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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: • Explore the educational content surrounding back pain as a means to advance optimal care outcomes. • Review pharmaceutical recommendations for the management of the new oral tetracyclines; omadacycline and sarecycline. • Apply medical management principles grounded in evidence-based medicine when comparing the harms, advantages, and costs from hematuria guidelines.

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

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

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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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Practical Management of Back Pain

Background and initial considerations:

Back pain is one of the most common presenting complaints to the primary care physician.[1] Over 80% of individuals will experience back pain sometime during their life.[2] In 20% to 30% of individuals, low back pain will persist at one year. This evidence-based review is intended to help guide the primary care physician through the clinical management of back pain. Subspecialty referrals, imaging, and therapies are addressed below.[3]

Step one in the evaluation of back pain is a thorough history, emphasizing the situations listed below that require urgent intervention, and physical exam, focusing on neurologic and functional impairments. Patient education should begin at the first evaluation.

Situations requiring urgent or special evaluation:

Urgent surgical evaluation is needed for less than one percent of cases seen in primary care, but these must not be missed. The relatively short list of conditions that warrant urgent evaluation include the following: active cancer, IV drug use, urinary retention, saddle anesthesia, loss of anal sphincter tone, major motor weakness, or fever.

In patients with neck pain, urgent imaging and referral is indicated for significant upper or lower extremity weakness or muscle atrophy, or other new neurologic deficits. When present, strongly consider urgent spine MRI and plain radiographic films (preferably standing) along with surgery and/or neurology referral(s).[4]

Radicular pain that is unrelenting and unresponsive to initial management should prompt the consideration of physical therapy referral. Lower back pain that has been present for more than three months should be evaluated with lumbar spine films. Imaging is primarily looking for three broad categories of pathology:

- Osteoporosis, which would prompt consideration of medical management
- Findings consistent with cancer, with referral to surgery and or oncology
- Spondylolisthesis or scoliosis, with resultant engagement of physical therapy

If imaging is normal or shows only expected degenerative changes, the clinical approach outlined below can be followed.[5]

Ongoing back pain management, practical guide:

Step two in management begins with ongoing education and reassurance accompanied by one or more of non-surgical treatment modalities. Each intervention listed in Table 1 has low to moderate levels of evidence supporting the efficacy in the treatment of low back pain. All have a low risk of adverse events.[6,7,8]

(continued on page 2)

Practical Management of Back Pain

(continued from page 1)

Table 1: Non-surgical therapies for Acute Low Back Pain (ALBP) or Chronic Low Back Pain (CLBP)

Non-surgical therapies	ALBP	CLBP
Exercise		✓
Local heat	✓	
Massage		✓
Acupuncture	✓	✓
Spinal manipulation	✓	✓
Mindfulness		✓
Tai Chi		✓
Cognitive behavioral therapy		✓
Yoga		✓
Multidisciplinary rehabilitation		✓

Shared decision making will help to identify the intervention best suited for each patient. The biggest barriers to practical implementation of these therapies is access to providers of the alternative, conservative approaches and insurance coverage.[9] Work to develop a list of providers your clinic can work with to provide these services.

Step three in management of patients with back pain is to add pharmaceutical agents. NSAIDs at the lowest effective doses are the preferred agents. Acetaminophen has been shown to not be effective in the treatment of low back pain. Tramadol for short term use can be tried when NSAIDs fail. Long-term opioid use, including tramadol, is not recommended.[10] In some circumstances, the addition of NSAIDS may appropriately be added along with the non-surgical treatments mentioned in Step Two.

Step four in management involves referral to physical therapy for active therapy and a home exercise program. Should PT not be sufficient, physiatry or conservative pain management specialty referral should be engaged. Consideration of an MRI before or after the evaluation and treatment may be indicated. The primary care physician team should track the patient's progress through these evaluations and continue to provide education and coaching to the patient.

Step five: Should PT and physiatry not resolve the pain the patient may benefit from epidural injections and/or surgical evaluation. Epidural injections tend to have only short term benefit, but may allow a bridge to recovery or to surgical intervention. Some trials have shown patients undergoing epidural steroid injections to have worse long term outcomes.[11] Specific indications for epidural injections include acute disk herniation with refractory radicular pain, degenerative disease with foraminal stenosis and refractory radicular pain, and palliative pain control in non-surgical candidates.

