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What's New on the Horizon Treatment Choices for Men Living with Advanced Prostate Cancer

Presented by

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CancerCare

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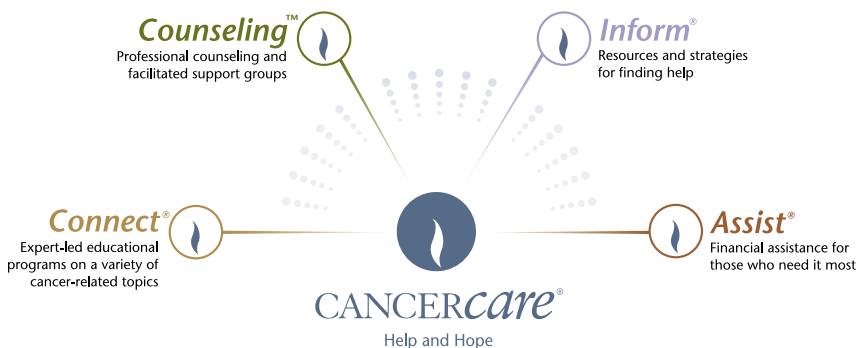
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What's New on the Horizon Treatment Choices for Men Living with Advanced Prostate Cancer

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The information in this booklet is based on the CancerCare Connect® Telephone Education Workshop "What's New on the Horizon: Treatment Choices for Men Living with Advanced Prostate Cancer," which took place in March 2005. The workshop was conducted by CancerCare in partnership with The Association of Clinicians for the Underserved, Prostate Cancer Foundation, The Prostate Net, and Us TOO Prostate Cancer Education & Support Network.

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This patient booklet provides an educational service
from Abbott Laboratories.

There are new and exciting steps forward in treating advanced prostate cancer.

Prostate cancer affects 233,000 men in the United States every year. Ideally, doctors prefer to find the disease in its earliest, most treatable stages. (See “Stages of Prostate Cancer,” at right.) But for men living with advanced prostate cancer, the prognosis is getting better all the time, with a number of effective treatments available. In this booklet we’ll talk about those treatments, new therapies on the horizon, and our ability to provide patients with a much improved quality of life.

When Prostate Cancer Comes Back

FINDING IT

By now you have probably spoken with your doctor about **PSA** testing. What does PSA mean? PSA refers to “prostate-specific antigen,” a protein produced by the prostate gland. High levels of PSA in the blood usually signal the presence of prostate cancer. And if a man has already been treated for the disease with surgery or radiation, rising levels of PSA often mean his prostate cancer has returned (recurred).

Doctors do use other methods to search for a recurrence of prostate tumors: spots of cancer cells can be found with X-rays of the bone, CT scans of the abdomen or the pelvis, and MRI scans. But the PSA test is probably the best indicator.

TREATING IT

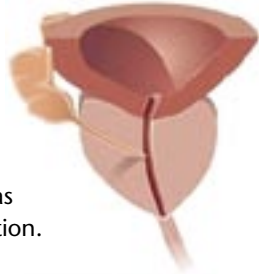
Today, the standard for treating advanced **metastatic** prostate cancer is hormonal therapy. This type of treatment was begun in the early 1940s, when doctors discovered that the male

Stages of Prostate Cancer

Stage T1, Early Disease

Microscopic tumor detectable only with a biopsy. Tumor has not spread beyond the prostate gland.

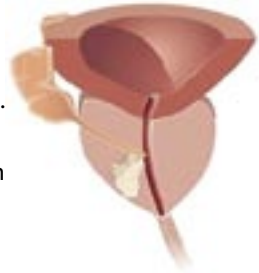
Common treatments: Watchful waiting, surgery (removal of the prostate, known as prostatectomy), external or internal radiation.



Stage T2, Intermediate Disease

Tumor can be felt during a rectal exam, but it has not spread beyond the prostate.

