

CLINICAL RESEARCH & OSTEOPOROSIS NEWSLETTER

A Publication of New Mexico Clinical Research & Osteoporosis Center

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Healthcare Reform and You

Congratulations if you have health insurance and are happy with the cost and the benefits you receive. Unfortunately, for many this is not the case. The number of uninsured is high, especially in New Mexico. The cost of health insurance is also high, and rising every year faster than the rate of inflation. If you are fortunate enough to have insurance, you may find that “co-pays” and “deductibles” are more than you can afford, impossible to understand, and sometimes charged in error. You may have difficulty finding and keeping a primary care provider, or have long waits before getting an appointment or having a test completed. You may be restricted in the hospital, lab, or X-ray facility you can use. Drugs may have to be obtained by mail order (no more friendly neighborhood pharmacist), with rules about generics, brand names, and “tiers” of drugs. With Medicare, you may encounter the “donut hole,” where you lose your drug coverage until you have first spent a specified amount of money. Medicare is running out of money as the population ages and there are fewer younger workers to contribute to the pool of available funds. Technological advances are pricey to develop and expensive to maintain. It costs about \$1 billion to develop a new drug before it is approved for use, but it may not be affordable even if it is available.

For these reasons and many others, our entire healthcare delivery system has rightfully come under great scrutiny. The three areas of major concern have been identified as coverage, cost, and quality. Universal health insurance coverage of some type is generally felt to be a desirable goal and is consistent with policies in most other Western countries. Cost containment, with inevitable restrictions on some types of medical care, is a necessary but contentious part of the package. But what about quality? Are there safeguards to assure that the medical care is as good as it can be? Is preventive healthcare available when it is needed? With bone density testing for osteoporosis, for example, Medicare cuts in reimbursement are so severe that most facilities are being paid far less than the cost of providing the test, forcing some to close down and others to restrict their services. The result is likely to be fewer patients with osteoporosis being diagnosed, fewer being treated, more broken bones, and higher fracture-related costs to Medicare.

What to do about all of this? First, stay informed. Organizations such as the AARP are a great source of information. Second, don't listen to bizarre rumors. There are no “death squads” for seniors being planned. Finally, make your thoughts heard. Tell your senators and congressman how you feel about your healthcare, so that we can get the best healthcare we can afford for ourselves and future generations.

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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.

IBS with Constipation

This is a randomized, placebo controlled study of an investigational medication to relieve the symptoms of Irritable Bowel Syndrome that is constipation predominant. You may qualify for this study if you are:

- Over the age of 18
- Have less than 3 bowel movements per week for at least the past month
- Have pain associated with your symptoms.

Forrest Lin-MD/31

Osteoarthritis of the Knee

This is a randomized placebo controlled study of an investigational IV medication vs Naproxen for treatment of the symptoms of osteoarthritis of the knee. You may be eligible to participate if you are:

- Over the age of 18
- Have osteoarthritis of the knee
- Are able to take NSAIDs such as Aleve, Advil or Celebrex

Pfizer OA

Osteoarthritis of the Hip

This is a, randomized, placebo controlled study of an investigational IV treatment for the symptoms associated with osteoarthritis of the hip. You may be eligible to participate if you are:

- Over the age 18
- Have osteoarthritis pain in either the hip
- Unable to take NSAIDs or are getting inadequate relief from current NSAIDs (i.e. Ibuprofen, Celebrex or Naproxen), or are considering invasive treatments such as injections or replacement.

Pfizer OA

Hypertension

This is a randomized, placebo controlled study of an investigational medication in combination with an approved medication for the treatment of hypertension. You may qualify for this study if you are:

- Over the ages of 18
- Have high blood pressure controlled with less than 3 medications
- Have no history in the past 6 months of heart attack or stroke.

