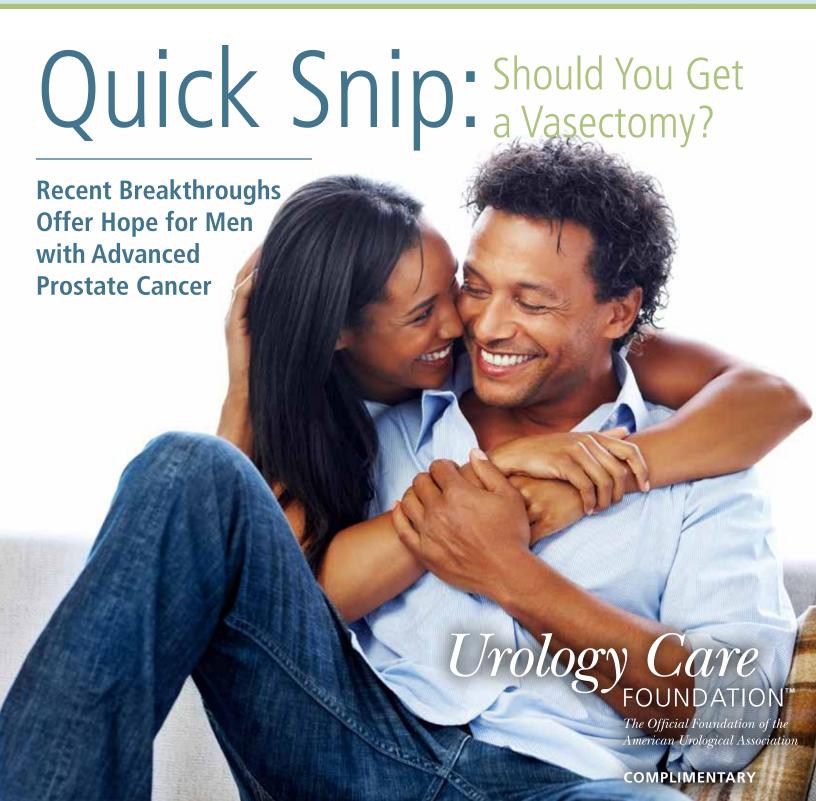
UrologyHealth

Winter 2014





Join Us in the Fight Against Metastatic Prostate Cancer

Bavarian Nordic, Inc., which specializes in developing cancer immunotherapies, is exploring a targeted immunotherapy for prostate cancer.

Our **PROSPECT** study is a global, randomized, double-blind, Phase 3 efficacy study of an investigational therapeutic cancer vaccine (PROSTVAC-VF) ± GM-CSF in men with metastatic, castrate-resistant prostate cancer (mCRPC).

Discover the PROSPECT study for yourself or for potential participants by visiting our PROSPECT website.





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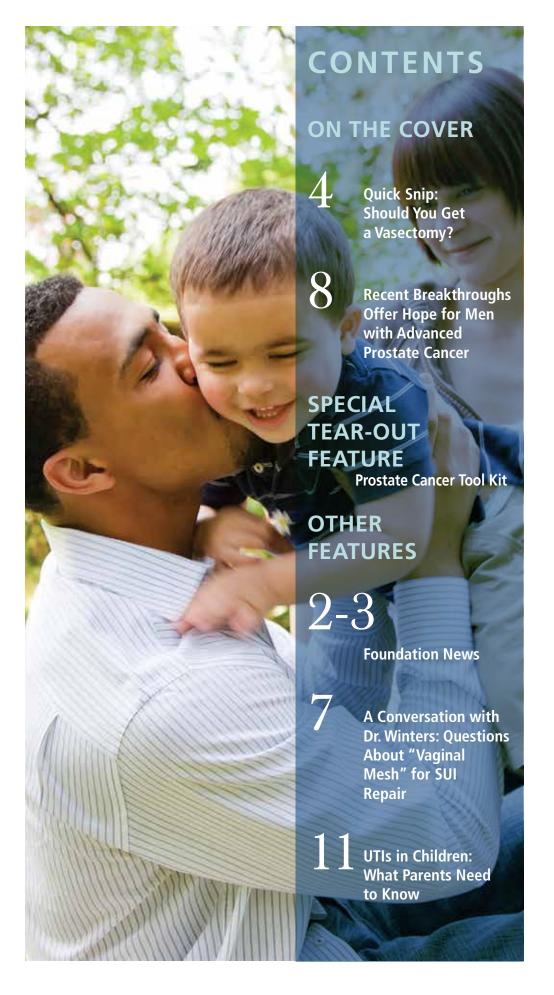
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Know Your Risk. Talk to Your Doctor.

