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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: • Review evidence on outcomes related to screening for ovarian cancer and recommended management of incidental ovarian cysts. • Identify pharmacological considerations of a new treatment for Alzheimer's disease. • Assess the cost effectiveness of SGLT-2i use in Type 2 diabetes. • Compare surgical and non-surgical treatment plans for patients with partial-thickness rotator cuff tears, and outcomes of abdominopelvic robotic surgical techniques.

Accreditation statement

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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.

Physicians
OptumHealth Education designates this enduring activity for a maximum of 1.00 *AMA PRA Category 1 Credit(s)*™. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

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Successful completion of this CME activity, which includes participation in the evaluation component, enables the participant to earn up to 1.0 Medical Knowledge MOC points in the American Board of Internal Medicine's (ABIM) Maintenance of Certification (MOC) program. Participants will earn MOC points equivalent to the amount of CME credits claimed for the activity. It is the CME activity provider's responsibility to submit participant completion information to ACCME for the purpose of granting ABIM MOC credit.Please note, by claiming ABIM points, you authorize OptumHealth Education to share your attendance information with the ABIM.

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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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Screening for ovarian cancer

Due to the nonspecific presenting signs and symptoms of ovarian cancer, which result in 58% of women presenting with late stage disease, there has long been interest in screening for ovarian cancer to improve the prognosis. Additionally, the availability of ovarian ultrasound and CA-125 testing often drives patients to request screening in the absence of evidence supporting any benefit to this approach.

The first large contemporary screening trial of ovarian cancer was the Prostate-Lung-Colorectal-Ovary Screening trial (PLCO Trial).[1] The long-term follow-up results were published in 2011. Over 78,000 women aged 55 to 74 years were assigned to undergo either annual screening with CA-125 and ultrasound, or no screening at ten screening centers across the U.S. After 15 years, there was no reduction in ovarian cancer mortality and 9% of women had significant false positive results which necessitated surgery in about a third of that group.

Flash forward to a second large trial which was published this spring.[2] The design of the trial was similar and enrolled over 202,000 women aged 50-74 with an average risk for ovarian cancer at screening centers across the UK. The women were enrolled in a 1:1:2 ratio to either multimodal screening (MMS) which consisted of annual CA-125 with trans-vaginal ultrasound (TVUS) for any patients with CA-125 elevations, annual TVUS alone, or usual care. They were followed for a median of 16 years.

The overall incidence of ovarian and tubal cancer was not significantly different between groups at the end of the study with each group having an incidence of 0.9%. Looking at the more important outcome of ovarian/tubal cancer mortality, each of the three groups also had an identical mortality rate at 0.6%. At 9.5 years after the end of screening, when compared with the no screening group, the MMS group had a 39% higher incidence of stage I or II disease and 10% lower incidence of stage III or IV disease. There was no evidence of a shift in incidence in any stage in the TVUS group compared with the no screening group. There was therefore a disconnect between the earlier stage at presentation in the MMS compared to no screening group and the absence of an effect on subsequent mortality. This was mostly accounted for by a higher case fatality rate for stage I disease in the MMS group compared to the no screening group (14.8% vs. 9.4%), and a lower case fatality rate for stage IV disease in the no screening group compared to the MMS group (79.5% vs. 83.7%).

The changes in stage distribution in the MMS group did not translate into mortality reduction. It seems probable that the cancers shifted to an earlier stage at diagnosis had an intrinsic poorer prognosis, which was not altered by earlier detection and the available treatments for early stage disease. This therefore emphasizes the importance of having disease-specific mortality as the primary outcome in ovarian/tubal cancer screening trials. In summary, these results, added to the PLCO trial results, indicate that there is no survival benefit to screening for ovarian/tubal cancer using either CA-125 or TVUS.

