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Activity description	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.
Target audience	This activity is designed to meet the educational needs of physicians, PAs, nurses, nurse practitioners and other HCPs who have an interest in EBM.
Learning objectives	At the end of this educational activity, participants should be able to: • Identify educational content on the management of acute diverticulitis. • Review the data on high dose semaglutide for weight loss in diabetic and nondiabetic obese patients. • Discuss opioid analgesics for diabetic neuropathy pain and prescribing for uncomplicated urinary tract infections. • Apply medical management principles grounded in evidence-based medicine regarding MRI for back pain, colon cancer screening, and management of patients with patent foramen ovale and stroke.

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Management of acute diverticulitis

Annually, there are close to two million outpatient visits for acute diverticulitis (AD) and over 200,000 inpatient admissions, with a cost of over $5 billion. The incidence has increased by 130% in individuals under age 50 over the past several decades.[1] The management of AD has changed significantly over the past several years and is now most often managed as an outpatient. The American Gastroenterological Association last published a guideline on management in 2015 and thus recently updated this guideline to reflect the new research on more conservative approaches to management. This article combines recommendations from the AGA guideline as well as from additional new studies published since the guideline update.

Broadly, patients can present with either uncomplicated or complicated AD. Eighty-eight percent of patients have uncomplicated AD, presenting with the acute or subacute onset of left lower quadrant pain. Associated findings may include fever, elevated WBC count and CRP level, nausea, and change in the bowel pattern. These patients typically have peri-colonic inflammation and thickening of the bowel wall. Complicated AD is seen in the other 12% and is most often associated with abscess formation, but may also include peritonitis, stricture with obstruction, and rarely, fistula formation. Most patients fully recover, however 5% of patients will evolve to smoldering diverticulitis characterized by ongoing pain and inflammatory findings on CT.[1]

Role of imaging. Because the clinical diagnosis is only correct about half the time, CT scan with oral and IV contrast is recommended for the initial presentation of AD since it is 95% accurate for the diagnosis, and may also reveal alternative diagnoses which may mimic AD. CT is also highly accurate for differentiating uncomplicated from complicated AD. Importantly however, for patients with an established diagnosis of diverticulitis in the past, CT is not indicated for recurrences unless complicated disease is suspected, or patients fail to recover with treatment.

Role of antibiotics. This is the largest area of new research on the management of AD, with important new recommendations arising from this research. Most importantly, antibiotics are not routinely indicated, as multiple studies have shown no benefit in patients with mild, uncomplicated AD. In a meta-analysis of nine studies encompassing over 2,500 patients with uncomplicated AD who were treated with antibiotics versus placebo, there was no difference in time to resolution or risk of admission, nor were there differences in progression to complicated disease or the need for surgery.[2] Patients who should be treated with antibiotics at the outset include those that are immunocompromised, and those with suspected sepsis or complicated AD. Importantly, among patients presenting with uncomplicated AD, the risk of progression to complicated AD is only 5%, highlighting the safety of avoiding antibiotics early in the course of uncomplicated AD. Indications of a worsening clinical course which would indicate the need for antibiotic therapy are:

- Symptoms longer than five days prior to presentation
- Fever and/or vomiting
- CRP level >140 mg/dl
- WBC count >15,000/mm
- Abscess or long segment inflammation (>8 cm) on CT scan

Although not specifically discussed in the guideline, there is an important point worth noting. When patients present with LLQ abdominal pain and other nonspecific GI symptoms and diverticulitis is not present, they often have IBS or other functional GI disorders which can be significantly exacerbated by the alterations of bowel flora that follow broad spectrum antibiotic use. Additionally, both the incidence and virulence of C. diff infection is rising due to broad spectrum antibiotic use in the community.[3] Avoidance of antibiotics in mild uncomplicated AD should therefore be viewed through the lens of avoiding potentially harmful care.

When antibiotics are indicated, the recommended regimens include the combination of metronidazole and a fluoroquinolone, or amoxicillin-clavulanate, for a 4–7 day course. Note that here, as with pneumonia, UTI, and sinusitis, short course antibiotic therapy is recommended to minimize antibiotic toxicity. The fluoroquinolones in particular, are a concern due to toxicities across multiple organ systems, predominantly neurological and musculoskeletal. A recent comparative effectiveness study examined antibiotics for AD.[4] Two data bases were queried, totaling 126,000 patients, both commercial and Medicare. The study compared outcomes using these two antibiotic regimens for acute AD. Overall, 90% of patients with AD received antibiotic treatment highlighting the ongoing overuse of antibiotics for uncomplicated AD.