About Prostate Cancer® A project of the Urology Care Foundation

Prostate cancer is the second most common cancer in men in the United States.

Prostate cancer will strike about 1 in 6 men in their lifetime.

One in 5 African-American men will get prostate cancer.

One in 3 men whose father or brother had prostate cancer will develop prostate cancer.

The Urology Care Foundation has teamed up with the National Football League (NFL) to raise awareness about prostate cancer. African-American men and men with a family history have a higher risk of prostate cancer than other men.

Visit **KnowYourStats.org** to:

- Sign the Pledge to Fight Prostate Cancer;
- Watch the video of NFL Commissioner and NFL Hall of Famers; and
- · Learn more about prostate health and prostate cancer.

Or call 1-800-828-7866 to have free information mailed to you.

Help raise awareness about prostate cancer!

Follow @KnowYourStats and share our awareness messages on Facebook and Twitter before and during Super Bowl XLVIII.



@KnowYourStats



/KnowYourStats

Urology Stats in the U.S.

About 500,000 men have vasectomies in the U.S.

each year.

More than 1.3 million children visit doctors' offices for urinary tract infections (UTIs) each year. UTIs are the most common urologic reason that children go to the doctor.

Treatment for UTIs in children costs more than billion include drug costs.)

The cost of a vasectomy can range from \$300 to more than 3,500.

UTIs in adult females prompt over 5 million visits to the doctor yearly in the U.S.

Adult males are half as likely to go to the doctor because of UTIs, at 2.3 million doctor visits each year.

Prostate cancer

costs society more than \$2.2 billion annually in Medicare costs (not including drug costs).

More than 230,000 men will be diagnosed with prostate cancer in 2014.

About 10,000 men are told they have advanced prostate cancer each year.

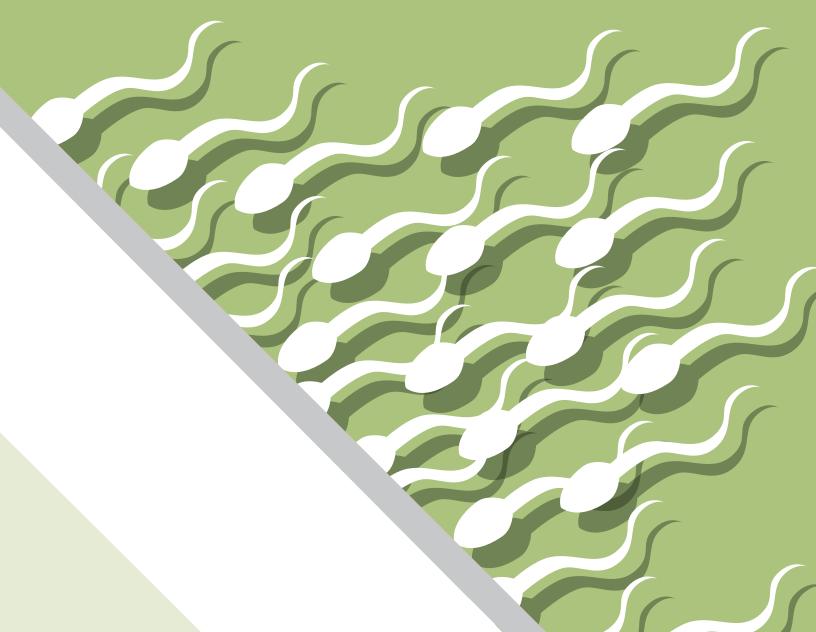
However, 2.5 million men in the U.S. are *prostate cancer survivors*.

In 2004, the chemotherapy drug Docetaxel was the first treatment shown to extend life in men with metastatic Castration-Resistant Prostate Cancer (mCRPC). mCRPC is when cancer spreads to bones or other areas far from the prostate. There is no cure for mCRPC. Since 2010, five more treatments that extend life for men with this advanced form of prostate cancer have been approved.