Follow-up of incidentally discovered ovarian cysts

A related topic is the intensity with which incidentally discovered ovarian cysts should be followed. A large study from Kaiser Permanente Washington evaluated the likelihood of ovarian cancer being related to the presence of simple ovarian cysts in over 72,000 women who underwent transvaginal US (TVUS) and were followed for three years.[3] The incidence of simple ovarian cysts was 23.8% under age 50 and 13.4% over age 50. This older group is particularly important since most ovarian cancer occurs in women over age 50 and simple ovarian cysts in this age group are not always considered innocent. As a result, these are frequently followed regularly with an associated increase in imaging and the potential for unnecessary treatment.

In the 13,000 women under age 50 with simple cysts, there were no ovarian cancers identified on follow up. Of the 2300 women who were over age 50 and had simple cysts, 86% of the cysts were under 5 cm in diameter. Overall, in these 2300 women there was only one ovarian cancer which was felt to be unrelated to the identified 1 cm simple cyst, as the patient had a CT done for abdominal pain which revealed extensive peritoneal metastatic disease. Complex cysts or solid masses on the other hand, increased the likelihood of ovarian cancer being present by 23–37-fold in both younger and older women. Even with this markedly elevated relative risk, the likelihood of a complex cyst in a woman over age 50 being an ovarian cancer in this study was still only 6.5%. It can be helpful to remind women of this to reduce the anxiety associated with the evaluation.

This study adds to the body of evidence suggesting that simple ovarian cysts are almost universally benign, irrespective of age. Assuming a high quality TVUS with all criteria met for a simple cyst, and given the anxiety, cost, and potential for further intervention with ongoing US surveillance, the concluding sentence in this study merits attention: "Simple cysts are frequently encountered incidental and normal findings on pelvic imaging, and additional evaluation of these findings is not warranted."

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Biogen's Aduhelm (aducanumab): Unproven benefits, known harms, and substantial costs

June 7, 2021, under the accelerated approval process, the FDA approved the amyloid beta-directed antibody, Aduhelm (aducanumab), for the treatment of Alzheimer's disease. The indication for aducanumab was later changed from "Alzheimer's disease" to mild cognitive impairment and mild dementia due to Alzheimer's disease.

Biogen conducted two phase-3 studies, ENGAGE and EMERGE. Initial analyses led to a conclusion of futility in both studies. The data were later reanalyzed focusing on outcomes from the high-dose treatment arm and the surrogate marker of beta-amyloid plaque burden assessed by amyloid PET. Both studies shared identical methodologies – randomized, controlled clinical trials with 78 weeks follow-up and three study arms: low dose, high dose, and placebo. Eligible patients had mild cognitive impairment attributed to insipient Alzheimer's disease or mild dementia with presumptive Alzheimer's disease. Although the results of these analyses have not been scrutinized through the peer-review process of journal publication, select data were made available by Biogen in December 2019.[4]

ENGAGE failed to show any significant difference in clinical outcome between treatment and placebo. EMERGE did demonstrate a difference in the primary outcome, the Clinical Dementia Rating Scale – Sum of Boxes (CDR-SB). Statistical significance was achieved because the comparison groups were large, but the clinical difference of -0.39 points on a scale ranging from 0-18 points does not represent clinically meaningful change. The published minimal clinically important difference for the CDR-SB is 1–2 points across the Alzheimer's disease spectrum.[5]

Both studies, however, demonstrated a decrease in beta-amyloid plaque burden on amyloid PET scan. The FDA approved aducanumab "based on reduction in amyloid beta plaques," a surrogate marker, in treated patients.[6] However, previous amyloid-targeting drugs have been able to decrease amyloid burden but failed to provide clinical benefit.[7]

Whereas the benefits of aducanumab were not clinically significant, the potentially severe adverse event were common. These include amyloid-related imaging abnormalities (ARIA) with cerebral edema, cerebral microhemorrhage, and cerebral superficial siderosis (an imaging sign of previous hemorrhage). Cerebral edema was temporary for most patients, although it was often associated with symptoms of headache, confusion, dizziness, vision changes, or nausea. The Table provides rates of adverse events compared to placebo and numbers needed to harm.

