, M. (2012). Effect of continuous positive airway pressure on the incidence of hypertension and cardiovascular events in nonsleeping patients with obstructive sleep apnea: A randomized controlled trial. *JAMA*, 307(20), 2161-2168.
3. McEvoy, R. D., Antic, N. A., Heeley, E., Luo, Y., Ou, Q., Zhang, Z., et al. (2016). CPAP for prevention of cardiovascular events in obstructive sleep apnea. *NEJM*, 375, 919-931.
4. Haselhubn, L. R., Brotman, D. J., & Wittstein, I. S. (2019). Heart failure guidelines: What you need to know about the 2017 focused update. *Cleveland Clinic Journal of Medicine*, 86(2), 123-139.
5. Chai-Coetzer, C. L., Antic, N. A., Hamilton, G. S., McArdle, N., Wong, K., Yee, B. J., et al. (2017). Physician decision making and clinical outcomes with laboratory polysomnography or limited-channel sleep studies for obstructive sleep apnea: A randomized trial. *Annals of Internal Medicine*, 166(5), 332-340.



## GINA (Global Initiative For Asthma) updated treatment guideline

As detailed in the September 2018 Forum, the SYGMA 1 and 2 trials<sup>6,7</sup> suggested a paradigm shift in the approach to the treatment of mild persistent asthma. Recall that 50-75% of asthma falls into the mild persistent category and up to 40% of all severe exacerbations occur in this group. The standard of care for mild persistent asthma had always been a daily inhaled corticosteroid (ICS) and an as needed short acting beta agonist (SABA). The SYGMA trials showed that by changing management to an as needed combination of budesonide and formoterol (Symbicort), an ICS/LABA combination, asthma outcomes were overall unchanged but the average ICS dose was reduced by 75-83% resulting in a much lower chronic exposure to inhaled corticosteroid and a savings to the healthcare system of \$1 billion yearly. This approach will not work for everyone as a few patients in these trials had slightly worse symptoms on this regimen and did better on the daily ICS regimen. Based upon these new studies, the Forum recommended consideration of this approach for all patients with mild persistent asthma, with the understanding that if they did not have adequate symptom control, return to the ICS and prn SABA regimen would be appropriate.

Now, GINA has updated the asthma treatment guideline to incorporate this important new research. The guideline went one step farther and stated that as needed albuterol alone should never be used without a background of ICS therapy. This recommendation was even extended to include patients with mild intermittent asthma, for whom the standard of care continues to be an as needed SABA. This stems from two data points<sup>8</sup>.

- Patients using more than three canisters of SABA yearly are more likely to have an exacerbation requiring an ER visit.
- 15-20% of adults who died of asthma had experienced symptoms on a less than weekly basis over the prior three months.

While the SYGMA trials lend support to this concept, they did not enroll patients with mild intermittent asthma or predominant exercise induced asthma. If albuterol use is very infrequent or needed pre-exercise only, most asthma treatment guidelines would support continuation of as needed SABA only in this group of patients. An exception might be those patients with more severe exercise induced asthma. In this group there may be a degree of chronic underlying airway inflammation such that they actually may fall into the mild persistent asthma category and respond better to the prn ICS/LABA combination. Open the link and refer to the new GINA recommendations and view the algorithm on page 18. <https://ginasthma.org/wp-content/uploads/2019/04/GINA-2019-main-Pocket-Guide-wms.pdf>

6. Gonzalez, A. V., Coulombe, J., Ernst, P., & Suissa, S. (2018). Long-term use of inhaled corticosteroids in COPD and the risk of fracture. *Chest*, 153, 321-328.

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8. Burki, T. K. (2019). New asthma treatment recommendations. *The Lancet*, 7(6), 497.



## Occult atrial fibrillation (AF) in the setting of cryptogenic stroke

About 25% of strokes are cryptogenic. These are also known as embolic stroke of undetermined source (ESUS), which is defined as a non-lacunar brain infarct without proximal arterial stenosis or cardioembolic sources. In individuals under age 60 with a paucity of vascular risk factors, evaluation for patent foramen ovale (PFO) is indicated. Additionally, in all individuals, evaluation for occult atrial fibrillation is indicated. The burden of AF needed to increase stroke risk is the subject of intense study.

