

Forum for Evidence-Based Medicine

March/April | 2019

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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: Explore the educational content regarding new trends in the management of osteoporosis and osteopenia as a means to advance optimal care outcomes and lower costs. Outline pharmaceutical recommendations using current evidence-based literature for cardiovascular conditions. Apply new medical management principles grounded in evidence-based medicine that could help modify and improve treatment and clinic guidelines for diabetes management. 	

Accreditation statement



In support of improving patient care, 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

Nurses

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)TM. Physicians should claim only the credit commensurate with the extent of their participation in the activity.

PAs

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 Trends in the Management of Osteopenia and Osteoporosis



The management of osteoporosis and osteopenia has recently evolved related to new evidence as well as new treatment options such that a review is timely. We'll begin by looking at the management of osteopenia. It has been long recognized that patients whose bone density falls into the osteoporosis range have a higher relative risk of fragility fracture than those in the osteopenia range. However, since there are so many more patients with osteopenia, the large majority of fragility fractures actually occur in the group with osteopenia¹.

There has not been a strong evidence base to support the treatment of osteopenia in older women and the guidelines from the ACP and the National Osteoporosis Foundation (NOF) differ in their recommendations.

- The ACP recommends that clinicians should make the decision whether to treat osteopenic women 65 years of age or older who are at a high risk for fracture based on a discussion of patient preferences, fracture risk profile, and benefits, harms, and costs of medications. (Grade: weak recommendation; low-quality evidence)
- The NOF recommends treatment in men or women over age 50 when the T score at the total hip, femoral neck, or lumbar spine is between -1.0 and -2.5 and the ten year risk of fracture (by FRAX score) is \geq 3% at the hip or \geq 20% at the spine².

A recent study adds significantly to the evidence base in support of treatment of osteopenia³. Reid, et al. studied 2000 women over age 65 with osteopenia and randomized them into two treatment arms which consisted of IV zoledronate 5 mg every 18 months for 4 doses, or placebo. All patients were given vitamin D and encouraged to take calcium at 1,000 mg daily through dietary sources. Over the six years of the study, 19% of the women in the placebo group had a fragility fracture compared to 12% of the women in the treatment group. Interestingly, even when the subgroup with more severe osteopenia as measured by

FRAX scores of \geq 3% at the hip or \geq 20% at the spine were excluded, there continued to be the same rate of fracture reduction with treatment. This represented an approximate 35% decrease in the rate of fragility fractures with a NNT of 10 women needing treatment over six years to prevent one fragility fracture. This equates to a cost to prevent one fracture of ~\$16,000 assuming a cost of generic zoledronate of ~\$250 with an associated infusion fee of ~\$150. This represents a favorable QALY. In addition, mortality, vascular events and cancer incidence were all lower in the treatment arm. There were very few adverse effects: however, 0.5% of women declined a second dose of zoledronate due to an acute phase response to the first dose. This is a common reaction with IV zoledronate and is almost always seen only with the first dose. It is usually prevented with pre-dose acetaminophen. Although these fracture prevention results should be reproducible with oral bisphosphonates, there are two caveats - zoledronate is a more potent bisphosphonate, and the use of oral bisphosphonates is marked by high rates of nonadherence. This well done trial should inform our management of osteopenia and is discussed in treatment recommendations below.

With respect to the management of osteoporosis, bisphosphonate therapy minimizes bone loss and reduces fracture risk by up to 50%⁴. The ongoing fear over the risk of treatment complications continues to hamper both prescribing by providers and adherence by patients. The bisphosphonates and denosumab, when used in standard doses for osteoporosis, carry risks of osteonecrosis of the jaw and atypical femur fractures. The incidence of osteonecrosis in treated patients is 1:100,000. Using the improvement in fracture rate with the above osteopenia treatment trial would mean that for every case of osteonecrosis induced by bisphosphonate therapy, 7,000 fractures would be prevented over the six years of the trial. Hopefully, when presented with this data, most patients would opt for treatment. Atypical femur fractures, defined as pathologic transverse fracture of the femoral shaft, are a rare but serious complication of treatment with bisphosphonates and denosumab. They are related to the duration of treatment. There are wide variations in risk estimates, however the highest estimate in patients on treatment for >5 years is 1:1,000 patient years. The risk declines by 70% per year after discontinuation of therapy, hence the recommendation for drug holidays in bisphosphonate users after 5 years of treatment. Using the data from a Swedish trial showed that about 70 hip fractures would be prevented for every atypical fracture that would occur. Once again, a shared decision making conversation would hopefully lead to treatment in the appropriate patients.

