

# CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

A Publication of New Mexico Clinical Research & Osteoporosis Center

300 Oak St. NE, Albuquerque, NM 87106

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## FRAX™ and the NEW OSTEOPOROSIS TREATMENT GUIDELINES

Years in the making, the new National Osteoporosis Foundation guidelines for treatment of osteoporosis and low bone density (osteopenia) have recently been published. They were developed by Dr. John Kanis, Professor Emeritus, University of Sheffield, UK for the World Health Organization (WHO) and adapted by the National Osteoporosis Foundation for use in the United States. These guidelines take the form of an online computer tool called FRAX™ (WHO Fracture Risk Assessment tool). The tool is still in the testing stage and the guidelines don't substitute for physician judgment. This attempts to bring some clarity to making a decision whether or not a patient should be treated with prescription medication. These guidelines are new because they use an assessment of ten-year fracture risk to aid physicians in determining if patients should be treated with medication.

The new guidelines take into account such factors as gender, race, age, weight, height, bone density score, personal history of fracture, family history of fracture, current smoking, corticosteroid therapy, the presence of rheumatoid arthritis, significant alcohol intake (3 or more servings per day) and any other underlying disorders strongly associated with osteoporosis, such as type I diabetes, premature menopause or malabsorption. Using clinical research studies to examine the risk of fracture associated with

each of the above conditions, FRAX™ is able to calculate an overall and hip fracture risk over the next 10 years.

When the 10-year risk of any fracture is 20% or greater or the 10-year risk of hip fracture alone is 3% or greater, drug treatment is recommended. The disability caused by fractures, the cost of treating fractures and the cost and effectiveness of drug therapy in reducing fracture risk are taken into account. There are many other risk factors for fracture that are not taken into account by these guidelines that were difficult to put into the tool or did not affect the outcome of the calculation.

What we have found is that there are some patients who would have been treated with medication under the old guidelines using bone density scores and underlying risk factors alone, who now don't qualify for treatment. Conversely, there are also some patients who may not have qualified for treatment under the old guidelines but who do qualify for treatment under the new guidelines.

It's important to note that guidelines do not substitute for the clinical judgment of your physician. Your doctor may feel that your fracture risk is higher than the calculated risk in which case drug treatment may be recommended anyway. Although the new guidelines provide some valuable guidance, they are not a substitute for physician-patient collaboration.

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## 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, 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.*

### Osteoarthritis of the Hip or Knee

A 18-week research study for an investigational medication for treatment of Osteoarthritis in the hip and knee.

#### You may be eligible to participate if you are:

- If you are between 30 and 80 years old;
- Currently taking Tramadol or other pain medications for relief of hip and knee pain due to Osteoarthritis.

*NMT 1077-302*

### Osteoarthritis of the Knee

This is an 18 week research study of an investigational treatment for osteoarthritis of the knee.

#### You may be eligible to participate if you are:

- Are at least 40 years old;
- Have been diagnosed with or think you might have osteoarthritis of the knee;
- Take medication for relief of pain in your knee at least 15 days a month.

*Combinatorx*

### Treatment for Irritable Bowel Syndrome

This is a 19-week, study of investigation medication in female subjects with Diarrhea pre-dominant or alternating Irritable Bowel Syndrome.

#### You may be eligible to participate if you are:

- A woman between 18 and 65;
- Suffering from abdominal pain or discomfort associated with diarrhea more than 3 days per month.

*VPI-TOFP-203*

### Insomnia

This is a 2-4-week, randomized, placebo controlled study for safety and efficacy of an investigational medication in patients with primary chronic insomnia. Upon completion of this study you may be able to participate in a 52-week open-label extension study.

#### You may qualify to participate if you are:

- Between the ages of 18 and 64;
- Suffer from insomnia at least 3 nights a week for the past year.

*Org176001*

## Diabetic Neuropathy

This is a 17-21 week study for an investigational medication for people suffering from pain associated with Diabetic Peripheral Neuropathy.

