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<th>Program Name:</th>
<th>Informed Decision-making for Prostate Cancer Testing</th>
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Learning Objectives
By the end of this course, the learner will be able to:

- Apply knowledge of prostate cancer epidemiology (prevalence, incidence, mortality) to patient discussions and health management
- Identify risk factors for prostate cancer and their influence on decision-making for prostate cancer testing
- Synthesize the current recommendations (Canadian and U.S.) for prostate cancer testing and apply them in terms of:
  - Who to test
  - When to start testing and how frequently to continue this
  - How to test
  - How to interpret results and communicate them to patients
  - Factors influencing when to stop testing
- Implement shared decision-making in tailoring clinical follow-up based on test results

Pre- and Post-Test

1. Prostate cancer represents approximately what proportion of all cancers diagnosed in Canadian men?
   a) 5%
   b) 10%
   c) 25%
   d) 40%
   e) 50%

2. According to Canadian Cancer Society statistics, what is the estimated 5-year survival rate for prostate cancer in Canada?
   a) 35-40%
   b) 55-60%
   c) 75-80%
   d) 95-100%

3. Which of these tests is/are considered the front-line test(s) for detection of prostate cancer?
   a) Digital rectal exam
   b) PSA test
   c) Transrectal ultrasound
   d) Prostate biopsy
4. What is the minimum number of PSA test results required to accurately calculate a PSA velocity (PSAV)?
   a) 6 tests over a one-year period
   b) 4 tests over an 18-month period
   c) 4 tests over a one-year period
   d) 3 tests over an 18-month period
   e) 2 tests over a six-month period

5. Which of the following could lead to an elevated PSA?
   a) Prostate cancer
   b) Recent sexual activity
   c) Recent digital rectal examination
   d) Benign prostatic hyperplasia
   e) Any of the above
   f) a, b & d

Patient Case Introduction

Jason is a 46-year-old Caucasian man presenting to his primary care physician with symptoms consistent with acute sinusitis. He does not have annual physical examinations – this visit is the first to the physician’s office in nearly six years.

As the visit is wrapping up, the physician asked if there is anything else that he can help with. Jason hesitated at first, but then mentioned that a friend in his early 50s was recently diagnosed with prostate cancer and he asked if he should be tested at some point.

The physician said that there was indeed some testing that can be done to help assess Jason’s chances of developing prostate cancer. He then looked into Jason’s history in a little more detail: Jason does not have any comorbidities and he does not recall any major health concern with first-degree relatives, but remembers that when he was younger, his paternal uncle died rather suddenly at age 58 from cancer.
Overview of Prostate Cancer in Canada

Epidemiology
Prostate cancer is the most common cancer among men in Canada, accounting for an estimated 25% of all cancer diagnoses annually.\textsuperscript{1} In absolute terms, this translated to approximately 23,600 new cases of prostate cancer in Canada in 2013.\textsuperscript{1} The lifetime risk of a diagnosis of prostate cancer is estimated to be approximately 1 in 7, with a lifetime risk of prostate-cancer-related mortality of 1 in 28.\textsuperscript{1} The risk of prostate cancer is age-related, as shown in Figure 1, with the risk increasing substantially after age 50, and peaking over the ages of 65 to 74 years.\textsuperscript{2}

Figure 1. Prostate cancer, incidence rates per 100,000, by age group, Canada (2007)


Impact
The estimated absolute number of deaths from prostate cancer in 2013 among men in Canada was 3,900.\textsuperscript{1} The mortality rate has been declining steadily over the past decade (at a rate of approximately 4% per year from 2001 to 2009), attributed to detecting prostate cancer earlier and better treatment options (Figure 2). The five-year survival rate for men with a diagnosis of prostate cancer is estimated to be 96% (based on 2006-2008 estimates).\textsuperscript{1} A recent analysis in Sweden showed that approximately 50% of individuals diagnosed with prostate cancer will eventually die of causes unrelated to prostate cancer.\textsuperscript{3}
Beyond the mortality figures, however, prostate cancer is also associated with considerable morbidity, particularly in advanced stages, which may be associated with difficulties with urination, significant fatigue, kidney failure, and bone pain.\textsuperscript{4} Interventions for prostate cancer can also be associated with substantial morbidity. For example, hormone therapy is associated with an increased risk of neurologic and psychiatric effects (e.g., decline in cognitive function, depression), hot flushes, osteoporosis, decrease in muscle mass, fatigue, cardiometabolic and endocrine effects (e.g., gynecomastia, weight gain, and erectile dysfunction) and potential hematologic abnormalities (e.g., anemia).\textsuperscript{5} Chemotherapies that are used to treat refractory prostate cancer (e.g., docetaxel) may also be associated with adverse events and/or serious toxicities.\textsuperscript{6} Surgical interventions may also lead to serious adverse events, such as erectile dysfunction and urinary incontinence.\textsuperscript{7,8} Radiation therapy may also cause urinary and/or bowel difficulties.\textsuperscript{9}

