Recent Advances in the Management and Treatment of Bone Diseases

9-27-08 Arlington Heights, Illinois
10-11-08 Tampa, Florida

These activities were supported through an educational grant or donation from the following companies:
Amgen, Lilly, Novartis, Roche, sanofi-aventis

National Association for Continuing Education (NACE)
7860 Peters Road, Suite F-111, Plantation, Florida 33324
1-866-266-6223
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Overview of CME Activity

The National Association for Continuing Education (NACE), held two CME activities entitled \textit{The Bone Course: Recent Advances in the Management of Bone Diseases—Update 2008}. These activities were held on September 27, 2008 in Arlington Heights, Illinois and on October 11, 2008 in Tampa, Florida. The course director for these activities was David Dempster, Ph.D. This was NACE’s second year in presenting \textit{The Bone Course}. The target audience for these activities was physicians, physician assistants, and nurse practitioners treating patients in a primary care setting.

The mission of NACE is to offer continuing education opportunities to provide learners in the fields of medicine, behavioral health, education, and related disciplines, with the most up-to-date, science-based information that will enable them to maintain or increase their knowledge, skills, and professional performance.

NACE is accredited by the Accreditation Council for Continuing Medical Education to provide continuing medical education for physicians. \textit{The Bone Course: Recent Advances in the Management of Bone Diseases—Update 2008} was planned by the NACE in joint sponsorship with the University of Massachusetts Medical School Department of Continuing Education (UMMS), an ACCME accredited provider. The University of Massachusetts Medical School designates this educational activity for a maximum of 4 \textit{AMA PRA Category I Credit™}. The planning and delivery of this CME activity conformed with the policies of the ACCME. This activity had also been reviewed and was acceptable for Prescribed credit(s) by the American Academy of Family Physicians.

The content of this activity was derived through a needs assessment of a variety of therapeutic areas that included identified gaps in knowledge, competence or performance of physicians and educational objectives in each therapeutic area to narrow these gaps.

This CME activity was assessed with respect to Kirkpatrick’s first four levels of evaluation: learner participation, learner satisfaction, effect on learner knowledge (and confidence), and effect on practice behavior. Data was collected via paper and pencil survey instruments and electronically via an audience response system at live symposia. NACE used case-based vignettes to demonstrate competence in applying critical knowledge and to measure practitioner practice patterns. The use of case vignettes for this purpose has considerable predictive value. Vignettes, or written case simulations, have been widely used as indicators of actual practice behavior. Peabody et al. (2000; 2004) compared the validity of three methods to assess quality of health care: case vignettes, observation of “standard patient” visits, and chart abstractions. Vignettes were found to be a valid and comprehensive method of assessing quality of health care provided in actual clinical practice. Vignettes can be used for diverse clinical settings, diseases, physician types, and situations in which case-mix variation is a concern. They can be useful to measure the effect of interventions intended to change clinical practice behavior.


NACE collaborated with Health Link Systems Inc. and Educational Measures Inc. to design the methodology used in the outcome study and to collect and analyze the data with respect to each of topics presented.

Conference Agenda

The conference agenda was as follows:

<table>
<thead>
<tr>
<th>Time</th>
<th>Event</th>
</tr>
</thead>
<tbody>
<tr>
<td>7:15-7:45 am</td>
<td>Registration and Continental Breakfast</td>
</tr>
<tr>
<td>7:45-8:00</td>
<td>Welcome Remarks</td>
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<tr>
<td></td>
<td>David Dempster, PhD</td>
</tr>
<tr>
<td>8:00-9:00</td>
<td>Pathophysiology and Treatment of Postmenopausal Osteoporosis and Osteoporosis in Men</td>
</tr>
<tr>
<td></td>
<td>David Dempster, PhD</td>
</tr>
<tr>
<td>9:00-10:00</td>
<td>Cancer and Bone: Pathogenesis and Treatment</td>
</tr>
<tr>
<td></td>
<td>Kenneth W. Lyles, MD</td>
</tr>
<tr>
<td>10:00-10:15</td>
<td>Break</td>
</tr>
<tr>
<td>10:15-11:15</td>
<td>Pathophysiology and Treatment of Paget’s Disease</td>
</tr>
<tr>
<td></td>
<td>G. David Roodman, MD, PhD</td>
</tr>
<tr>
<td>11:15-12:00</td>
<td>Interactive Panel and Case Discussion</td>
</tr>
</tbody>
</table>
Learner Participation

A total of 90 people attended this activity in the two locations: Arlington Heights, Illinois and Tampa, Florida. Each of these people earned a CME certificate. Of those attending, 70% were physicians in primary care, 6% were Rheumatologists, 6% were OB/GYNs, 2% were Gastroenterologists, and 16% were other health providers. The breakdown in terms of degree is provided in the table.

<table>
<thead>
<tr>
<th>City</th>
<th>MD</th>
<th>DO</th>
<th>NP</th>
<th>PA</th>
<th>RN</th>
<th>Other</th>
<th>Did Not Respond</th>
<th>TOTAL</th>
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</thead>
<tbody>
<tr>
<td>Arlington Heights, IL</td>
<td>32</td>
<td>1</td>
<td>1</td>
<td>5</td>
<td>0</td>
<td>1</td>
<td>40</td>
<td></td>
</tr>
<tr>
<td>Tampa, FL</td>
<td>38</td>
<td>2</td>
<td>6</td>
<td>3</td>
<td>1</td>
<td>0</td>
<td>50</td>
<td></td>
</tr>
</tbody>
</table>

Learner Satisfaction and Comments

Attendees were asked to complete survey instruments regarding their satisfaction with the CME activity, whether they found the information presented to be relevant to their practice needs, and the likelihood that they would incorporate new information learned at the activity into their patient care.

Compared to other CME activities that I have participated in over the past year, I would rate this activity as . .

How effective was this activity in meeting the stated learning objectives?
How useful and relevant was the information provided to your practice.

