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: • Evaluate falls in the elderly and the interventions to help reduce morbidity, mortality and cost of care. • Review pharmacological considerations in the reduction of cardiovascular disease and progression of renal disease in Type 2 diabetes and UTI treatment in afebrile men. • Discuss studies regarding detection and treatment of atrial fibrillation and stroke risk, metabolic-bariatric surgery and glucose control in the elderly.

Accreditation statement

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Falls in the elderly–Reducing the morbidity, mortality, and cost of care

Every year, 30% of patients over age 65 will fall and 10% of falls result in serious injury or death. Falls are the leading cause of hip fracture and traumatic brain injury in seniors. From 2000 to 2016, the annual death toll from falls in seniors increased over threefold to 25,000. The annual financial toll is estimated at $50 billion.[1]

Given this burden of death and disability, there is intense interest in interventions to identify and reduce fall risk. The major risks for falls are frailty (gait and balance difficulties), drugs, cognitive decline, peripheral neuropathy, visual loss and home hazards (area rugs, power cords, oxygen tubes, etc.). The key questions are how should these patients be screened and which interventions have been demonstrated to decrease fall risk?

Screening tests

There are multiple available screening tests and none has emerged as the optimal approach.[2] An evidence-based screen can be performed quickly by the MA. It consists of two questions that should be asked of all seniors at their Annual Wellness Visit.

- Have you fallen in the past year, and if so, how many times and were you injured?
- Are you feeling unsteady when standing or walking?

If the answer to either is affirmative, patients should undergo the "Timed Up and Go Test (TUG)". The TUG, a test of functional mobility, involves timing a person standing up from a chair with armrests (using their assistive device if they normally use one), walking 10 feet at their usual pace, turning, returning to the chair, and sitting down. A TUG time greater than or equal to 12 seconds suggests a high fall risk.

Patients who fail the TUG, or fall into the category of having multiple falls or one fall with injury require a more extensive evaluation and treatment plan. The key elements of the evaluation are a risk assessment to identify factors contributing to fall risk followed by a mitigation plan to reduce future risk.

Risk assessment

The following are the major areas of focus:

Physical exam: Exam is focused on evidence of orthostasis, cognitive function, visual impairment, arthritis of the hip, knee and foot, peripheral neuropathy, or neurodegenerative disease.

Fall-Risk Increasing Drugs (FRIDs): FRIDs include antihypertensives, antiarrhythmics, anticholinergics, antihistamines, sedatives-hypnotics, antipsychotics, anticonvulsants, anti–depressants, and opioids. These drugs may increase fall risk by producing orthostatic hypotension, bradycardia, sedation, sleep disturbance, confusion, or dizziness. Contemporary trials have identified the highest fall risk with the use of antihypertensives (when orthostasis is present), anticonvulsants, and benzodiazepines.[3] Strikingly, the percent of persons who received at least one prescription for a FRID increased from 57% in 1999 to 94% in 2017.[4]

Home safety evaluation: While this may not be feasible for every patient at increased risk, those who use mobility aids or oxygen and those at very high risk will benefit.

Interventions

- Interventions based on physical exam findings can include improved vision correction (although multifocal lenses increase fall risk) or cataract surgery, corrective footwear, programs for early cognitive decline, and improved use of mobility aids.
- Fall risk specific physical therapy–Exercise interventions that focus on improving strength and balance are the most effective single intervention for reducing falls and fall-related injuries.[5] Patients should be told that on average, they must spend two hours weekly for six months to see a meaningful decrease in fall risk. These interventions can be fall risk specific physical therapy programs such as those outlined in the CDC *Stopping Elderly Accidents, Deaths and Injuries (STEADI) Toolkit*, the Matter of Balance program, or Tai Chi, among others. These are highly effective and cost effective with a NNT of 16 to prevent one fall over 12 weeks.
- Deprescribing–Deprescribing is key to reducing future fall risk, particularly with psychoactive drugs and with antihypertensives when orthostasis is present. Unfortunately, randomized trials have not shown a significant decrease in fall rates with deprescribing, not because this approach is not valid, but rather because successful discontinuation and adherence to deprescribing protocols were low in all studies.[6] PCP directed deprescribing should be able to achieve what non-physician interventions were unable to achieve in these trials. This is particularly true when the evidence base to support meaningful clinical benefit of the drug is lacking. This is the case with chronic opioid therapy, gabapentinoids, sedative-hyponotics, and anticholinergics.