It is felt to be hours to days and not minutes. Because patients may be unaware of paroxysms of AF, continuous heart monitoring is recommended, but the optimal duration of monitoring is unknown. The standard of care is a 30 day event monitor which can be as simple as an adhesive monitoring patch. Two new technologies have recently gained more widespread use and therefore examining the evidence around these newer technologies is timely. The first is the implantable cardiac loop monitor (ICM). The cost of these is dependent on the time it is in place but is in the range of \$20,000 and is an invasive procedure with attendant risks of infection which sometimes warrant excision and re-implantation. Compared to 30 day event monitoring, an ICM in place for one year will detect an additional 10% of cases of atrial fibrillation of >6 minutes duration. 100 ICM's would need to be placed to prevent one additional stroke at a cost of \$2,000,000 per prevented stroke, currently making this technology cost prohibitive<sup>9</sup>. The second new development holds greater promise due to both low cost and low risk. These are the new wearable "watch" monitors that have algorithms to detect sudden changes in heart rate and rhythm unrelated to exercise. KardiaMobile is an FDA approved system that works through an Apple Watch band. The band replaces the existing Apple watch band and costs \$100. A new stand-alone watch that does not require an Apple watch will soon be released for about \$150. KardiaMobile has a 97% overall accuracy for the detection of occult AF<sup>10</sup>. These are not recommended for population screening for AF because the false positive rate will be high when the prevalence of occult AF in the screened population is low. They will likely however, soon become the technique of choice to evaluate for occult AF in the setting of cryptogenic stroke.



## Active surveillance of prostate cancer in younger men

Although active surveillance (AS) is recognized as the optimal course in older men with low risk prostate cancer, there has been a paucity of data to inform decision making in younger men. Because of the very high 10 year survival of low risk prostate cancer, a randomized prospective trial is not feasible due to the number of patients that would need to be enrolled and the length of the follow up before results would become available. A recent study in the Journal of Urology adds important knowledge in this area<sup>11</sup>. An observational data base studied 2100 men monitored with active surveillance between 1995 and 2016. 417 of the men were under age 60 and this group was compared to the older men who comprised the remainder of the group. The younger men all had low volume Gleason 6 cancers. There were no differences in outcomes between the younger and older cohorts. Specifically the results of the younger compared to the older cohorts were as follows:

Surveillance Type	Young Men Survival	Older Men Survival
Prostate cancer	100%	99.7%
Metastasis free	99.7%	99%
Biopsy progression free	83%	83%

Of those younger patients followed for 10 years, the metastasis free survival remained high at 97.5%. Over a six year period, 31% of younger men underwent definitive treatment, typically for biopsy progression. Because the toxicity of treatment (impotence and bladder leakage) may be more impactful in younger individuals, this study adds important new data. At 6 years, over 70% of younger men with low risk disease remained in active surveillance demonstrating that the majority of men were able to avoid or at least significantly delay the toxicity of aggressive treatment, with an option to treat later if disease progression occurs.

9. Mayo Clinic. (2019). Implantable loop recorders in patients with cryptogenic stroke. Retrieved from Mayo Clinical Web site: <https://www.mayoclinic.org/medical-professionals/cardiovascular-diseases/news/implantable-loop-recorders-in-patients-with-cryptogenic-stroke/MAC-20430116>

10. Ip, J. E. (2019). Wearable devices for cardiac rhythm diagnosis and management. JAMA, 321(4), 337-338.

11. Salari, K., Kuppermann, D., Preston, M. A., Dahl, D. M., Barrisford, G. W., Efstathiou, J. A., et al. (2019). Active surveillance of prostate cancer is a viable option for men younger than 60 years. Journal of Urology, 201(4), 721-727.



## Risks of total shoulder arthroplasty (TSA)

For all surgical procedures, shared decision making should be informed by evidence and include a full discussion of the risks, benefits, and alternatives to surgery. TSA is being performed more frequently, having increased almost six fold over the past two decades. The long term outcomes, reoperation rates, and complication rates of TSA are not well studied and therefore precise information about these risks are not generally shared with patients. A recent paper in the BMJ<sup>12</sup> looked at over 58,000 TSA procedures performed in Great Britain between 1998 and 2017, and reported both reoperation rates and complication rates. For both of these parameters, there was a marked variation by age with younger patients having high reoperation rates and older patients having high complication rates. Overall, the rate of a second operation was much higher than anticipated with 19% of all patients requiring a second surgery. This risk of reoperation was particularly high in men under age 59 in whom over 30% required a second surgery, with the risk of reoperation highest in the first five years after the original surgery. In other words, these were not predominantly late prosthesis failures. With respect to serious post-operative complications, these too were higher than the general perception. In younger individuals, the risk of serious complications including death, PE, MI, stroke, or serious infection was about 4% but rose to almost 8% in men over 75 and to 21% in men over 85. In order to help our patients make an informed decision, these real world reoperation rates and complication rates should be transparently shared with our patients who are considering TSA surgery.