How effective will the information you learned during this activity be in helping you improve your skills or judgment?

How well did this activity include opportunities to learn interactively from faculty/participants?
How likely are you to make changes in your practice based on the information presented during this CME activity?

<table>
<thead>
<tr>
<th></th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Very likely</td>
<td>42</td>
</tr>
<tr>
<td>Pretty Likely</td>
<td>39</td>
</tr>
<tr>
<td>Somewhat likely</td>
<td>14</td>
</tr>
<tr>
<td>Unlikely</td>
<td>5</td>
</tr>
</tbody>
</table>

In what areas will you make changes in practice? (Please check all that apply.)

<table>
<thead>
<tr>
<th>Area</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Screening/d</td>
<td>32</td>
</tr>
<tr>
<td>Treatment/</td>
<td>32</td>
</tr>
<tr>
<td>Staff</td>
<td>9</td>
</tr>
<tr>
<td>Patient</td>
<td>24</td>
</tr>
<tr>
<td>I do not</td>
<td>3</td>
</tr>
<tr>
<td>Other</td>
<td>1</td>
</tr>
</tbody>
</table>

How soon will you incorporate the information from this CME activity into your practice?

<table>
<thead>
<tr>
<th>Time</th>
<th>%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Within 1</td>
<td>54</td>
</tr>
<tr>
<td>1-3 months</td>
<td>21</td>
</tr>
<tr>
<td>4-6 months</td>
<td>1</td>
</tr>
<tr>
<td>I am already</td>
<td>19</td>
</tr>
<tr>
<td>I do not plan</td>
<td>5</td>
</tr>
</tbody>
</table>
Which statement(s) best reflects your reasons for participating in this activity (Please check all that apply):}

- Future CME activities in these subject areas are necessary.

**Topic Desired by Attendees for Future CME Activities**

- CHF
- Infectious diseases
- New trends and approach to HTN/MI in primary care settings
- Diabetes/Lipids/ Autism
- More on incretins and insulin use
- GI/Urology/Geriatrics/Psychiatry
- Hyperlipidemia and GI disorders
- Malignancies-GI/Lung/Pancreas/Brain/Spinal Cord
- More on stroke/A review on thyroid
- Immunologic diseases
- Breast cancer
- Constipation/LUTS/OAB/Women's care
- Chronic kidney disease/Gouty arthritis/Sciatica/Hypertension/Sports injuries
- Lipids
- HIV/AIDS/Domestic violence and medical errors
- Nephrology related
- Bullous and contact dermatology
- Women's health issues
- Metabolic bone disease and billing
- Therapeutic exercises for rheumatologic conditions
- Sleep apnea
- Radiology/Antibiotics/Alternative medicines
- GYN in family medicine/Dementia
- Osteoporosis management
- Sarcoidosis
- Antiphospholipid Syndrome/SLE
- Diagnostic tests related to surgery
- Neurodegenerative diseases like Lou Gehrig’s
- Vasculitis/Gout
- COPD and Sleep apnea
- More neurology
- Pulmonary embolism and DVT/Chronic kidney disease
- Chronic kidney disease
- Coronary artery disease
- Hypertension
- COPD/CAD
- Recognizing kidney insufficiencies from blood work
- Neurology-CMND/Infectious disease-HIV update
- Medical errors/HIV/Domestic violence
- Renal disease
- New Tx for CHF
- Chron’s and FAP
- Lymphomas and connective tissue disease
- Obesity and exercise
- Anticoagulation therapy in
- Cardiovascular
- CNS/Manifestations of Rheumatic
- Hepatitis
- C/ADHD/Chronic
- Metabolic Syndrome
- Autism
- Orthopedic emergencies
- Breast MRI/Viral colonoscopy
- Contraception management
- COPD
- Liver transplant
- Addiction treatment
- Dermatology/Women's Health
- Peri-op medicine
- More pain management
- Treatment of psychiatric patients
- Hypertension/Metabolic Syndrome
- Bipolar disorder
- Obesity-managing patients and lifestyle
• Osteoporosis/Metabolic syndrome/Dementia/Myocardial Infarction
• Preventative medicine/COPD/Asthma
• Infectious diseases
• Urology/Hypercholesterolemia/HPV/Teenage drug use/Cystic fibrosis
• Basic overview of HIV infection and AIDS diagnosis and treatment
• Sports medicine
• Disability evaluation and requirements US/MRI use in Dx of Rheum diseases
• Continue updates and risks in treatment of Rheumatic disease
• Better control of pain management
• Dermatology/Orthopedic/Spine/Neurology
• Any on internal medicine and rheumatology
• HTN-DM
• Gout/Lups
• Abdominal pain/IBS/Chron’s
• Parkinson’s/Alzheimers
• ADHA/PTSD/Psychometrics
• Hospital settings
• Cardiology/COPD/Asthma
• Treatment of STD’s/Update on immunization for adults
• Adult vaccines/Preventive care/IBS/Insomnia
• More on diabetes management and dermatology
• Polycystic Ovarian Syndrome/Depression/Sexual dysfunction
• More Osteoporosis
• Hyperthyroidism
• HTN Treatment/Parkinson’s Disease
• Outpatient management of CHF
• Diabetes
• Tx of obesity
• Electronic medical records
• Tx of infectious diseases in outpatient
• CV disease/Alzheimers
• Type2 diabetes
• Bone densitometry
• Paget’s disease

The following pages describe the responses of attendees to questions specific to each topic presented.
Pathophysiology and Treatment of Postmenopausal Osteoporosis and Osteoporosis in Men

Presenter
David W. Dempster, PhD
Professor of Clinical Pathology
Columbia University, New York
Director, Regional Bone Center
Helen Hayes Hospital
West Haverstraw, New York

Presented at
The Bone Course: Recent Advances in the Management of Bone Diseases
Update 2008
September 27, 2008 in Arlington Heights, Illinois
and on October 11, 2008 in Tampa, Florida
Pathophysiology and Treatment of Postmenopausal Osteoporosis and Osteoporosis in Men

Presenter: David Dempster, Ph.D.

