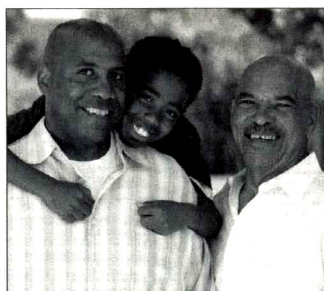


2014 *Annual Report on* PROSTATE DISEASES

Covering advances in the diagnosis and treatment of prostate cancer, benign prostatic hyperplasia, erectile dysfunction, prostatitis, and related conditions



IN THIS REPORT

Why the controversy over PSA testing continues

Should you have a PSA test?

Treating prostatitis

Innovative surgery for BPH

The emerging science of biomarkers

New options for treating prostate cancer

Managing erectile dysfunction



HARVARD MEDICAL SCHOOL

2014
Annual Report
on
Prostate Diseases



*Covering advances in the diagnosis and treatment of
prostate cancer, benign prostatic hyperplasia, erectile dysfunction,
prostatitis, and related conditions*

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**A message from
Editor in Chief
Marc B. Garnick, M.D.**

The good, the not-so good, and continued complexity

Progress in medicine, as in all walks of life, isn't a march at all. It's unpredictable and comes in spurts, with setbacks, adjustments, and hard-won learning. As documented here, in the 2014 edition of the *Annual Report on Prostate Diseases*, we've seen amazing developments lately in prostate health and disease, some slowdowns, and continued complexity—all of which underscore the need to continually expand our knowledge of prostate disease.

On the positive front, the American Urological Association (AUA) revised its PSA screening guidelines in 2013 to no longer recommend routine use of the test. The AUA joined other organizations in recognizing that blanket use of the PSA test leads to over-diagnosis and overtreatment of prostate cancers that weren't going to do men any harm. But as we move into the post-PSA screening era, the need for new and better biomarkers to guide screening, diagnosis, and treatment decisions has never been greater. This year's *Annual* has a special section on biomarkers and provides a window into the future of how practices will change.

One of the truly bright spots in prostate cancer treatment—in fact, in all of cancer treatment—has been the development of new treatments for men whose cancer has spread despite hormone therapy. Metastatic castration-resistant prostate cancer (mCRPC) is the unfortunate medical jargon for cancer at this stage. The treatment options for these patients used to be limited. In the past few years, however, five new medications have been approved for men with this late-stage cancer. In 2013, a sixth, radium-223, marketed as Xofigo, came on board. (Full disclosure: I am a stockholder in the company that makes Xofigo.) Radium-223 is a novel agent that works by directing tiny amounts of radiation at prostate cancer cells that have spread to the bone. We now face the challenge of deciding when to use radium-223 and the other new drugs, in what sequence, and for which patients.

I am delighted, of course, about all the resources and investment being committed to prostate cancer care and treatment. But one of the overriding issues in American health care today is making sure we get a return on that investment. As we discuss in this *Annual*, research is showing that we should be concerned about whether expensive proton beam therapy has advantages over less expensive conventional radiation therapy. Another study raised questions about the overuse of intensity-modulated radiation therapy. A vaccine for advanced prostate cancer is extremely costly, provides questionable benefit, and needs more scientific investigation, which has been lacking.

So we are left with . . . continued complexity. Looking ahead to 2015, 2016, and beyond, one thing is certain: there will be more of that. This is the fifth edition of the *Annual Report on Prostate Diseases*. We don't shy away from complexity. Our purpose is to explain it so that you—with the help of your loved ones, your doctors, and other clinicians—can make careful, reasoned, and informed decisions about your prostate health.

Marc B. Garnick, M.D.
Editor in Chief, 2014 *Annual Report on Prostate Diseases*

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An introduction to the prostate gland