Quick Snip:

Should You Get a Vasectomy?

If you are thinking about having a vasectomy, you are not alone. Each year, about 500,000 men in the U.S. choose vasectomy as permanent birth control. During vasectomy, each vas deferens (the two tubes that move sperm) are cut or sealed off. This blocks sperm from reaching the semen ejaculated from the penis. The testicles still make sperm after a vasectomy, but they are absorbed by the body. A vasectomy is more effective than any other method of birth control, besides abstinence. Only one or two women out of 1,000 will get pregnant in the first year after their partners have had a vasectomy.





THE PROCEDURE

Your doctor can perform a vasectomy in an office or hospital. Vasectomy is a minor surgery that should take about 20 minutes. We spoke with Urology Care Foundation Outreach Committee member Dr. Paul Turek, who specializes in men's reproductive health. He tells his patients: "Take a long hot shower the morning before with a lot of soap. And make sure you have a bag of frozen peas and a couple of rented movies at home."

Before the vasectomy, your scrotum will be shaved and cleaned. Usually local anesthesia is used. So you will be awake but should not feel any pain. Some patients may also be given medicine to reduce anxiety. With a standard vasectomy, the urologist makes one or two small cuts in the scrotum. The vas deferens tube is cut and tied or sealed with heat. The tube is replaced inside the scrotum. The procedure is then repeated on the other vas deferens. Lastly, the skin is closed with stitches that dissolve and do not have to be removed.

Another popular option is a no-scalpel vasectomy. In this procedure, a small clamp with pointed ends is used instead of a scalpel to puncture the skin. Then each vas deferens is lifted out, cut, sealed and then put back in place. A no-scalpel vasectomy works just as well as a standard vasectomy. Some benefits of a no-scalpel vasectomy are less bleeding, swelling and pain, and a smaller hole in the skin.

"Vasectomy is a minor surgery that should take about 20 minutes."

RISKS

Up to one-in-five men may have ongoing pain or discomfort after a vasectomy. Most commonly, it is due to congestion of sperm in the system behind the blockage and eventually resolves with time. This is most often treated with anti-inflammatory drugs, like ibuprofen. One to six percent of men may need additional treatment to relieve their pain. Otherwise, the risk of bad side effects after a vasectomy is very low, but may include:

- Bleeding under the skin, which may cause swelling or bruising. (Contact your doctor if your scrotum swells significantly soon after your surgery.)
- Infection at the site of the cut. It is rare for an infection to occur inside the scrotum.
- A small lump forming because sperm leaks from a vas deferens into nearby tissue. This is usually not painful. If it is painful, it can be treated with rest and pain medicine. Sometimes surgery may be needed to remove the lump.
- Swelling of the vas deferens.
- In rare cases, the vas deferens may grow back together, which would enable the man to have children again.

Older studies showed a risk of prostate cancer in men who have had vasectomies. But many years of research since then have found that no clear link exists between a vasectomy and prostate cancer.

RECOVERY

Your scrotum will be numb for one-to-two hours after a vasectomy. Put cold packs on the area. (The bag of frozen peas Dr. Turek mentioned above works well.) Lie on your back as much as possible for the rest of the day. Mild discomfort or pain is normal after a vasectomy, and should be treated with pain relievers. Wearing snug underwear or a jockstrap will help ease discomfort and support the area.

You may have some swelling and minor pain in your scrotum for several days after the surgery. According to Dr. Turek, "If you are feeling up to it, you may be able to return to work in one or two days, but should avoid heavy lifting for a week. You can resume sexual activity as soon as you are comfortable, usually in about a week. But do not assume the vasectomy is effective from day one." Sperm may still be in the semen for many months after a vasectomy. It takes about 20 ejaculations or three months to clear the sperm from the tubes. However, results vary for different men. Usually three months later, your urologist will test your sperm count to make sure your semen is clear of sperm. Until the sperm count is zero, sex without some other method of birth control may lead to pregnancy.

After recovering from a vasectomy, "a man and his partner should notice no difference during sexual activity," said Dr. Turek. The ejaculation and orgasm are generally not changed. The amount of semen does not decrease more than 5 percent. Still, your partner may be able to feel the vasectomy site, especially if a lump has formed. An uncomplicated vasectomy does not cause erection problems.