Executive Summary

The topic, Pathophysiology and Treatment of Postmenopausal Osteoporosis and Osteoporosis in Men, was presented in Arlington Heights, IL and Tampa, FL in September and October, 2008 as part of The Bone Course.

The need for continued education in the evaluation and management of patients at risk for, and suffering from, osteoporosis was demonstrated based on the literature review and survey data described below. Dr. Dempster received very high ratings on his effectiveness in delivering this material.

Attendee knowledge was assessed using the questions listed above with results indicating a clear improvement in the post testing in all areas. Specifically, participants are more likely, as a result of this lecture, to recognize who should be screened for osteoporosis using the 2008 NOF Guidelines. In addition, there is a greater awareness now of the heightened risk of a fracture in patients with low bone density, as well as the role of the WHO (FRAX) algorithm for the management of osteoporosis. Participants also showed a better understanding of the differing mechanisms of action of osteoporosis drugs and a better recognition of the cut-off for vitamin D sufficiency. There was also a dramatic increase in confidence levels in the management of these patients, as reported by conference attendees.

These notable changes in post test scores signify a clear gap in knowledge and an unmet need amongst primary care clinicians. It continues to be an important area for future educational programs. Additional programming should continue to educate clinicians on the National Osteoporosis Foundation Guidelines, use of the FRAX scoring system for management of osteoporosis, and recognition of risks and benefits of various non-pharmacologic and pharmacologic treatment regimens.

Statement of Need for Postmenopausal Osteoporosis and Osteoporosis in Men

Literature Review

Osteoporosis affects approximately 25 million American women, and about 8 million have had a documented fracture. Those at highest risk include postmenopausal women with bone mineral density (BMD) test T-score ≤ 2.5, or those with a clinical diagnosis based on having sustained a hip or spine fracture. [1] Osteoporotic fractures are more common in white women, the lifetime risk of a 50-year-old white woman having an osteoporotic fracture being 40%. [2] Fractures and pain associated with postmenopausal osteoporosis are associated with increased morbidity and mortality, poorer quality of life, and economic costs. [3, 4]

Prevention is a key issue, involving an intake of 1,200 mg of calcium and 800-1,000 IU of vitamin D3 daily for women age >50 years, regular weight-bearing and muscle-strengthening exercise, avoidance of smoking and excessive alcohol, and bone density testing and medications as appropriate. [1] Bisphosphonates are the first-line treatments for patients with osteoporosis. [3]

Many gaps exist in osteoporosis diagnosis and management. Physicians are uncomfortable with BMD measurements and osteoporosis treatment, and many may have never used BMD screening. Barriers may include cost, unfamiliarity with guidelines, uncertainty about clinical applicability, and questions about the effect on treatment decisions. [5] In the 6-12 months after are hip fracture, osteoporosis treatment rates are less than 10-20%, even though 80% of these patients have low bone mass. [6] Many patients do not receive bisphosphonates when indicated. [5, 7] Less than 5% of patients with osteoporotic fractures are referred for medical evaluation and osteoporosis treatment. [5] Clinical practice guidelines are available, but adherence to guidelines is low, possibly due to the multiplicity of osteoporosis guidelines, which show similarities as well as variations and inconsistencies. [8]

Although osteoporosis is usually considered a condition that affects postmenopausal or elderly women, in fact, it poses a significant threat to > 2 million men in the United States. About 4-6% of men aged > 50 years have osteoporosis, and 33-47% have osteopenia. Nearly 30% of all hip fractures occur in men, and 6% and 5% of all men aged >50 years develop in hip and vertebral fractures respectively. [9,10]

Osteoporotic fractures in men are associated with higher morbidity and mortality rates than in women. [10]

Osteoporosis in men is primarily related to aging and genetic factors, but secondary risk factors (e.g., glucocorticoid use, hypogonadism, anticonvulsant drug use, tobacco and alcohol use) are involved in a large proportion of patients. Screening measures include diagnostic radiologic studies using dual-energy x-ray absorptiometry of the hip and spine, heel ultrasonography, or quantitative computed tomography. Treatments options include calcium, vitamin D, bisphosphonates, androgen replacement, and parathyroid hormone. [9-14]

There exists a diagnostic and therapeutic gap in osteoporosis management in men. The condition is under-recognized in men. Males aged > 65 years are commonly not screened for osteoporosis, and primary care providers may be unaware of the prevalence and complications of osteoporosis in men, and of osteoporosis screening guidelines for men. [15,16] Following a hip fracture, therapy is rarely initiated in men, and only 1 in 4 men with
osteoporosis receive pharmacotherapy to reduce the risk of fracture. [16] In one study, [16] only 2.3% and 10.3% of men with a clinical fracture were diagnosed at baseline and at year 5 respectively. Furthermore, at year 5, 90% of men with a clinical fragility fracture were untreated.

**Survey of Needs:**
To obtain additional data on the needs of health care providers with respect to their interest in learning more about Postmenopausal Osteoporosis and Osteoporosis in men, NACE conducted a survey of 104 health providers who attended NACE live CME conferences targeted to primary care providers. A majority of respondents to the survey indicated that they had a moderate to very strong interest in learning more about this topic. They responded to the following survey questions

**How interested are you in learning about postmenopausal Osteoporosis?**

![Interest in learning about postmenopausal Osteoporosis](chart1)

**How interested are you in learning about Osteoporosis in Men?**

![Interest in learning about Osteoporosis in Men](chart2)

This educational activity discussed the role of various therapeutic options in the management of Osteoporosis and the barriers to successful therapy. At the conclusion of this CME activity, attendees should be able to:

1. Describe the epidemiology and pathogenesis of postmenopausal Osteoporosis and Osteoporosis in men
2. Explain and implement the current guidelines for the assessment, diagnosis and treatment of postmenopausal Osteoporosis and Osteoporosis in men
3. List successful measures to prevent Osteoporosis

**Speaker Bias**
Attendees were also asked to rate the extent to which each speaker presented information in a manner that was fair, balanced, and free of commercial bias on a five-point scale, with one being “Unsatisfactory” and five being “Excellent”.