Takeda 491

Heartburn

This is a randomized, placebo controlled study of an investigational medication for Heartburn or Gerd. You may qualify for this study if you are:

- Over the ages of 18
- Take heartburn medication such as Prevacid or Nexium twice a day
- Have less than 1 episode of heartburn a week on your current medications

Takeda 178

Male Osteoporosis

A 24-month study to assess the safety and efficacy of an investigational drug in men with osteoporosis. You may be eligible to participate if you are:

- Between the ages of 30 and 80
- Have osteoporosis or are concerned you may have osteoporosis
- Are not currently being treated for osteoporosis

Amgen-Male

Gout Prevention

A six-month study to assess the prevention of gout flares when starting allopurinol or other urate lowering therapy. You may be eligible to participate if you are:

- Over the age of 18
- Are willing to start daily medication to prevent flares

Regeneron 815

Gout Flare

An 4-week research study for an investigational medication for treatment of active gout flares. You may be eligible to participate if you are:

- Over the age of 18
- Currently experiencing a gout flare for less than 2 days

Regeneron-814

Diabetes

A 3 and half year study of an investigational medication given once weekly to help control diabetes. You may be eligible to participate if you are:

- Over the age of 18
- Have type 2 Diabetes and are currently taking Metformin alone or Metformin plus one additional medication for the past 3 months
- Are not currently well controlled.

GSK Harmony

Nocturia

A 12 week study to assess the safety and efficacy of an investigational inhaled medication for the treatment of frequent night time waking to urinate. You may be eligible to participate if you are:

- Between the ages of 50 and 80 and
- Have more than 2 episodes a night, at least 5 nights a week, for the past 6 months

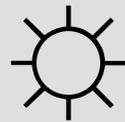
Serenity

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.



Osteoporosis

A 48-week research study of oral calcitonin vs. inhaled calcitonin in postmenopausal women with osteoporosis. You may be eligible to participate if you:

- Are a postmenopausal woman over 45 years of age
- Have osteoporosis and currently not be taking any bone medications
- Not currently being treated with hormone replacement therapy. *Unigene*

Osteoporosis

A clinical trial to assess the safety and efficacy of an investigational medication compared to already approved medications. You may be eligible to participate if you:

- Are a postmenopausal woman between 55 and 85
- Have osteoporosis
- Have not been treated with IV bone medications and have not taken oral bone medications in the past year. *Amg785*

Osteoporosis

This is a 4-year study of an investigational medication vs. placebo in postmenopausal women with osteoporosis. You may qualify for this study if you are:

- Over age 65
- Have not broken a hip
- Have osteoporosis that is not currently being treated with medications *Merck -018*

Osteoporosis

This is a 12-month open-label, randomized research study to compare Forteo (a daily injection) with Reclast a once a year infusion and includes a bone biopsy procedure. You may be eligible to participate if you:

- Are a postmenopausal woman between 55 and 89
- Have osteoporosis
- Have not been treated with Forteo or Reclast and not taken any oral bone medication within the past 2 years. *Lilly-SHOTZ*

Osteoporosis Prevention/Postmenopausal Symptoms

A 12-month study to assess the safety and efficacy of using a SERM with estrogen or alone in treating osteoporosis, postmenopausal hot flashes and endometrial hyperplasia. You may be eligible to participate if you are:

- Postmenopausal between 6 months and 5 years
- Do not yet have osteoporosis
- Are suffering from postmenopausal symptoms such as hot flashes, night sweats etc. *Wyeth-3307*

**Do you have
heartburn related
to
Gastro-
Esophageal
Reflux Disease
(GERD)?**

**Do you take
medication twice a
day for it?**

**We are participating in
a research study that
will help determine if
an investigational
medication can
control your
heartburn related to
GERD.**

**If you have GERD
related heartburn that
is controlled by taking
medication twice a
day you may qualify
for this study.**

**To learn more, call:
923-3232
to speak to our study
specialists.**

**If you qualify you will
receive study care and
study medication at no
cost
Financial compensation
for time and travel may be
provided.**



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

Back to Bolivia

I recently had the privilege of traveling back to Bolivia in South America where I once served in the Peace Corps for two years. This was my first trip back since I left in 1968.

The highlight of my return to the village was discovering that the little two room schoolhouse Escuela Maxwell, has been improved and is still in use. The school was named in honor of my hometown, Maxwell New Mexico. I took off my shoes and physically helped to make the adobes and to construct the school between 1966-1968. It gives me great pleasure to see that efforts from the past continue to affect people in positive ways.

Healthcare in underdeveloped countries can be challenging. As I visited with my 66 year old Bolivian friend, I discovered that she has osteoporosis. Her only treatment options were calcium and vitamin D and generic alendronate. Since she cannot afford the alendronate she really has no other options. I told her to do weight bearing exercises. This typically is not a problem in our country where we have more options and should discuss them with our provider. If you need to discuss your options please feel free to give us a call.