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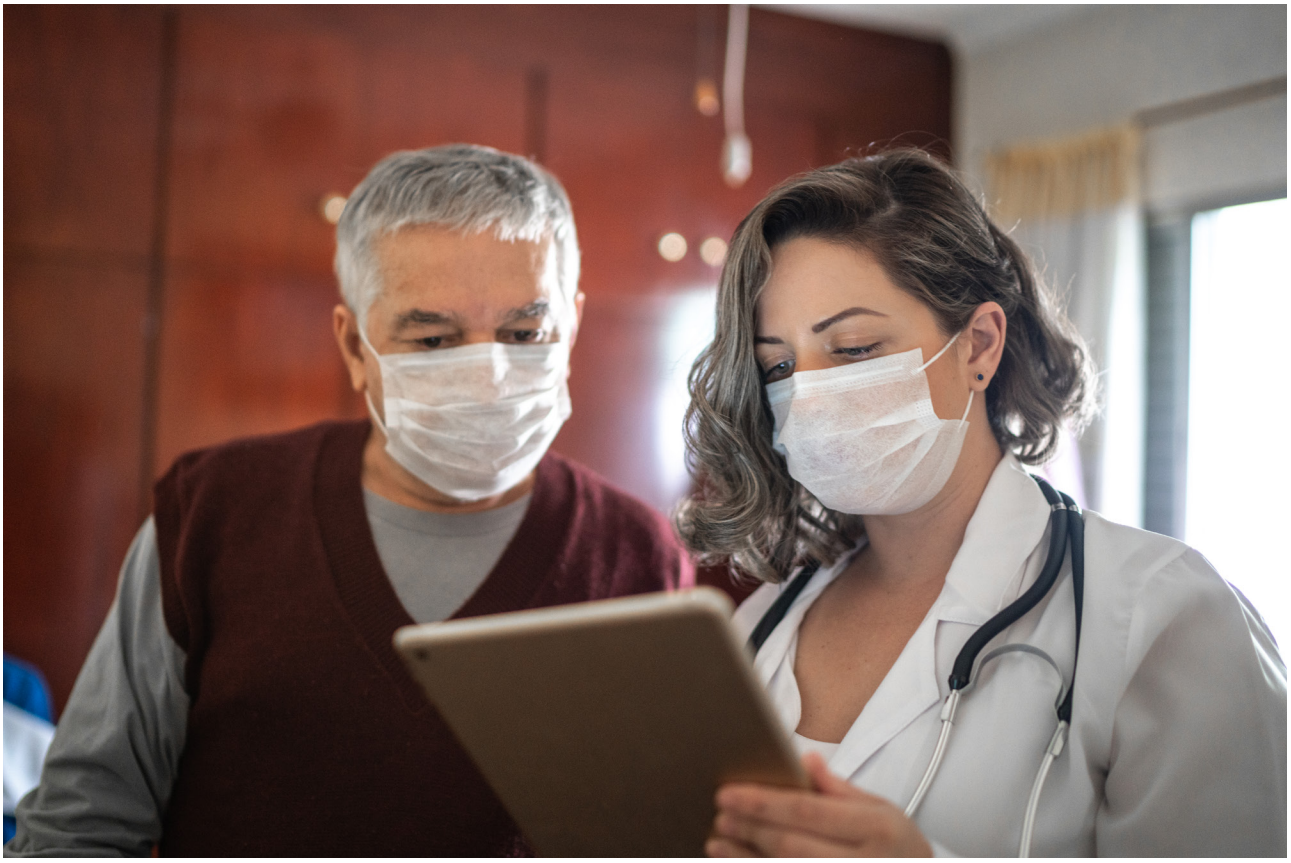
Eighty-seven percent of the treated patients received the metronidazole/fluoroquinolone regimen with only 13% receiving amoxicillin-clavulanate. AD outcomes examined included the need for hospital admission, the need for urgent surgery and the need for elective surgery at three years post episode. With one exception, there were no significant differences in any outcome between the two antibiotic regimens in either the commercial or Medicare populations. The one exception was the incidence of C. diff infection which occurred with twice the frequency in the Medicare population that received metronidazole-fluoroquinolone, although the absolute incidence was low at 1.2%. Given these data, amoxicillin-clavulanate might be considered the safest initial choice.