**Speaker** | **Excellent** | **Very Good** | **Good** | **Fair** | **Unsatisfactory**
---|---|---|---|---|---
David Dempster, Ph.D. | 72% | 27% | 1% | 0% | 0%

**Effect on Learner Knowledge**

*Case Vignettes, Questions, and Preferred Answers (bolded)*

The following questions were delivered through an ARS system to attendees at the CME activities in which this topic was presented. Pre and post test responses were collected from attendees who responded to the ARS questions. The graphs below (first bar=pre; second bar=post; preferred answer in bold) display the results of each question below.

The National Osteoporosis Foundation has recently incorporated the FRAX absolute fracture risk assessment tool in its guidelines for treatment. What is the cut-off for 10 year probability of hip fracture above which pharmacological intervention becomes cost effective?

1. 3%
2. > 6%
3. > 9%
4. > 12%

**P Value: <0.001 - Significant**

<table>
<thead>
<tr>
<th></th>
<th>Pre %</th>
<th>Post %</th>
</tr>
</thead>
<tbody>
<tr>
<td>3%</td>
<td>37</td>
<td>97</td>
</tr>
<tr>
<td>&gt; 6%</td>
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<tr>
<td>&gt; 9%</td>
<td>37</td>
<td>3</td>
</tr>
<tr>
<td>&gt; 12%</td>
<td>7</td>
<td>0</td>
</tr>
</tbody>
</table>

There are a number of pharmacological agents available for the prevention and/or treatment of osteoporosis. Which of the following agents does not inhibit bone resorption?

1. Risedronate
2. Teriparatide
3. Raloxifene
4. Estrogen

**P Value: <0.001 - Significant**

<table>
<thead>
<tr>
<th></th>
<th>Pre %</th>
<th>Post %</th>
</tr>
</thead>
<tbody>
<tr>
<td>Risedronate</td>
<td>7</td>
<td>7</td>
</tr>
<tr>
<td>Teriparatide</td>
<td>43</td>
<td>83</td>
</tr>
<tr>
<td>Raloxifene</td>
<td>27</td>
<td>7</td>
</tr>
<tr>
<td>Estrogen</td>
<td>23</td>
<td>3</td>
</tr>
</tbody>
</table>
Effect on Learner Confidence

Confidence in treating patients with this condition was measured during the pre and post-tests. Practitioner confidence relates directly to the likeliness of actively using knowledge. Practitioner confidence in his/her ability to diagnose and treat a disease or condition can affect practice behavior patterns.

On a scale of 1 to 7 please rate how confident you would be in treating a patient with this condition.
1. Not at all confident
2. Only slightly confident
3. Somewhat confident
4. Moderately confident
5. A little more than moderately confident
6. Pretty much confident
7. Very confident

Summary and Conclusions

The need for continued education in the evaluation and management of patients at risk for, and suffering from, osteoporosis was demonstrated based on the literature review and survey data described above. Dr. Dempster received very high ratings on his effectiveness in delivering this material.

Attendee knowledge was assessed using the questions listed above with results indicating a clear improvement in the post testing in all areas. Specifically, participants are more likely, as a result of this lecture, to recognize who should be screened for osteoporosis using the 2008 NOF Guidelines. In addition, there is a greater awareness now of the heightened risk of a fracture in patients with low bone density, as well as the role of the WHO (FRAX) algorithm for the management of osteoporosis. Participants also showed a better understanding of the differing mechanisms of action of osteoporosis drugs and a better recognition of the cut-off for vitamin D sufficiency. There was also a dramatic increase in confidence levels in the management of these patients, as reported by conference attendees.

These notable changes in post test scores signify a clear gap in knowledge and an unmet need amongst primary care clinicians. It continues to be an important area for future educational programs. Additional programming should continue to educate clinicians on the National Osteoporosis Foundation Guidelines, use of the FRAX scoring system for management of osteoporosis, and recognition of risks and benefits of various non-pharmacologic and pharmacologic treatment regimens.

References

Cancer and Bone: Pathogenesis and Treatment

Presenter
G. David Roodman, MD, PhD
Professor of Medicine
Vice Chair for Research School of Medicine
University of Pittsburgh
Director, Center for Bone Biology
UPMC Health System
Director, Myeloma Program at UPCI
Pittsburgh, PA

Presented at

The Bone Course: Recent Advances in the Management of Bone Diseases

Update 2008

September 27, 2008 in Arlington Heights, Illinois

and on October 11, 2008 in Tampa, Florida
Cancer and Bone: Pathogenesis and Treatment
G. David Roodman, MD, PhD

Executive Summary
The topic, Cancer and Bone: Pathogenesis and Treatment, was presented in Atlanta, GA and Tampa, FL in September and October, 2008 as part of The Bone Course.

The need for continued education in the evaluation and management of patients at risk for, and suffering from, metastatic bone disease was demonstrated based on the literature review and survey data described below.

Dr. Roodman received very high ratings on his effectiveness in delivering this material. Attendee knowledge was assessed using the patient vignettes and questions listed above with results indicating a clear improvement in the post testing in all areas. Specifically, participants are more likely, as a result of this lecture, to appreciate the prevalence of metastatic bone disease, to differentiate between osteolytic and osteoblastic metastases, and to recognize the bone involvement in different types of primary tumors. In addition, understanding of current theories regarding the pathogenesis of metastatic bone disease was improved and there was a greater awareness of the most effective diagnostic tools and treatment options, as well as the side effects of treatment. There was also a dramatic increase in confidence levels in the management of these patients, as reported by conference attendees.

