FDA Health News for Older Adults, Their Families and Caregivers

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Editors' Note:

In Winter/Spring 2007, we devoted our entire issue to female cancers. Now, we have devoted this issue exclusively to men's health. The topics we chose for our readers include prostate health, erection problems, urinary incontinence, penile cancer, osteoporosis, and breast cancer. Yes, men do get breast cancer, although it is rare.

According to the Centers for Disease Control and Prevention (CDC), prostate cancer is one of the most commonly diagnosed cancers in the U.S. In 2004 (the most recent year for which statistics are currently available), about 189,000 men were diagnosed with prostate cancer and about 29,000 men died from this disease. Prostate cancer is the second leading cause of cancer deaths among men in the United States, after lung cancer, and the seventh leading cause of death overall for men in this country. All men are at risk for prostate cancer but age, race, and family history may further increase the risk.

Prostate Health: What Every Man Needs to Know

Background

The prostate is a small gland that lies in front of the rectum, sits just below the bladder where urine is

stored, and surrounds the tube (urethra) that carries urine from the bladder out of the body through the penis. The prostate gland functions as part of the male reproductive system by making a seminal fluid that becomes part of semen, the white fluid that contains sperm. As men age, the prostate may become a source of troubling symptoms

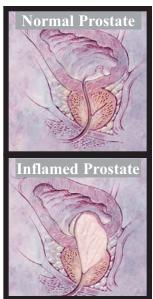
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such as decreased urinary stream, getting up one or more times during the night to urinate, and urgency to urinate due to increased levels of urinary blockage by an enlarged prostate gland.

There are several reasons for enlargement of the prostate. The most serious cause is prostate cancer, but the most common reasons for enlargement of the prostate is **NOT** from cancer but from other causes. Diagnostic tests and procedures developed in the last 15 years have increased the ability of doctors to distinguish between the cancer and non-cancer causes of urinary symptoms in men. The goal is to catch cancer early when it is treatable and to relieve unpleasant urinary symptoms in all men.

According to the National Cancer Institute (NCI), other than skin cancer, prostate cancer is the most common form of cancer and the second leading cause of cancer-related deaths among men in the United States. The current prostate specific antigen (PSA) test, first approved in 1986 by FDA, is widely used to screen for prostate cancer with the goal of detecting the disease in its early stages when cure is most possible.





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PSA Testing

The FDA approved the PSA test for use with a digital rectal exam (DRE) to help detect prostate cancer in men 50 and older. A DRE refers to the examination a doctor performs using a gloved finger (digit) to exam the prostate gland for nodules or masses that may be from benign or malignant tumors or growths. PSA is a normal protein produced in the prostate gland and is specific for the prostate gland. Elevation of the PSA levels in the blood is the most important warning sign to alert the doctor to potential problems. (See Questions and Answers on page 5).

Various conditions in the prostate can elevate the level of PSA in the blood including inflammation (prostatitis), age-related enlargement of the prostate (benign prostatic hyperplasia), and prostate cancer. Doctors often use the PSA test and DRE as prostate cancer screening tests; together, these tests can help doctors diagnose prostate problems.

Prostatitis

The first problem that can occur is prostatitis. It is a medical term used to describe a wide range of disorders ranging from acute bacterial infection to chronic pain syndrome affecting the prostate and may occur in young, middle-aged, and elderly men. Prostatitis is one of the non-cancer conditions that can raise the levels of prostate specific antigen (PSA). A biopsy of the prostate may be needed to make sure that the elevation of the PSA is not due to the presence of prostate cancer.

Benign Prostatic Hyperplasia

The second problem that may occur is benign prostatic hyperplasia (BPH). "Benign" means "not cancerous"; "hyperplasia" means "too much growth." BPH becomes increasingly common as men age, especially after age 60. The result is that the prostate becomes enlarged. As the gland grows in size, the prostate tissues narrow the urethra that passes through the middle of the prostate. The narrowing of the urethra progressively blocks the free flow of urine. The blockage leads to urinary problems: frequent urination, weak flow, and incomplete emptying of the bladder.