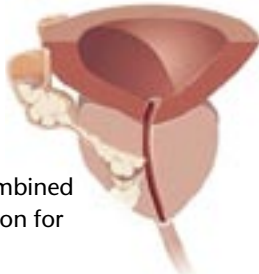
Common treatments: Surgery, external or internal radiation, possibly combined with hormonal therapy.



Stage T3, Locally Advanced Disease

Tumor has spread to nearby tissues and/or lymph nodes or has invaded the seminal vesicles. No spread of the cancer to other organs.

Common treatments: Radiation, often combined with hormonal therapy. Surgery is an option for some patients.



Stage T4, Advanced Disease

Tumor has spread beyond the prostate to other parts of the body.

Common treatments: Hormonal therapy, possibly combined with radiation, and promising new chemotherapies. Treatment is geared toward easing symptoms and slowing the disease.



hormone testosterone acts like a fertilizer, encouraging the cancer to grow. In those days, they often removed the testicles in order to take away the source of the testosterone and send prostate cancer into **remission**. That type of surgery for prostate cancer isn't used much in the United States anymore, although in some parts of the world it still is.

Without male hormones, prostate cancer retreats—goes into remission—often for many years. Removing the testicles is a drastic-sounding solution. But today, doctors can reduce the production of testosterone and other male hormones to very low levels by:

- **Injecting a drug known as an LHRH analog** These drugs act like a natural hormone secreted by the pituitary, a gland in the brain. The drugs signal the body to turn off testosterone production in the testicles. LHRH analogs include leuprolide (Eligard, Lupron, Viadur), goserelin (Zoladex), triptorelin (Trelstar), and histrelin (Vantas).



- **Giving a pill containing a female hormone** Estrogen pills also decrease male hormone levels. Taking estrogen, however, carries a risk of side effects,

ranging from swelling of the breasts to blood clots. As a result, estrogen treatment is usually not given unless other ways of reducing testosterone levels are no longer effective.

- **Using a combined hormonal approach** Another way to block testosterone is with drugs called **antiandrogens**. Examples include flutamide (Eulexin), bicalutamide (Casodex), and nilutamide (Nilandron). Doctors give these pills in combination with LHRH analog injections to lower

the testosterone level. The pills block male hormones that the injections miss.

An important note: Because the liver is the clearinghouse for all poisons in the body, it needs to be checked with periodic liver function blood tests, especially if you are taking antiandrogens. Tell your doctor immediately if you experience nausea, vomiting, stomach pain, excessive tiredness, loss of appetite, flu-like symptoms, dark yellow or brown urine, and/or yellowing of the skin or eyes.

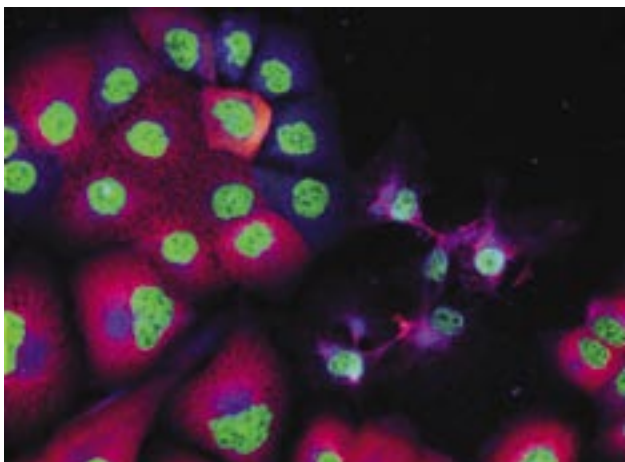
Beating Prostate Cancer at Its Own Game

When first treated, advanced prostate cancer usually “plays by the rules.” It yields to hormone treatments and goes into remission. But sometimes cancer cells can outsmart the treatments thrown at them. Prostate cells learn how to thrive, even without male hormones. Doctors call this condition

hormone refractory prostate cancer.

They treat it with chemotherapy.