12. Craig, R. S., Lane, J. C., Carr, A. J., Furniss, D., Collins, G. S., & Rees, J. L. (2019). Serious adverse events and lifetime risk of reoperation after elective shoulder replacement: Population based cohort study using hospital episode statistics for England. *BMJ*, 364(1298), 1-10.



## Kenneth Roy Cohen, MD, FACP

*Chief Medical Officer*

Dr. Kenneth Cohen is an experienced physician leader, practicing internist, and researcher who has attained national recognition for health care quality improvement. He has successfully developed and reported numerous clinical quality studies in primary care, including tobacco cessation, osteoporosis, asthma, diabetes, hypertension, and ischemic vascular disease. He was one of the founding physicians of New West Physicians, which is the largest primary care group practice in Colorado and now part of OptumCare. He has served as Chief Medical Officer since 1995. Dr. Cohen has received awards of recognition and distinction for teaching, including the Lutheran

Medical Center Physician of the Year award in 2011. Under his stewardship New West Physicians was awarded the AMGA Acclaim award in 2015 and the Million Hearts Hypertension Champion Award in 2017. He is a Clinical Associate Professor of Medicine and Pharmacy at the University of Colorado School of Medicine. Dr. Cohen holds degrees from Dickinson College and Hahnemann University. He is a Fellow of the American College of Physicians and a member of the Phi Beta Kappa and Alpha Omega Alpha honor societies.



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Today we are highlighting how OptumCare Arizona has begun to integrate the Optimal Care program within their organization. This CDO is an affiliated market with no direct control over member referral decisions. They chose an intentional and creative way to implement the Optimal Care program using two strategies:

- Directing patients to more efficient specialists
- Providing point-of-care decision support for referral decisions

These strategies have helped to establish a foundation for future expansion while addressing the greatest near-term opportunities. Using scorecards, the team identifies both sub-populations with high utilization and the specialists who deliver the majority of care in those areas. A one-on-one communication process brings the specialists onboard, while the clinical team works to ensure quality conservative care alternatives. Recently, they established a partnership with the local osteopathic school to improve high quality, options for pain management.

The Optimal Care program has a strong educational foundation and Dr. Cary Schnitzer has successfully embedded the education into traditional network meetings and performance reporting. The team implemented the program using the following methods:

- Created an “Optum Prime” preferred narrow network (network within our network) of select specialty groups who have agreed to follow Optimal Care guidelines. This network was selected on data, input from PCPs, and direct meetings with specialty groups.
- Directs patients to specialist groups aligned with OptumCare Arizona through a mutual specialist compact agreement (terms that outline expectations of the relationship, including access to care).
- Works closely with the contracting department to align specialists into value-based models when applicable.
- Specialists aligned with Optimal Care will be listed preferentially in their referral portal. (Begins June 1, 2019)
- Holds mandatory community meetings to leverage, present, and discuss expected guidelines for care.
  - **Scorecards:** Present low value care utilization measures at the PCP panel and risk pool level. Promote discussion about where partner physicians should be in relation to the benchmarks.
  - **CME Modules/Forum:** Lay out expectations around CME achievement and providing accessibility.
  - **Care Pathways:** Provide all partners in care with the tools necessary to ensure understanding of the path, to eliminate waste using clinical algorithms.
  - **Open Invitation:** “Optum Prime” specialists are invited to attend community meetings to rebuild the physician community (a specific specialist attends each meeting).

While OptumCare Arizona is still in the beginning phase of implementation, their experience to date shows how data can strengthen partnerships, support education strategies, establish care expectations, and align on a common language for success. The “Optum Prime” network that is being constructed with the aforementioned strategies pushes the market in a consistent evidence-based direction. All of these components help lead us all to better patient care, experience, and value.