In addition to the doctor's performing a DRE to check the size and condition of the prostate, the doctor may need to request special X-rays or ultrasound scans to check the urethra, prostate, and bladder. BPH can lead to urinary problems like those with prostatitis. BPH can also elevate the blood level of PSA. By age 60, many men have signs of BPH. By age 70, almost all men have some prostate enlargement. At its worst, BPH can lead to a weak bladder, bladder or kidney infections, complete blockage in the flow of urine, and kidney failure. Because of the potential problems, all men, especially after age 50, should have a thorough medical exam that includes the PSA test and DRE every year. It should be noted that the FDA approval for PSA testing is for men aged 50 and over and is based on FDA's scientific review. However, there are studies in the medical literature that recommend African-American men and men with a strong family history of prostate cancer be screened at age 40.

A Roundup of Non-Surgical Treatments

For men who are having prostate problems, the good news is that many new and effective treatments are available for prostatitis and BPH.

Prostatitis caused by an infection is treated with antibiotics. Although BPH cannot be cured, FDA-approved medicines can often relieve its symptoms. Because these medicines are not always effective and surgeries are often associated with serious complications, researchers have developed a number of procedures using FDA-approved or cleared medical devices to relieve BPH symptoms.

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The following two procedures are considered minimally invasive, non-surgical treatments.

- Transurethral (through the urethra) microwave thermotherapy (TUMT). Use of microwaves to heat and destroy excess prostate tissue.
- Water-induced thermotherapy (WIT). Use of heated water to destroy excess prostate tissue.

Surgical Treatments for BPH

A number of devices with different technologies to remove prostatic tissue have been cleared by the FDA to perform prostate surgery to relieve symptoms associated with any urethral blockage and enable the bladder to empty. Many of these are considered less invasive than the traditional open prostatectomy which is the surgical removal of the prostate.

- Transurethral needle ablation (TUNA) removes prostate tissue electrosurgically with a needle.
- Transurethral vaporization of the prostate (TUVP) removes prostate tissue by vaporizing the tissue.
- Transurethral resection of the prostate (TURP) is the surgical removal of tissue.
- Transurethral incision of the prostate (TUIP) cutting a portion of the prostate to relieve symptoms.

These procedures often require patients to wear a catheter for one to seven days after surgery. Each carries risks of urinary leakage (incontinence) and sexual dysfunction (impotence).

Prostate Cancer

The third major problem that can occur in the prostate is cancer. In most cases, it grows slowly for years, giving most men with the early disease no obvious symptoms.

About 15 percent to 50 percent of men treated for prostate cancer by surgery, radiation therapy, or hormonal therapy will have urinary incontinence and sexual impotence. Some patients with other pre-existing serious medical conditions may be advised by their doctor to consider "watchful waiting" (or "active surveillance") to monitor the progress of the cancer to see if it advances.

Men who are treated for prostate cancer will have one of the following therapies:

- surgery to remove the entire prostate and surrounding tissues (radical prostatectomy)
- external beam radiation with high energy x-rays
- internal radiation therapy which involves implanting tiny radioactive pellets ("seeds"), such as Iodine-125, directly into the prostate, with or without additional external beam radiation
- hormonal therapy that uses medicines to reduce testosterone production and to prevent further growth and spread of the cancer

Projected Outcome (Prognosis)

The complication rates differ significantly by the treatment used. For example, those who have surgery have a much higher rate of inability to control urine leakage than if they had been given radiation therapy.



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It is important to have an accurate assessment of the prostate cancer before beginning surgery or radiation therapy. This assessment can establish the:

- severity of the prostate cancer
- general health of the patient (other than the prostate cancer)

This overall clinical assessment helps to identify the risks and benefits of each proposed therapy. This process helps reduce the risk for significant harm from the treatment.

Your doctor may be able to determine how likely your cancer will spread by using a system of grading called a Gleason score.

Men 50 to 75 years of age should discuss with their doctor the risks and benefits of prostate cancer screening on a yearly

Gleason Score

A system of grading prostate cancer tissue based on how it looks under a microscope. Gleason scores range from 2 to 10 and indicate how likely it is that a tumor will spread. A low Gleason score means the cancer tissue is similar to normal prostate tissue and the tumor is less likely to spread; a high Gleason score means the cancer tissue is very different from normal and the tumor is more likely to spread.

http://www.cancer.gov/Templates/db_alpha aspx?CdrID=45696

basis and earlier if they are African-American or have a family history of prostate cancer.