Recently, the U.S. Food and Drug Administration has approved docetaxel (Taxotere) for this use. The drug, which is used against a number of cancers, can increase survival in men with hormone refractory prostate cancer. It is a new



Photograph taken through the microscope of prostate cancer cells spreading. When cancer cells spread to other parts of the body, they can cause new tumors to grow.

and exciting step forward in dealing with this disease.

ON THE HORIZON

Atrasentan (Xinlay) This promising drug, now in **clinical trials**, comes in pill form. It blocks a protein called endothelin, which is thought to help spread cancer cells. Atrasentan has few side effects, and in early tests it has increased survival and quality of life of men with hormone refractory prostate cancer.

Toremifene (Fareston) blocks hormone receptors on the prostate cancer cell. Currently it is used to treat breast cancer in women and is still in clinical trials for men. The side effects appear to be mild.

Sipuleucel-T (Provenge) Another promising drug still in clinical trials is a vaccine that is custom made from a patient's own cells. The vaccine combines a man's immune system cells with a protein that is found in most prostate cancer cells plus a substance called GM-CSF. This combination helps the immune system recognize the cancer as a threat so that it will attack the tumor cells as a foreign invader. In clinical trials, sipuleucel-T caused few side effects, most commonly fever and chills lasting one or two days. In early tests it has increased survival in men with advanced prostate cancer.

Other experimental treatments In addition to atrasentan, other treatments that target specific genetic changes in prostate cancer cells are under development now. Many of these drugs are still in very early clinical trials.

Managing Side Effects

Hot flashes (sometimes called hot flushes) In most men treated with hormones for their advanced prostate cancer, hot flashes are fairly limited and not too severe. If you are especially troubled by hot flashes, ask your doctor about medications such as low doses of female hormones (estrogen or progesterone) that can help.

Osteoporosis (“porous bones”—bones full of holes)

Lowered testosterone leads to a loss of calcium, which is essential to bone health. Drugs called **bisphosphonates** can be given by mouth or intravenously (through a vein) to help reverse the effects of osteoporosis. That’s especially important, to lower the risk of broken bones and bone pain.

Loss of erections (erectile dysfunction) Ask your doctor whether any of the following approaches are right for you:

- A drug such as sildenafil (Viagra), vardenafil (Levitra), or tadalafil (Cialis) to improve erections.
- A penile implant (which involves surgery). It literally pumps up the penis.
- **Urethral suppositories** or injections of prostaglandin E1 (alprostadil) to promote erections.
- Vacuum devices that draw blood into the penis for an erection.

Weight gain When men’s testosterone levels go down, their metabolism can change, they retain fluid, and they gain weight. Hormone treatments can result in a loss of muscle mass. Stay active by walking, doing chores, engaging in activities you enjoy, and lifting weights, for instance.