WHAT TO CONSIDER

Choosing to have a vasectomy is a very personal choice. Talk with your partner, and think about what is best for you and your family. Be sure to bring up any questions you may have with your health care provider.

Below are some things to keep in mind:

- · Vasectomy is safer and cheaper than tubal ligation (blocking the fallopian tubes to prevent pregnancy) in women.
- The one-time cost of a vasectomy may be cheaper over time than the cost of other birth control methods, such as condoms or medication.
- · A vasectomy does not protect against sexually transmitted diseases (STDs). Use condoms to protect against STDs.

Lastly, it is important to note vasectomy is a permanent method of birth control. This may be a plus or a minus based on your own situation. You should not have a vasectomy if you may want to father children in the future. While it is possible to have a vasectomy reversed, this can be a difficult and costly procedure. Also, reversing or "undoing" a vasectomy does not always result in pregnancy. So it is important to think through all your choices carefully before deciding to have a vasectomy. *

The following was submitted by Dr. Turek and taken directly from his blog.

WHY DO MEN GET VASECTOMIES?

I ask most patients why they are considering a vasectomy. The responses vary, but can be very amusing. Here are a dozen of the funniest answers I've heard in my practice:

- My wife said: "the factory is closed," so I'm here.
- I was told that they broke the mold after they made me, but I want to make sure of it.
- My wife said: "It's your turn now."
- After this, I won't ever have to say I'm sorry again.
- I'm married! Condoms are sooo high school!
- Have you seen the movie 'One Fine Day?' That's why I'm here!
- Every time I look at my wife, she gets pregnant. 7.
- Apparently, sacrificing some limbs just isn't the same...
- She told me: "Enough, get your wings clipped already!"
- 10. I was told that I can shoot the gun all I want and no one will get hit.
- 11. I heard that it's easier than getting your teeth pulled out...
- 12. My wife told me that it's time for juice without seeds.

So, hats off to those men who chose the "emission impossible" way to an unburdened and unbridled sex life.

To access Dr. Turek's blog, visit http://theturekclinic.com/blog.



A Conversation with Dr. Winters

Questions About "Vaginal Mesh" for SUI Repair



In 2011, the Food and Drug Administration (FDA) issued a safety statement about the use of surgical mesh to treat pelvic organ prolapse (POP). The FDA asked for more studies of the material, especially when used for POP repair. POP can be a serious health problem in which some organs (such as your uterus or bladder) fall into your vagina. This can cause a vaginal bulge and often a sense of pressure or discomfort.

The Urology Care Foundation and the American Urological Association (AUA) are concerned that patients are confused about the use of mesh for prolapse repair versus its use in stress urinary incontinence (SUI) repair. Pelvic organ prolapse and SUI are different health conditions. Surgeries that use mesh to treat these conditions have their own unique risks and benefits.

Dr. J. Christian Winters is president of the Society of Urodynamics, Female Pelvic Medicine and Reconstructive Surgery. Dr. Winters answers patients' questions on the safety of "vaginal mesh" in SUI repair.

Q: I have heard that vaginal mesh isn't a safe treatment for stress urinary incontinence (SUI). What do women with SUI need to know about vaginal mesh?

A: Surgical mesh is used to treat a number of health problems, most commonly for hernia repair. In urology, this mesh is often used to treat SUI. SUI is a common health problem. People with SUI leak urine when coughing, sneezing, laughing, or doing other physical activities. One treatment for SUI is "sling" surgery. During this surgery, a sling is placed under the urethra, the tube that carries urine out of the body. The sling gives support to help stop urine leakage. Slings can be made from surgical mesh, one's own tissue or donor tissue.

All surgeries carry a risk of side effects. The FDA found that long-lasting side effects from treating SUI with mesh seem to be rare.

Q: What does the American Urological Association (AUA) recommend to treat SUI?

A: There are many treatments for SUI, including pelvic floor muscle exercises, lifestyle changes, medical devices and absorbent pads. For some people, these options may not be enough, and they may choose to have surgery. You should talk to a urologist about what options are best for you.