These notable changes in post-test scores signify a clear gap in knowledge and an unmet need amongst primary care clinicians. It continues to be an important area for future educational programs. Additional programming should continue to educate clinicians on the epidemiology, pathogenesis, diagnosis and management of metastatic bone disease, and on the risks and benefits of various pharmacologic treatment regimens.

Statement of Need for Cancer and Bone

Literature Review
Every year, cancer of the bones and joints affects 0.9 per 100,000 men and women in the United States, and 0.4 per 100,000 die from the condition. One in 1353 men and women can expect to be diagnosed with cancer of the bones and joints during their lifetimes. [1] Cancer involving the bone is usually metastatic, most commonly associated with tumors of the breast, prostate, lung, and kidney, and with multiple myeloma. [2] Bone metastases cause skeletal morbidity that may be refractory to treatment and can negatively affect quality of life. [3]

Bone metastases are associated with osteolysis and abnormal new bone formation. Stimulation of osteoclasts and osteoblasts occurs, together with a response of the bone microenvironment. Patients commonly have evidence of both bone destruction and bone formation. Other factors, e.g., sex steroid deficiency, also contribute to tumor growth in bone. [4] Symptoms of bone metastases include bone pain, fractures, and spinal cord compression. Laboratory tests, radiographic examination, computerized axial tomography (CAT) scanning, magnetic resonance imaging (MRI), and bone marrow aspiration and biopsy may be employed for diagnosis. [5] Management involves radiotherapy, hormones, bisphosphonates, and palliative therapy as needed. [6, 7]

Bone metastasis is underdiagnosed. Patients needing an orthopaedic surgeon may not be referred to one, and patients needing surgery may not undergo it. [8] Palliation of bone pain is critical in patients with bone metastases, but pain management is often inadequate. Factors include lack of physician education and failure to follow existing guidelines. [9-12] The use of intravenous bisphosphonates falls short of recommendations, resulting in painful and debilitating complications from untreated bone metastases. [13]

Survey Data
To obtain additional data on the needs of health care providers with respect to their interest in learning more about bone diseases, NACE conducted a survey of 104 health providers who attended NACE live CME conferences targeted to primary care providers. A majority of respondents to the survey indicated that they had a moderate to very strong interest in learning more about this topic. They responded to the following survey question.

How interested would you be in learning about learning about the epidemiology and pathogenesis of common bone diseases: Osteoporosis, Bone Cancer, Paget’s Disease
This educational activity discussed the role of various therapeutic options in the management of Osteoporosis and the barriers to successful therapy. At the conclusion of this CME activity, attendees should be able to:

- Recognize the skeletal complications related to bone metastases.
- Identify osteolytic and osteoblastic bone involvement in different tumor types
- Discuss approved agents for treating metastatic bone disease, as well as new agents in development.

**Speaker Bias**

Attendees were also asked to rate the extent to which each speaker presented information in a manner that was fair, balanced, and free of commercial bias on a five-point scale, with one being “Unsatisfactory” and five being “Excellent”.

<table>
<thead>
<tr>
<th>Speaker</th>
<th>Excellent</th>
<th>Very Good</th>
<th>Good</th>
<th>Fair</th>
<th>Unsatisfactory</th>
</tr>
</thead>
<tbody>
<tr>
<td>G. David Roodman MD</td>
<td>74%</td>
<td>20%</td>
<td>5%</td>
<td>1%</td>
<td>0%</td>
</tr>
</tbody>
</table>

**Effect on Learner Knowledge**

**Case Vignettes, Questions, and Preferred Answers (bolded)**

The following questions were delivered through an ARS system to attendees at the CME activities in which this topic was presented. Pre and post test responses were collected from attendees who responded to the ARS questions. The graphs below (first bar=pre; second bar=post; preferred answer in bold) display the results of each question below.

65 YO Female Initial Visit

A 65-year-old female presents with progressive fatigue and back pain over the previous three months. Her back pain localizes to the mid-thoracic region and is worse when she ambulates. It initially improved when she was in bed. However, more recently the pain became constant and was no longer relieved with aspirin. The pain was described as a dull ache, which was exacerbated with movement. Her past medical history was unremarkable, and she denied a history of cardiac, renal or pulmonary disease.

On physical exam, the patient was a pale-appearing female in moderate discomfort. Her physical exam is remarkable only for pale conjunctiva and tenderness to deep palpation over T4-T6.

Screening laboratories demonstrated that she had a hemoglobin of 9.4 gm%, a normal white blood cell count and platelet count, and her total serum protein level was elevated. Her serum creatinine was 1.2 mg%.

Thoracic spine films showed two compression fractures at T4 and T6 and a lytic lesion in T5. The other vertebral bodies appeared normal. A bone scan was unremarkable and did not reveal increased uptake at either T4, T5 or T6.

On serum protein electrophoresis, a monoclonal protein of 4.5 gm% was detected, which was identified as IgAx by immunofixation.

Bone marrow studies revealed 40% plasma cells on the aspirate that were κ light chain restricted, and the biopsy showed sheets of plasma cells.
A metastatic bone survey showed two compression fractures in her thoracic spine and multiple lytic lesions throughout her skeleton. MRI of her spine showed increased signal intensity at T4, T5 and T6.

Further laboratory screenings showed an elevated ?2 microglobulin of 4.5 mg% and a decreased albumin of 2.8 g%. The initial treatment for her bone disease should be:

1. alendronate
2. pamidronate or zoledronate
3. radiation therapy

65 YO Female Follow Up Visit

Two months later the patient continues to complain of severe back pain in her thoracic spine in spite of aggressive analgesic therapy. She is scheduled for stem cell harvest as soon as she has achieved a maximum response to her current therapy.

Repeat thoracic and lumbar spine films show the two compression fractures at T4 and T6. MRI of the spine reveals a marked decrease in the signal intensity previously seen at T4, T5 and T6. The patient has normal bowel and bladder function and no neurologic deficits on exam.