Table 1. Aducanumab adverse reactions versus placebo[6]

Adverse reaction	Aducanumab, N=1105	Placebo, N=1087	Number needed to harm[D]
Cerebral edema (ARIA-E)[A]	35%	3%	4
Headache	21%	16%	20
Cerebral microhemorrhage (ARIA-H)[B]	19%	7%	9
Cerebral siderosis (ARIA-H)	15%	2%	8
Falls	15%	12%	34
Diarrhea	9%	7%	50
Confusion/delirium/Disorientation[C]	8%	4%	25

[A]ARIA-E, Amyloid-related imaging abnormality – Edema
[B]ARIA-H, Amyloid-related imaging abnormality – Hemorrhage
[C]Also includes altered mental status
[D]Number needed to treat to produce one adverse event

The financial burden of aducanumab is also very high. The drug is currently estimated to cost $56,000 per year, not including the costs related to monthly infusion, serial MRIs, or potential downstream costs from adverse events. It is difficult to estimate the out-of-pocket costs to patients as this will vary by health plan, but it is expected to be $8,000 or more yearly.

Overall, aducanumab has not been shown to provide a clinically meaningful benefit but poses substantial risks of harm at an exorbitant financial cost. If CMS elects to cover aducanumab, the estimated spend will significantly exceed the total for all other part B drugs combined, including all chemotherapies for all cancers. An analysis by the Institute for Clinical and Economic Review (ICER) states that the evidence is insufficient to demonstrate that aducanumab benefits patients.[5] The ICER statement reads: "…[T]he FDA, in approving aducanumab (Aduhelm™, Biogen) for the treatment of Alzheimer's disease, has failed in its responsibility to protect patients and families from unproven treatments with known harms."[8]

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Unfortunately, effective treatments for Alzheimer's disease — treatments that halt progression and lead to stable improvements in cognition — do not currently exist. The lack of effective treatments can lead to desperation among patients, families, and healthcare providers. But desperation should never overwhelm a rational approach to medicine: the potential benefits of a treatment must outweigh the potential harms. Aducanumab does not appear to meet this basic standard.

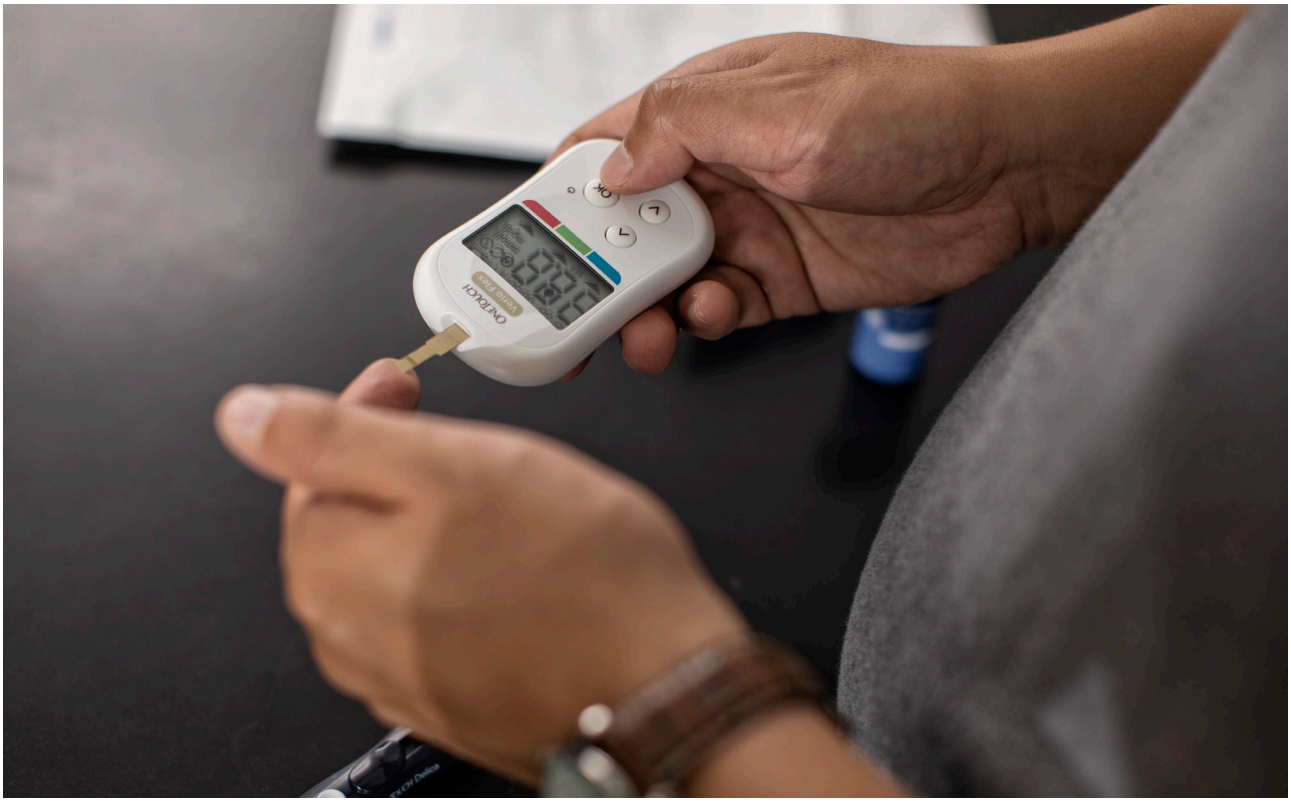
SGLT-2i use in type 2 diabetes: When is it cost effective?