If you enjoyed this newsletter and would like to be placed on an electronic mailing list, email ybrusuelas@nmbonecare.com. The newsletter is produced on a quarterly basis.

**Osteoporosis Foundation
of New Mexico**

**Educational
Presentations**

Manzano Mesa
Multigenerational Center
501 Elizabeth SE
Albuquerque, NM 87123
(505) 275-8731

1:30 - 3:00PM

Quarterly in 2009:

February 19, 2009

Barbara Thorpe

Topic: "Vitamin D and Osteoporosis"

May 14, 2009

E. Michael Lewiecki, MD

Topic: "Update on Osteoporosis"

August 13, 2009

Shelley A. Rael, MS, RD, LD

Topic: "Nutrition and Bone Health
~more than Milk"

November 12, 2009

Elliot Pirece, MD

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

These meetings are open to the public. It is a great opportunity to talk to osteoporosis experts for as long as you want. There is limited space, so please sign up by calling 275-8731 in order to attend. A \$1 fee is collected in order to cover the cost of educational material.

Consider attending if:

- ❖ You have osteoporosis,
- ❖ You have a loved one with osteoporosis, or
- ❖ You are interested in learning more about osteoporosis.



www.ofnm.org

Ask Dr. Mike Lewiecki about . . . OSTEOPOROSIS

Dear Dr. Lewiecki— I have osteoporosis, but my doctor says it is just part of getting old and not to worry about it. What should I do? I don't want to end up being stooped over like friends I have seen who are now in nursing homes.

Rebecca V., Durango, CO.

Dear Rebecca – Osteoporosis is a common disease with serious consequences. Broken bones (fractures) due to osteoporosis may lead to persistent pain, disability, loss of independence, and death. Although osteoporosis is more common with advancing age, it is not “normal” and should not be placed in the same category as gray hair or wrinkled skin. More women than men have osteoporosis, primarily due to having smaller bones and bone loss after menopause. However, 2 out of every 10 patients with osteoporosis are men. It is not just a disease of women.

Osteoporosis can be easily diagnosed with a simple bone density test. This is recommended for all women age 65 and older, all men age 70 and older, and younger

women and men with “risk factors” for osteoporosis, such as smoking, family history of osteoporosis, or previous fracture as an adult.

Once osteoporosis is diagnosed, tests should be done to determine why the bone density is low and help with selecting the best treatment. These tests are very easy and routine, usually just a fasting blood specimen and often a 24-hour urine collection to measure calcium and a few other chemistries. Abnormalities that may be detected that are important for bones include a blood calcium level that is too high or too low, vitamin D deficiency, abnormal kidney function, evidence of intestinal diseases with malabsorption, abnormal hormone levels, and diseases of proteins that are harmful to bone (see sidebar to the right).

When the evaluation is complete, a comprehensive program to reduce the risk of fractures can be recommended. This will include healthy lifestyle and good nutrition, with particular attention to calcium and vitamin D intake, avoidance of falls, and medication to strengthen bones.

Mike Lewiecki

MGUS

Monoclonal gammopathy of uncertain significance (MGUS, pronounce EM-gus) is a disease that affects about 3 out of every 100 people over the age of 50. It is caused by plasma cells, a type of white blood cell, producing an excess amount of abnormal protein. It is detected with a blood test (serum protein electrophoresis) that is commonly done in the evaluation of osteoporosis. MGUS is considered to be a “pre-malignant” disease, since it increases the risk of multiple myeloma and some other malignant conditions. For this reason, a bone marrow test may be done to be sure this is not already present. However, most patients with MGUS feel fine, never develop multiple myeloma, and live long and hopefully happy lives.

A recent study from the Mayo Clinic showed that patients with MGUS are at increased risk of osteoporosis and fractures of the hip and spine. For this reason, it is a disease of particular interest for physicians treating osteoporosis. If your evaluation for osteoporosis shows MGUS, then it may need to be monitored with a blood test about once a year. The osteoporosis can still be treated with medications to reduce fracture risk.

If you have questions about MGUS or other diseases that are associated with osteoporosis, ask your doctor. The more you know about your health, the better you can do at staying healthy.



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