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- Home interventions–There is a strong evidence base to support this approach. For example, the CAPABLE (Community Aging in Place–Advancing Better Living for Elders) Model has robust evidence showing improvements in patient outcomes as well as cost of care.[7] In the model, an interdisciplinary team is comprised of a registered nurse, an occupational therapist, and a home repair specialist. The nurse addresses pain and medication management, the occupational therapist serves both PT functions as well as provided mobility devices when needed, along with home modifications such as removing throw rugs, etc. The home repair specialist makes necessary home modifications and repairs to ensure a safe environment. Over a five-month period, in a population of dual-eligible patients, the CAPABLE intervention reduced fall-related ER visits by 26%, fall-related hospitalization by 36%, and cost by an annualized $10,000 per member per year. The savings continued for at least 24 months following completion of the five-month intervention, largely driven by reductions in hospitalizations and long-term services and supports.
- Other interventions–Bone density should be measured, and osteoporosis treated if present. There are some data suggesting a decreased fall risk with vitamin D and calcium replacement.[8]

In summary, falls and their associated injuries are common, often serious, and usually result from one or more fall risk factors, many of which may be modifiable. PCPs play a critical role in reducing fall risk factors among their older patients. A fall risk assessment and intervention program can be highly effective in improving patient outcomes and cost of care. Of the above, the three most important interventions are aimed at improving balance, deprescribing FRIDs, and improving safety in the home.

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Finerenone a new mineralocorticoid receptor antagonist: Reduction of cardiovascular disease and progression of renal disease in Type 2 diabetes

It is well appreciated that the mineralocorticoid receptor antagonists (MRA), spironolactone and eplerenone, reduce symptoms, hospitalization, and cardiovascular (CV) related mortality in patients with congestive heart failure (CHF) (Table 1) [9, 10] In these earlier trials, the effect an MRA has on progression of renal disease was not studied. Recently, finerenone, an MRA, has also been shown to decrease CV related mortality compared to placebo. Importantly, the trial was also designed to determine finerenone's effect on the progression of renal disease compared to placebo in Type 2 diabetes.[11] Patients with Type 2 diabetes and nephropathy were enrolled as two groups:

- A urinary albumin–to–creatinine of 30 to less than 300, an estimated glomerular filtration rate (eGFR) of 25 to less than 60 ml. per minute, and diabetic retinopathy
- A urinary albumin–to–creatinine ratio of 300 to 5000 and an eGFR of 25 to less than 75 ml. per minute.

Patients were also treated (as in the earlier trials demonstrating reduction of CV mortality) with either an ACE (angiotensin-converting enzyme) inhibitor or ARB (angiotensin-receptor blocker). Primary outcomes included kidney failure, a sustained decrease of at least 40% in eGFR from baseline and death from renal causes. The number needed to treat to prevent a primary outcome was 29. This equates to an approximate cost to prevent one renal outcome of $232,000. The CV outcomes were secondary outcomes with a number needed to treat to prevent a CV outcome of 42. (Table 1).

Table 1. Trial outcomes

Agent	Adverse CV outcome (%)		# needed to treat	Renal disease progression (%)		# needed to treat
	Trial drug	Placebo		Trial drug	Placebo	
Spironolactone	35	46	NR	Not studied		
Eplerenone	18.3	25.9	19 (1)	Not studied		
Finerenone	13	14.8	42 (2)	17.8	21.1	29

1. Per year of follow up. 2. After 3 years. NR = not reported

Renal failure in Type 2 diabetes is frequent and significant both clinically and financially for patients. Reduction in the progression of renal failure is important. It has long been appreciated that adequate blood pressure control is essential to forestalling the progression of renal disease in diabetes. Notably the mean systolic blood pressure (sBP) at study entry was 138, well above recommended targets. It is noted that sBP decreased only 3 mm. Hg over the study.