Metformin remains the initial guideline directed choice for treatment of type 2 diabetes. It is well appreciated that SGLT-2i agents reduce cardiovascular risk alone or in combination with metformin in patients with established CVD or at very high risk of CVD. The advantage of SGLT-2i agents over sulfonylureas (SU) has not been demonstrated and the subset of patients in which SGLT-2i agents are most cost effective is being defined.

The new use of SU or SGLT-2i in the presence of metformin was studied in 123,293 (104,423 (SU); 23870 (SGLT-2i)) patients from the VA.[9] The use of SGLT-2i resulted in a reduced overall mortality relative to SU use of 5.1 fewer deaths per 1,000 patient years. This effect was more evident in patients with Stage 3 CKD (GFR 30-59 ml/min), but not more evident in those with compared to those without CVD.

The annual out-of-pocket costs for SGLT-2i ranges from $1298 to $1615 and total cost from $5967 to $6118. Some estimates suggest that despite this high cost, the utilization of SGLT-2i is cost effective for all patients.[10] Using the above data from the VA trial, the cost to avert one death by use of an SGLT-2i over an SU would be approximately $1.2 million. A recent guideline was proposed suggesting the use of SGLT-2i only in a higher risk subset of patients with type 2 diabetes.[11] The guideline published in the British Medical Journal recommends SGLT-2i for patients with four or more cardiovascular risk factors or with established cardiovascular or renal disease. Targeting this population of patients for SGLT-2i use is likely to be cost effective.

The use of SGLT-2i agents alone or in combination with metformin should be part of a shared decision-making conversation with patients considering patients risk factors, costs and expected benefit.



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Outcomes from non-surgical and surgical treatments do not differ among patients with partial-thickness rotator cuff tears

Rotator cuff disease (RCD) is the most common cause of long-term shoulder pain and dysfunction among adults.[12] RCD comprises a spectrum of acute-to-chronic tendon damage, ranging from tendinopathy without frayed tendons to full-thickness tendon tears. Non-surgical forms of treatment are generally recommended first. Several previous studies have demonstrated equivalent outcomes from subacromial decompression and non-surgical treatments for RCD in the absence of full-thickness tears, and subacromial decompression is therefore no longer recommended.[13] Less is known about the benefits of tendon repair for RCD, especially when full-thickness tears are present.