In its early stages, prostate cancer that stays in the prostate may not be life-threatening. But without treatment, cancer can eventually spread to other parts of the body. When the cancer spreads to other parts of the body, the patient is at risk of death. The choice of treatment depends on many factors, such as whether or not the cancer has spread beyond the prostate, the patient's age and general health, and how the patient feels about the treatment options and their side-effects.

Chemotherapy medicines are also approved to treat the various advanced stages of cancer that are no longer responding to hormonal treatment.

In 2005, FDA cleared for marketing a computer- or robot-assisted surgical system for use in all urological procedures, including the removal of the prostate because of cancer. For more information: <u>http://www.fda.gov/fdac/features/2002/302_bots.html</u>

Source: <u>http://www.fda.gov/fdac/features/2006/306_prostate.htm</u>l FDA Consumer May/June 2006

Additional Information: Understanding Prostate Changes: Health Guide for Men http://www.cancer.gov/cancertopics/understanding-prostate-changes



The Prostate-Specific Antigen (PSA) Test: Questions and Answers and Key Points

• Prostate-specific antigen (PSA) is a protein produced by the cells of the prostate gland. The PSA test measures the level of PSA in the blood (see Question 1 in the link below).*

• The FDA has approved the use of the PSA test along with a digital rectal exam (DRE) to help detect prostate cancer in men age 50 and older. If the PSA level exceeds a clinically recognized threshold, the patient is referred for a biopsy of the prostate for microscopic examination to confirm for the presence of prostate cancer. This is called PSA screening. The FDA has also approved the PSA test to monitor patients with a history of prostate cancer to see if the cancer has come back (see Question 2).*

- Doctors' recommendations for screening vary (see Question 3).*
- The higher a man's PSA level, the more likely it is that cancer is present, but there are many other possible reasons for an elevated PSA level (see Questions 4 and 5).*
- The PSA screening test has limitations and is still controversial (see Questions 6 and 7).*
- *For a complete list of the Questions and Answers on Prostate-Specific Antigen Test, go to: <u>http://www.cancer.gov/cancertopics/factsheet/Detection/PSA</u>

Can Men Get Breast Cancer?

In 2004 (the most recent year numbers are available):

- 186,772 women and 1,815 men developed breast cancer.
- 40,954 women and 362 men died from breast cancer.

In men, breast cancer can happen at any age, but is most common in men who are between 60 and 70 years old. Male breast cancer is not very common. For every 100 cases of breast cancer, less than one are in men.

For men, signs of breast cancer and treatment are almost the same as for women.

For more information, visit the <u>National Cancer Institute (NCI) – General Information</u> <u>About Male Breast Cancer.</u>

Source: http://www.cdc.gov/cancer/breast/basic_info/facts.htm

Erection Problems: Many Causes

Erectile dysfunction (ED) is the continued inability to get or maintain an erection that is firm enough for a man to have intercourse. You may be unable to get an erection at all, or you may lose the erection during intercourse.

Erection problems are common in adult men and almost all men experience temporary difficulty getting or maintaining an erection. For others it is an ongoing problem. If you have difficulty having or keeping an erection more than 25% of the time, it is considered a problem. An erection requires the interaction of your brain, nerves, hormones, and blood vessels. Anything that interferes with the normal process can result in erectile dysfunction.

Common causes include:

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- Diseases and conditions such as diabetes, high blood pressure, heart or thyroid conditions, poor circulation, low testosterone, depression, spinal cord injury, penile nerve damage (for example, from prostate surgery), or neurological disorders (such as multiple sclerosis or Parkinson's disease)
- Certain medicines such as blood pressure medicines (especially beta-blockers) and antidepressants

Sometimes lifestyle changes can improve erectile function. These are:

Recall of Illegal 'True Man' and 'Energy Max' Drug Products

FDA has asked America True Man Health Inc. to recall its True Man Sexual Energy Nutrient Capsules and Energy Max Energy Supplement Men's Formula Capsules because the agency considers the products to be illegal drugs that contain potentially harmful ingredients. The products are often advertised as "all-natural" alternatives to approved erectile dysfunction (ED) medicines, but they contain substances similar in structure to approved ED medicines.