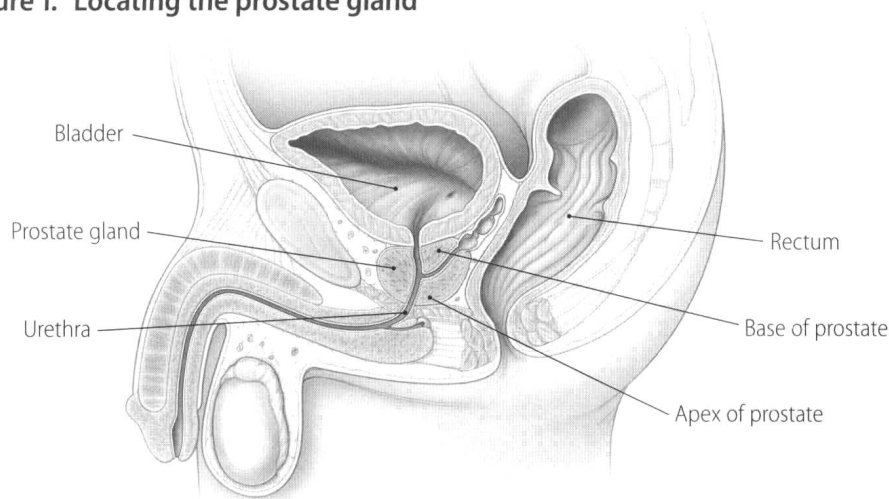
The where, what, and why of a male-only gland

How can a gland the size of a walnut that weighs only about an ounce cause so much trouble? To answer this question, one must look at the prostate's position in a very crowded place in the body. The prostate is located in front of the rectum, the last part of the colon, and just below the bladder, the hollow organ that holds urine before it is excreted out the body (see Figure 1, below). One source of the trouble is the fact that the prostate wraps around the upper part of the urethra, the slender tube that carries urine from the bladder out of the body through the penis. At birth, a baby boy's prostate gland weighs less than half an ounce, and the gland goes through growth spurts during adolescence and young adulthood. It's normal for the prostate to start to grow again when men are in their late 40s and 50s. But when it does, the gland may press on the urethra, preventing urine from flowing freely. That leads to a variety of urinary problems.

But the prostate isn't just a troublemaker. It's the job of the testicles to produce sperm, but the prostate gland helps supply the semen, the thick, milky fluid that nourishes and protects sperm cells during their travels. The prostate's contribution to semen is alkaline, so it helps sperm survive in the acidic environment of the vagina.

The inside of the gland is made up of an intricate series of ducts lined with cells that produce the prostatic fluid. During ejaculation, the prostate pushes that fluid

Figure 1. Locating the prostate gland



The prostate is located just below the bladder, in front of the rectum, and wraps around the upper part of the urethra. Counterintuitively, the base is located at the top of the gland and the apex at the bottom.

through those ducts and then into the urethra, where it combines with sperm. Seminal vesicles—slender glands that sit on either side of the prostate—also contribute secretions to semen. By volume, their contribution is actually greater than that of the prostate gland.

The prostate is also tied in to the body's infinitely complex system of hormones. To function properly, it requires adequate amounts of certain hormones, including testosterone, produced by the testicles, as well as other hormones that come from the pituitary gland, which hangs off the base of the brain, and the adrenal glands, which sit on top of the kidneys.

Although the prostate is sometimes depicted as having a simple round shape, the prostate is actually divided into right and left lobes. It's also tapered at one end. The wider part, called the base, is nestled up next to the bladder, and the tip, or apex, is farthest away from the bladder. If the prostate were an arrow, it would be pointing down. If the orientation is front and back, then the front is referred to as the anterior of the gland and the back, the posterior. These divisions of the gland and the medical terms for them matter when it comes to prostate cancer. Cancers that are located near the base have a propensity to spread to the surrounding tissue, including the seminal vesicles. Cancers in the apex can make surgical removal difficult. ♥

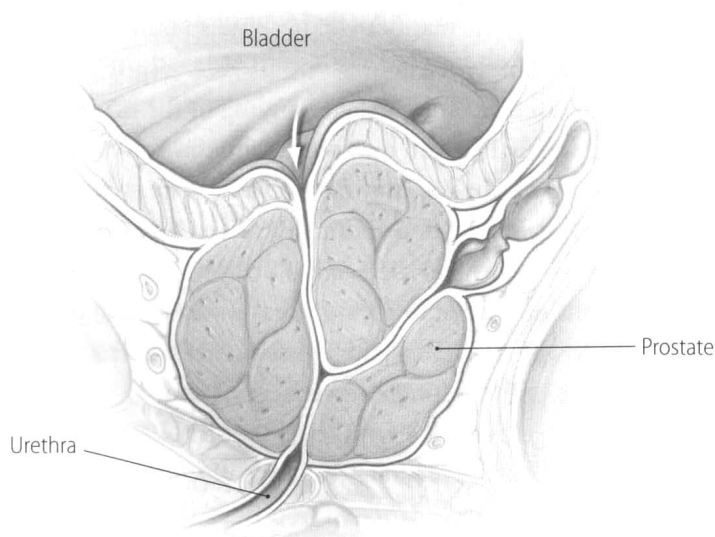
Prostate enlargement (benign prostatic hyperplasia)