The impact of prostate cancer is also felt in terms of financial and resource burden on the healthcare system. A Canadian economic impact analysis, published in 2000, estimated that the annual cost of managing prostate cancer was approximately $3.89 billion.\textsuperscript{10} This represented about 5\% of the total healthcare budget for the year of analysis. With newer therapies now available to treat men with hormone refractory prostate cancer, these costs are likely to further increase.

**Test Yourself**

1. Which of the following is true?
   a) Age-standardized prostate cancer mortality rates have been increasing over the past decade
b) Age-standardized prostate cancer mortality rates have been decreasing over the past decade

c) Age-standardized prostate cancer mortality rates have not changed appreciably over the past decade

2. Approximately what proportion of total Canadian healthcare expenditures is attributable to managing prostate cancer?
   a) 0.5%
   b) 1%
   c) 2%
   d) 5%
   e) 10%

Pathophysiology and Natural History
The pathophysiology and natural history of prostate cancer can vary substantially from individual to individual. Although the exact mechanisms are not completely understood, some of the underlying pathologic processes are thought to be chronic inflammation, infection and carcinogen exposure, which can lead to damage of the prostatic epithelium and the formation of precancerous lesions and adenocarcinoma itself.\(^\text{11}\)

In terms of prostate cancer itself, the natural history is not fully understood. Most patients will have indolent disease, which will never progress to a lethal stage. However, as mentioned in the epidemiology and impact section, there is a small subset of prostate cancer patients who will die from their disease and/or who may develop distant metastases over time. Why these cases evolve differently is not fully understood. While efforts are made to distinguish between lower-risk, indolent disease and higher-risk, aggressive disease at the time of diagnosis (e.g., grading and staging, discussed in the prostate cancer testing section), there is no definitive method--prior to a biopsy--of determining whether a patient will go on to have aggressive disease.

Risk Factors
The most important risk factors for prostate cancer are age (risk increases substantially after age 50), race (more common in men of African or Caribbean descent, less common in men of Asian descent), family history, low-fibre, high-fat diet, and obesity.\(^\text{12}\) Positive family history typically refers to a history of prostate cancer in a first-degree relative (i.e., brother or father), although statistics also show a trend towards increased risk among men with second-degree relatives with a history of prostate cancer.\(^\text{13}\)
What are the tests for Prostate Cancer?

Overview
Noninvasive testing represents the front-line approach to early detection of prostate cancer. This should involve both the digital rectal exam (DRE) and laboratory measurement of prostate specific antigen (PSA). As will be demonstrated in the description of current guidelines below, there is some variability in expert recommendations about timing and frequency of testing, but together, these two tests remain the best options for early detection.

PSA Test
PSA is a protein produced primarily by the prostate epithelial cells lining prostatic structures. An elevated PSA is a potential indicator of prostate cancer in that the disruption of the local environment caused by prostate tumor growth causes greater amounts of PSA to reach the systemic circulation and be detectable by a blood test. Importantly, many other factors can also cause an elevation in PSA, including sexual activity, exercise, direct pressure near the prostate (e.g., from bicycling), many medications (e.g., 5-alpha reductase inhibitors [e.g., finasteride], and supplements and other conditions affecting the prostate (e.g., benign prostate enlargement) or urinary tract (e.g., infection). There are also some common medications that may lower the PSA value, including statins and NSAIDs.

See the interpretation section of this program for information about the significance of PSA findings.

