

CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

A Publication of New Mexico Clinical Research & Osteoporosis Center

300 Oak St. NE, Albuquerque, NM 87106

www.nmbonecare.com

Tel. (505) 855-5525

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Bone School for Doctors

We all know that education "counts." The more we know about something the better we can do it. This is true for our personal relationships, sports, hobbies, and job. For the medical profession, continuing education is a way of life. Since medical knowledge is expanding at a tremendous pace, doctors and nurses need to use all the tools available to them to keep up.

At New Mexico Clinical Research & Osteoporosis Center, we take special pride in our efforts to teach ourselves, and others, about new medical developments. Through our research programs we are constantly challenged to learn new concepts for patient care, and to use them in the safest possible way with our patients. While we are interested in all aspects of medical care, our special focus is on the management of osteoporosis.

Many of our research studies are testing new ways to prevent and treat osteoporosis. To learn more about how to do this, we are continually learning from others. We do this by reading medical journals, talking to our colleagues in

person or by email, and traveling to meetings. If one of us is not in the office when you need to be seen, it is most likely because of an out of town meeting.

It is traditional in the medical profession to combine teaching with learning. We therefore donate time to teaching medical students, healthcare providers, and the public about osteoporosis. We have all participated in writing scientific papers for presentation at medical meetings and publication.

Julia Chavez speaks to groups about bone health. Dr. Rudolph is a regular mentor to medical students seeing hospital patients. Dr. Lewiecki, in his role as President of the International Society for Clinical Densitometry, has traveled throughout the US, as well as in Europe, Asia, and South America to lecture on quality in bone density testing and the treatment of osteoporosis. He is a teacher at what could be called an international "Bone School for Doctors."

It is our goal to apply the latest in medical advances, in the most humane way possible, to the care of our patients, and to share our knowledge with others.

Staff

E. Michael Lewiecki, MD, FACP

*Osteoporosis Director
Internal Medicine*

Lance A. Rudolph, MD

*Research Director
Internal Medicine*

Julia R. Chavez, CNP

Adult Healthcare

Eric W. Best, MD

Internal Medicine

Yvonne Brusuelas

*Management Director
Osteoporosis Education*

Valerie White, CCRC

*Research Manager
Drug Study Coordinator*

Teri Cordova

Research Executive Assistant

Sheri Romero, LRV, CCRC

Drug Study Coordinator

Michele Dingman, BA, CCRC

Drug Study Coordinator

Aspen Montoya, CRC

Drug Study Coordinator

Beatrice Santillanes

Research Medical Assistant

Donna Partington, LPN

Research Medical Assistant

Amaris Puzak

Research Assistant

Isabel Torres, RT(R), CDT

Bone Densitometry Technologist

Patricia Katz, LPN

Drug Study Recruiter

Ginni Laroi

Drug Study Recruiter

Janette Wiggins

Medical Assistant

Julianne Morris

Medical Assistant

Jo Ann Chavez

Billing Supervisor

Lois Kollars

Billing/Bookkeeping Specialist

Rebecca Herrera

Medical Secretary

Sofia Cruz-Howerton

Medical Secretary

Would you like to receive this newsletter in electronic format?

We have had requests for distribution of our newsletters outside of the office. There are two ways to do this electronically: 1. Visit our website at www.nmbonecare.com to download the newsletter in PDF format, which you may then print on your home printer, or 2. To be placed on a list for automatic quarterly distribution of the newsletter as a PDF file attached to email, send your request to Yvonne Brusuelas at ybrusuelas@nmbonecare.com.

Clinical Research

Our clinical research program is recruiting patients to participate in studies to test new medications and evaluate new uses for currently available drugs. By participating in a study you will have the opportunity to use one of these medications, have free examinations and tests, and receive reimbursement for your time and travel. If this interests you, please take a few minutes to read the major criteria for participation.

If you think you may qualify for a study, ask for Valerie White, the Research Manager, or call the Research Dept. at (505) 923-3232.

Feel free to pass this newsletter to a friend or relative who may be interested. The drug study information will be updated quarterly, since we are continually starting new studies and closing out old ones. If there is nothing for you now, there may be next time.

Postmenopausal Osteoporosis Treatment & Prevention

This is a 1-year study for postmenopausal women with osteoporosis or low bone mass to compare two approved medications, monthly oral ibandronate with once weekly alendronate.