(continued on page 2)

New Trends in the Management of Osteopenia and Osteoporosis

(continued from page 1)

Although most providers are well aware of the bone loss associated with glucocorticoid (GC) use, it is often unrecognized that this progresses rapidly with the risk of vertebral fracture increasing after only 3 months of treatment and peaking at 12 months. It is also important to recognize that fracture risks increase by 50-100% with prednisone doses as low as 5 mg daily. There is also well documented bone loss with the chronic use of inhaled GC therapy, although the magnitude of the bone loss is considerably less. Fortunately, fracture risk falls quickly with discontinuation of GC therapy and increased bone density is seen within six months of discontinuation. *The Forum for Evidence-Based Medicine* (9/2018) reviewed the use of inhaled GC's with recommendations on how to limit inhaled GC use to those patients most likely to benefit in both asthma and COPD.

Screening recommendations:

- Women over age 65 and men over age 70 should be screened. Men and women over age 50 with additional risk factors should also consider screening. Since the FRAX tool includes GC therapy as a risk factor, this is useful for screening patients who are on long term oral or parenteral GC therapy. Screening should begin six months after initiation of GC therapy.
- A fragility fracture is an indication for screening and/or treatment. This is an important point as this population is often neither screened nor treated. This is also a CMS Star measure which measures the percentage of women 67 years of age and older who suffered a fracture and who had either a bone mineral density (BMD) test or prescription for a drug to treat or prevent osteoporosis in the six (6) months after the fracture. Fractures of fingers, toes, face and skull are not included in this measure.

A full discussion on treatment is beyond the scope of this article but general cost effective guidelines for treatment recommendations include:

- Indications for treatment may include a fragility fracture or bone density criteria. The latter may be either an absolute T-score ≤ -2.5, or osteopenia with a FRAX score 10 year fracture risk of ≤ 3% at the hip or ≤ 20% at the spine. Given the new study on treatment of osteopenia reviewed above, consideration should be given to treatment using shared decision making in patients with significant osteopenia who do not meet FRAX criteria, particularly if there are additional risk factors or frailty.
- Therapy should begin with a generic oral bisphosphonate at weekly dosing along with vitamin D replacement. The cost of monthly generic ibandronate is \$4,000 yearly and this should therefore not be first line treatment.

- For intolerance, nonadherence, or lack of response to oral bisphosphonate therapy, yearly IV zoledronate 5 mg should be second line therapy. Potential symptoms from the acute phase response should be prophylactically treated with acetaminophen. It is uncommon to see recurrences after the first dose.
- Denosumab (Prolia) is an option for patients intolerant of IV bisphosphonate therapy with similar efficacy and risks of bisphosphonate treatment. The cost is \$2800/year and is a SQ injection given every six months. If prescribed, patients should self-administer or have this done at the PCP office. We have seen claims paid to hospital owned infusion centers in excess of \$5,000 per injection for the SQ administration of denosumab!
- There are now two available agents for parathyroid hormone (PTH). Abaloparatide (TYMLOS®) has similar indications, efficacy and toxicity to teriparatide (Forteo®). Abaloparatide cost is \$24,000 yearly, compared to \$42,000 yearly for teriparatide and therefore should be preferred. Because of the cost and potential toxicity of these drugs, prior to initiation, consideration should be given to a consultation for osteoporosis management.
- Monitoring of therapy is another area of controversy with the ACP guideline not recommending a repeat DXA or bone turnover markers for the first 5 years that patients are under treatment. The NOF guideline, on the other hand recommends a first DXA at 1-2 years on treatment followed by every two years thereafter, with or without bone turnover markers. Bone turnover markers can help to document compliance and response to treatment, and may therefore be useful. If DXA is monitored, it is important to recognize that <u>stability</u> of bone density represents a positive response to treatment including a decrease in fracture risk, even if bone density does not actually increase on treatment.

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PHARMACY

Fish Oil for the Prevention of CV disease

Although population studies have suggested a cardiovascular benefit to diets high in fish oil, particularly with respect to a reduction in sudden CV death, there is a paucity of randomized trial data supporting a benefit. Two studies on the topic appeared in the January 2019, NEJM^{5,6}. The first study looked at fish oil for primary prevention in over 25,000 individuals at a dose of 1 gram daily compared to placebo and showed no CV benefit after 5 years. The second study is of more interest. On average, available therapy directed at lowering LDL levels results in about a 35% risk reduction in CV events leaving a large 65% residual risk. We currently do not have pharmacotherapeutic options for atherogenic dyslipidemia (elevated triglycerides and low HDL) despite the knowledge that much of the residual risk lies in this area. Studies of fibrates, niacin, and earlier fish oil trials have not shown improvements in CV event rates when added to a background of statin therapy.