Digital Rectal Exam
The digital rectal examination is a procedure that should be viewed as complementary to PSA testing for identification of prostate cancer, as many cases that can be identified by DRE may not necessarily be picked up by PSA alone. As such, the DRE should be part of prostate cancer testing, complementing the PSA test whenever it is performed (see the recommendations section for frequency of testing). The abnormalities that can be identified by DRE that are suggestive of prostate cancer include: asymmetry, induration and hard nodules. Notably, there is considerable variability in DRE testing based on provider comfort and skill with the procedure.
Transrectal Ultrasound
Although this imaging modality is important to help guide biopsy of the prostate, as a screening tool by itself, it is not recommended. Research has shown that most cases of prostate cancer would be missed by ultrasonography, even among patients with abnormal PSA and/or DRE testing.16

Biopsy
When the suspicion of prostate cancer is raised (e.g., by PSA testing, DRE or both), a biopsy should be ordered, to confirm a diagnosis and enable histologic grading and classification if prostate cancer is confirmed (see the interpretation section of this program).

How Do You Interpret the Results?
PSA
In the past, thresholds defining an elevated PSA (e.g., > 4 ng/mL) have been suggested. However, research has clearly shown that the risk of having prostate cancer is directly and continuously correlated with increasing serum PSA, and is influenced by other factors (e.g., the age of the individual). As such, expert recommendations do not endorse any single value above which further investigation is clearly indicated.

Furthermore, as mentioned in the description of the tests, although an elevated PSA may be caused by prostate cancer, there are many other causes of an increase in PSA, including other urologic abnormalities (e.g., BPH, prostatitis) or invasive procedures (e.g., catheter insertion, prostate biopsy). A recent DRE or recent ejaculation are also possible causes of transient elevation of PSA in some men.

The baseline PSA value can be used as an additional variable in an individual’s risk profile. Consideration of this value in conjunction with all risk factors can help tailor clinical follow-up.

Medications can also affect the PSA; 5-alpha reductase inhibitors, routinely used to treat benign prostate enlargement, for example, are associated with a substantial reduction in PSA (50% reduction by 6 months).14 Drawing a baseline PSA prior to prescribing these drugs is essential.

Because of these realities, interpretation of PSA findings has been the subject of vigorous research and debate.
A key concept in the use of PSA testing for detection of prostate cancer is the need for repeated testing over time (see also the section of this program on the **current recommendations** for testing). This is important in that PSA values may vary in any given individual from test to test (due to a number of factors as described in the **interpretation** section) and results may also vary from laboratory to laboratory. Repeat testing therefore provides more certainty that a value obtained is accurate for that individual, and repeat testing over time allows for the determination of PSA velocity (PSAV). A calculation of the PSAV requires at least 3 PSA values over a period of 18 months.

Other methods that can be used to help augment the diagnostic utility to PSA testing are the **free:total PSA ratio**, **PSA density** (PSAD) and **PSA isoforms**. The free PSA should not be routinely ordered, but it can be particularly helpful when the PSA is between 4 and 10 ng/mL.

PSA values are also an important part of prostate risk calculators, which can be used to estimate an individual’s risk of developing prostate cancer. There are several such calculators available, including the [Sunnybrook Prostate Cancer Risk Calculator](#), which includes seven variables: age, ethnicity, family history of any relatives diagnosed with prostate cancer, presence of urinary symptoms (measured by the International Prostate Symptom Score [IPSS] index), total PSA value, free:total PSA ratio value and DRE (normal or abnormal).

**KOL VIDEO: Do you have to order multiple PSA tests to be confident about the results?**

**KOL VIDEO: Why do you think there is still such a dichotomy in recommendations with respect to whether or not to use PSA tests to help identify prostate cancer?**

**Test Yourself**

3. What is the approximate anticipated effect on the PSA of six months of therapy with a 5-alpha-reductase inhibitor (e.g., finasteride)?
   a) Increase of 50% of pre-treatment value
   b) Increase of 100% of pre-treatment value
   c) Decrease of 100% of pre-treatment value
   d) Decrease of 50% of pre-treatment value
   e) No effect
4. A PSA velocity above what threshold would be considered abnormal in a 55-year-old man?
   a) 0.15 ng/mL/year
   b) 0.25 ng/mL/year
   c) 0.4 ng/mL/year
   d) 0.5 ng/mL/year
   e) 0.75 ng/mL/year

