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Forum for Evidence-Based Medicine

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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 heart failure with reduced EF and the role of SGLT-2 inhibitors. • Review the pharmacological considerations for prescribing SGLT-2 inhibitors and GLP1-RA therapy for diabetics to reduce cardiovascular death. • Discuss the harms versus the benefits for asymptomatic carotid screening. • Apply medical management principles grounded in evidence-based medicine regarding weight-loss surgery, knee locking and catching, elevated liver enzymes and osteoporosis screening in older men.

Accreditation statement

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In support of improving patient care, this activity has been planned and implemented by OptumHealth Education. OptumHealth Education is jointly accredited by the Accreditation Council for Continuing Medical Education (ACCME), the Accreditation Council for Pharmacy Education (ACPE) and the American Nurses Credentialing Center (ANCC) to provide continuing education for the health care team.

Credit designation statements

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The participant will be awarded up to 1.00 contact hour(s) of credit for attendance and completion of supplemental materials.

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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The American Academy of Physician Assistants (AAPA) accepts credit from organizations accredited by the ACCME.

Attendance
A certificate of attendance will be provided to learners upon completion of activity requirements, enabling participants to register with licensing boards or associations that have not been pre-approved for credits. To apply for credit types not listed above, participants should use the procedure established by the specific organization with which they wish to obtain credit.

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New research on the role of SGLT-2 inhibitors in the management of heart failure with reduced EF (HFrEF)

Existing data suggest that the clinical course of HFrEF (EF<40%) might be significantly improved with the use of SGLT-2 inhibitors (SGLT2i) in both diabetics and non-diabetics. These clinical benefits include an improvement in performance status and a reduction in hospital admissions and cardiovascular death. It is understood that this drug class exerts a diuretic effect due to glycosuria, raising the question as to whether this might be the dominant mechanism of action. If that were to be the case, given the annual cost of ~$6,000 for these drugs, other less expensive diuretics might be of equal value. Another important consideration when thinking about adding an SGLT2i for HFrEF is that there are now five classes of drugs recommended to manage HFrEF. Since most of these patients have other comorbidities requiring additional pharmacotherapies, drug regimens could quickly become overwhelming for patients based both on their complexity and their cost. Although there have been no head-to-head trials comparing the SGLT-2i's to other diuretic agents, three studies published in the *Journal of the American College of Cardiology* (JACC) this spring add considerable knowledge to the role of this drug class in the management of HFrEF and suggest that the beneficial mechanisms of action go well beyond diuresis.

The first two studies were sub-studies of the large EMPEROR Reduced Trial (Empagliflozin Outcome Trial in Patients With Chronic Heart Failure With Reduced Ejection Fraction). The first study addressed the question of whether glycosuria and the related diuresis is the primary beneficial mechanism of action of the SGLT2i's in HFrEF.[1] It was a double-blind placebo-based trial that examined over 3,700 patients with HFrEF, both with and without diabetes. Half of the patients were randomized to receive empagliflozin 10 mg daily and the other half placebo, on a background of guideline directed medical therapy. In the four weeks prior to randomization, about 40% had volume overload. This group was sicker with more comorbidities, a higher NYHA CHF classification and higher brain natriuretic peptide (BNP) levels. The subsequent risk reduction in hospital admissions for CHF was higher in the euvolemic group at 40%, compared to 16% in the volume overload group, with results in both groups being significant. Also, irrespective of volume status, the patients on SGLT2i therapy were less likely to require diuretic intensification, had greater decreases in BNP levels, and were more likely to see improvements in their NHYA class. They also scored higher on the Kansas City Cardiomyopathy questionnaire.

The second study examined whether there was a beneficial or harmful interaction with the addition of SGLT2i's in a population of patients who were already on guideline directed medical therapy that included a mineralocorticoid receptor antagonist (MRA) with spironolactone or eplerenone.[2] The study population was the same as above, and 71% of patients were on MRA therapy and 29% were not. The beneficial effects of the SGLT2i were additive to those of aldosterone blockade. The study showed that the overall beneficial effects of the SGLT-2i were similar whether or not the patient was already receiving treatment with an MRA. Perhaps related to clinical improvements from the SGLT-2i, those patients who were not on an MRA at baseline were 35% less likely to start treatment with an MRA when on empagliflozin compared to placebo. Also, looking at the group of patients treated with an MRA, those also taking an SGLT2i were 22% less likely to discontinue it due to hyperkalemia, possible related to the SGLT2i effect of increasing sodium delivery to the distal nephron which increased urinary potassium excretion.