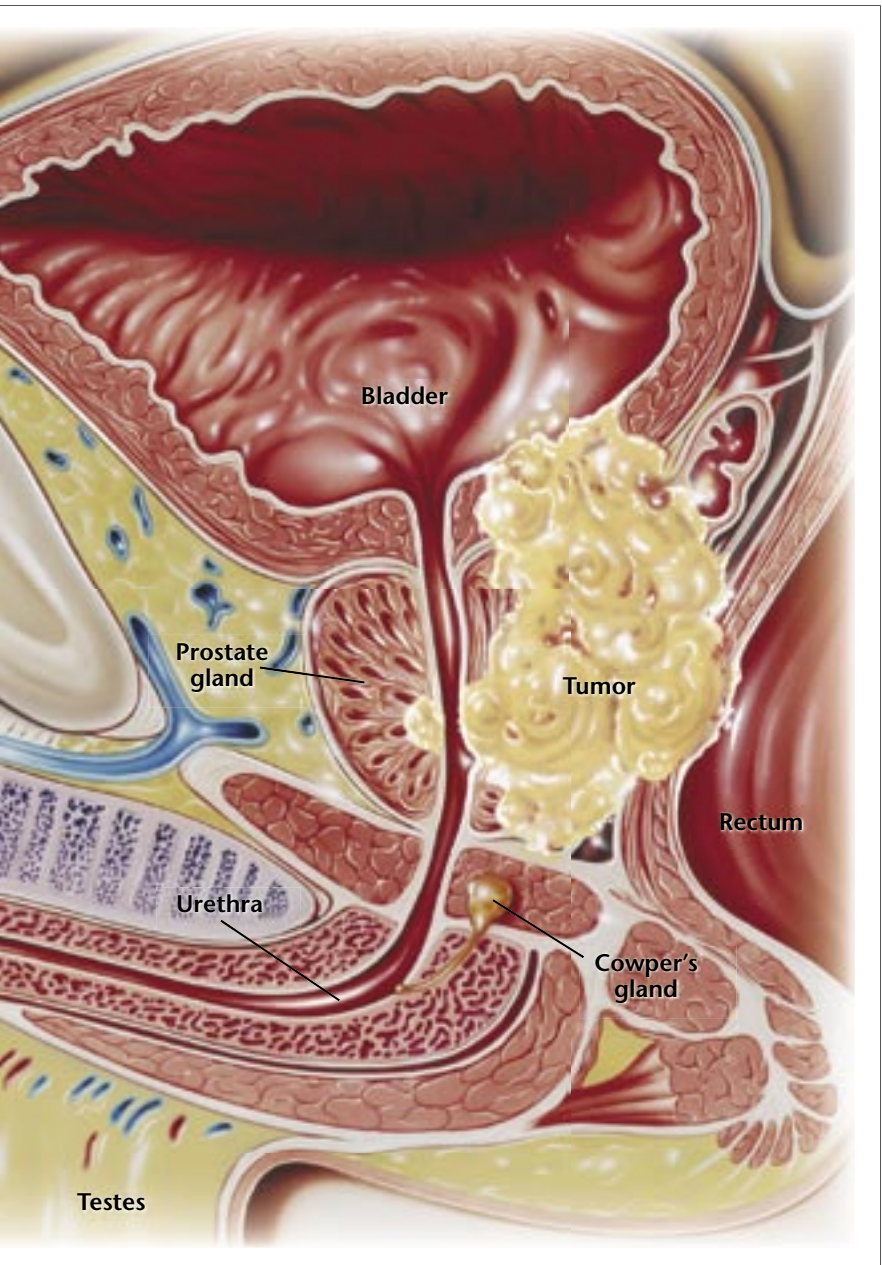


Fatigue Some days you may feel so tired that just getting dressed seems too exhausting. But gentle exercise—short walks building up to longer walks—does help relieve fatigue. Try taking 30-minute “power naps” during the day. They’ll give you a boost without upsetting your sleep schedule.

The Anatomy of Prostate Cancer

This drawing shows a cross-section through the male genital region, as seen from the side, with the front of the body at the left. A large prostate tumor has broken out of the gland to affect important organs nearby: the bladder, **urethra** (the tube through which urine leaves the body), and the rectum. The male urethra also carries sperm and seminal fluids during ejaculation. Just below the prostate is Cowper's gland, which makes a lubricating fluid to prepare the penis for intercourse.





Let's Talk About Pain

Many men believe they shouldn't complain about pain, that they should just be able to grin and bear it. But there's something you ought to know: *Pain stresses your body, and that can interfere with your recovery and grind down your spirit.*

If you are the primary breadwinner in the household, your having to live with pain can test your family's finances. It may force you to change your role; your spouse may have to take more time off from work to help care for you.

It's not unusual for patients in pain to feel depressed, anxious, or angry.

Proper management of your pain can improve your quality of life.

Talk with your doctor about forming a good pain management team. Physicians, nurses, social workers, psychologists, psychiatrists, and clergy can all devise strategies to help you and your family.