A recent pragmatic, randomized, controlled trial sought to compare RCD outcomes from surgical and non-surgical treatments.[14] An initial cohort (n=664) underwent three months of non-surgical treatment. Of those, 377 patients continued to have pain and remained eligible for study. Ultimately, 187 patients (190 shoulders) were randomized: 95 shoulders in each study arm. Primary outcome measures included the Visual Analogue Scale (VAS) for pain and the Constant-Murley Score for shoulder function. Analyses were based on an intention to treat (ITT) principle.

At the 2-year follow-up, data from 80 shoulders were available from each study arm. Reductions in pain and improvements in function were seen in both cohorts. Among patients with partial-thickness tears, the VAS decreased by 38 in the non-surgical group and 31 in the surgery group (p=0.19). The mean Constant-Murley Score improved by 21.6 in the non-surgery group and by 20.9 in the surgery group (p=0.79). Accordingly, non-surgical and surgical treatments did not produce statistically different outcomes when patients had partial-thickness tendon tears.

In contrast, when outcomes for patients with full-thickness tears were analyzed separately, patients treated with surgery reported greater decreases in VAS compared to patients treated without surgery (37 versus 24, p=0.002) and greater increases in Constant-Murley Score (20 versus 13, p=0.008). These results suggest that surgery leads to less pain and improved function.

In summary, all patients presenting with RCD should have a period of non-surgical treatment prior to contemplation of surgery. Those who have full-thickness tears and persistent pain at 3–6 months may benefit from surgery. But surgery does not improve outcomes when a partial tear is present. This study had limitations including high attrition rates prior to and following randomization and a high rate of treatment crossover (13% of patients in the non-surgical arm had surgery and 38% in the surgical arm did not have surgery).

A related study published in *The Lancet* looked at one-year outcomes for physical therapy versus home exercise, with or without a subacromial corticosteroid injection. Patients had rotator cuff disorders that were present for a median of four months. Patients with trauma or acute full thickness tears were excluded. Over 700 patients were randomized to receive a single PT session for home exercise instruction versus six visits with a physical therapist. In both arms patients were randomized to either receive or not receive a corticosteroid injection.

At the end of one year, as measured by the Shoulder Pain and Disability Index, outcomes were equivalent with both a full course of PT and a single visit/home exercise program. With respect to the injection, there was no measurable benefit at one year. However, compared with no injection, injection provided superior outcomes at eight weeks for pain and function as well as most other patient-relevant secondary outcomes, including insomnia severity and return to desired activities.

In summary, the cost-effective approach to persistent rotator cuff pain in the absence of trauma or an acute full thickness tear should be conservative. Similar results can be achieved with a course of PT or a single visit to the physical therapist to instruct patients on a home exercise program. Out-of-pocket costs will be much lower for patients using the single visit approach. This home exercise instruction could likely also occur at the PCP level although this was not studied. For patients with significant pain and reduced function there is short term, but not long term, benefit to subacromial corticosteroid injection. For patients who fail conservative therapy, MRI is indicated. For those patients with full thickness RC tears, there is a benefit to surgical rotator cuff repair. Patients should however be counseled in a shared decision-making process, that this benefit is small, with for example a 1.3 point pain improvement on the 10 point VAS scale.

Diabetes prevalence and adequacy of risk factor control in adults in the U.S. 1999–2018

The data from the National Health and Nutrition Examination Survey spanning ten survey cycles from 1999 to 2018 was reviewed examining diabetes prevalence and control and the prevalence of risk factors for diabetes.[15] Patients were included based on a self-report of diabetes, a hemoglobin A1C of 6.5% or greater or a fasting plasma glucose 126mg/dl or greater. This resulted in an inclusion of 28,143 participants. The prevalence of diabetes was noted to increase from 9.8 % in 1999–2000 survey to 14.3% in the 2018-2019 survey. Risk factor control was improved for LDL cholesterol and blood pressure but not for A1C (Table 1). Only a minority of adults, 21% (95% CI, 15.5–26.8) achieved control of all three factors.