Surgical treatment of low back pain still lacks well designed long term outcomes studies. There is data that in carefully selected patients surgical treatment can be of benefit, particularly patients with severe lumbar spinal stenosis with refractory symptoms.[12] The utility of lumbar fusion in addition to laminectomy is in question[13] There is no dispute that surgical intervention can have frequent complications and additional surgeries with complications occurring in 10- 24% of cases.[14]

Summary: The initial history and physical exam allows selection of patients appropriate for urgent referral or for the vast majority of patients to begin conservative, non-surgical treatments. Create a network of conservative alternative therapies available to your patients. Understand the treatment philosophy and surgical options utilized by the surgeons to whom you refer and assure those practices are consistent with what is best for your patients.

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The New Oral Tetracyclines: Do they provide value?

In the last several years, two new oral tetracyclines (TCN) have been approved for use in the United States: omadacycline and sarecycline.

Omadacycline is an extended spectrum TCN with proven efficacy in treatment of community acquired pneumonia (CAP), skin and soft tissue infections (SSTI), and intra-abdominal infections (IAI).[15] It is effective for complex infections in hospitalized patients.[16] However, omadacycline may also have a role in treating CAP or SSTI in observation patients or outpatients. Of note, the omadacycline treatment arm of a CAP treatment trial exhibited increased mortality relative to other antibiotics.[17] Omadacycline is available for intravenous or oral administration, and treatment can be initiated as an infusion with a rapid change to the oral route. The economic justification for the high price of omadacycline is avoided hospital days with a more rapid transition to outpatient therapy. A treatment course of omadacycline is just under $4000.

Sarecycline is a niche TCN approved exclusively for the treatment of the inflammatory lesions of non-nodular, moderate to severe acne vulgaris in patients over nine years of age (see table).[18] Sarecycline is an expensive orally administered agent with a relatively limited therapeutic success in the treatment of acne vulgaris. There are no available data comparing outcomes in treating acne with doxycycline vs sarecycline. The yearly cost is over $10,000.

All tetracyclines, including these new agents, are bacteriostatic, meaning they prevent bacterial replication. This static activity can adversely affect the bacteriocidal activity of other antibiotics administered in conjunction with tetracyclines. For example, the addition of tetracyclines to penicillins has resulted in worse outcomes. Many tetracyclines have the potential of permanently staining developing teeth and should be avoided in children under the age of eight years. Tetracyclines all maintain activity against atypical organisms and in some instances they are the best treatment option (e.g., Rickettsia rickettsia the causative agent for Rocky Mountain Spotted Fever).

In summary, omadacycline retains the coverage common to all tetracyclines but offers greater efficacy against resistant gram negative and gram positive organisms. It has potential application in both inpatient and outpatient settings for CAP and SSTI. Currently, its high cost limits its application in the general population. Sarecycline is extremely expensive and has only modest treatment success for treatment of the inflammatory lesions of non-nodular, moderate to severe acne. Consider carefully the use of these new agents based on the reports of increased mortality associated with the use of omadacycline, treatment failures, higher cost and possible interactions with bacteriocidal agents.

Approved Indications, Efficacy and Cost of Select Tetracyclines

	Approved indications				Clinical efficacy (sensitive in vitro)					
	CAP	SSTI	IAI	Acne	Atypicals	VRE	MSSA	MRSA	RGNR	cost/day ($)
Omadacycline	Yes	Yes	No	No	Yes	Yes	Yes	Yes	Yes	475
Sarecycline	No	No	No	Yes	na	na	na	na	na	30
Doxycycline	Yes	Yes	No	Yes	Yes	No	Yes	No	No	4

Atypicals – refers to the broad array of organisms (eg, Parasites, Rickettsia species, Mycoplasma); VRE – Vancomycin Resistant Enterococci; MSSA – Methicillin Sensitive Staphylococcus; MRSA – Methicillin Resistant Staphylococcus; RGNR – Resistant gram-negative rods; na – not available

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Comparison of Harms, Advantages, and Costs from Hematuria Guidelines

As many as two million Americans are referred to urologists annually for a finding of gross or microscopic hematuria.[19] Although several guidelines address the clinical evaluation of urinary tract cancers when hematuria is present, [20, 21, 22, 23, 24] each guideline varies in terms of the recommended testing modalities (cystoscopy, ultrasonography, computed tomography [CT] urography) and the risk factors that warrant testing. The Table lists five guidelines, ordered from least aggressive testing recommendations (Dutch, top) to most aggressive (American Urologic Association [AUA], bottom). The Dutch guidelines, for example, recommend cystoscopy and ultrasonography as the initial evaluation for hematuria, but only in patients 50 years of age and older, whereas the AUA guidelines endorse uniform cystoscopy and CT evaluations for patients with hematuria aged 35 years and older.