The third study looked at a group of patients with either ischemic or non-ischemic cardiomyopathy with reduced EF, and evaluated ventricular function and patient performance before and after the addition of a SGLT2i. It was a small double-blind trial in 84 patients without diabetes.[3] Patients were randomized to empagliflozin versus placebo on a background of guideline directed medical therapy and followed for six months. The results using cardiac MRI showed decreases in both end systolic and end diastolic volume and a significant 6% increase in ejection fraction. Treated patients walked about 120 yards further on the six-minute walk test and had about a 20% improvement in the quality of life score on the Kansas City Cardiomyopathy questionnaire. Among the potential mechanisms thought to account for the benefit include the known diuretic effects of the SGLT2i's as well as a switch in the myocardial metabolism away from glucose utilization into consumption of fatty acids, ketone bodies, and branched-chain amino acids, which enhances myocardial energetics and improve contractility in animal models. There may be other mechanisms in play that have not yet been elucidated.

It therefore appears that the mechanism of actions of the SGLT2i's in HFrEF extend beyond their diuretic effect, and they appear to exert their beneficial effect on top of other guideline directed medical therapies including MRA's. There may be an effect on ventricular remodeling that improves left ventricular function. There continue however, to be many unanswered questions. This includes understanding whether this drug class has any benefits in the larger group of CHF patients with preserved EF. Two ongoing studies will likely soon answer this question. Most importantly, we need to determine if there are incremental benefits to each of the four classes of guideline directed medical therapy for HFrEF such that the cost and complexity of a four drug regimen could be rationalized for use in daily patient care.

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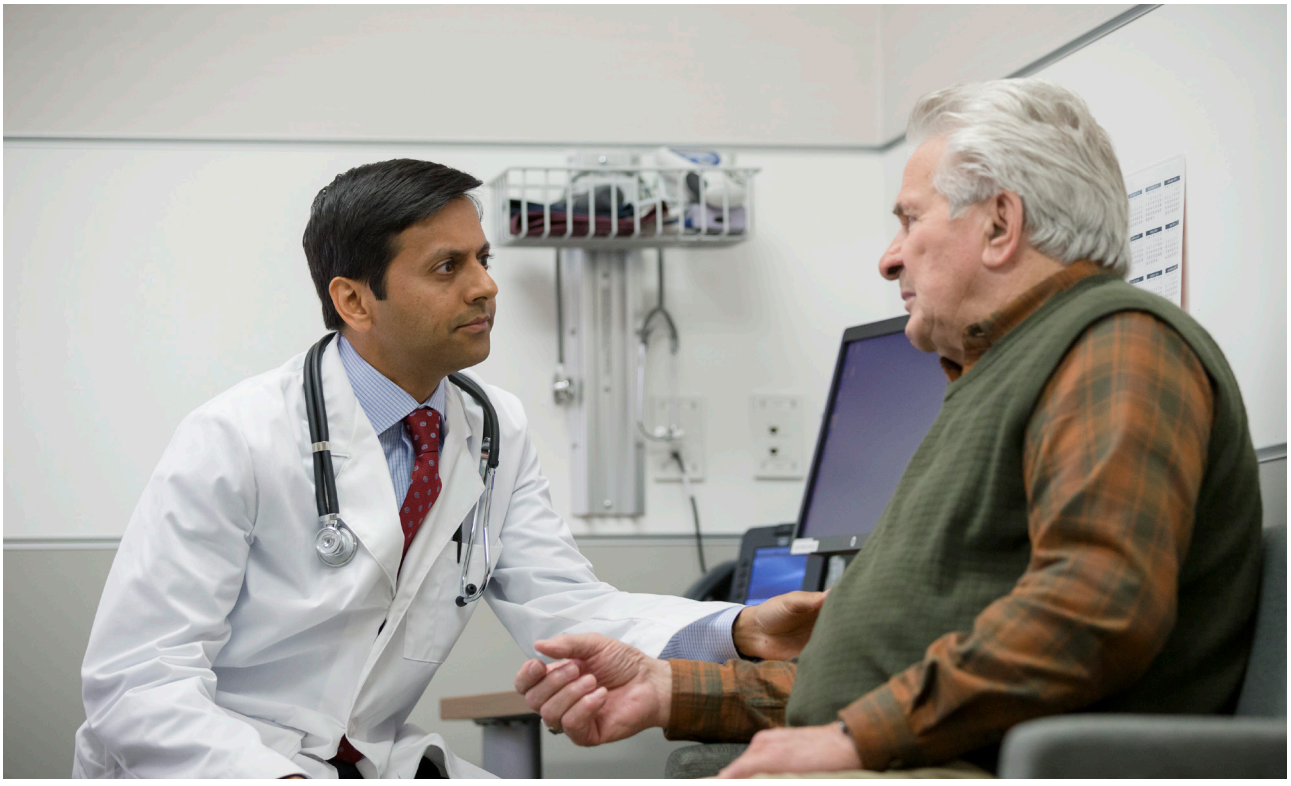
With respect to broad cost effectiveness analyses of the SGLT2i's, the results are dramatically impacted by the degree of underlying risk in the patient, as well as which outcome we are attempting to prevent. The three main outcomes of interest with this drug group are reductions in major adverse cardiac event (MACE), improvements in CHF outcomes, and prevention of renal outcomes. We have data available for the first two of these. Let's first look at the cost to prevent MACE in the population of DM2 patients with either established CAD or very high CV risk. This cost is approximately ~$500k per event avoided and would therefore not be cost effective for this purpose. Data on the cost effectiveness related to CHF outcomes were just published this month.[4] The cost per QALY gained was $83,600, which would fall into the borderline cost-effective category. The authors estimated an acceptable QALY of $50,000 could be achieved if the drug cost would be reduced by 43%. Lastly, it may be cost effective to use SGLT2i's in the subset of patients with CKD and proteinuria since renal outcomes improve in this group, although formal cost-effective analyses have not yet been published for this outcome. We are working on calculating the SGLT2i cost effectiveness in each of these subgroups as well as combinations of these subgroups, using our internal data. Given the difficulty in proving robust cost effectiveness in these high-risk populations, it is doubtful that this class of drugs will be cost effective in those patients who do not fall into the above three categories of risk. See the accompanying article in the pharmacy section for further prescribing recommendations of both the SGLT2i and GLP1 RA classes of drugs.