You may qualify for this study if you are:

- A woman, age 55 to 84 at least five years postmenopausal
- Able to walk
- Low Bone Density of the spine and hip
- Able and willing to comply with the protocol for its duration.

2250

Once A Year Treatment For The Prevention Of Bone Loss In Postmenopausal Women With Osteopenia

You may be eligible to participate in a 2-year clinical research study designed to evaluate the efficacy and safety of a new investigational drug for the prevention of bone loss in postmenopausal women with Osteopenia. Compensation is available to qualified participants.

You may qualify for this study if you are:

- A female, at least 45 years of age, and

- Naturally or surgically postmenopausal, and
- Generally in good health, and
- Must not have been on hormone replacement therapy for the last six months, and
- Meet all other entry criteria.

2254

Osteopenia Research Study

This is a clinical research study designed to evaluate the safety and effect of an investigational oral medication on bone density in postmenopausal women with Osteopenia (low bone density).

You may qualify if you:

- Are female, between the ages of 50 and 75 inclusive
- Are postmenopausal, defined as no menstrual period for at least 2 years

- Have not been on hormone replacement therapy for the last 6 months
- Are generally in good health
- Meet all other entry criteria

Reimbursement for time and travel is available to qualified participants.

2256

Restless Legs Syndrome

We are looking for men and women to participate in a 12 week study testing an investigational treatment of Restless Legs Syndrome (RLS) using a marketed drug.

You may qualify for this trial if you meet all study entry criteria:

- Men and Women who are between the age of 18 to 79

- Females should be non-child bearing potential (i.e., physiologically incapable of becoming pregnant, including any female who is postmenopausal)
- Must experience sleep disturbance when RLS symptoms are present
- Usually experience onset of RLS symptom no earlier than 5PM and prior to bedtime.

2258

Osteoporosis In Men

We are looking for men to participate in a 2 year clinical research study testing an investigational treatment for osteoporosis.

You may qualify for this clinical research study if you:

- Are age 25 to 85
- Have a low bone mineral density and diagnosis of osteoporosis
- Do not have any major exclusionary medical conditions
- You have not had therapies such as treatment with bisphosphonates in the last 2 years,

- Prior use of PTH for more than one week
 - Any prior use of strontium, ranelate or sodium fluoride
 - Use of systemic corticosteroids in the last year,
 - Prior exposure to anabolic steroids. (abbreviated list)
 - You are willing to attend scheduled study visits and procedures per protocol
- Reimbursement for time and travel is available to qualified participants.

2263

Hypertensive Diabetics

This is a 22 week clinical research study designed to look at the ability of several different drugs, alone or in combination to lower blood pressure in people with diabetes. Compensation is available to qualified participants.

You may qualify for this clinical research study if you:

- Are Male or female, age 30-75

- Diagnosed with Type 2 Diabetes, on stable treatment for at least 2 months $HbA1c \leq 9.0\%$
- Have high blood pressure
- No heart attack, coronary artery bypass, or intra-coronary interventions within 6 months
- No donation of blood/blood products for 30 days before, during or after treatment

2235

**Osteoporosis Foundation
of New Mexico
Osteoporosis Support
Group's**

**Educational
Presentations**

2nd Thursday of every month:
Downtown Osteoporosis
Support Group
Rehabilitation Hospital of New
Mexico
(formerly St. Joseph's
Rehabilitation Hospital)
505 Elm St NE
Albuquerque, NM 87102
1:30 - 3:00PM

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April 14, 2005
Kathleen Blake, CDT
"What is Bone Mineral
Density"

May 12, 2005
Dr. E. Michael Lewiecki
"What's New in Osteoporosis"

June 9, 2005
Dr. Kristine Bordenave
Topic to be determined

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The support group is open to the public. It is a great opportunity to talk to osteoporosis experts for as long as you want.

Consider attending if:
You have osteoporosis,
You have a loved one with
osteoporosis, or
You are interested in
learning more about
osteoporosis.

To RSVP your attendance
call 338-6333

Postmenopausal Osteoporosis

This is an open label, 12 month research study of the effect of an investigational medicine in postmenopausal women with osteoporosis treated previously with risendronate or alendronate. Reimbursement for time and travel is available to qualified participants.

You may qualify for this study if you are a:

- Woman, at least 10 years post

- menopausal (natural)
- Have been using resendronate or alendronate (daily or weekly) uninterrupted for a minimum of 24 months
- Must be able to self-inject or have a person to perform daily injections
- Take at least 1000 mg of calcium (from all sources)
- Generally in good health

2249

Treatment of Chronic Low Back Pain

This is a 1-year study to evaluate the safety of bicifadine in patients with moderate to severe chronic low back pain.