Getting this “going”—and “growing”—problem under control

Around the time of a man's 50th birthday, his prostate begins to grow. This natural enlargement is called benign prostatic hyperplasia (BPH). It is called benign because it is not cancerous, and hyperplasia is the medical term for an increase in the number of cells in a tissue or an organ. BPH is the most common cause of prostate enlargement; indeed, if a man lives long enough, he will almost certainly experience some degree of BPH. It is a benign condition that does not lead to prostate cancer, although the two problems can coexist.

No one knows exactly why BPH occurs. One popular theory suggests that the prostate begins to grow because of shifts in the balance between testosterone, a male hormone, and estrogen, a female hormone that is present in men in small amounts. Testosterone production declines with advancing age, changing the ratio of testosterone to estrogen. Some animal studies have shown that this shift in hormone balance may start a chain reaction, causing the rapid cell multiplication that results in BPH. Other animal studies suggest that the accumulation of another male hormone, dihydrotestosterone (DHT), in the prostate may encourage cells in the prostate to divide. Researchers are also beginning to investigate whether inflammatory processes might underlie BPH.

Figure 2. An inside look at BPH



As the prostate gland enlarges, it constricts the urethra, the tube that carries urine out of the body, and impedes urine flow. The bladder has to work harder to force stored urine out. Over time, the bladder walls thicken, leaving less room for urine.

Risk factors for BPH include abdominal obesity, diabetes, and lack of physical activity. Research shows that even light exercise cuts the risk of developing BPH by 25%. Drinking alcohol also seems to lower the risk of BPH but not the risk of the lower urinary tract symptoms it may cause. Whether African American men are more likely to get BPH than white men isn't clear; the results from epidemiological studies have been split on that question.

Lots of LUTS: Symptoms of BPH

The most common symptoms of BPH involve changes or problems with urination. In medical articles, they are often grouped together and referred to as LUTS, which stands for lower urinary tract symptoms. They include

- a hesitant, interrupted, or weak urine stream
- urgency, leaking, or dribbling
- a sense of incomplete emptying
- more frequent urination, especially at night.

Note that while many men with BPH have LUTS, there are other causes of LUTS, so not all men with LUTS have BPH.

Diet definitely seems to matter. Several large studies have found a correlation between Western dietary patterns (high intake of red meat, refined grains, and sugar) and prostate enlargement.

Between 50% and 60% of men with BPH may never develop symptoms, while others find that BPH can make life miserable (see “Lots of LUTS: Symptoms of BPH,” at left) and seek treatment. The odds of experiencing symptoms increase with age. Although the size of the prostate would seem to be related to symptoms, that's not always the case: some men with large glands never have symptoms, while others with small glands do. When symptoms do occur, patients and their physicians have several medications to choose from. If one doesn't do the trick, another one might. Thanks to some important refinements, surgical treatments are more effective and have fewer side effects than ever before.

How BPH progresses

As the prostate enlarges, it starts to press against the urethra and the bladder (see Figure 2, page 7), like a foot stepping on a garden hose or fingers pinching a straw. This pressure eventually obstructs the flow of urine, forcing the bladder to squeeze harder to push urine through the urethra. But straining to urinate, although unavoidable, only makes matters worse. Like any muscle, the bladder wall becomes thicker with work. That thickness reduces the amount of urine the bladder can hold and causes it to contract even when it contains only small amounts of urine, causing more frequent urination. Eventually, the bladder can become so bulked up that it loses its elasticity and can no longer empty itself.

The narrowing of the urethra and partial emptying of the bladder cause many of the problems associated with BPH. You may feel as though you have to urinate immediately, yet have to strain to do so. You may have a weak urinary stream or one that stops and starts. You may dribble after urinating or feel as if you're not emptying your bladder completely. And you may feel the need to urinate frequently—even every few minutes; at night, the continual need to go to the bathroom can make it impossible to sleep well, causing all sorts of negative health consequences. Some men also experience urinary incontinence, the involuntary discharge of urine.