She should be:

1. referred for radiation therapy to T4 and T6
2. considered for kyphoplasty
3. have her antitymoma therapy changed
Effect on Learner Confidence

Confidence in treating patients with this condition was measured during the pre and post-tests. Practitioner confidence relates directly to the likeliness of actively using knowledge. Practitioner confidence in his/her ability to diagnose and treat a disease or condition can affect practice behavior patterns.

On a scale of 1 to 7 please rate how confident you would be in treating a patient with this condition.
1. Not at all confident
2. Only slightly confident
3. Somewhat confident
4. Moderately confident
5. A little more than moderately confident
6. Pretty much confident
7. Very confident

Summary and Conclusions

The need for continued education in the evaluation and management of patients at risk for, and suffering from, metastatic bone disease was demonstrated based on the literature review and survey data described above.

Dr. Roodman received very high ratings on his effectiveness in delivering this material. Attendee knowledge was assessed using the patient vignettes and questions listed above with results indicating a clear improvement in the post testing in all areas. Specifically, participants are more likely, as a result of this lecture, to appreciate the prevalence of metastatic bone disease, to differentiate between osteolytic and osteoblastic metastases, and to recognize the bone involvement in different types of primary tumors. In addition, understanding of current theories regarding the pathogenesis of metastatic bone disease was improved and there was a greater awareness of the most effective diagnostic tools and treatment options, as well as the side effects of treatment. There was also a dramatic increase in confidence levels in the management of these patients, as reported by conference attendees. These notable changes in post-test scores signify a clear gap in knowledge and an unmet need amongst primary care clinicians. It continues to be an important area for future educational programs. Additional programming should continue to educate clinicians on the epidemiology, pathogenesis, diagnosis and management of metastatic bone disease, and on the risks and benefits of various pharmacologic treatment regimens.

References

3. Fred S. Impact of Bone Metastases on Patient's Quality of Life and Importance of Treatment. 2006;5:547-550.


Pathophysiology and Treatment of Paget’s Disease

Presenter
Kenneth W. Lyles, MD
Professor of Medicine
Duke University Medical Center
Durham, NC

Presented at
The Bone Course: Recent Advances in the Management of Bone Diseases
Update 2008
September 27, 2008 in Arlington Heights, Illinois
and on October 11, 2008 in Tampa, Florida
Pathophysiology and Treatment of Paget’s Disease
Presenter: Kenneth W. Lyles, MD

Executive Summary
The topic, Pathophysiology and Treatment of Paget’s Disease, was presented in Arlington Heights, IL and Tampa, FL in September and October, 2008 as part of The Bone Course.

The need for continued education in the evaluation and management of patients at risk for, and suffering from, Paget’s disease was demonstrated based on the literature review and survey data described below.

Dr. Kenneth Lyles received very high ratings on his effectiveness in delivering this material. Attendee knowledge was assessed using the questions listed above with results indicating a clear improvement in the post testing in all areas. Specifically, participants are more likely, as a result of this lecture, to recognize the prevalence of Paget’s disease and the current theories regarding its pathogenesis. In addition, there is a greater awareness of the most effective diagnostic tools and treatment options, as well as the side effects of bisphosphonate therapy, including transient flu-like illness. There was also a dramatic increase in confidence levels in the management of these patients, as reported by conference attendees.

These notable changes in post-test scores signify a clear gap in knowledge and an unmet need amongst primary care clinicians. It continues to be an important area for future educational programs. Additional programming should continue to educate clinicians on the epidemiology, pathogenesis, diagnosis and management of Paget’s disease, as well as on the risks and benefits of various pharmacologic treatment regimens.

Statement of Need for Pathophysiology and Treatment of Paget’s Disease

Literature Review
Paget’s disease is the second most common bone disorder after osteoporosis, with an increased prevalence in older individuals. It affects about 3% of people in the United States, and about 10% of those > 80 years of age. Approximately 70% of patients experience no symptoms, but Paget’s disease can also be a cause of chronic back pain and joint pain, skeletal deformities, hearing loss, cranial nerve compression, and can reduce function and mobility. The diagnosis is often made incidentally from radiographs and laboratory investigations. [1-3] Differentiation from metastatic disease can be a challenge, with metastatic disease of bones afflicted with Paget’s disease further adding to possible diagnostic confusion. [4] Osteomyelitis can also mimic Paget’s disease. [5] Bisphosphonates are the treatment of choice, and have helped to improve treatment outcomes, but there remains the challenge of inducing prolonged remission and enhancing adherence/persistence. [6]

Survey Data
To obtain additional data on the needs of health care providers with respect to their interest in learning more about Paget’s Disease, NACE conducted a survey of 104 health providers who attended NACE live CME conferences targeted to primary care providers. A majority of respondents to the survey indicated that they had a moderate to very strong interest in learning more about this topic. They responded to the following survey question.

How interested would you be in learning about the epidemiology, clinical manifestations, and etiology of Paget’s Disease?
How interested would you be in learning about the safety and efficacy of treatments for Paget’s Disease and risks for relapse?

This educational activity discussed the role of various therapeutic options in the management of Osteoporosis and the barriers to successful therapy. At the conclusion of this CME activity, attendees should be able to:

- describe the epidemiology and pathogenesis of common bone diseases: Paget’s Disease
- understand and implement current guidelines for the assessment, diagnosis and treatment of Paget’s Disease

**Speaker Bias**

Attendees were also asked to rate the extent to which each speaker presented information in a manner that was fair, balanced, and free of commercial bias on a five-point scale, with one being “Unsatisfactory” and five being “Excellent”.

<table>
<thead>
<tr>
<th>Speaker</th>
<th>Excellent</th>
<th>Very Good</th>
<th>Good</th>
<th>Fair</th>
<th>Unsatisfactory</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kenneth Lyles, MD</td>
<td>73%</td>
<td>24%</td>
<td>3%</td>
<td>0%</td>
<td>0%</td>
</tr>
</tbody>
</table>

**Effect on Learner Knowledge**

*Case Vignettes, Questions, and Preferred Answers (bolded)*

The following questions were delivered through an ARS system to attendees at the CME activities in which this topic was presented. Pre and post-test responses were collected from attendees who responded to the ARS questions. The graphs below (first bar=pre; second bar=post; preferred answer in bold) display the results of each question below.