You may qualify for this study if you are:

- Male or female, ages 18-65

- Women must be postmenopausal, surgically sterile or using birth control
- Able to walk
- Requires an average, daily analgesics for the treatment of low back pain over the past 3-months

2261

Postmenopausal Osteoporosis

This is a clinical research study designed to evaluate an investigational medication in the treatment of postmenopausal osteoporosis. If you meet all study criteria you may be eligible to participate. The study will last approximately 3 years. Compensation is available to qualified participants.

You may qualify if you are a:

- Postmenopausal female, between 60 and 90 years
- Have osteoporosis
- No use of bisphosphonate treatment for osteoporosis for three or more years cumulatively,
- Generally in good health, Meet all other criteria.

2253

Are you a postmenopausal woman with osteoporosis or osteopenia?

This 12 month study is for postmenopausal women with Osteoporosis or Osteopenia, previously treated with daily/weekly Fosamax® or Actonel® and not tolerating the GI side effects of the medication (e.g., dyspepsia, abdominal pain, nausea, and diarrhea).

You may qualify for this study if you meet all study entry criteria

- Have discontinued daily/weekly Fosamax® or Actonel® therapy because of GI intolerance
- Have discontinued previous osteoporosis medication for at least 3 months
- Are able to stand or sit in the upright position for 60 minutes
- History of major, upper GI disease or active ulcer
- Generally in good health

2260



Woman to Woman By

Julia Chavez, CNP

Is Your Back Your Weak Spot?

More than 80% of adults in the U.S. experience low back pain at some time in their life. Most people recover with time and self-care. Low back pain can occur with or without an injury. It can materialize as a dull ache or a very sharp pain and even radiate down the legs.

Low back pain and sciatica often occur together. Sciatica is caused by a problem with the sciatic nerve, which starts at the low back. It is usually caused by nerve inflammation rather than a "pinched nerve." It can create symptoms of pain, numbness or tingling. Sometimes it is difficult to distinguish nerve irritation from a pulled muscle.

The good news is that low back pain, including sciatica, has an excellent chance of complete recovery. Back pain is common because we spend a lot of time sitting. One common cause is just being out of shape. Osteoporosis is also a common cause.

You must seek urgent care if you have significant leg pain along with numbness in the groin or loss of bladder or bowel control. Other symptoms that require urgent care are intense low back pain accompanied by unexplained weight loss, fever or trauma. These conditions are unusual, but based on your symptoms and physical examination, your doctor can determine if you need an x-ray or MRI.

On The Light Side

In the beginning, God covered the earth with broccoli, cauliflower, and spinach, with green and yellow and red vegetables of all kinds, so that Man and Woman would live long and healthy lives. Then using God's bountiful gifts, Satan created Ben and Jerry's and Krispy Kreme. And Satan said: "You want hot fudge with that?" and Man said: "Yes!" And Woman said: I'll have one too, with sprinkles." And so, they gained 10 pounds,

And God created the healthful yogurt that Woman might keep the figure that Man found so fair. And Satan brought forth white flour from the wheat, and sugar from the cane, and combined them. And Woman went from size 2 to size 14. So God said: "Try my fresh green garden salad." And Satan presented crumbled blue cheese dressing and garlic toast on the side." And Man and Woman unfastened their belts following the repast.

God then said: "I have sent you heart healthy vegetables and olive oil in which to cook them." And Satan brought fourth deep-fried coconut shrimp. And Man's cholesterol went through the roof.

God then brought forth running shoes so that his Children might lose those extra pounds. And Satan came forth with cable TV with remote control so Man would not have to toil changing the channels.

God then gave lean beef so the Man might consume fewer calories and still satisfy his appetite. And Satan created McDonald's and the 99-cent double cheeseburger. Than Satan said: "Yes!" and Super size 'em!" And Satan said: "It is good." And Man and Woman went into cardiac arrest.

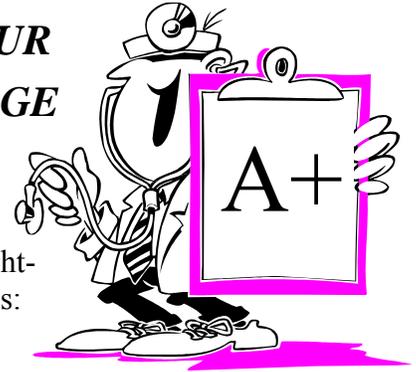
God sighed and created quadruple bypass surgery.