Role of colonoscopy post recovery from AD. This stems from the concern that colon cancer can be misdiagnosed as AD. In a meta-analysis looking at over 50,000 patients diagnosed with AD, the prevalence of colon cancer was 1.3% after a diagnosis of uncomplicated AD and 7.9% following a diagnosis of complicated AD. The recommendation is therefore to perform colonoscopy 6–8 weeks after an episode of complicated AD. For uncomplicated AD, the suggestion is to perform colonoscopy if a recent screening colonoscopy has not already been performed.

Other guideline recommendations

- Because AD can transiently compromise the bowel lumen, clear liquid diet is initially recommended until clinical improvement has been documented.
- Up to 50% of the AD risk may be genetic. However, avoidance of tobacco and NSAID therapy, and improvement in diet quality with an increase in plants, grains, and fruit fibers may reduce recurrences. Avoidance of nuts, seeds, and corn is not recommended.
- Complicated AD, when present, is most often seen as the initial presentation. With subsequent episodes, the risk of complicated AD lessens. The overall risk of recurrence for AD in any given patient is only 20%, but those that recur often have multiple recurrences and the recurrence risk is higher in those with an initial episode of complicated AD. That being said, current guidelines no longer recommend surgery solely based on the number of recurrences. This should be a shared decision-making process looking at the symptom burden and the risks and benefits of the surgery.



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High dose semaglutide for weight loss in diabetic and nondiabetic obese patients

Our obesity epidemic continues to worsen with over 42% of the population now categorized as obese. Obesity related metabolic disease has eclipsed hyperlipidemia as the most important risk factor for cardiovascular disease. Pharmacotherapy for obesity has been hampered by intolerable side effects and intolerable cost of therapy, and many patients are hesitant to consider bariatric surgery. The combination of phentermine/topiramate, and liraglutide have both been approved for weight loss and have achieved weight loss in the 10% total body weight (TBW) range in many patients. Phentermine/topiramate resulted in a 10% TBW loss in 55% of patients,[5] however it is often discontinued due to intolerable side effects of fatigue, cognitive difficulties, and constipation. Liraglutide provided 10% TBW loss in 35% of patients[6] however, at ~$15,000 yearly, is unaffordable for many patients and often not covered by insurance.

Two important pharmacotherapy weight loss trials were recently published, both using the more potent GLP1-RA, semaglutide. The first study looked at 1,961 obese, nondiabetics and compared counseling on diet and exercise alone to counseling on diet and exercise plus semaglutide 2.4 mg SQ weekly.[7] The mean change in body weight from baseline to week 68 was –14.9% in the semaglutide group as compared with –2.4% with placebo, for an estimated treatment difference of –12.4% ($p<0.001$). More participants in the semaglutide group than in the placebo group achieved weight reductions of 10% or more (69.1% vs. 12.0%), and 15% or more (50.5% vs. 4.9%) at week 68 ($P<0.001$). A third of patients lost over 20% of TBW. The change in body weight from baseline to week 68 averaged –34 lbs. in the semaglutide group as compared with –6 lbs. in the placebo arm.

The second study looked at 1,210 patients with DM2, a BMI ≥ 27, and a HbA1c between 7–10%. The study design was similar to the above study, but also had a semaglutide dose arm of 1.0 mg. At 68 weeks, the average HbA1c in the 2.4 mg arm was 6.4%, compared to 7.8% in the placebo arm. Twenty-eight percent of patients had a concomitant decrease in their other medications for DM2.

Semaglutide is attractive as a weight loss drug for several reasons, including improvements in dyslipidemia, improvements in blood pressure, and reductions in cardiovascular risk. When used in the nondiabetic population, future risk of DM2 is also reduced. Side effects of treatment can be problematic. Nausea was seen in 44% of participants with about a quarter of the patients experiencing vomiting, constipation or diarrhea. We participated in both of the above phase III trials at the New West Physicians Clinical Research Center and noted that with careful slow titration, most patients were able to reach the 2.4 mg dose and in those that were not, significant weight loss was noted at the lower doses.