Finerenone has both anti-inflammatory and antifibrotic effects which may have contributed to the observed improved renal outcomes. The extent to which the renal protective effects observed in this most recent trial translate to other MRAs is unknown. However, there are data from a network meta-analysis of 13 RCT's in over 13,000 patients with heart failure.[12] In that analysis, spironolactone, eplerenone and finerenone performed similarly for CHF with the exception of a mortality benefit with finerenone in one underpowered study of 160 patients. In terms of safety, it can be seen on the below table that eplerenone and finerenone have similar outcomes, with a higher rate of adverse events with spironolactone.

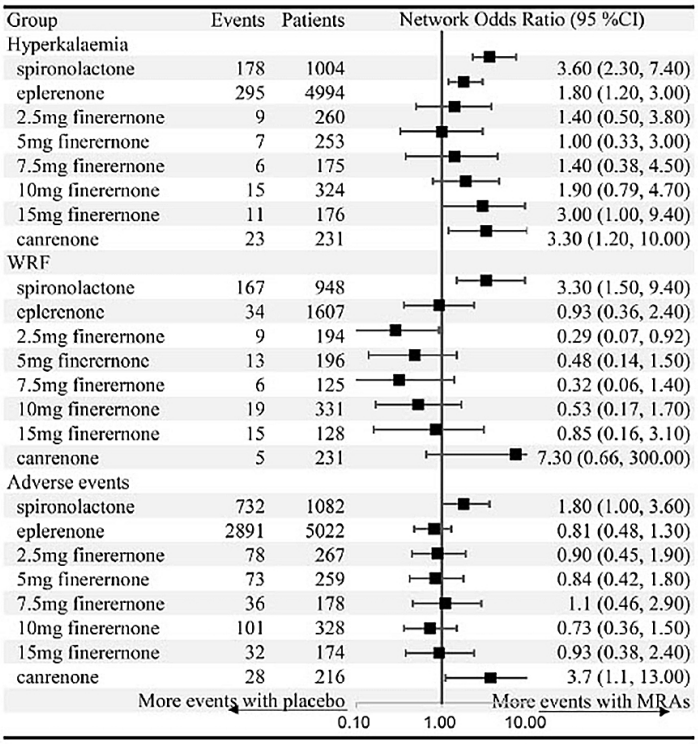

Fig. 6 Data of network comparisons with estimates for the safety outcomes of hyperkalemia, worsening renal function, and adverse events

Because of the fundamental difference in molecular structure and additional mechanisms of action, it cannot be assumed that renal preservation seen with finerenone in diabetics will be a class effect. This is an issue of substantial importance and a comparative efficacy study of renal outcomes is needed, as the yearly cost of finerenone is $8,500 and the other two MRA's are inexpensive generics. Until that data becomes available, when MRA's are needed in the presence of diabetic nephropathy, finerenone has demonstrated efficacy in retarding progression of the nephropathy.

UTI treatment in afebrile men: How long is long enough?

Increasingly, clinicians have come to realize more about the adverse effects of antibiotics. Prominent among these considerations are increasing antibiotic resistance, and the alteration of the host biome with an increasing incidence and severity of C. Diff. This has given rise to widespread antibiotic stewardship programs. Traditional courses of antibiotic treatment often were not developed as a result of trial data. For example, we now appreciate that shorter courses of antibiotics may be used for UTIs in women and pneumonia.

A recent study looked 7 vs 14 days of therapy for men with a UTI (defined as having at least one symptom of dysuria, frequency of urination, urgency of urination, hematuria, costovertebral angle (CVA) tenderness, or perineal, flank, or suprapubic pain). [13] Urine cultures were not required for enrollment, although 93% of patients had a urinalysis and 88% of the patients had a urine culture. Patients were not febrile. Patients were randomized to either ciprofloxacin (Cipro) or trimethoprim/ sulfamethoxazole (TMP/Sulfa) for a course of 7 vs 14 days. The study was designed to find a non-inferiority for the 7-day treatment course. Success was considered symptom resolution. Results are summarized in the table.

Antibiotic treatment in men 7 vs 14 days

Patient group	Symptom resolution (%)	Recurrence within 28 days
7 days Rx + 7 days placebo	122/131 (93.1)	13/131 (9.9)
14 days Rx	111/123 (90.2)	12/123 (12.9)

There was no statistical difference in outcome (symptom resolution) based on antibiotic selection or duration of therapy (7 vs 14 days). The 28-day recurrence rate was also no different.