Satan chuckled and created HMO's.



HOW MUCH DO YOU KNOW ABOUT OSTEOPOROSIS?

TEST YOUR KNOWLEDGE



- Which of the following are considered weight-bearing exercises:
 - Jogging
 - Walking
 - Stair climbing
 - Dancing
 - All of the above
- Osteoporosis is strictly a women's disease.
True / False
- Osteoporosis is often called a "silent disease."
True / False
- The recommended amount of calcium per day is 1200-1500 mg for all adults.
True / False

- Answers:**
- All of the above. Weight-bearing exercises are important for building and maintaining bone mass.
 - False. Osteoporosis is not strictly a women's disease, though it is less common in men. Today, 2 million men in the United States have osteoporosis, and another 12 million are at risk.
 - True. Osteoporosis is often called a "silent disease" because there are no symptoms, so you can't feel your bones becoming weak. Sometimes, you will not know you have thinning bones until a bone breaks.
 - True. The National Osteoporosis Foundation recommends 1200-1500 mg of calcium per day for all adults. There are about 1200 mg of calcium in 3 cups of low-fat yogurt, or 6 oz of cheddar cheese.

Ask Dr. Mike Lewiecki about . . . OSTEOPOROSIS

Dear Dr. Lewiecki– I have been told that some people break bones and don't even know it. How is this possible, and how do I know if I have broken any bones? And if I have broken bones without knowing it, what will that do to me? Please give me the answers, because I have osteoporosis and I worry about these things. Jane C. Los Lunas, NM.

Dear Jane – What you have heard is true. The most common type of fracture due to osteoporosis is in the spine, called a vertebral fracture, or VF. Each year in the US, there are about 700,000 VFs. Only one-third of these are “clinically apparent.” This means they caused enough pain for a patient to seek care, get an X-ray, and have it interpreted and reported correctly. The rest of those with VFs probably have minor back pain or no pain at all. They don't see a doctor, or see a doctor and don't get additional tests.

The consequences of VFs, even those that are undiagnosed, are significant. They can cause loss

of height, stooped posture (Dowager's hump), be harmful to lung function, reduce the quality of life, and increase the risk of death due to many causes. In addition, anyone with a VF is at very high risk of having more fractures in the spine and in other bones. Aggressive treatment to reduce the chances of more fractures is usually advisable.

If a VF is suspected, the only way to know for sure is to get an image of the spine. In the past, this required an X-ray. Recently, a new procedure has been developed that can diagnose VFs with greater convenience, less radiation, and lower cost than conventional X-ray. It is called VFA, for Vertebral Fracture Assessment. This can be done with a DXA machine at the same time it is used to measure bone density. The results of this simple additional test may alter the diagnostic classification and change the treatment plan for some patients. VFA is now covered by Medicare and some health plans.

Sincerely,

Mike Lewiecki

THE T-SCORE STORY

Do you ever wonder why things are the way they are? If the answer is no, stop reading now and turn on the TV. If you are the curious type, read on. This is the story behind a term that is familiar to anyone with an interest in osteoporosis.

The “T-score” is a number used to report bone mineral density. A T-score of -2.5 or below means you have osteoporosis. But why “T?” Why is it not a “B”-score or “Q”-score? A recent article in the Journal of Bone and Mineral Research sheds some light on this matter. The man who gets credit for coining this term is Dr. Robert Neer, a clinician and medical researcher in Boston. After working for years in his bone density laboratory with his friend and co-worker Tom Kelly, the time came when it seemed necessary to have a name for the number the instruments were generating. Many ideas were tossed around, but the final decision, and one that greatly amused Dr. Neer, was to call it a T-score, “T” for Tom. Both men went on to make great contributions to the field of os-



Support osteoporosis education in New Mexico. The Osteoporosis Foundation of New Mexico is a local non-profit 501(c)(3) foundation. Consider a tax-deductible donation or bequest. Donations may be mailed to Osteoporosis Foundation of New Mexico at 300 Oak St. NE, Albuquerque, NM 87106. For more information, call Yvonne Brusuelas at 505-855-5627, or visit the web site at www.osteoporosisfoundationnm.org.