The highest dose of semalgutide currently available is 1.0 mg and the indication is for treatment of diabetes. It is anticipated that the 2.4 mg dose of semaglutide will be marketed for the indication of weight loss following FDA approval this spring/summer. There is also an oral formulation of semaglutide which is currently being studied for weight loss in phase III trials, but currently is indicated only for DM2. The degree of weight loss in these new trials begins to approach the weight loss seen with bariatric surgery, which is in the range of 25% TBW at one year with sleeve gastrectomy, and 28% with Roux-en-Y bypass.[8] Although the upfront costs of bariatric surgery are higher, at the current cost of liraglutide, surgery becomes cost-effective within several years. The cost-effectiveness of semaglutide will need to be addressed when the pricing becomes available. When used in patients with DM2, part of the cost may be offset if other expensive diabetes drugs can be eliminated. Overall, patient acceptance of pharmacotherapy is higher than that of bariatric surgery. As providers, we need to improve our utilization of both pharmacotherapy and bariatric surgery in the appropriate patients, as the percent of the population with obesity continues its inexorable rise.

Opioid analgesics not a recommended or appropriate treatment for diabetic neuropathy pain

Pain from diabetic neuropathy is common and can result in debility, disability, and poor life quality. To promote safe long-term pain management, clinical guidelines recommend use of anticonvulsants (pregabalin, gabapentin) and antidepressants (serotonin-norepinephrine reuptake inhibitors).[9] Additionally, topical analgesics, low dose tricyclic antidepressants, and other anticonvulsants are considered acceptable. Opioid medicines are not recommended. A retrospective cohort study examined first-line analgesic medications prescribed to patients with new diagnoses of diabetic peripheral neuropathy over a study period from 2014 to 2018.[10]

Among 3,495 patients with new diabetic neuropathy diagnoses, 1,406 were prescribed a pain medicine. Opioids were prescribed to 616 (43.8%), while recommended medicines and acceptable medicines were prescribed to 603 (42.9%) and 289 (20.6%), respectively. Men had more opioid prescriptions than women (odds ratio [OR] 1.26), and patients with fibromyalgia had less opioid prescriptions than patients without fibromyalgia (OR 0.67). Over the five-year study period, opioid prescribing decreased (OR 0.71), and prescribing of recommended medicines increased (OR 1.25).

Since the study methods did not account for other preexisting pain conditions, it is possible that not all prescribed opioids were intended to treat diabetic neuropathy. That being said, aside from palliative treatment, opioids should not be used for long-term pain management, which includes diabetic neuropathy.

Antibiotic prescribing for uncomplicated urinary tract infection: still a challenge

Uncomplicated urinary tract infection (UTI) in women results in 10.5 million health care visits annually in the United States.[11] The appropriate use of antibiotics in the treatment of uncomplicated UTI in women is outlined in national guidelines (Table 1).[12]

Table 1. Recommended antibiotics for uncomplicated UTI in women

Recommended agent	Duration
Nitrofurantoin	5 days
Trimethoprim–sulfamethoxazole	3 days
Fosfomycin	Single dose (not used frequently in U.S.)

Beta-lactams and fluoroquinolones are not considered appropriate therapy

Clinical practice frequently deviates from recommendations. Commercial insurance medical claims for uncomplicated UTI from 670,450 women ages 18–44 from 2011 to 2015 were examined to determine the choice and duration of antibiotic therapy.[13] Urinalysis was performed in 83% of cases and urine culture in one-half of cases. The incorrect antibiotic was chosen in 47% of cases and the duration of antibiotic therapy was inappropriate in 76% of cases (Table 2).

Table 2. Utilization of antibiotics in the treatment of uncomplicated UTI in women

	Recommended antibiotics		Antibiotics NOT recommended	
	Nitrofurantoin	TMP/sulfa	Fluoroquinolones	Beta-lactams
Antibiotic choice (%)	21	33	41	5
Antibiotic duration incorrect by drug (%)	81	70	78	37

TMP/sulfa = trimethoprim–sulfamethoxazole

When the correct drug was chosen the duration was incorrect in most cases. The recommended duration of antibiotic therapy is three days for fluoroquinolones and 3–7 days for beta-lactams; however, these agents are not recommended for UTI treatment; therefore, any duration is essentially inappropriate. Understanding local antibiotic susceptibility patterns is essential in determining the optimal antibiotic choice and this data is not universally available.

Inappropriate antibiotic use contributes to the development of resistant pathogens and adversely effects patient's microbial biome with multiple negative health impacts.[13] This study underscores the difficulty in translating national guidelines into practice and the urgent need for more comprehensive antimicrobial stewardship programs.