For more information, go to:

http://www.fda.gov/bbs/topics/NEW S/2007/NEW01737.html November 2, 2007

- Elimination of alcohol, tobacco and illegal drugs
- Increased rest and time to relax
- Exercise and a healthy diet
- Open communication between both partners in a sexual relationship
- Counseling by a professional

Physical causes are more common in older men, while psychological causes are more common in younger men.

Call your doctor if you have difficulty having or keeping an erection more than 25% of the time or if you have noticed a change in your ability to obtain an erection after starting a new medicine. Your doctor will take a complete medical history, perform a physical examination, and order tests. These tests may include:

- Urine analysis
- Blood tests, chemical tests (including Prostate Specific Antigen-PSA) and tests to determine the level of sexual hormones in the body
- Penile ultrasound (to evaluate for blood vessel or blood flow problems)
- Night-time penile monitoring using a medical device to see if you are having adequate erections during sleep. (This helps to determine if your problem with erections is psychological or physical)
- Neurological testing
- Psychological testing of behaviors

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Erection Problems - continued from page 6

The treatment depends on the cause. For example, if you have a hormonal imbalance, your doctor will prescribe medicine to treat the underlying cause. If your doctor notes a deficiency of male hormone, testosterone replacement therapy can be prescribed with one of the following:

- a skin patch
- gel containing testosterone
- periodic injection of testosterone

There are many other treatment options also available. These include medicines taken by mouth, injections into the penis, vacuum devices, and penile implant surgery.

Viagra, Levitra, and Cialis are three medicines prescribed for erectile dysfunction caused by either physical or psychological problems. (See Additional Information below).

If pills do not work, other options are available, such as Alprostadil (FDA approved in 1995) that is injected into the penis or inserted as pellets into the urethra. For some patients, doctors may recommend a vacuum pump which draws blood into the penis to create an erection.

If other methods do not work, a penile implant (prosthesis) is considered. It is surgically implanted and works well on demand. In about 10 percent of the cases, a patient may have a minor or major complication requiring corrective surgery, treatment for infection, and in some cases, removal of the device. If the implant has to be permanently removed, the ability to have natural erections is completely lost.

Sources--: <u>http://www.nlm.nih.gov/medlineplus/ency/article/003164.htm</u> Update Date: 8/4/2005

Recall of Encore Tablets Supplement for Erectile Dysfunction

Bodee LLC and FDA notified consumers and healthcare professionals of a nationwide recall of Encore Tablets, a dietary supplement sold in health food stores, via the internet and by mail order nationwide and in Canada. The product was recalled because it contains potentially harmful, undeclared ingredients. One lot of the product contained the active ingredient of a FDA-approved drug used for erectile dysfunction. The undeclared chemical poses a threat to consumers because it may interact with nitrates found in some prescription drugs (such as nitroglycerin) and may lower blood pressure to dangerous levels.

Consumers who have this product should stop using it immediately and contact their physician if they have experienced any problems that may be related to taking this product.

Read the company's press release at: http://www.fda.gov/oc/po/firmrecalls/bodee1 1_07.html November 21, 2007

Additional Information:

FDA Approves Impotence Pill, Viagra <u>http://www.fda.gov/bbs/topics/ANSWERS/ANS00857.html,</u> FDA Talk Paper, March 27, 1998

FDA Approves New Drug for Erectile Dysfunction in Men http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01249.html, FDA Press Release, August 19, 2003

FDA Approves Third Drug to Treat Erectile Dysfunction http://www.fda.gov/bbs/topics/ANSWERS/2003/ANS01265.html, FDA Press Release, November 21, 2003

FDA Updates Labeling for Viagra, Cialis and Levitra for Rare Post-Marketing Reports of Eye Problems <u>http://www.fda.gov/bbs/topics/NEWS/2005/NEW01201.html</u>, FDA Statement, July 8, 2005.