For patients who choose to have surgery, mesh sling surgery is the most common procedure used. It is a less invasive surgery, and patients tend to recover quicker than with the alternative surgeries to correct SUI. (These alternatives are slings using patients' own tissues and bladder suspension procedures.) The AUA's guidelines list mid-urethral, mesh slings as a "standard" treatment for SUI. The AUA points to a large number of scientific studies that support the use of mesh slings to treat SUI.

For more information on SUI and treatment choices, visit UrologyHealth.org/SUI.

Q: Has the FDA "recalled" vaginal mesh for SUI repair or found it to be "defective"?

A: No. The FDA has not "recalled" any mesh slings for SUI repair or asked doctors to stop using it. It is still available for doctors to use in appropriate patients because it has not been found to be "defective."

To view the FDA's "Information for Patients with SUI," which includes a list of questions to ask your doctor, visit: http://tinyurl.com/mxdxbuo.

Q: What if I already have had surgery with mesh to treat my SUI? Should I have the mesh removed?

A: Surgical mesh is designed to be a permanent implant. If you are not having any side effects, there is no need to remove the mesh. When mesh is removed, side effects can occur. These can include injury to tissue near the mesh or repeat incontinence.

If you are thinking about sling surgery, or if you have undergone sling surgery for SUI and have concerns about the use of mesh, the Urology Care Foundation offers this advice:

- Before surgery, talk with your urologist about which type of sling (mesh or human tissue) will be used. You should learn what results you can expect and why this surgery is being recommended for you.
- Ask your doctor how often they have done this surgery, what training they have and what side effects their patients have seen.
- It is important to recognize bad side effects early so they can be taken care of right away. Talk with your doctor about what symptoms (such as bleeding, pain or problems voiding) need immediate attention.
- Many side effects of sling surgery for SUI may not be related to the mesh itself. Some problems can happen with non-mesh sling surgeries as well.
- Mesh-related side effects from sling placement for SUI repair are usually easier to address than those related to POP repair.



Recent Breakthroughs Offer Hope for Men with Advanced Prostate Cancer

In February 2008, Pete's prostate-specific antigen (PSA) blood test came back high – 18.2. It turned out that Pete had cancer. "When I was first told I had prostate cancer, I didn't hear much else. Just the word 'cancer' was a great shock," Pete said. "Some men may find it hard to think of anything else for a while." The news that your cancer has returned after treatment can hit even harder and revive long-buried fears. "When I learned nearly five years later my cancer had returned and was now in my bones, I didn't know what to think."

Prostate cancer is the second most common cancer found in men. (Skin cancer is the most common cancer.) More than 230,000 new cases will be diagnosed this year. Chances are you know someone who has prostate cancer or has been treated for it. More than 2.5 million men in the United States are survivors of prostate cancer. The survival rate is rising. Awareness, screening and better treatments are some of the reasons. If found at an early stage, prostate cancer has a very high chance of cure. Also, many prostate cancers that are found early may not be fast-growing or life threatening.

However, when prostate cancer spreads outside the prostate or reappears after initial treatment, it is known as advanced prostate cancer. Some men are told they have advanced prostate cancer when they are first diagnosed. Other men are diagnosed with advanced prostate cancer when their PSA levels rise months or years after surgery or radiation. At first, your doctor may suggest hormone therapy if you have advanced prostate cancer.

"Chances are you know

someone who has

prostate cancer or has

been treated for it."

Hormone Therapy. Male hormones can act as fuel to help prostate cancer grow. This is why one of the first treatments for advanced prostate cancer is hormone therapy. The goal is to lower or block male hormones, such as testosterone. This can cause prostate cancer to shrink or grow more slowly. Hormone therapy choices may include shots or oral pills to help control hormones. Another

option is surgery to remove the testicles, where the male hormones are made.

Most often, prostate cancer responds to this treatment, and patients see their PSA levels drop. Still, hormone therapy does not cure the cancer. It often returns after a few years, even though hormonal therapy has lowered testosterone levels.

When prostate cancer shows signs of growing despite hormone therapy, it is known as castrate-resistant prostate cancer (CRPC). If your only sign of CRPC is rising PSA levels while on hormone therapy, your CRPC is non-metastatic. The American Urological Association (AUA) recommends that men continue with hormonal therapy when diagnosed with non-metastatic CRPC.