What is the best test to evaluate this patient’s extent of Paget’s disease?

1. Serum alkaline phosphate level
2. **Total body bone scan**
3. Radiographs of painful areas
4. Bone specific alkaline phosphatase
The patient developed flu-like symptoms six hours after his zoledronic infusion. How often does this occur with IV bisphosphonate therapy?

1. Less than 5%
2. **10-40%**
3. 50-65%
4. Over 70%

P Value: <0.001 - Significant

The patient asks you if there are data that his treatment will prevent him from developing bowing in his femur. What percentage of deformity is know to be prevented by treatment with bisphosphonates?

1. **Zero Percent**
2. 5-10%
3. 10-20%
4. 20–30%
Effect on Learner Confidence

Confidence in treating patients with this condition was measured during the pre and post-tests. Practitioner confidence relates directly to the likeliness of actively using knowledge. Practitioner confidence in his/her ability to diagnose and treat a disease or condition can affect practice behavior patterns.

On a scale of 1 to 7 please rate how confident you would be in treating a patient with this condition.

1. Not at all confident
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3. Somewhat confident
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6. Pretty much confident
7. Very confident
Summary and Conclusions
The need for continued education in the evaluation and management of patients at risk for, and suffering from, Paget's disease was demonstrated based on the literature review and survey data described above.

Dr. Kenneth Lyles received very high ratings on his effectiveness in delivering this material. Attendee knowledge was assessed using the questions listed above with results indicating a clear improvement in the post testing in all areas. Specifically, participants are more likely, as a result of this lecture, to recognize the prevalence of Paget's disease and the current theories regarding its pathogenesis. In addition, there is a greater awareness of the most effective diagnostic tools and treatment options, as well as the side effects of bisphosphonate therapy, including transient flu-like illness. There was also a dramatic increase in confidence levels in the management of these patients, as reported by conference attendees.

These notable changes in post-test scores signify a clear gap in knowledge and an unmet need amongst primary care clinicians. It continues to be an important area for future educational programs. Additional programming should continue to educate clinicians on the epidemiology, pathogenesis, diagnosis and management of Paget's disease, as well as on the risks and benefits of various pharmacologic treatment regimens.

References
Change in Practice Behavior Follow Up Survey Data

The ultimate goal of the CME activity was to influence participants to apply competencies and critical knowledge learned in the CME activity in their medical practice. Practitioner's self-ratings on a survey measuring perceived change in practice behavior in each of the learning objectives was used as an indicator of actual changes that could ultimately lead to improved patient care and health outcomes.

Approximately four weeks after the CME activity, attendees were asked to rate how much they agree with the following statements on a five point scale:

As a result of attending this program I have made changes in my practice behavior and I am able to describe the epidemiology and pathogenesis of common bone diseases: Osteoporosis, Bone Cancer, Paget’s Disease.

I have made changes in my practice behavior that enable me to understand and implement current guidelines for the assessment, diagnosis and treatment of bone diseases.

I have made changes in my practice behavior and I am more aware of the gap between knowledge and practice in the management of bone diseases and strategies for rectifying this.
I have made changes in my practice behavior and I can understand the mechanism of action of current approved therapies for bone diseases, as well as those in development.

Sample Comments

I enjoyed it
Excellent! I learned a lot
Dr Lyles is one of the best presenters I've ever listened to! Great clinical case photos
What a panel! You don't usually see this level of leaders in their fields. They were all great lecturers! Thank you for a great seminar!
Roodman's talk was excellent but too advanced for my benefit in primary care
Excellent presentation
Very good CME
Question cards would help
Good place but parking was difficult
Excellent topics and speakers
The room lights should be brighter during the presentation. Difficult to read the outlines
For primary care providers-need a summary of take home and when to refer
Informative and direct to the point lectures. Excellent lecturers
Conference Registration
Please print or type.
Register online at www.naconline.com or this form may be mailed or faxed.
Onsite registration will be accepted provided space is available. Return completed form to:
National Association for Continuing Education (NACE)
7860 Peters Road, Suite F-111, Plantation, Florida 33324
For Registration — Phone Toll Free: 1-866-266-6223 • Fax: 954-723-0353

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Fax ______________________________ Email Address (Required) ______________________________
Check one: ☐ Physician ☐ Physician Assistant ☐ Nurse Practitioner ☐ Nurse
☐ Other __________________________________________________________________________________________________________________

The Bone Course: Recent Advances in the Management and Treatment of Bone Diseases

Recent Advances in
the Management and Treatment
of Bone Diseases

September 27, 2008
at the
Doubletree Hotel Chicago –
Arlington Heights

This activity is for primary care physicians, rheumatologists, endocrinologists, OB/GYNs, and other health care providers who treat patients with bone diseases.

Jointly sponsored by the University of Massachusetts Medical School Office of Continuing Education and the National Association for Continuing Education.

UMMS designates this educational activity for a maximum of 4.0 AMA PRA Category 1 Credit(s)™.

There is No Charge for Program Registration.
PROGRAM SUMMARY

The purpose of this course is to provide health care professionals with an authoritative review and update on the management of common bone diseases including post menopausal osteoporosis and osteoporosis in men, Paget’s disease and skeletal malignancies. An expert faculty will address state of the art approaches to prevention, diagnosis and treatment of bone disease, including a brief consideration of new drugs in development.

In planning this CME activity, the National Association for Continuing Education (NACE) performed a needs assessment. A literature search was conducted, national guidelines were reviewed, survey data was analyzed, and experts on each therapeutic area were consulted to determine gaps in practitioner knowledge, competence or performance.