Pain Medications that strengthen bones can also help relieve some of the pain that may be associated with metastatic disease. Radiation therapy can also help provide "comfort care" by relieving pain.

Your Support Team

Forming a good partnership with your doctor is one of the most important things you can do for yourself during treatment. It's vital that you communicate freely with your doctor; let him or her know how you are doing and what you are concerned about. Although your doctor is the expert in biology and medicine, you are the expert about your own life. Don't be afraid to bring up any topic you wish. Your doctor cannot treat a problem if you don't make him or her aware of it.

Learn as much as you can about your treatments and possible side effects The internet is a great place to

start, but even if you're not computer savvy, there is a lot of information available through the mail and by telephone.

Organizations such as CancerCare® offer free—and reliable—information. Visit www.cancercare.org or call 1-800-813-HOPE (4673). CancerCare has worked with the American Society of Clinical Oncology on a website called People Living With Cancer (www.plwc.org). For more resources, see page 16.

Seek the help of a social worker or an oncology nurse practitioner

Advanced cancer can create many stresses in the lives of patients and their families, including medical, financial, and emotional

concerns. People with this disease often need someone to talk with who can help them sort through all the complex issues that arise. Social workers and oncology nurses can help you and your family cope with treatment and its side effects, provide emotional support, and guide you to resources. CancerCare offers free counseling from professional oncology social workers on staff.

Join a support group You and your family members may benefit from a support group, which can reduce the sense of isolation, the feeling that you are going through cancer alone. Support groups focus on adapting to cancer and living with the disease. They provide reassurance, suggestions, and insight, and they allow you to share similar concerns with your peers in a safe and supportive environment.



Frequently Asked Questions

Q How accurate is the PSA test when it comes to remission? Can I trust that the low numbers mean I am disease-free?

A The PSA test is one of the best tumor markers we have in all of oncology. It's not perfect, but in medicine we work every day with things that aren't perfect. Doctors don't usually look at only one PSA reading. We watch and see how the numbers progress. In general, after surgical removal of the prostate, most physicians believe the PSA level should be undetectable—that is, less than 0.2 nanograms per milliliter (ng/mL). If the number goes up twice during consecutive tests, then we start to question whether there is a recurrence of the cancer. In patients treated with radiation, we look for three consecutive rises in the PSA number.

Q If the PSA numbers are rising, when is it time to have a scan to check for a cancer recurrence?

A It would be very unusual for a scan to show a tumor outside the prostate if the man's PSA score is lower than 15 ng/mL. For that reason, scans are usually not done on such patients. However, some doctors do choose to scan men with low PSA numbers, particularly if they are planning to give chemotherapy for a prostate cancer recurrence.

Q I find hormonal therapy very difficult, emotionally. I've read that one problem is lack of estrogen. If that's the case, why aren't estrogen patches used more widely?

A There is some suggestion that lowered estrogen could have something to do with your distress. But using a patch

could create its own problems. For instance, estrogen can lead to fluid retention, congestive heart failure, and an increased risk of blood clots. A lower dose of estrogen would be safer but also less effective. So this is why estrogen patches and supplements aren't used as much as they have been in the past. Individual counseling does help some men deal with the emotional issues of hormone therapy.

Q Is it all right to take a “drug holiday” and use hormone therapy off and on?

A Intermittent hormone treatment is an experimental concept. With this technique, so the theory goes, you can discourage the tumor from growing without male hormones. To do that, you periodically “feed” the tumor testosterone, then take the testosterone away. By using hormone treatments off and on, you can reduce the level of side effects and potentially improve quality of life. But this is not the standard recommended treatment.

Q How effective is ketoconazole (Nizoral) and prednisone after hormone therapy for a prostate cancer recurrence?