Consequences of early and unnecessary MRI for back pain far exceed the cost from imaging

Back pain is a common complaint, and many patients with uncomplicated acute back pain will recover with minimal intervention. A joint clinical practice guideline from the American College of Physicians and the American Pain Society recommends using a focused history and physical examination to categorize patients as either (1) nonspecific low back pain, (2) back pain potentially associated with radiculopathy or spinal stenosis, or (3) back pain potentially associated with another specific spinal cause.[14] There is no evidence that the routine use of imaging (plain films, CT, or MRI) improves clinical outcomes for patients with uncomplicated acute pain. Previous guidelines have recommended allowing a 4–6 week recovery period before obtaining imaging.[14,15]

A recent study examined the downstream effects of early lumbar spine imaging, defined as less than six weeks from the onset of pain when no red flags were present.[16] The retrospective study was conducted from primary care clinics in the U.S. Department of Veterans Affairs. Patients with early MRI were compared to patients with similarly uncomplicated lower back pain, but without early MRI. Several measures were evaluated including lumbar spine surgery, prescription opioid use, acute health care costs, and the last pain score within one year from the index visit.

There were 1.17 million VA primary care visits for nonspecific low back pain during the study period, 405,695 patients were included in the matched cohort for analysis. Comparing patients with early imaging to patients without early imaging the early imaging cohort characteristics included:

- Younger age
- Less likely to have an assigned PCP
- Reported higher pain levels
- Fewer chronic medical conditions

An early scan was associated with more opioid prescriptions, an over ten-fold increase in lumbar surgery rate, greater than twice the cost for acute care in the initial period, higher cost at follow-up, and more pain reported at follow-up. Since opioids are rarely indicated for prolonged pain (pain beyond 3–7 days), the number of patients prescribed opioids for longer than 3–7 days was excessive in both groups. (See Table 3.)

Table 3. Early imaging cohort outcomes vs. no early imaging cohort outcomes

Early imaging cohort	Early imaging outcomes (n=9,977)	No early imaging outcomes (n=395,718)
Need or increased prescriptions	35.1%	28.6%
Need for surgical intervention	1.48%	0.12%
Initial acute care cost	$2,254	$1,100
Follow-up care cost	$7,501	$5,112
Mean pain score at follow-up	3.87	3.28

The study results demonstrate that early MRI among patients without red flags for lower back pain led to more medical interventions and higher costs but did not improve relative pain reporting. A study limitation is that patients with early MRI may have had other confounding problems, and those variables may have influenced the study outcomes.

A similar study focused on an older population.[17] Here early imaging is often done due to concerns about a higher incidence of underlying systemic disease such as cancer or infection causing spine disease in this population. A total of 5,239 patients over age 65 presenting with new onset back pain were followed for one year following diagnosis, comparing cost and outcomes in those who had early MRI imaging with those that did not. In only one of the 1,630 patients with early imaging was a cancer found and this was an incidental abdominal lymphoma. Only 2% of the group with early imaging had a spinal fracture for which earlier diagnosis did not likely affect treatment decisions. The cost of care over one year was almost $1,500 higher in the group with early imaging and the functional back pain outcomes were not different between the two groups.

These studies once again emphasize the important point that most patients with acute, uncomplicated back pain recover on their own, early MRI rarely changes management, but has the potential to cause harm and drives excess utilization and cost of care.

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Meta-analysis supports colon cancer screening interval recommendations

Appropriate screening for colorectal cancer (CRC) remains a challenge. Initial screening is often delayed and there is continued oversurveillance of low risk adenomas, which increases both the costs and risks associated with CRC screening.[18] In a meta-analysis of 12 studies involving 510,019 patients, the correlation between findings at initial colonoscopy and colorectal cancer (CRC) were examined.[19] The incidence of CRC per 10,000 person-years was examined in those patients having no adenoma (NA), low-risk adenoma (LRA), and high-risk adenoma (HRA) as defined by the United States Multi-Society Task Force (USMSTF) guidelines.[20] Across all studies the median patient age was 59 years and 55% were male.

The incidence of CRC per 10,000 person-years based on initial colonoscopy was insignificantly higher in patients with LRA vs. NA, at one additional case of CRC for every 10,000 patient years (4.5 vs. 3.4; odds ratio [OR], 1.26; 95% CI, 1.06–1.51). However, in those patients with a HRA, the incidence of CRC was significantly higher than those without adenomas (13.8 vs. 3.4; odds ratio [OR], 2.92% CI, 2.31–3.69). The CRC-related mortality followed this pattern with no significant difference in mortality between persons with NA vs. LRA (OR, 1.15; 95% CI, 0.76–1.74) but was significantly higher in patients with HRA vs. patients with LRA (LRAs (OR, 2.48; 95% CI, 1.30–4.75) and no adenomas (OR, 2.69; 95% CI, 1.87–3.87).