Learning objectives (see below), linked to identified gaps, were developed and will be addressed by each presenter. This multidisciplinary program will utilize a variety of educational techniques incorporating the various aspects of Adult Learning Principles. There will be emphasis on audience participation utilizing interactive case-based presentations to deliver educational material. Participants will be asked to engage in pre and post testing to collect data for outcome studies and to uncover unmet needs for future programming. Each participant will be provided with a syllabus containing presentations, clinical tools, and practical guidelines at the start of the program to be used for future reference.

LEARNING OBJECTIVES

At the conclusion of this CME activity, attendees will be able to:

- describe the epidemiology and pathogenesis of common bone diseases: Osteoporosis, Bone Cancer, Paget’s Disease
- understand and implement current guidelines for the assessment, diagnosis and treatment of bone diseases
- identify successful measures to prevent disorders of bone and mineral metabolism
- discuss current controversies in the management of bone diseases
- explain the gap between knowledge and practice in the management of bone diseases and strategies for rectifying this
- recognize and avoid pitfalls in the use of bone densitometry
- understand the mechanism of action of current approved therapies, as well as those in development
- recognize the skeletal complications related to bone metastases and cancer therapy
- identify unmet needs in the management of bone diseases and ongoing research initiatives

FACULTY

David W. Dempster, PhD
Course Director
Professor of Clinical Pathology
Columbia University, New York
Director, Regional Bone Center
Helen Hayes Hospital
West Haverstraw, New York

Kenneth W. Lyles, MD
Professor of Medicine
Duke University Medical Center
Durham, NC

G. David Roodman, MD, PhD
Professor of Medicine Vice Chair for Research School of Medicine,
University of Pittsburgh
Director, Center for Bone Biology
UPMC Health System
Director, Myeloma Program
at UPCI Pittsburgh, PA

AGENDA

Saturday, September 27, 2008

7:15 - 7:45 AM  Continental Breakfast and Registration
7:45 - 8:00 AM  Introduction – David W. Dempster, PhD
8:00 - 9:00 AM  Pathophysiology and Treatment of Postmenopausal Osteoporosis
And Osteoporosis in Men
David W. Dempster, PhD
9:00 - 10:00 AM  Cancer and Bone: Pathogenesis and Treatment
G. David Roodman, MD, PhD
10:00 - 10:15 AM  Break
10:15 - 11:15 AM  Pathophysiology and Treatment of Paget’s Disease
Kenneth W. Lyles, MD
11:15 - 12:00 PM  Interactive Panel and Case Discussion

CONTINUING EDUCATION

Application for CME credit has been filed with the American Academy of Family Physicians. Determination of credit is pending.

This activity has been planned and implemented in accordance with the Essential Areas and Standards of the Accreditation Council for Continuing Medical Education (ACCME) through the joint sponsorship of the University of Massachusetts Medical School (UMMS) and the National Association for Continuing Education. The University of Massachusetts Medical School is accredited by the Accreditation Council for Continuing Medical Education (ACCME) to provide continuing medical education for physicians. The University of Massachusetts Medical School designates this educational activity for a maximum of 4.0 AMA PRA Category 1 Credit(s)™. Physicians should only claim credit commensurate with the extent of their participation in the activity.

Under the auspices of the University of Massachusetts Medical School Office of Continuing Education this offering meets the requirements for 4.8 contact hours, as specified by the Massachusetts Board of Registration in Nursing (244-CMR 5.04). Each nurse should claim only those hours of credit that he/she actually spend in the educational activity.

Policy on Faculty and Provider Disclosure: It is the policy of the University of Massachusetts Medical School to ensure fair balance, independence, objectivity and scientific rigor in all activities. All faculty participating in CME activities sponsored by the University of Massachusetts Medical School are required to present evidence-based data, identify and reference off-label product use and disclose all relevant financial relationships with those supporting the activity or others whose products or services are discussed. Faculty disclosure will be provided in the activity materials.

SUPPORTER

This program was supported through an educational grant from

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7860 Peters Road, Suite F-111, Plantation, Florida 33324
For Registration — Phone Toll Free: 1-866-266-6223 • Fax: 954-723-0353

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City_____________________________________ State ______ Zip Code/Postal Code ________________
Day Phone Number _________________________ Eve. Phone Number ___________________________
Fax ______________________________ Email Address (Required) ______________________________

Check one: □ Physician □ Physician Assistant □ Nurse Practitioner □ Nurse
□ Other ____________________________________________________________

The Bone Course: Recent Advances in the Management and Treatment of Bone Diseases

Saturday, October 11, 2008
At the
Tampa Marriott Westshore
1001 N. Westshore Blvd. • Tampa, FL • 813-287-2555

There is no charge for this activity.
Attendees must register in advance. Reservations for this program will be taken on a first come, first reserved basis. Space is limited so please register early. You will receive a confirmation as to your registration by mail or email. This confirmation will serve as your admission ticket for the program.
**PROGRAM SUMMARY**

The purpose of this course is to provide health care professionals with an authoritative review and update on the management of common bone diseases including post menopausal osteoporosis and osteoporosis in men, Paget’s disease and skeletal malignancies. An expert faculty will address state of the art approaches to prevention, diagnosis and treatment of bone disease, including a brief consideration of new drugs in development.

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Professor of Medicine  
Vice Chair for Research School of Medicine  
University of Pittsburgh  
Director, Center for Bone Biology  
UPMC Health System  
Director, Myeloma Program  
at UPCI Pittsburgh, PA

**Saturday, October 11, 2008**

7:15 - 7:45 AM  
Continental Breakfast and Registration

7:45 - 8:00 AM  
Introduction – David W. Dempster, PhD

8:00 - 9:00 AM  
Pathophysiology and Treatment of Postmenopausal Osteoporosis  
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10:00 - 10:15 AM  
Break

10:15 - 11:15 AM  
Pathophysiology and Treatment of Paget’s Disease  
Kenneth W. Lyles, MD

11:15 - 12:00 PM  
Interactive Panel and Case Discussion

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