A Interestingly, ketoconazole is designed to treat fungal infections. But doctors have used it against prostate cancer with the cortisone-like medicine prednisone, which goes under many brand names. More and more, physicians are moving directly to chemotherapy to treat a prostate cancer recurrence rather than the so-called secondary hormone manipulations. Recent clinical trials have shown chemotherapy to be more effective.

Q What about herbal treatments? Are they safe or effective?

A The herbal medicine market in the United States is not well regulated, which means you need to be very cautious. For

instance, a few years ago the compound known as PC SPES was widely promoted as a cure for prostate cancer. The U.S. Food and Drug Administration warned consumers to stop taking the product because it contained undeclared prescription drug ingredients that could cause serious health effects. In February 2002, BotanicLab, the California-based manufacturer of the product, voluntarily recalled PC SPES. Later that year, the lab closed.

Before you take any herbal treatments, consult with your oncologist. You can also look at a very reliable website from Memorial Sloan-Kettering Cancer Center on all types of supplements, www.mskcc.org/aboutherbs, or the website of the National Center for Complementary and Alternative Medicine, <http://nccam.nih.gov>.

Q I've heard that prostate cancer responds to the level of acidity in the body—that it's "pH dependent." If that is true, can you shift the pH level of the body with nutrition?

A You probably have seen infomercials on television that claim coral calcium can lead to dramatic pH changes in the body. You may be able to change the pH of prostate cancer cells in a test tube or a laboratory animal but not in humans. And even if you do, there's no evidence that it's going to have a significant antitumor effect. The standard for believing in a treatment is whether it is rooted in what doctors call "evidence-based medicine." That is, has the drug or treatment technique been tested in large clinical trials against the current standard, if there is one, or against a placebo ("dummy pill") if no good treatment exists? And do those tests show that what you are testing is safe and effective? Doctors advise and treat patients based on that information.

Glossary

antiandrogens Drugs that block the actions of testosterone and other male hormones on the prostate gland and other organs.

bisphosphonates Drugs that can be used to maintain bone health in men with prostate cancer who are receiving hormonal therapy.

clinical trials Research studies that test new treatments in patients, under carefully controlled conditions. Clinical trials are the standard by which doctors and scientists measure the worth of new therapies.

hormone refractory prostate cancer When prostate cancer cells resist hormone treatments and learn to thrive even without male hormones.

LHRH analog Stands for luteinizing (*LOO-tee-ni-zing*) hormone-releasing hormone analog (copy cat), a drug that prevents the production of testosterone in the testicles.

metastatic A tumor that has spread to distant parts of the body.

PSA Refers to “prostate-specific antigen,” a protein produced by the prostate gland. High blood levels of PSA may flag the presence of prostate cancer. Generally, levels under 4 nanograms per milliliter (ng/mL) of blood (a very tiny amount) are considered normal, although new studies have called this into question.

remission When cancer responds to treatment or is under control. In a complete remission, all the signs and symptoms of the disease disappear. In a partial remission, the cancer shrinks but does not completely disappear.

urethra The tube through which urine leaves the body.

urethral suppository A medicated solid preparation, usually in the form of a small cylinder or cone, that melts at body temperature and is designed to be inserted into the urethra, or urinary tube.

Resources

CancerCare®

1-800-813-HOPE (4673)

www.cancercares.org

Prostate Cancer Foundation

1-800-757-2873

www.prostatecancerfoundation.org

The Prostate Net

1-888-477-6763

www.prostate-online.org

Us TOO Prostate Cancer Education & Support Network

1-800-808-7866

www.ustoo.com

American Cancer Society

1-800-227-2345

www.cancer.org

People Living with Cancer

www.plwc.org

National Cancer Institute

Cancer Information Service

1-800-422-6237

www.cancer.gov



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All people depicted in the photographs in this booklet are models and are used for illustrative purposes only.

Microphotograph of prostate cancer cells on page 5 © Nancy Kedersha/Photo Researchers, Inc. Medical illustration on pages 8 and 9 © John Bavosi/Photo Researchers, Inc.

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