This analysis lends further support to the screening intervals outlined in the USMSTF guidelines cited above. Patients should be encouraged to begin screening for CRC at age 45 years of age if at average risk, with further screening dictated by the results of initial colonoscopy. Based on the above analysis of over a half million patients, surveillance colonoscopy at an interval of less than 10 years for patients with LRA would be highly cost-ineffective and expose patients to the increased risks of screening, without significantly reducing CRC mortality. Based on the most recent AGA guideline, we are now offered the option of a 10-year screening interval in those patients with 1–2 LRA, which is by far the largest population of patients who have polyps on colonoscopy. This study supports adopting this 10-year screening interval.

American Academy of Neurology management recommendations for patients with patent foramen ovale and stroke

The prevalence of patent foramen ovale (PFO) in the general population is about 25%. Although the risk of ischemic stroke is far lower in younger adults compared to older adults, younger patients who have strokes are more likely to have PFOs, especially if the stroke is cryptogenic (meaning the cause cannot be determined).[21,22] The American Academy of Neurology recently published recommendations about the management of patients with a history of stroke or transient ischemic attack, who are found to have a PFO.[23]

A summary of the recommendations follows:

- If PFO closure is under consideration, clinicians should ensure that alternative stroke mechanisms have been ruled out (moderate recommendation).
- Clinicians should perform baseline EKG (strong recommendation) to look for atrial fibrillation and, for those patients at high risk of atrial fibrillation, prolonged monitoring should be performed for at least 28 days (moderate recommendation).
- If PFO closure is under consideration, clinicians should counsel the patient about the high prevalence of PFO, the uncertainty about whether a PFO caused a stroke, and that PFO closure probably reduces the stroke risk in select patients under 60 years of age with embolic-appearing stroke(s) (moderate recommendation).
- Among patients who opt for medical therapy (without PFO closure), clinicians may recommend an antiplatelet therapy or anticoagulation (weak recommendation).

Although robust data are available about the safety and efficacy of PFO closure in select patients with cerebral vascular disease, there are procedure-related complications including new stroke and self-limited atrial fibrillation.

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Kenneth Roy Cohen, MD, FACP

Dr. Kenneth Cohen is an experienced physician leader, practicing internist, and researcher who has attained national recognition for health care quality improvement. 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 Optum Care. He served as Chief Medical Officer from 1995 - 2020. He now serves as the Executive Director of Clinical Research for UHG R&D and Senior National Medical Director for Optum Care. 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.

John Hitt, MD, MBA

Dr. Hitt has been a physician executive for more than 25 years. Most recently he was the CMO of Ativa Medical a medical device startup company and an independent health care consultant. Previously, he was CMO at Maricopa Integrated Health System (MIHS) and a key member of the senior leadership team having responsibility for Medical Staff Services, Grants and Research, Academic Affairs, Risk Management, physician contracted services and the activity of Residency Program Directors, Clinical Department Chairs, and Medical Staff.

Dr. Hitt has over 25 years of experience in quality and performance improvement, clinical integration, academic and medical staff affairs. He served as the Chief Medical Quality Officer for Hennepin Health System, a premier Level 1 Adult and Pediatric Trauma Center. He was a physician leader for VHA (now Vizient). He was the national Medical Director for Disease Management at Caremark International and the VP of Medical Affairs at the University of Minnesota Hospital.

Dr. Hitt is a graduate of the University of Virginia where he played Division 1 soccer. He received his Medical Doctorate from the Medical College of Georgia in 1984 (AOA honors) and completed his Internal Medicine and Infectious Disease Fellowship training at the University of Minnesota Hospital and Clinics. Dr. Hitt completed his MBA at the Carlson School of Management at the University of Minnesota in 2003. He is the proud father of seven children.

Geoffrey Heyer, MD

Dr. Heyer is board certified in neurology with special certification in child neurology and in headache medicine. Prior to joining our team, Dr. Heyer was an associate professor of neurology and pediatrics at The Ohio State University and Columbia University Medical Center, specializing in autonomic disorders, headache, and pain management. He has published over 50 peer-reviewed research papers and numerous editorials, clinical reviews, and textbook chapters. He also co-authored a textbook on childhood stroke and cerebrovascular disorders.

Dr. Heyer received his medical degree from Columbia University, College of Physicians and Surgeons. He completed his neurology and child neurology residencies at Columbia-Presbyterian Medical Center. He has additional research training from the Mailman School of Public Health, Columbia University.