FDA Announces Revisions to Labels for Cialis, Levitra and Viagra http://www.fda.gov/bbs/topics/NEWS/2007/NEW01730.html, FDA Press Release, October 18, 2007

Urinary Incontinence in Men

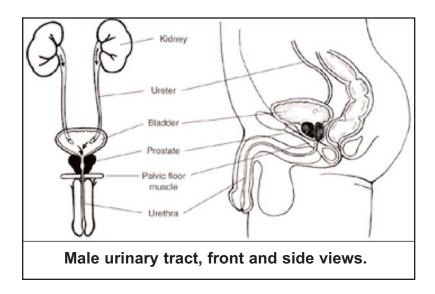
Urinary incontinence (UI) is the accidental leakage of urine. Many men suffer from incontinence. This problem increases with age, but UI is not an inevitable part of aging and it is treatable.

Four of the most common forms of UI in men include:

- Urge Incontinence Involuntary loss of urine following an overwhelming urge to urinate that cannot be stopped (most common in men)
- Overflow Incontinence the constant dribbling of urine (urinating frequently in small amounts)
- Stress Incontinence involuntary loss of urine during actions—such as coughing, sneezing, and lifting—that put abdominal pressure on the bladder (least common in men)
- Mixed Incontinence the combination of stress and urge incontinence

The majority of cases of urinary incontinence in men can be divided into two major categories:

- the bladder contracts when one does not wish it to
- the urinary sphincter muscle (narrow ring of muscle around the urethra, which is the tube that carries urine from the body) does not work properly

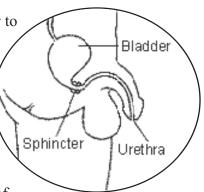


What causes UI in men?

For the urinary system to do its job, muscles and nerves must work together to hold urine in the bladder and then release it at the right time. Nerves carry signals from the brain to the bladder and sphincter. Any disease or injury that damages nerves can lead to urination problems including an enlarged prostate due to a benign growth, cancer or a stricture (abnormal narrowing) of the urethra. Over time, an enlarged prostate may press against the urethra, making it hard to urinate. It may cause dribbling after you urinate or a pred to urinate often aspecially at pight. One

dribbling after you urinate or a need to urinate often, especially at night. One of the complications from prostate surgery is UI where part of the urinary sphincter is cut away or damaged so that it cannot properly control the release of

urine. Stricture of the urethra, resulting from disease or trauma, can also result in urinary retention and UI.



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Urinary incontinence - continued from page 8
Nerve Problems
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Nerve problems can occur at any age. Any disease or injury that damages nerves can lead to urination problems. Examples are:

- Men who have diabetes may develop nerve damage that affects their bladder control.
- Stroke, Parkinson's disease, and multiple sclerosis all affect the brain and nervous system, so they can also cause bladder problems.
- Spinal cord injury may affect bladder emptying by interrupting the nerve signals required for bladder control.
- Injury during prostate surgery

Overactive Bladder

Urinary Incontinence can also occur with an overactive bladder. This is a condition in which the bladder squeezes at the wrong time. The condition may be caused by a nerve problem, or it may occur without any clear cause. A person with overactive bladder may have any two or all three of the following symptoms:

- urinary frequency—urination eight or more times a day or two or more times at night
- urinary urgency-the sudden, strong need to urinate immediately
- urge incontinence—urine leakage that follows a sudden, strong urge to urinate.

How is Urinary Incontinence Treated?

- Behavioral treatments
- Medicines
- Surgery
- Medical devices (pads, clamps, etc.)

Source: <u>http://kidney.niddk.nih.gov/kudiseases/pubs/uimen/index.htm</u>



Prosthesis for Urinary Incontinence

The AMS Sphincter 800[™] Urinary Prosthesis is an implanted device designed to allow patients who have loss of urinary control (incontinence) due to prostate surgery to control their urination. The device mimics the function of the urinary sphincter, the muscle that opens and closes the urethra. (PMA approved 2000)

For more information on this device, please go to: http://www.fda.gov/cdrh/mda/docs/p000053.html

Penile Cancer

Penile cancer is a disease in which cancer cells form in the skin of the penis and may spread into the deep tissues of the penis. While penile cancer is rare, especially in circumcised men in the US, it affects only about one in every 100,000 men. According to the National Cancer Institute, in 2007, it is estimated that there will be 1300 new cases of penile and other male genital cancers and a death rate of approximately 300 men per year.