Metastatic CRPC (mCRPC) is when cancer has spread to bones or other areas far from the prostate, despite hormone therapy. There is no cure for mCRPC. Still, there is a lot of hope that symptoms can be managed, and life can be extended. Quite a few new treatments have been approved for mCRPC in the past few years. Yet there is no good scientific proof that these new treatments benefit men with non-metastatic CRPC. And all treatments have possible side effects. So the AUA recommends men with non-metastatic CRPC not use these treatments unless as part of a clinical trial.

New Breakthroughs and Treatment Options for Metastatic Castrate-Resistant Prostate Cancer (mCRPC)

In recent years, scientists have made some landmark discoveries in how to treat mCRPC. New treatments for this form of cancer are being found. Also, changes are being made to existing treatments so they work better. If you are diagnosed with mCRPC, your doctor may prescribe one of these treatments:

Vaccines or Immunotherapy. Usually, vaccines (shots) prevent infections. Lately, researchers have been looking into using vaccines to treat mCPRC. If your prostate cancer returns despite hormone therapy and is metastatic, your doctor may offer the cancer vaccine sipuleucel-T (Provenge®). Sipuleucel-T works by boosting the body's immune system so it attacks cancer cells. This is the first vaccine that has been shown to help men with prostate cancer live longer. Other

> prostate cancer vaccines are also being studied.

> new kinds of hormone therapies have helped men with mCRPC delay symptoms and live longer.

> Androgen synthesis inhibitors. The oral drug abiraterone acetate (Zytiga®) stops your body and the cancer from making steroids (including testosterone). Because of the way it works, this drug must

be taken with an oral steroid known as prednisone. Abiraterone is approved by the FDA for use before or after chemotherapy in men with mCRPC.

Androgen receptor binding inhibitors. Enzalutamide (Xtandi®) is an oral drug that blocks testosterone from binding to the prostate cancer cells. Because it works differently than abiraterone, men do not need to take a steroid with this drug. Enzalutamide was approved in August 2012 by the FDA for use in men with mCRPC after chemotherapy.

Bone Targeted Therapy. If you have advanced prostate cancer or are taking hormonal therapy for your cancer, your doctor may offer calcium or Vitamin D supplements. Some newer drugs can also help strengthen and protect your bones such as denosumab (Xgeva®, approved in 2010) or zoledronic acid (Zometa®). Both drugs help prevent bad side effects from the cancer growing in your bones.

Another new treatment approved for men whose mCPRC has spread to their bones is radium-223 (Xofigo[®], approved in 2013). This treatment is injected into your veins using an intravenous (IV) drip. It collects in the bones, mostly in areas with fast growth - like where cancer has spread. There, it gives off small amounts of radiation that can only travel

New Hormone Therapies. Two

Continued on page 10 •

Continued from page 9

short distances. This can target radiation to the exact areas of the bone where cancer cells are growing. Radium-223 has been shown to help men live longer.

Chemotherapy. Another treatment choice for men with mCRPC is chemotherapy. Chemotherapy drugs slow the growth of cancer and lessen symptoms. Most of the drugs are given into the vein (IV). Chemotherapy does not cure CRPC. Still, it can lessen pain linked to prostate cancer, shrink tumors and lower levels of PSA. Studies in recent years have shown that many chemotherapy drugs can affect prostate cancer. Some, such as docetaxel (Taxotere®, Docefrez™) and cabazitaxel (Jevtana®, approved in 2010), have been shown to help men live longer. Other new chemotherapy drugs and mixtures of drugs are now being studied.

Radiation. If your cancer has spread far from your prostate, your doctor may also suggest radiation. In mCPRC, radiation therapy can help ease pain or other symptoms. The bones are a common place for prostate cancer to spread. Radiation can help ease pain caused by cancer spreading to the bone. The radiation is most often given in one or a few visits. The treatment is like having an X-ray, and uses high-energy beams to kill tumors. New radiation techniques focus on cancer cells

while saving healthy tissue nearby. Many radiation therapies use computers to map the prostate and target radiation just where it is needed. New software allows doctors to better plan and target radiation doses. These methods are expected to increase the success of radiation therapy while reducing the side effects. Studies are being done to find out which radiation methods are best suited for which men with prostate cancer.