The REDUCE-IT Trial looked at over 8,000 patients on statin therapy who were randomized to treatment with purified eicosapentaenoic acid (EPA) at a dose of 2 gms BID or a mineral oil "placebo", and followed for five years. This was a high CV risk population. 70% of the patients had prior CV events and 30% had diabetes and at least one additional CV risk factor. LDL cholesterol was well controlled and averaged 75 mg/dl. Although TG levels fell only modestly by about 20%, there was a reduction in the composite CV endpoint from 22% in the placebo group to 17.2% in the treatment group. This represented a 25% relative risk reduction and a 4.8% absolute reduction and included a reduction in the CV death rate of 0.9%. This results in a NNT of 21 to prevent one event over 5 years. For comparison, the NNT to prevent one event in secondary prevention with statin therapy is ~16. When evaluating the magnitude of this risk reduction, it should also be kept in mind that the recent large trials looking at CV risk reduction with the addition of the PCSK-9 inhibitors, SGLT-2 inhibitors, and GLP-1 agonists, all resulted in absolute CV risk reductions only in the range of 2%, with a cost to prevent one event which ranged from \$480,000 to \$2.1 million. The cost to prevent one event in this trial is approximately \$80,000 which is just above the generally accepted quality-adjusted life year (QALY) threshold of \$75,000.

Although the benefit in this trial did not correlate with the magnitude of TG reduction and was consistent across every subgroup, some of the largest improvements in event rates were seen in the subset of patients who had TG levels >200 mg/dl combined with an HDL level of <35 md/ dl suggesting that at least a portion of the benefit may be related to improvements in atherogenic dyslipidemia. There was an unexplained 1.4% increase in the atrial fibrillation rate with fish oil treatment but no other significant adverse effects. Because DHA fish oils slightly raise LDL levels, it is not known whether the benefits conferred by this EPA trial would be generalizable to other fish oil preparations which are usually a mix of EPA and DHA. Ongoing trials of EPA/DHA fish oil preparations should answer this question. The cost of the drug used in this trial (VASCEPA) is \$3800 yearly.

Alirocumab use after an Acute Coronary Syndrome⁷

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As noted above, prior studies of the PCSK-9 inhibitors have shown absolute CV risk reductions in the range of 2% with no improvements in mortality. The cost to prevent one non-fatal CV event was \$930,000 in the FOURIER Trial and thus not considered cost effective. A new study focusing on the very high risk population of patients who are post acute coronary syndrome (ACS) looked at over 18,000 patients on a background of high dose statin therapy who were treated with alirocumab or placebo and followed for almost three years. Once again, even in this very high risk group, the decrease in CV event rate was limited to 1.6% without a significant decrease in cardiovascular death. The NNT over 4 years to prevent one event was 49, which calculates to a cost to prevent one event of \$686,000, nine fold higher than the accepted QALY threshold of \$75,000. A subsequent cost effectiveness analysis looked at the use of either ezetimibe or alirocumab as add on for secondary prevention when the LDL level was suboptimally controlled. Compared with the combination of statin and ezetimibe, replacing the ezetimibe with alirocumab cost \$997,000 per QALY8. Both of the FDA approved PCSK-9 inhibitors recently lowered their prices by 60% due to these cost effectiveness analyses and subsequent poor sales. Even with these price reductions, the cost remains many times above the QALY criteria for cost effectiveness.

Dual antiplatelet therapy (DAPT) for high risk TIA and small stroke⁹

The pathophysiology of TIA and small stroke progressing to completed stroke is understood to be analogous to an acute coronary syndrome progressing to a completed myocardial infarction. Both involve plaque disruption in a major vessel which can lead to clot propagation, vessel occlusion, and distal embolization. Just as in an ACS, the highest risk of progression with TIA/small stroke is early after the onset of symptoms. This was confirmed in the recent POINT Trial which looked at aspirin alone versus aspirin plus clopidogrel following a high risk TIA or small stroke that was not related to atrial fibrillation or critical carotid artery stenosis.

Close to 5000 patients were randomized and followed for 90 days. The stroke rate was 5.0% with DAPT and 6.5% with aspirin alone. The bleeding rate was also higher at 90 days in the DAPT group at 0.9% compared to 0.4% in the aspirin group. The trial was stopped early due to the excess in major bleeding on DAPT. The reduction in the stroke incidence with DAPT was seen almost entirely in the first couple of weeks of treatment and the bleeding risks accumulated over the course of the trial. To put this in context, a recent clinical practice guideline¹⁰ in the BMJ noted that for every 1,000 patients treated with DAPT for 90 days, 19 strokes would be prevented and 2 major hemorrhages would be created. The guideline therefore recommended DAPT for the first 10-21 days following a high risk TIA or small stroke, followed by conversion to daily aspirin therapy for long term management.