Risk Factors for Penile Cancer

- An infectious virus called human papillomavirus infection (HPV) may increase the risk of developing penile cancer; circumcision may help prevent HPV.
- Being older
- Having a condition in which the foreskin of the penis cannot be pulled back over the glans
- Having poor personal hygiene, especially with the genital organs
- Having many sexual partners (increases the risk of getting HPV)
- Using tobacco products

Possible signs of penile cancer include sores, usually on the glans or foreskin with discharge and bleeding, especially if a lesion does not heal on cleansing. Other conditions may cause the same symptoms.

Consult your doctor if any of the following problems occur:

- Redness, irritation, or a sore on the penis
- A lump on the penis especially at lower portion of the organ.

Tests and Procedures

The following tests and procedures may be used to find and diagnose penile cancer:

- History A history of the patient's health habits and past illnesses and treatments
- Complete physical exam
 Manual and visual exam of penis for signs of disease
- Biopsy The doctor may recommend the removal of a tiny sample of cells or tissues from the penis to be examined under a microscope by another doctor (pathologist) to diagnose the disease. The sampling is done under local anesthetic and is relatively painless.



Certain factors affect chance of recovery (prognosis) and treatment options. As with other cancers, penile cancer can also spread within the penis and to other parts of the body.

The outcome or course of a disease and treatment options depend on the following:

- The stage of the cancer is the cancer early, localized to a small area, or has the cancer spread?
- The location and size of the cancer
- The diagnosis does the cancer show a low or high level of malignancy?
- Occurrence is this a first-time discovery of the cancer (primary cancer), or is it the return of the cancer (recurrence)?
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Penile cancer - Continued from page 10

The process doctors use to find out if cancer has spread within the penis or to other parts of the body is called staging (performing exams and tests to learn the extent of the cancer within the body). The information gathered from the staging process determines the stage of the disease.

It is important to know the stage in order to plan penile cancer treatment.

- **Stage 0** Precancerous lesion in the surface of the penis (abnormal cells)
- Stage I Cancer spread to connective tissue just under the skin
- Stage II Cancer has spread into the shaft of the penis
- Stage III Cancer has spread to the groin and is found in more than one lymph node
- Stage IV Cancer has moved beyond the groin nodes to distant parts of the body
- **Recurrence** Cancer has returned after a treatment



The following tests and procedures may be used in the staging process:

- CT scan (also called CAT scan) A procedure that makes a series of detailed pictures of areas inside the body, taken from different angles. The pictures are made by a computer linked to an x-ray machine.
- MRI (Magnetic Resonance Imaging) A procedure that uses a magnet, radio waves, and a computer to make a series of detailed pictures of areas inside the body.
- Ultrasound A procedure in which high-energy sound waves (ultrasound) are bounced off internal tissues or organs that make echoes. The echoes form a picture of body tissues called a sonogram.

Treatment:

There are different treatment options for penile cancer, and the choice depends on the staging status of the disease. As with any disease, a patient should discuss the treatment options with their doctor.

- Surgery the most common treatment for all stages of penile cancer (removal of the tumor, laser surgery, and removal of the penis).
- Radiation therapy uses high-energy X-rays or other types of radiation to kill cancer cells or keep them from growing.
- Chemotherapy uses medicines to stop the growth of cancer cells, either by killing the cells or by stopping them from dividing.
- Biologic Therapy boosts or restores the ability of the immune system to fight cancer, infections, and other diseases.

Osteoporosis and Men

According to the National Institute of Health, it is estimated that 10 million people in the U.S. over the age of 50 have osteoporosis. In addition, there are approximately 34 million people who have low bone mass that puts them at increase risk for developing osteoporosis. Four out of five people who have osteoporosis are women, but about 2 million men in the U.S also have the disease. One in two women and as many as one in four men over age 50 will have an osteoporosis-related fracture in their lifetime.

Osteoporosis affects women and men of all races and ethnic groups. It is most common in non-Hispanic white women and Asian women. African American women have a lower risk of developing the disease, but they are still at a significant risk.

Osteoporosis gradually weakens bones and can lead to painful fractures. It is distinguished by low bone density (how solid bones are) and structural breakdown of bone tissue. Often called the "silent disease," osteoporosis usually progresses without symptoms until it is diagnosed following a fracture.