"After the initial shock wore off, I realized I needed time to take in the information. I spent the next few days talking about my options with family and friends," Pete said. "I was encouraged to learn all I could about my disease and treatment choices so I could help make decisions about my care. One of the best ways to get information is to ask your doctor and other health care professionals. And when talking to your doctor, don't forget to ask how the treatment will change your daily life, how your diet might have to change and how you will look and feel," he continued. Ask how successful the treatment usually is and find out about the risks and possible side effects. Even if you have advanced cancer, there are many treatments ready to help make your daily life better. There is also a lot of hope. Many new treatments are being explored every day. •

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UTIs in Children: What Parents Need to Know

About 8 percent of girls and 1 - 2 percent of boys have had a urinary tract infection (UTI) by the time they are 5 years old. UTIs are caused by bacteria infecting the urinary tract – the organs and tubes in our body that make, store and pass urine. The urinary tract is made up of the kidneys, ureters, bladder and urethra. Bacteria are not normally found in urine. However, they can enter the urinary tract from the skin near the anus. UTIs are more common in girls than boys. In girls, the opening of the urethra is closer to the anus and the length of the urethra is shorter. Infections are more common in the urethra and bladder, which make up the lower part of the urinary tract. Infections that move up the ureters to the kidneys can be more serious. If left untreated, these infections may lead to kidney failure.

Signs and Symptoms

UTIs are easier to spot in older children who are toilet-trained and can talk about their symptoms. Some signs of a UTI are:

- pain, burning, or a stinging sensation when urinating
- frequent urination or feeling an increased urge to urinate, even without producing urine
- foul-smelling urine that may look cloudy or contain blood
- fever
- · low back pain or pain in the area of the bladder

The clearest sign of a UTI in babies may be a fever. Babies with UTIs may also act fussy, vomit and feed poorly. If the

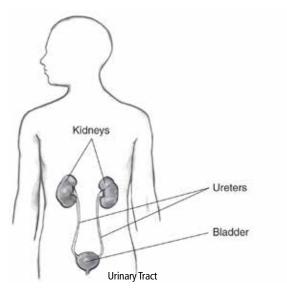


Image provided courtesy of National Institute of Diabetes and Digestive and Kidney Diseases, National Institutes of Health

UTI becomes a kidney infection, the child or infant is more likely to have a fever with shaking chills, pain in the back or side, or vomiting.

Diagnosis and Treatment

Your child's health care professional will take a urine sample to test for a UTI. Older children will most often be asked to urinate in a sterile cup. Babies and small children in diapers may need a catheter (tube) to collect urine. The catheter keeps

Continued from page 11

the sample from being contaminated by bacteria on the skin. The urine will then be tested for bacteria. The type of bacteria found may help decide the best drug to treat the UTI, usually antibiotics. It is important for your child to keep taking all the antibiotics, even if he or she is feeling better. Most UTIs will be cured within a week if treated properly. Urge your child to drink plenty of fluids, and keep track of his or her symptoms. If symptoms worsen or do not get better within three days, the child may need to go to the hospital. If a child has more than one UTI, he or she should see a pediatric urologist. They can see if anything is abnormal in your child's urinary tract. A common problem causing UTIs in children is a backwards flow of urine. When urine flows from the bladder up toward the kidneys, it is called vesicoureteral reflux (VUR).

Prevention

Frequent diaper changes can help prevent UTIs in babies and small children. When children start toilet training, it is important to teach them good bathroom habits. After each bowel movement, girls should wipe from front to rear - not rear to front. This keeps germs from spreading from the anus to the urethra. When feeling the urge to urinate, children should also avoid "holding it" if they can reach a bathroom. Urine remaining in the bladder gives bacteria a good place to grow.

If your child gets more than one UTI or you suspect a problem, visit www.UrologyHealth.org/FindAUrologist to find a pediatric urologist in your area. •



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The Urology Care Foundation is committed to advancing urologic research and education. We collaborate with researchers, health care professionals, patients, caregivers, families and the public to improve patients' lives. The Urology Care Foundation is the official foundation of the American **Urological Association.**



Learn more about the Foundation! Visit UrologyHealth.org to:

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- Tangible Property
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