For men with afebrile UTI a 7-day course of antibiotic therapy was equally efficacious as a 14-day course, and should be the preferred, evidence-based regimen.

Early detection and treatment of atrial fibrillation does not reduce stroke risk in the elderly

A randomized clinical trial was recently conducted to evaluate if screening for atrial fibrillation, with subsequent anticoagulation if atrial fibrillation is detected, can prevent stroke in individuals at high stroke risk.[14] Arterial embolism was also included as a primary outcome. Monitoring for atrial fibrillation was performed using an implantable loop recorder (ILR).

Researchers recruited individuals aged 70-90 years, without known atrial fibrillation, but with at least one stroke risk factor including hypertension, diabetes, previous stroke, or heart failure. ILR monitoring was done in 1,501 individuals and 4,503 individuals received usual care. During a median follow-up period of 64.5 months, atrial fibrillation was diagnosed in 477 (31.8%) of those with ILR monitoring versus 550 (12.2%) of those without monitoring, p<0.0001. Oral anticoagulation was initiated in 445 individuals in the ILR group and 591 in the usual care group, while some individuals received anticoagulation for indications other than atrial fibrillation. Although ILR monitoring improved atrial fibrillation detection compared to usual care, it did not significantly reduce the rates of stroke or arterial embolism, which occurred in 4.5% of individuals with ILR monitoring and 5.6% without monitoring, p=0.11. Major bleeding occurred in 4.3% and 3.5% of individuals with and without ILR monitoring, respectively.

A different study evaluated whether early detection and treatment of atrial fibrillation[15] reduced stroke risk and mortality among 75-76-year-olds without known atrial fibrillation. Individuals were randomized to a 14-day intermittent ECG screening (n=14,387) and control (n=14,381) groups. Whenever atrial fibrillation was diagnosed, treatment with oral anticoagulation was offered. The primary endpoint was analyzed as a composite of each of the following events: ischemic or hemorrhagic stroke, systemic embolism, bleeding requiring hospitalization, and all-cause mortality. After a median follow-up of 6.9 years, fewer primary endpoints occurred in the screening group compared to the control group (5.45 events per 100 years versus 5.68 events per 100 years). The results achieved statistical significance because the cohorts were large, but the difference between cohorts was not clinically meaningful. Ninety-one individuals would need to be invited to screen and then treated for seven years to prevent one event.

In summary, the early detection and treatment of atrial fibrillation does not appear to improve outcomes. In the first study, ILR monitoring resulted in "a three–times increase in detection of atrial fibrillation and concomitant anticoagulation, but no significant decrease in the risk of stroke or systemic arterial embolism." Given the high cost of ILR (estimated at $20,000) and potential harms, the evidence does not support the use ILR monitoring for atrial fibrillation, even among patients at high stroke risk.

Metabolic-bariatric surgery reduces all-cause mortality among adults with obesity

Previous research has shown that metabolic-bariatric surgery can lead to substantial weight loss and improvements of obesity–related complications among obese individuals. A recent meta-analysis demonstrates that the surgery also improves long–term survival when compared to standard care.[16] The survival effect was considerably greater among patients with pre–existing Type–2 diabetes.

The authors identified 16 matched cohort studies and one prospective controlled trial comparing all–cause mortality between patients with obesity and metabolic-bariatric surgery versus patients managed without surgery. The meta-analysis cohort comprised 174,772 patients with a median follow-up of 69.4 months and a total 7,712 deaths over 1,156,376 patient-years.

Among 65,785 patients (496,771 patient-years) with metabolic-bariatric surgery, 1,813 deaths occurred compared to 5,899 deaths among 108,987 matched controls (659,605 patient-years) without surgery. Metabolic-bariatric surgery led to a reduction in the hazard rate for all-cause mortality of 49.2% (p<0.0001). The number needed to treat was 25 at 10 years follow-up and 11 at 20 years follow-up. In subgroup analyses of patients with diabetes, the median life expectancy was 9.3 years longer for those with surgery compared to those without surgery. The number needed to treat was 9 at 10–year follow–up and 6 at 20–year follow–up.