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Comparison of physicians and APC's on the quality of diabetes care

Most of our CDO's are significantly invested in the incorporation of NP's and PA's with the expectation that quality of care will be excellent. Although there have been several small trials confirming this expectation, a recent large trial deserves exploration¹¹. The VA system looked at close to 370,000 patients with diabetes who were managed for at least two years by either physicians, NP's or PA's. Patients were assigned to the provider if >75% of the visits occurred with that provider. The results were striking in terms of the Advanced Practice Clinicians (APC) ability to manage care with quality that were assigned to the provider if >75% of the visits occurred with that provider.

was equal to the physicians, as noted in the below chart.

Provider Type	Patients With Measurements, n	Estimated Mean Level (95% CI), %
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NP	63,246	/.53 (/.51-/.56)
PA	23,789	7.59 (7.56-7.62)
Physician	263,209	7.58 (7.56-7.61)
Provider Type	Patients With Measurements, n	Estimated Mean Level (95% CI), <i>mg/dL</i>
		LDL-C
NP	59,037	85.47 (84.72-86.21)
PA	22,151	85.97 (84.99-86.95)
Physician	245,046	84.89 (84.16-85.63)
Provider Type	Patients With Measurements, n	Estimated Mean Level (95% CI), mm/Hg
		SBP
NP	66,442	133.03 (132.72-133.34)
PA	25,147	133.09 (132.66-133.51)
Physician	274, 873	133.11 (132.74-133.47)

The glycated hemoglobin, hypertension, and hyperlipidemia control was identical across all three groups. A portion of these results might be biased by the strong culture of the patient centered medical home and team based care at the VA practices, although this culture is hopefully mirrored within our CDO's. This report is important as measuring quality of care at the APC level is very difficult to study outside of the VA system. Many of our APC's are billing "incident to" their physicians such that accurately abstracting the care they provide can be difficult. Assuming our CDO's have similar levels of population health management and team based care as the VA system, this data should serve as evidence that our APC's are providing diabetes care of equal quality to our physicians.

Do simple ovarian cysts require follow up imaging?

A large study from Kaiser Permanente Washington¹² 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. 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, increase 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".

^{11.} Jackson, G. L., Smith, V. A., Edelman, D., Woolson, S. L., Hendrix, C. C., Everett, C. M., . . . Morgan, P. A. (2018). Intermediate diabetes outcomes in patients managed by physicians, nurse practitioners, or physician assistants: A cohort studty. Annals of Internal Medicine, 169(12), 825-835. doi:10.7326/M17-1987

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The Genetic Testing Scam - An example of the need for cost effectiveness analyses

In 2018, CMS approved certain genetic tests when ordered by a physician and used for the management of advanced metastatic cancers. These tests can sometimes predict the response to chemotherapy, allowing patients to avoid the toxicity and expense of cancer therapies that are unlikely to be of benefit. Even when appropriately used, this is an expensive technology which is not always cost effective. An ongoing scam involves distorting this regulation to directly market genetic testing to patients as a cancer screening tool, which is not a

covered Medicare benefit since it was not ordered by a physician and does not meet the guidelines for use. These companies will then bill Medicare with reimbursements in excess of \$1,000 per test. This is fraud and abuse, but nonetheless the claims are paid unless audited by CMS. Recently, one of these companies began to market these tests to our providers in one of the WellMed markets. This is critically important because if we order the test, Medicare will pay the claim and we are potentially liable since the correct indication for testing was not present. The language the scam artists use in direct patient and provider marketing includes:

"The genetic tests are so advanced that cancer can often be detected years before the first symptom ever occurs. Possible gene mutations can be identified and millions of lives can be potentially saved because of this advancement in healthcare. CMS is funding the tests 100% so there is NO COST to the Medicare beneficiaries"

As a critical element of the Optimal Care program, we will begin to study the clinical and cost effectiveness of new tests and technologies and make recommendations for their use in daily practice. These analyses can serve as the "source of truth" for our patients and providers.



Kenneth Roy Cohen, MD, FACP

Chief Medical Officer

Dr. Kenneth Cohen is an experienced physician leader, practicing internist, and researcher who has attained national recognition for health care quality improvement. He has successfully developed and reported numerous clinical quality studies in primary care, including tobacco cessation, osteoporosis, asthma, diabetes, hypertension, and ischemic vascular disease. He was one of the founding physicians of New West Physicians, which is the largest primary care group practice in Colorado and now part of OptumCare. He has served as Chief Medical Officer since 1995. Dr. Cohen has received awards of recognition and distinction for teaching, including the Lutheran Medical Center Physician of the Year award in 2011. Under his stewardship New West Physicians was awarded the AMGA Acclaim award in 2015 and the Million Hearts Hypertension

Champion Award in 2017. He is a Clinical Associate Professor of Medicine and Pharmacy at the University of Colorado School of Medicine. Dr. Cohen holds degrees from Dickinson College and Hahnemann University. He is a Fellow of the American College of Physicians and a member of the Phi Beta Kappa and Alpha Omega Alpha honor societies.



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