### You may be eligible to participate if you are:

- If you are a Diabetic over the age of 18;
- Experiencing pain tingling and numbness in your feet for at least 6 months.

*GSK PXN 110448*

## Osteoporosis & Kidney Function

This is a 1 year, randomized study of open label Ibandronate (Boniva) or Alendronate (Fosamax) in postmenopausal women with Osteoporosis at risk for renal disease. This study will compare the effects of different methods of administering the medication.

### You may be eligible to participate if you are:

- Over the age 65;
- Have been diagnosed with Osteoporosis;
- This study is open to women who have been previously treated for Osteoporosis.

*Roche BA 20341*

## Diabetes treated with Metformin

This study is 12 week, study of an investigational medication in conjunction with Metformin to determine if it can help in the control of Type 2 Diabetes.

### You may be eligible to participate if you are:

- If you have Type 2 Diabetes;
- Are not taking Insulin;
- Are currently taking Metformin as part of your Diabetes regimen.

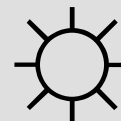
*Pfizer A 7941006*

## Why Should I Participate In A Clinical Trial?

As a volunteer in a clinical research trial you will not only take on an active role in your own health care but you will also:

- Participate in the development of medical therapies that may offer better treatments and cures for diseases.
- Gain access to new research treatments before they become publicly available in the marketplace.
- Receive closely monitored health care for your condition.
- May receive compensation for your time and travel expenses.

Whatever reason you chose to participate in clinical research, be assured that you are engaging in the advancement of medical treatments, therapies, and cures for chronic or life-threatening diseases.



# IT'S A FACT — AGE AFFECTS A BODY

Osteoporosis and low kidney function –  
conditions you may not be aware of.



**IF YOU ARE OVER AGE 65 WITH OSTEOPOROSIS OR LOW KIDNEY FUNCTION  
YOU MAY QUALIFY TO PARTICIPATE IN A CLINICAL TRIAL TO EVALUATE THE EFFECTS OF  
APPROVED OSTEOPOROSIS MEDICATIONS ON KIDNEY FUNCTIONS.**

**IF YOU ARE INTERESTED IN LEARNING MORE CALL**

**923-3232**

**or visit [www.nmbonecare.com](http://www.nmbonecare.com)**

COMPENSATION FOR TIME & TRAVEL IS AVAILABLE FOR QUALIFIED PARTICIPANTS

**NEW MEXICO CLINICAL RESEARCH & OSTEOPOROSIS CENTER**

300 Oak Street NE, Albuquerque, New Mexico 87106

E. Michael Lewiecki, MD Lance A. Rudolph, MD



**Woman  
To  
Woman**  
By  
Julia Chavez, CNP

**ALLERGIES AND TREATMENTS**

Allergy symptoms include sneezing and itching, nasal congestion runny nose, and post-nasal drip (the sensation that mucus is draining down the back of the throat). These symptoms can also occur from overuse of certain drugs, some medical conditions and other factors that may not be identified. Fortunately, the symptoms of allergic rhinitis can usually be controlled with a combination of watching your environment, medications and immunotherapy.

I would like to address immunotherapy. This is a very confusing treatment for many because many people refer to it as "allergy shots". Many people come into our office requesting an allergy shot because someone has told them that they can get one shot and feel better immediately. The shot they are referring to is a steroid shot which is not recommended in this day and age. This was a treatment which was used quite extensively many years ago but that was not without its consequences.

Immunotherapy shots are tiny doses of the allergen given twice a week over a period of several years in order to build immunity. It is still a very good method for dealing with your allergies but is not a "once a year shot".

Preferable methods of dealing with allergies are nasal sprays which have the steroid in them but only affect the head and not the entire body. If that method doesn't help then antihistamines are a good addition to the treatment. And if your allergies are still not controlled with nasal sprays and antihistamines, there is a once a day tablet that can also be added to your treatment regimen. The last resort treatment is prednisone for a week.