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Evidence-based guideline for SGLT-2i and GLP1-RA use in DM2

A recent guideline in the *British Medical Journal* (BMJ) attempted to identify the subsets of patients with DM2 in whom SGLT2i and GLP1-RA therapy would be most appropriate. It used a meta-analysis of 764 trials in over 421,000 patients. This study confirmed the reduction in MACE, CV death, and progression to ESRD seen with both drug classes but precise cost effectiveness could not be studied due to marked differences in drug cost in the multiple countries involved in these studies.[4] We know that the drug costs in the U.S. for example, are over twice those in the other countries represented. In order to approximate cost in their recommendations, they considered the number needed to treat (NNT) along with the relevant clinical data in the strength of their recommendations. For example, looking at reduction in CV death, the NNT for five years to prevent one death varied from 21 (high efficacy) for patients with established CAD who were at the highest risk up to 200 (low efficacy) for those at lower risk. In this lower risk group, assuming a yearly drug cost of $6,000, the yearly cost to prevent a single MACE event would be $6 million. The authors looked at similar considerations for renal outcomes and used these data to build a guideline recommending use of these two drug classes in different clinical scenarios. This guideline is more granular, addressed both the benefits and harms of therapy, and is more cost attentive than the current U.S. guidelines from the endocrine and diabetes societies. It did not address the subset of DM2 patients who have HFrEF, but it is clear from the above three studies that these patients derive meaningful benefit from SGLT2i's. The BMJ guideline suggests:

- Not using either drug class in the absence of diabetic renal disease or at least four CV risk factors (CV risk factors are listed on the guideline).
- In patients with four or more CV risk factors, SGLT2i's are recommended.
- In patients with either established CAD or established renal disease, either drug class can be considered.
- When both diseases are present, SGLT2i's are preferred.