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Table 1. Risk factor control

Risk factor target ↓/ Time period→	1999–2002 (%)	2015–2018 (%)
Hemoglobin A1C control (A1C < target)	58.9 (95% CI, 54.4–63.3)	66.8 (95% CI, 63.2–70.4)
Blood pressure control (130/80 mg Hg)	38.5 (95% CI, 33.6–43.5)	48.2 (95% CI, 44.6–51.8)
LDL cholesterol (< 100 mg/dl)	35.4 (95% CI, 27.2–43.6)	59.7 (95% CI, 54.2–65.2)

Only non-Hispanic whites had a decrease in undiagnosed diabetes over the period. Importantly, diabetes prevalence increased among young adults (18–44 years of age). This group of patients tended to have worse diabetic and risk factor control. Obesity measured by both BMI and waist circumference increased during the survey period for both men and women.

Strikingly, less than half of the patients had controlled BP and a third did not achieve control of their diabetes. Although LDL cholesterol control showed the most improvement, control remains under 60%. This data clearly outlines the work that needs to be done to better control diabetes in adults in the U.S. Improved control will both improve survival and decrease health care costs.

Robot-assisted abdominopelvic surgeries do not have clear clinical advantages, but lead to higher costs and longer operative durations

Robot-assisted surgery was introduced about 35 years ago and has gradually increased in use since. Dhanani and colleagues recently conducted a systematic review of 50 publications (41 clinical trials) with 4,898 patients comparing robot-assisted abdominopelvic surgery to laparoscopic surgery, open surgery, or both.[16]

All included studies were randomized and placebo-controlled. Non-human, non-clinical, and pediatric studies were excluded. Trial sample size ranged from 20 to 471 (median 99). Follow up ranged from zero to 60 months. Five surgical subspecialties were included – antireflux, other gastrointestinal, colorectal, urology, and gynecology.

Operative duration: Forty-one studies reported operative durations. Robot-assisted surgeries were generally longer in duration than the conventional surgeries across each subspecialty. Data from each study were pooled to develop ranges of operative duration, but statistics for these pooled data (other than range) were not reported.

Outcomes: Long-term outcomes (≥24 months) were reported in eight studies. No differences were seen in disease-specific or overall mortality. A single study of prostate surgery demonstrated a decrease in biochemical recurrence of prostate cancer favoring robot-assisted surgery, but no differences were seen in image-based recurrences in that study. Otherwise, the other studies reporting recurrence rates did not demonstrate differences between surgery types.

Adverse events: Few studies showed differences in adverse events, but when differences were present, they favored robot-assisted surgery. The Clavien–Dindo complication reporting system consists of seven grades (I, II, IIIa, IIIb, IVa, IVb and V). Robot-assisted surgeries had slightly lower rates of Clavien–Dindo complications compared to conventional surgeries. There was also a slight benefit from robot-assisted surgeries compared to laparoscopic surgeries when evaluating conversion to open surgery. The conversion rates for robot-assisted surgeries ranged from 0% to 8% compared to conversion rates for laparoscopic surgery ranging from 0% to 12%. Pooled rates for adverse events were not reported.

Costs: The robot-assisted platform costs at least $1.5 million. In addition to the initial cost of the platform, the costs from additional training, disposable instruments, service contracts, and longer operating room times are considerable when compared to conventional surgeries. Perhaps most importantly, since ASC's do not have robotic capabilities, the use of robotics mandates the use of a HOPD facility, with costs typically at 50–100% higher than ASC costs.

Surgeon experience: No differences were seen in primary or secondary outcomes between inexperienced and experienced surgeons.

Summary: Although some studies favored robot-assisted surgery due to fewer adverse events, the overall difference in adverse events appears to be small. In contrast, costs from robot-assisted surgery and surgical times are much higher than for laparoscopic and open surgeries, yet outcomes are similar. Accordingly, based on this systematic review, robot-assisted surgeries cannot be recommended as superior to conventional forms of surgery at this time.

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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.