How large the prostate gets and the symptoms that BPH causes vary from one man to the next. In some cases, the prostate reaches a certain size, and the symptoms plateau at a mild level and never worsen. In others, the prostate may continue to enlarge, but as it does, it grows away from the urethra, so it doesn't cause additional impingement. Particularly in the early years of the condition, the symptoms may ease up before getting worse again. But in some men, the disease progresses, and the symp-

toms intensify steadily, year after year. In extreme cases, the prostate, normally walnut-sized, can grow as large as an orange.

Most physicians advise against medical or surgical treatment for men with mild symptoms because the side effects of the treatment outweigh the potential benefits. But if the symptoms worsen, ordinary activities may become a challenge. A man may find it hard to sit through a lengthy meeting. Aisle seats become a necessity so there's a quick escape to the bathroom. Many men wear absorbent pads or limit themselves to dark clothing to conceal their incontinence.

BPH can also result in some serious complications. If an enlarged prostate keeps your bladder from emptying completely, you may be vulnerable to frequent urinary tract infections. The risk of developing bladder stones increases. A growing prostate can rupture blood vessels in the urethra, causing blood to appear in the urine. A thorough medical evaluation is necessary any time there's blood in the urine.

If obstructive BPH goes untreated for too long, the bladder may get stretched out, causing the muscular part of the wall to weaken. Your bladder may not have enough power to push urine past the obstructing prostate gland, a condition known as acute urinary retention. The bladder may become so stretched out that urine cannot adequately empty from the kidneys. In the worst cases, this can lead to kidney failure.

Not being able to urinate at all is painful and a true medical emergency, requiring the temporary passage of a catheter (a thin tube) through the urethra to allow the bladder to drain. Fortunately, such complications are uncommon because most men seek medical attention well before serious problems develop.

Getting help

If you experience the symptoms of BPH, see your doctor. Expect questions about your urinary flow problems, how long the symptoms have been present, and any prior genitourinary surgery or procedures. You will probably be asked about your health habits and the medications you are taking. Medications that have antihistamine effects can cause urinary symptoms because they affect the muscle in the wall of the bladder. If you are taking blood pressure medication, swapping out a diuretic such as furosemide (Lasix) for a nondiuretic such as an ACE inhibitor can help with a variety of urinary symptoms.

Your doctor may also ask you to complete a questionnaire, such as the American Urological Association Urinary Symptom Score, to help evaluate the severity of your BPH (see "Your urinary symptom score," page 10).

An adequate physical exam and diagnostic workup includes a digital rectal examination (DRE; see page 43) and, if you and your doctor agree, a prostate-specific antigen test (PSA test; see page 44). It also includes several other laboratory tests, such as a urinalysis, which allows your doctor to rule out bacterial infections and look for untreated diabetes, which can produce frequent urination, particularly at night.

Treating BPH

Often a man's lifestyle will determine how burdensome he finds BPH. The symptoms that disrupt the daily activities of a man who is conducting business or traveling may

Your urinary symptom score

To evaluate the severity of your benign prostatic hyperplasia (BPH) and determine what treatment, if any, might be best for you, your doctor may ask you to complete a questionnaire like the one below. Choose one number to respond to each question, and then calculate the total score.

In general, if your symptoms are mild (scores of 1–7), no treatment is needed. If your symptoms are moderate (scores of 8–19), you probably need some form of treatment, such as medication. If your symptoms are severe (scores of 20 or greater), surgery is likely to be your best treatment option if medications do not improve urinary function.