The link will bring you to the full article with the attached infographic guideline. https://doi.org/10.1136/bmj.n1091

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Asymptomatic carotid artery stenosis - harms outweigh benefits when screening asymptomatic populations

The U.S. Preventive Services Task Force reaffirmed in its 2021 statement that the harms of screening asymptomatic patients for carotid artery stenosis outweigh the benefits.[5] In this context, "asymptomatic" means no previous stroke, transient ischemic attack in an anterior circulation distribution, or other signs/symptoms referrable to carotid disease. Importantly, syncope, lightheadedness, vertigo and other nonspecific neurological symptoms are not referable to the carotid artery distribution. A recent editorial adds further context.[6]

With few exceptions, professional societies have recommended against the carotid artery screening among asymptotic individuals. The Choosing Wisely campaign has added carotid artery screening to its "do not do" list. The recommendation against screening is based on two principles:

- The benefits of asymptomatic carotid endarterectomy are unclear and the stroke rate in asymptomatic carotid stenosis has markedly declined due to improved medical management.[5]
- Carotid endarterectomy has substantial associated risks of stroke, CV events and death, which currently appear to be substantially higher than those in patients who are medically managed.[6]

Yet, patients continue to have carotid artery imaging for various reasons, as part of a syncope evaluation, for a carotid bruit, or because of direct-to-consumer advertising, none of which is supported by the evidence. The editorial concludes that when carotid artery stenosis is identified, mitigation of cardiovascular risk factors is the best treatment strategy. Focus on the risk factors; avoid the screening.

Weight-loss surgery significantly improves survival among adults with obesity

Projections suggest that one of every two adults in the United States will have obesity (BMI of 30 to <35 kg/m2) by the year 2030, and nearly 25% of adults will have severe obesity (BMI ≥35 kg/m2).[7] Obesity – or more specifically, visceral adiposity – is one of the components of the metabolic syndrome, which is associated with diabetes, coronary heart disease, stroke, certain cancers, and premature death. Weight-loss surgeries have been shown to facilitate improvements in metabolic complications including Type 2 diabetes, dyslipidemia, and obstructive sleep apnea, which is the reason such procedures have been termed "metabolic-bariatric surgery." However, most outcome studies of metabolic-bariatric surgery have been small.

Syn and colleagues conducted a meta-analysis of matched cohort and prospective controlled metabolic-bariatric surgeries to develop more robust outcomes data.[8] Sixteen matched cohort studies and one prospective controlled trial were included in the analysis for an overall patient population of 174,772 and 1.2 million patient-years. The procedures included gastric bypass, banding, and sleeve gastrectomy.

The study showed that metabolic-bariatric surgery was associated with a reduction in the hazard rate of death of 49.2% and an improvement in median life expectancy of 6.1 years when compared to usual care without surgery. The number needed to treat to prevent one death over a 10-year period was 8.3. When stratified by the presence or absence of Type 2 diabetes, the treatment effect was more pronounced in those with diabetes. Patients with diabetes and metabolic-bariatric surgery had a median life expectancy of 9.3 years longer than patients with diabetes but no surgery. The gain in life expectancy associated with metabolic-bariatric surgery was 5.1 years in patients without diabetes. The treatment effects did not differ between the various types of procedures. Compared to many other pharmaceutical and surgical interventions, these are very favorable NNT's.

Given the substantial improvements in life expectancy from metabolic-bariatric surgery, primary care providers should consider these procedures early in the care of patients with obesity, especially if they also have diabetes. Bariatric surgery is highly cost effective and significantly underutilized.

All that clicks, pops, grinds or locks is not a meniscal tear

The historic attribution of "knee locking or catching" to meniscal pathology is being challenged. Researchers in Boston prospectively collected patient reported knee symptoms (PRKS) pre-arthroscopy over seven years.[9] A total of 565 patients were included. The surgical teams recorded PRKS and details of any meniscal tears or damage and details of cartilage damage. The operative findings were then compared to the PRKS using regression analysis.

Importantly, a correlation between PRKS and meniscal pathology was not found. There was an association between the extent of underlying cartilage damage (i.e. DJD) but not specifically to meniscal pathology. The severity of PRKS seems to correlate well with the overall cartilage damage reflecting the overall extent of degenerative knee disease. The symptom complex previously known as "meniscal" symptoms should more accurately be termed "degenerative knee" symptoms.