Georgieva and colleagues [25] conducted a microsimulation that compared the potential advantages, harms, and costs of the five guidelines listed in the Table. The simulation used published prospective hematuria cohort studies to model data about patient age, sex, cancer risk factors (e.g., smoking status and gross hematuria), and prevalence of urinary tract cancer (bladder, renal cell carcinoma, and upper-tract urothelial carcinoma). The cohort included 100,000 hypothetical patients, ≥35 years old.

The investigators found that cancer detection rates increased in parallel with more aggressive evaluations. But aggressive evaluations, especially uniform CT imaging, also led to more radiation-induced cancers, more false-positive cancer diagnoses, more procedural complications, and higher monetary costs per evaluation. The Table provides detailed simulated cancer detection rates and potential harms and costs for each published guideline. Since the Dutch and Canadian Urologic Association guidelines do not include CT as part of the initial evaluation, no secondary cancers developed in those cohorts.

It is helpful to compare the AUA and Kaiser Permanente (KP) guidelines as these two are the most frequently used in the US. For the simulated population of 100,000 patients, the AUA guideline compared to the KP guideline would diagnose an additional 48 cancers while causing:

- 467 radiation induced cancers
- 13,000 additional false positive findings
- 3200 additional cases of contrast nephropathy
- Cost to diagnose one additional cancer close to $900,000

Additionally, the microsimulation cost calculations did not include potential downstream costs associated with further testing for patients with false-positive diagnoses or with potential incidental findings from abdominal and pelvic CT scanning. Incidental findings can be seen from abdominal and pelvic CT in up to 30% of patients.[26]

These data suggest that the routine use of CT for all cases of microscopic hematuria per the AUA guidelines is both harmful and cost-ineffective compared to the more conservative KP guideline. The approach to initial testing of patients with hematuria should incorporate both the patients' risk factors for cancer as well as potential harms from testing. Based on the results of this study, it is reasonable to not perform CT urography as an initial screening test for patients with microscopic hematuria, especially when they are at low risk of cancer.

Table. Microsimulation estimated cancer detection rates, harms, and costs associated with hematuria guideline recommendations

Guidelines	Testing recommendations	Cancer detection rates	Radiation-associated cancers (n)	False-positives (n)	Procedural complications[1]	Cost in millions, US dollars
Dutch	Cystoscopy and renal ultrasonography for patients ≥50 years	92.9%	0	6,452	7,999	$44.3
Canadian Urologic Association	Cystoscopy and renal ultrasonography for patients ≥40 years	95.1%	0	6,740	8,344	$46.2
Kaiser Permanente	Cystoscopy and renal ultrasonography only with cancer risk factors;[2] CT and cystoscopy with gross hematuria; no evaluation without risk factors	96.3%	108	9,099	9,582	$51.9
Hematuria Risk Index	Cystoscopy and renal ultrasonography with moderate cancer risk; CT and cystoscopy with high risk; no evaluation if low risk	96.7%	136	13,811	9.709	$59.8
American Urologic Association	Cystoscopy and CT for patients ≥35 years	97.7%	575	22,189	17,637	$93.9

[1]CT contrast allergy, contrast nephropathy, dysuria, urinary tract infections
[2]Smokers, male sex, ≥50 years

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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.

John Hitt, MD, MBA | *Senior Medical Director*

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 Univ of Virginia where he played division one 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 Univ of Minnesota Hospital and Clinics. Dr. Hitt completed his MBA at the Carlson School of Management at the Univ of Minnesota in 2003. He is the proud father of seven children.

Geoffrey Heyer, MD | *Senior Clinical Practice Performance Consultant*

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.