1. Over the past month, how often have you had a sensation of not having emptied your bladder completely after you finished urinating?
 - 0 ☐ Not at all
 - 1 ☐ Less than 1 in 5 times
 - 2 ☐ Less than half the time
 - 3 ☐ About half the time
 - 4 ☐ More than half the time
 - 5 ☐ Almost always
2. Over the past month, how often have you had to urinate again less than two hours after you last finished urinating?
 - 0 ☐ Not at all
 - 1 ☐ Less than 1 in 5 times
 - 2 ☐ Less than half the time
 - 3 ☐ About half the time
 - 4 ☐ More than half the time
 - 5 ☐ Almost always
3. Over the past month, how often have you stopped and started again several times while urinating?
 - 0 ☐ Not at all
 - 1 ☐ Less than 1 in 5 times
 - 2 ☐ Less than half the time
 - 3 ☐ About half the time
 - 4 ☐ More than half the time
 - 5 ☐ Almost always
4. Over the past month, how often have you found it difficult to postpone urination?
 - 0 ☐ Not at all
 - 1 ☐ Less than 1 in 5 times
 - 2 ☐ Less than half the time
 - 3 ☐ About half the time
 - 4 ☐ More than half the time
 - 5 ☐ Almost always
5. Over the past month, how often have you had a weak urinary stream?
 - 0 ☐ Not at all
 - 1 ☐ Less than 1 in 5 times
 - 2 ☐ Less than half the time
 - 3 ☐ About half the time
 - 4 ☐ More than half the time
 - 5 ☐ Almost always
6. Over the past month, how often have you had to push or strain to begin urination?
 - 0 ☐ Not at all
 - 1 ☐ Less than 1 in 5 times
 - 2 ☐ Less than half the time
 - 3 ☐ About half the time
 - 4 ☐ More than half the time
 - 5 ☐ Almost always
7. Over the past month, how many times, typically, did you get up to urinate between the time you went to bed at night and the time you got up in the morning?
 - 0 ☐ None
 - 1 ☐ Once
 - 2 ☐ Twice
 - 3 ☐ Three times
 - 4 ☐ Four times
 - 5 ☐ Five times or more
8. How would you feel if you had to live with your urinary condition the way it is now, no better, no worse, for the rest of your life?
 - 0 ☐ Delighted
 - 1 ☐ Pleased
 - 2 ☐ Mostly satisfied
 - 3 ☐ Mixed
 - 4 ☐ Mostly not satisfied
 - 5 ☐ Unhappy

Total score: _____

not bother another man who spends much of his day at home within easy reach of a bathroom. When symptoms are not particularly bothersome, you and your doctor may elect to hold off on treatment and instead monitor your BPH. For more troubling symptoms, most doctors begin by recommending a combination of lifestyle changes (see “Tips for relieving BPH symptoms,” at right) and medication. Often these changes will be enough to relieve the worst symptoms, so you won’t need surgery. Another option is learning intermittent self-catheterization (see Figure 4, page 12).

Should surgery become necessary, keep in mind that there are several surgical techniques available and that just because a technique is new doesn’t mean it is better. Before proceeding, check with your health insurance company to make sure your choice is covered.

Medications that treat BPH

Before suggesting surgery, your doctor is likely to recommend medication for BPH (see Table 1, page 13). The FDA has approved three types of drugs for BPH:

- alpha blockers, including alfuzosin (Uroxatral), doxazosin (Cardura, generic), silodosin (Rapaflo), tamsulosin (Flomax, generic), and terazosin (Hytrin, generic)
- 5-alpha-reductase inhibitors, including dutasteride (Avodart) and finasteride (Proscar, generic)
- a PDE5 inhibitor, tadalafil (Cialis).

The FDA has also approved Jalyn, a combination of the 5-alpha-reductase inhibitor dutasteride and an alpha blocker, tamsulosin. These drugs work in different ways to alleviate urinary symptoms, and they often work well together (see Figure 3, below).

A good way to think about the difference between alpha blockers and 5-alpha-reductase inhibitors is that alpha blockers help the “going” problem while 5-alpha-reductase inhibitors help with the “growing” problem. By relaxing certain muscles

Tips for relieving BPH symptoms

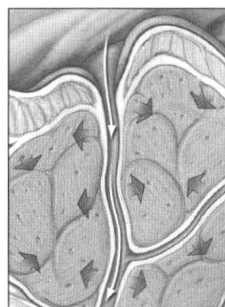
These simple steps can help relieve some of the symptoms of BPH:

- Reduce stress by exercising regularly and practicing relaxation techniques such as meditation. Some men who are nervous and tense urinate more frequently.
- When you go to the bathroom, take the time to empty your bladder completely. This will reduce the need for subsequent trips to the toilet.
- Talk with your doctor about all your prescription and over-the-counter medications; some, such as antihistamines and decongestants, may affect urination. Your doctor may be able to adjust dosages, change your schedule for taking these drugs, or prescribe different medications that cause fewer urinary problems.
- Avoid drinking fluids in the evening, particularly caffeinated and alcoholic beverages. Both can affect the muscle tone of the bladder and stimulate the kidneys to produce urine, leading to nighttime urination.