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As such, mechanical knee symptoms other than trauma related in a younger patient are not an indication for arthroscopy. Treatment should be conservative, as we know the majority of these patients will have degenerative meniscal tears. Therefore, should an MRI be obtained, a "surgical indication" will most often be found in the absence of any data suggesting a benefit to meniscal surgery in this group of patients. The Optimal Care knee algorithm has been updated to reflect these new data.

Steatosis with and without elevated liver enzymes: Risk of cirrhosis and hepatocellular carcinoma

With the increased rate of obesity in the US, we are facing a potential epidemic of non-alcoholic fatty liver disease (NAFLD) related cirrhosis over the next couple of decades. The significance of liver steatosis in those patients without an increase in alanine aminotransferase (ALT) is unknown. Researchers used medical record data to follow patients selected from 130 VA hospitals over eight years with liver steatosis either with or without an elevation of ALT.[10] They compared these two groups to a control group of patients who had normal ALT levels with no known liver disease. Patients were excluded if they had any known liver disease. Records were examined for evidence of cirrhosis or hepatocellular carcinoma (HCC). Results are detailed in table one.

Table 1

Patient characteristic	Cirrhosis			Hepatocellular carcinoma		
	Case #	Person years	Incidence / 1000 PY (95% CI)	Case #	Person years	Incidence / 1000 PY (95% CI)
Steatosis normal ALT	31	25336	1.22 (0.83,1.74)	5	25441	0.2 (0.06,0.46)
Steatosis elevated ALT	435	112950	3.85 (3.5,4.2)	42	114749	0.37 (0.26,0.49
No Steatosis	61	67955	0.97 (0.74,1.24)	4	63232	0.06 (0.02,0.16)

Importantly, patients with "incidental" steatosis without an elevation in ALT had no statistically significant increase in cirrhosis or HCC over the eight years of follow-up and compared similarly to those patients with no known liver disease. The patients with steatosis with an increase in ALT were younger and more often obese than those with steatosis without an increase in ALT. Based on the data, they were at much higher risk of cirrhosis and/or HCC. There are two easy to use prediction tools (FIB4 and NAFLD calculators) that incorporate ALT along with other parameters available in the patient chart to estimate risk of advancing fibrosis. These tools should be used in any patient with known hepatic steatosis or risk factors for hepatic steatosis. If the result is intermediate or elevated, a Fibroscan (US derived transient elastography) should be performed to evaluate for NASH with accompanying early hepatic fibrosis, since treatment at an early stage can prevent the development of cirrhosis.

Screening for osteoporosis is cost-effective in older men with prior falls

The prevalence of osteoporosis increases with age, and osteoporosis affects an estimated two million men.[11] In their 2018 statement, the U.S. Preventive Services Task Force recommended screening for osteoporosis in all women 65 years and older and all postmenopausal women under 65 years at increased osteoporosis risk to prevent fractures.[12] But they found that the evidence was insufficient to recommend screening as a method of decreasing bone fractures among average-risk men without previous osteoporotic fractures.

In a recent publication, the cost-effectiveness of osteoporosis screening with dual-energy x-ray absorptiometry (DXA) and treatment of those with osteoporosis was assessed among men with previous falls.[13] A Markov model was used to develop a hypothetical population of community-dwelling men, aged 65, who had at least one fall in the previous year. Data sources were gathered from published literature about osteoporosis prevalence, fracture incidence, treatment effects, mortality, quality of life, and costs. The model demonstrated good external validity by simulating lifetime fracture risks among men aged 50 years and comparing to published estimates. Modeling of men aged 65 demonstrated an incremental cost-effectiveness ratio of $33,169 per quality-adjusted life-year gained. The number needed to screen to prevent one hip fracture was 1,876, and to prevent any fracture was 746. The findings were robust to wide variations in model assumptions. Increasing the age of the target population to 77 years improves health outcomes and overall costs. By age 70, the number needed to screen to prevent any osteoporotic fracture was 393; by age 80, the number needed to screen was 104.

Fall risk should be assessed in all older adults and preventative measures implemented when a fall risk is present. Among older men with at least one fall in the previous year, screening for osteoporosis and treating those with disease can be a cost-effective method of fracture prevention, particularly in those men aged 70 and older.

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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.