Osteoporosis is seen less often in men than in women because men generally have larger, stronger bones. Additionally, men do not usually experience the sudden and substantial hormonal changes that women do following menopause. Also, bone loss begins later and advances more slowly in men than in women.

However, the National Institutes of Health says that the problem of osteoporosis in men recently has been recognized as an important public health issue especially in light of the fact that the number of men above age 70 is estimated to double between 1993 and 2050.

Bone Life

Some men have a hormonal drop-off in testosterone, with bone loss consequences that may result in an increased risk of osteoporosis. Testosterone may be reduced due to the decreased function of the testicles, which may occur naturally as a man ages. This loss of sex hormone can result in bone loss. Whether or not bone loss at this point translates into osteoporosis, however, depends on how much bone a man has when the loss begins, and how quickly he loses it.

By age 65 or 70, men and women lose bone mass at similar rates, and the absorption of calcium, an essential nutrient for bone health throughout life, decreases in both sexes.

Prevention, Diagnosis and Treatment

In men, there are two main types of osteoporosis: primary and secondary. Often, these two conditions overlap. In primary osteoporosis, there may be no identifiable cause or it may be the result of age-related bone loss.

Secondary osteoporosis in men can be due to a

variety of causes. Low testosterone, medicines such as prednisone that can lead to steroid excess, and alcoholism are among the important causes of secondary osteoporosis in men. *Continued on page 13*

Osteoporosis: Facts and Figures

About 1 out of every 2 women and 1 in 8 men over 50 will have an osteoporosis-related fracture in their lifetimes.

More than 2 million American men suffer from osteoporosis, and millions more are at risk. Each year, 80,000 men suffer a hip fracture; and one-third of these men die within a year, generally as a result of an accompanying illness.

Osteoporosis is responsible for more than 1.5 million fractures annually, including 300,000 hip fractures, approximately 700,000 spine fractures, 250,000 wrist fractures, and more than 300,000 fractures at other sites.

Hospitals and nursing homes in the United States spend an estimated \$14 billion each year in direct costs for osteoporosis and related fractures.

Sources: <u>http://www.fda.gov/Fdac/features/2002/502_men.html</u> FDA Consumer, September - October 2002 <u>http://www.fda.gov/fdac/features/2005/105_bone.html</u> FDA Consumer, January - February 2005

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It is extremely important that men be evaluated and treated before significant bone loss occurs.

Once bone is lost, it cannot be completely replaced using currently available medicines. Although it cannot be cured, the onset of osteoporosis can be slowed down. Currently available medicines can increase bone density, although they are not able to completely correct bone loss.

A special kind of x-ray technique, Dual Energy X-Ray Absorption (DEXA) is most commonly used to measure bone mineral density (BMD). The BMD test is a safe, accurate, quick, painless and non-invasive way to diagnose osteoperosis, detect low bone density (which is related to bone strength), monitor the effectiveness of treatments, and predict the risk of future fractures. When a person has a BMD test, the individual's bone density is measured and then compared to that of a normal population. The measurement is usually made on the spine, hip or wrist.

Several different medicines have been approved by the FDA for the management of osteoporosis in men and women.

Bisphosphonates

Bone in the body is constantly being reformed. Some cells break down bone and other cells rebuild it. Bisphosphonates work by reducing the activity of the cells that cause bone loss. Two medicines within this class have been approved for the treatment of osteoporosis in men. Fosamax and Actonel are indicated for the increase in bone mass in men and to treat steroid-induced osteoporosis. Bisphosphonates that are taken orally can cause irritation of the esophagus. It is therefore very important to closely follow the instructions when taking any of these medicines. Other side-effects include muscle or bone pain, or aches that may be disabling. Rare reports of bone death of the jaw have been reported with these types of medicines.

Parathyroid Hormone - Forteo

Another treatment available for osteoporosis in men due to low testosterone levels is Forteo, or parathyroid hormone (PTH). The PTH is a naturally produced hormone that regulates calcium and phosphate metabolism in bones.