**Biopsy**

A biopsy should be considered when the suspicion of prostate cancer exists after evaluation of various clinical variables including PSA, DRE, family history and general health. A prostate cancer risk calculator can also be part of the decision-making process. The biopsy typically consists of samples from 10-12 areas within the prostate. If features consistent with prostate cancer are detected, pathologists provide the clinician(s) and the patient with such information as the size and location of the tumor, the estimated tumor volume and other relevant characteristics (e.g., perineural invasion, extraprostatic extension). The pathology report will also include a Gleason score, the tool most often used to grade the aggressiveness of prostate cancer. The overall Gleason score is the sum of the primary and secondary Gleason grades, determined by pathologic examination of the prostate biopsy.

The primary and secondary Gleason scores are each assigned a value of 1 to 5, with lower scores associated with a more favorable prognosis. Total Gleason scores of 2-5 are usually considered to be low-grade cancers, Gleason 6 is usually considered to be moderately differentiated, but low risk, while Gleason 7 is moderately differentiated and intermediated risk. Scores of 8-10 are poorly differentiated or high-grade cancers. These scores, along with the clinical staging information are important for counseling patients about the prognosis and helping make decisions on whether or not to initiate treatment and, if so, which treatment modality(ies) to choose.

**Test Yourself**

5. Which of the following is the range of Gleason scores most often considered to be high-grade, aggressive cancers?
   a) 8-10
   b) 5-7
   c) 2-4
What are the Current Recommendations for Prostate Cancer Testing (Who, When, How)?

Prostate Cancer Canada’s PSA recommendations
In 2013, Prostate Cancer Canada (PCC) published a position paper on the use of the PSA test for detection of prostate cancer in Canadian men.¹⁸ The position paper, along with an educational campaign encouraging men to “Know Your Number” recommends that men have a PSA test conducted during their 40s, to establish baseline value and allow healthcare providers to better tailor clinical follow-up (e.g., frequency of testing). The recommendations also specify that those individuals deemed to be at high risk of prostate cancer (i.e., African or Caribbean ancestry, family history of prostate cancer) should talk to their primary-care physician about prostate cancer and devise a plan for when to begin PSA testing. A third recommendation states that the decision of when to stop PSA testing should be made on an individual-by-individual basis after the age of 70 years. Importantly, the PCC position paper also mentions the importance of separating the PSA test results from treatment. Test results should not, on their own, be used to make treatment decisions. This is also a key statement of the Melbourne Consensus Statement on Prostate Cancer Testing (see Other Relevant Guidelines).

The recommendation to establish the baseline PSA number is based on the fact that prostate cancer, when detected early, is associated with very high survival rates, and on findings from a Swedish study, which suggested that PSA testing beginning in the mid-to-late 40s can serve as an indicator of future risk of prostate cancer.¹⁹

In addition, Prostate Cancer Canada recommends strongly that the concept of testing be uncoupled from treatment. Having a PSA test does not mean that a patient will be treated for prostate cancer. PSA testing is primarily a means of monitoring prostate health. One abnormal test result does not mean treatment is a foregone conclusion.

Canadian Urologic Association’s guidelines for prostate cancer screening
In the most recent Canadian Urologic Association (CUA) guidelines for prostate cancer screening (2011), the authors recommend that PSA testing begin after age 50 among individuals with at least a 10-year life expectancy.¹⁴ The CUA does, however, state that “There may be benefit in offering a baseline PSA for men 40 to 49 years of age to establish future prostate cancer risk.”
In terms of frequency of testing, there is no strong recommendation in the CUA guidelines. Although the authors state that annual testing is the norm, they also recognize that testing every two to four years has also proven to be beneficial.

For the decision of when to stop testing, the CUA guidelines state that “Strong consideration should be given to discontinuing PSA screening for Canadian men over 75 years of age.”

Other relevant guidelines
In addition to the Canadian recommendations listed above, there are also several other sets of recommendations, some of which contradict those of the Canadian recommendations, that both healthcare professionals and patients may be aware of.