Figure 3. How BPH medications can help



Alpha blockers attach to certain receptors in the prostate, bladder, and urethra, blocking chemical signals that tell muscles in these structures to contract. As a result, the muscles relax, allowing urine to flow more freely.

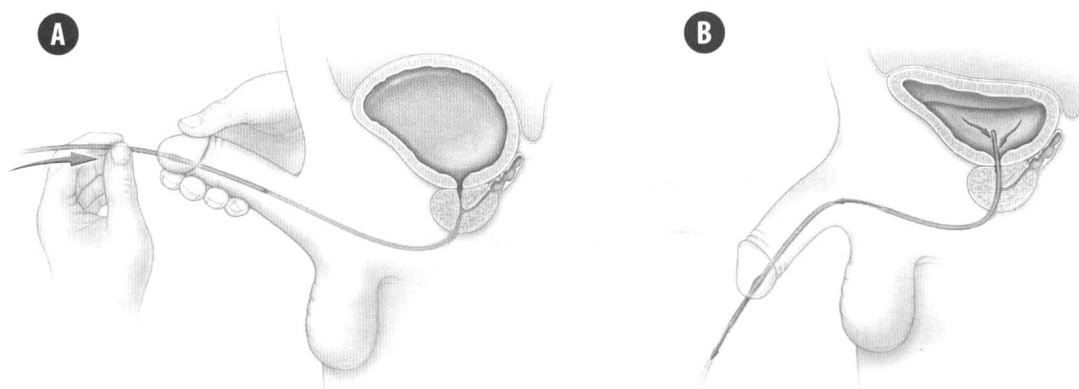


The 5-alpha-reductase inhibitors block the hormone responsible for prostate growth, eventually causing the prostate to shrink.

Figure 4. Intermittent self-catheterization for urinary retention

One of the reasons a man with BPH might have to urinate so frequently is that he is unable to empty his bladder completely—a problem known as urinary retention. When the bladder does not empty on a regular basis, a man may feel a constant sense of fullness in his abdomen and a nagging need to urinate, yet when the time comes, his urine stream may be weak or intermittent. The amount of urine left in the bladder is known as the post-void residual. The amount of retained urine that causes urinary retention symptoms varies. For most men, it is about 10 ounces.

If urinary retention is a problem for you, one option that may help is chronic intermittent catheterization. Learning this technique allows you to empty your bladder more completely by using a home catheter that is smaller and more portable than the Foley catheters used in medical procedures. This technique—along with some commonsense additional strategies such as not drinking a lot of water, alcohol, or caffeinated beverages (all increase urination)—may help you get through your next long plane trip or meeting. Here's how to practice chronic intermittent catheterization:



1. Find a clean and private environment, preferably with counter or desk space, where you can remain uninterrupted for a few minutes. You'll need a catheter (your doctor can provide you with one) and a toilet or container to drain urine into.
2. If a sink is available, wash your hands with soap and water, and clean the tip of your penis, including the opening to the urethra. (You can use disposable towelettes if you prefer.)
3. Lubricate the catheter using a water-based lubricant such as K-Y Jelly. Do not use a petroleum-based lubricant such as Vaseline.
4. Get into a comfortable position. Some men prefer to catheterize themselves standing up, while others prefer to be seated or propped up in a bed.
5. Grasp your penis just below the head and pull it out and slightly upward to straighten the urethra.
6. If you are not circumcised, retract the foreskin. Gently insert the catheter into the opening of the urethra and slide it slowly inward, toward your belly. The lubricated catheter should slide easily through the urethra (A).
7. You may notice some resistance once you reach the level of the prostate (especially if tissue is pressing against the walls of the urethra) and at the sphincter located at the entrance of the bladder. If so, breathe deeply or practice another relaxation technique so that you can continue gently advancing the catheter.
8. Continue advancing the catheter until urine starts to flow downward into the toilet bowl or other container. This is a sign that the catheter has entered the bladder (B).
9. Advance the catheter another inch and then hold it in place until the urine stops flowing. At that point, the bladder is empty.
10. Slowly withdraw the catheter.
11. Discard a disposable catheter immediately. If the catheter is reusable, wash it completely, dry it, and store it in a clean container. Even a secure plastic bag is sufficient. Check with your health provider about how often a reusable catheter can be used.
12. Keep extra catheters on hand for use as needed.