With the advent of more potent GLP1-RA's such as semaglutide, we now have pharmacologic therapies that approach bariatric surgery in terms of magnitude of weight loss and have confirmed reductions in cardiovascular mortality. However, semaglutide has been priced at an egregious ~$26,000 yearly, pricing it beyond the ability of most patients to afford, and weight loss is promptly regained with discontinuation of treatment. Thus, bariatric surgery is significantly more cost effective than semaglutide at its current price.

Based on the results of this study, the authors estimated that every 1% increase in the rate of metabolic-bariatric surgery utilization would yield 5.1 million life-years globally for obese patients with diabetes and 6.6 million life–years for obese patients without diabetes. Given these clear benefits, surgical intervention should be considered early for patients with obesity who are unsuccessful at achieving weight loss goals through diet and exercise.

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Glucose control in the elderly: How tight is tight enough?

Glucose control involves a balance between control intensive enough to prevent long-term consequences from hyperglycemia and overtreatment that risks severe hypoglycemia. Insulin and sulfonylureas are associated with the highest risks of hypoglycemia, particularly when patients are treated to HbA1c targets below recommended levels. Previous studies have demonstrated that hemoglobin A1c targets should be set higher for older patients. Hypoglycemia may be less recognizable in the older patient and the long–term consequences of higher HbA1c targets are less relevant. This is important as 25% of people over 75 years of age have diabetes.

In an effort to better characterize the risk of intensive control, diabetic patients were identified using administrative data for the province of Ontario. People were included if they had HbA1c less than 8.5% and had been prescribed with the last year at least one high-risk agent (insulin, sulfonylurea) or one or more low-risk agents (metformin, dipeptidyl peptidase 4 inhibitor, acarbose thiazolidinediones). Patients treated with a high-risk and low-risk agent were placed in the high–risk group. Glycemic control was defined as intensive (HbA1c <7.0%) or conservative (HbA1c 7.1-8.5%).[17]

The primary outcome was a composite measure of diabetes-related (involving hypoglycemia) hospitalization, emergency room visits or death within 30 days of reaching glycemic control. The study included 108,620 people. These individuals had diabetes diagnosed for an average of 13.7 years. Baseline characteristics of people on high–risk agents vs. low-risk agents and those with intensive vs conservative treatment were not statistically different. Primary outcomes are summarized in the table.

Control agent	Glycemic control strategy	Number (%) of study group	People with diabetes-related primary outcome (%)	Relative risk of adverse primary outcome vs high-risk tight control
High risk	Tight control	23,484 (21.6)	217 (0.92)	NA
	Conservative	25,792 (23.7)	174 (0.67)	RR 2.22 (95% CI 1.82, 2.71)
Low risk	Tight	42,857 (39.5)	178 (0.42)	RR 1.37 (95% CI 1.12, 1.67)
	Conservative	16,488 (15.2)	68 (0.41)	RR 2.24 (95% CI 1.74, 2.94)

As noted on the table, intensive control with a high–risk agent introduced an increased risk of the composite outcome of hospitalizations, emergency room visits or death, when compared to the other three groups. This increase was related to a moderate 15 % increase in emergency department and hospital use among those people using high-risk agents to reach intensive control targets. There was no difference in all-cause mortality between any of the treatment groups.

In terms of further understanding the hypoglycemic risk and cardiovascular outcomes of the sulfonylureas, it is helpful to examine the results of the CAROLINA trial. This is the only large randomized cardiovascular outcomes trial of sulfonylurea (SU) therapy. The trial compared the SU glimepiride to the DPP-IV inhibitor linagliptin in over 6,000 patients with a mean age of 64 years. Investigators intensified medication if the HbA1c was >7.5%. The goals of the trial were to prospectively address the three potential adverse consequences of SU therapy: cardiovascular risk, severe hypoglycemia, and weight gain. At the end of six years, comparing linagliptin to glimepiride, the major cardiovascular event rate was statistically identical in both treatment arms.[18] With SU treatment, the incidence of severe hypoglycemia was 1 in 200 patient years, and the average weight gain was about three pounds. This trial, as in the above trial, highlights that sulfonylureas can be safely used when guideline directed practices are followed.

In summary, seniors with diabetes are frequently overtreated. Particularly when sulfonylureas or insulin are used in a senior population, intensive control is inappropriate and associated with adverse outcomes. HbA1c levels in the 7.5% -8% range should be the target.

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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.