Forteo is manufactured and acts similarly to the naturally produced hormone. Daily injections of this hormone can stimulate some new bone formation. The injections can cause pain at the injection site and low blood pressure. Temporary increases in blood calcium levels have also been observed in clinical trials. Animal studies have shown an association between PTH and rare bone cancer. Therefore, the medicine is not recommended in certain patients and use should not exceed two years.

Sources: <u>http://www.fda.gov/Fdac/features/2002/502_men.html</u> FDA Consumer, September-October 2002

Additional Information:

NIH National Institute of Arthritis and Musculoskeletal and Skin Diseases:

Tips to Prevent Male Osteoporosis

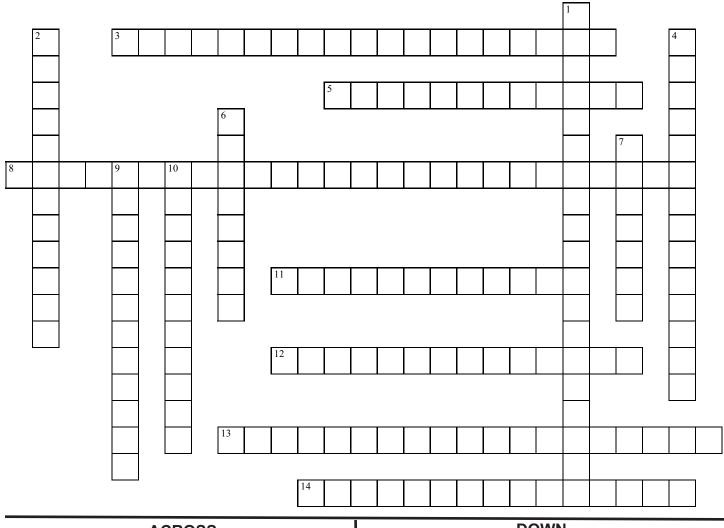
The advice is very similar to what is given to women.

- Stop smoking and drinking in excess; these habits can harm bones.
- Concentrate on the best nutrition for bone health that includes lots of fruits and vegetables, adequate protein, and a calcium-vitamin D-rich diet.
- Exercise, both weight-bearing and balanceenhancing.

This advice is also key to strengthening aging bones and avoiding dangerous falls. All of these factors will reduce the likelihood of suffering from osteoporosis-related fractures.

Source:<u>http://www.4woman.gov/NEWS/eNGLISH/607094.HTM,</u> Women'sHealth.Gov 8/7/07

Maturity Health Matters - Crossword



ACROSS

- 3 Three medicines FDA has approved for erectile dysfunction. (in alphabetical order)
- 5 Cancer that men can get in addition to women.
- 8 Enlargement of the prostate gland.
- 11 Gradually weakens bones; can lead to painful fractures.
- 12 FDA has approved these two bisphosphonates for osteoporosis in men. (in reverse alphabetical order)
- 13 Diabetes, stroke, Parkinson's disease, or multiple sclerosis can cause this bladder problem.
- 14 Class of medicines that reduce activity of cells that cause bone loss.

DOWN

- 1 Continued inability to get/hold an erection firm enough for intercourse.
- 2 Not being circumcised at birth may increase risk of this cancer.
- 4 One of the most common forms of diagnosed cancers; second leadingcause of cancer-related deaths among U.S. men.
- 6 A digital rectal exam (DRE) is used to diagnose problems with this gland.
- 7 The test approved by FDA to help detect prostate cancer in men 50 and older.
- 9 A system of grading prostate cancer tissue based on how it looks under a microscope.
- 10 Inflammation or infection of the prostate gland.

Maturity Health Matters is an FDA publication for older adults, their families and caregivers. We provide our readers with current information on FDA-regulated medical products. This publication can be reproduced. If you have comments about our publication, please send them to the editors.

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- 14 Bisphosphonates
- 13 Urinary Incontinence
- 12 Fosamax Actonel (No Spaces)
 - 11 Osteoporosis
 - Benign Prostatic Hyperplasia 8
 - Breast Cancer G
- Cialis Levitra Viagra (No Spaces) 3
 - **ACROSS**

- 10 Prostatitis
- Gleason Score 6
 - JS91 A24 7
 - Prostate 9
- Prostate Cancer 7
- Penile Cancer 2
- Erectile Dysfunction L
 - - DOWN
 - CROSSWORD ANSWERS