If you have questions, please see your healthcare provider.

**Osteoporosis Foundation  
of New Mexico**

**Educational  
Presentations**

2nd Thursday of every month:  
Manzano Mesa  
Multigenerational Center  
501 Elizabeth SE  
Albuquerque, NM 87123  
(505) 275-8731

1:30 - 3:00PM

April 10, 2008

Steven Wong

Topic: "Dreaming the Bones: A  
Jungian Approach to Osteoporosis"

May 8, 2008

Dr. Elliot Pierce

Topic: "Diagnosing Osteoporosis and  
Tips on How to Treat Without Meds"

June 12, 2008

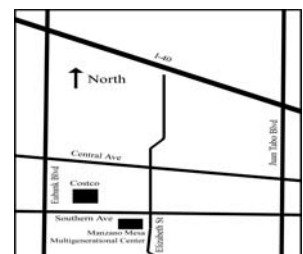
E. Michael Lewiecki, MD

Topic: "Osteoporosis Treatment  
Secrets"

These meetings are 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.



**Ask Dr. Mike Lewiecki about . . . OSTEOPOROSIS**

**Dear Dr. Lewiecki— I am 74 years old and definitely shorter than I used to be. Is this a normal part of aging, or does it mean there is something wrong with my bones? Alice R., Gallup, NM.**

Dear Alice – Most of us get shorter with age. This is commonly due to degenerative disc disease, or dehydration and shrinkage of the cushions between each of the vertebral bodies in the spine. Changes in posture due to weakened back muscles may cause some loss of height. Scoliosis, a sideways curvature of the spine, may cause height loss if it worsens with age.

When there is more than one and one-half inches of height loss compared to your maximum height, or more than three-quarters inch height loss as measured in a doctor’s office with an instrument called a stadiometer, it could be due to a fracture in the spine. While it is possible to have spine fractures with less height loss or no measurable height loss, these levels of height loss are suspicious for a spine (vertebral) fracture. It is

important to know whether you have such a fracture, because it places you in a high risk category for future fractures and may mean that you need strong treatment.

Any adult with a vertebral fracture that is not due to major trauma, such as an auto accident or falling off a ladder, probably has osteoporosis, regardless of what a bone density test shows. How do we know if you have a vertebral fracture? A simple image of the spine by X-ray or with a bone density machine using dual-energy X-ray absorptiometry (DXA) can usually provide the answer. Doctors look to see if there is a change in the shape of the vertebral body. If it is crushed or wedge-shaped instead of having its normal block-like appearance, then it may be a vertebral fracture. Since deformities of vertebral bodies may also be result of diseases other than osteoporosis, additional tests may be necessary. If it is an osteoporotic vertebral fracture, treatment can reduce the risk of having it happen again.

For more information on diagnosing vertebral fractures, see the column to the right.

*Mike Lewiecki*

**DIAGNOSING VERTEBRAL FRACTURES**

Vertebral fractures are different than fractures of other bones. They may cause no pain, and may not be recognized without looking at an image of the spine. Even if there is no pain, it is important to recognize that they are there, because it may mean that there is a high risk of future fractures that could be much more serious. And there is good medicine to reduce that risk, if necessary.

Vertebral fracture assessment (VFA) is an image of the spine that can be made at the same time that bone density is measured. It is fast and painless, with less radiation and greater convenience than having a standard spine X-ray. When interpreted by a skilled physician, it can be very helpful in managing your skeletal health. Knowledge of a vertebral fracture may change the diagnostic classification, estimation of fracture risk, and treatment decisions.

The main problem with VFA is insurance coverage. Although it is inexpensive, it is not covered by all insurance plans. As with many new tests, it sometimes takes time for insurance to recognize its value.



**Support osteoporosis education in New Mexico. Help to reduce the burden of osteoporotic fractures. 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.**