In 2013, a guidance statement on prostate cancer testing was published by the Clinical Guidelines Committee of the American College of Physicians (ACP). The recommendations in this document are of a completely different tone than those of their Canadian colleagues. The ACP recommends that “clinicians inform men between the age of 50 and 69 years about the limited potential benefits and substantial harms of screening for prostate cancer,” and that “clinicians should not screen for prostate cancer using the prostate-specific antigen test in patients who do not express a clear preference for screening.” The United States Preventive Services Task Force (USPSTF) has also come out against routine PSA testing, stating simply that “The USPSTF recommends against PSA-based screening for prostate cancer.”

In an effort to reconcile the conflicting viewpoints on PSA testing worldwide, an international group of experts convened at the 2013 Prostate Cancer World Congress in Melbourne, Australia. The result of their deliberation was five consensus statements on PSA testing (widely known as the Melbourne Consensus Statement on Prostate Cancer Testing). Their recommendations, which are also found on the BJU International blog, are as follows:

Consensus Statement 1: For men aged 50–69, level 1 evidence demonstrates that PSA testing reduces prostate cancer-specific mortality and the incidence of metastatic prostate cancer.

Consensus Statement 2: Prostate cancer diagnosis must be uncoupled from prostate cancer intervention.

Consensus Statement 3: PSA testing should not be considered on its own, but rather as part of a multivariable approach to early prostate cancer detection.
Consensus Statement 4: Baseline PSA testing for men in their 40s is useful for predicting the future risk of prostate cancer.

Consensus Statement 5: Older men in good health with over ten year life expectancy should not be denied PSA testing on the basis of their age.

Test Yourself
6. Which is the most recent recommendation with respect to prostate cancer testing?
   a) Canadian Urologic Association (CUA) guidelines for prostate cancer screening
   b) Melbourne Consensus Statement on Prostate Cancer Testing
   c) Prostate Cancer Canada (PCC)'s position paper on PSA testing
   d) Guidance statement on prostate cancer testing by the Clinical Guidelines Committee of the American College of Physicians (ACP)

7. What is the recommended frequency of PSA testing among men older than 50 years, according to the Canadian Urologic Association (CUA) guidelines for prostate cancer screening?
   a) At least annually
   b) Annually
   c) At least every 2 years
   d) At least every 4 years
   e) There is no firm recommendation for frequency of testing

Conclusions
The Canadian recommendations (both those of Prostate Cancer Canada and those of the CUA) are in line with those of the Melbourne Consensus Group. Men should be encouraged to obtain a baseline PSA value when they are in their 40s, which will allow their healthcare provider to better tailor a strategy for subsequent follow-up.

Patient Case Continuation
In the case of Jason, a 46-year-old man who does not schedule annual physical examinations and who has expressed concern about prostate cancer, the physician take this opportunity to explain that experts recommend a PSA test for all men in their 40s, to establish a baseline level (i.e., in line with Prostate Cancer Canada’s Know Your Number recommendations). The physician explains that Jason’s history does not suggest that his is at high risk of prostate cancer but, nonetheless, all men are at risk for this common malignancy. In addition, although Jason does now know what kind of cancer his uncle died of, there is the possibility that it was metastatic prostate cancer.
He explains that depending on the result of the initial testing (more than one test is usually required to conclusively establish a baseline), they will be able to plan the future plan for monitoring (e.g., annual or biannual PSA testing once he reaches his 50s).

The physician explains that prostate cancer is highly treatable, with very high survival rates for disease detected in its early stages: having regular screening done as part of routine check-ups will help ensure that if abnormalities do develop, they are detected and addressed in a timely manner.

Click here to see a video example of a patient and his physician.

Video script:

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<td>Doctor: I know you’re here today to have your sinusitis looked after, but I wanted to talk to you about prostate health as well.</td>
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<td>Jason: Um, can it wait until another time? I just want to get back home and lie down.</td>
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<td>Doctor: Well, we don’t really know when the next time I’ll see you will be. When did I see you last?</td>
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<td>Jason: Not sure... maybe four or five years ago.</td>
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<td>Doctor: Right. Well, the conversation I want to have with you today is important at your age right now, not in four or five years. It won’t take long.</td>
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<td>Jason: OK. I’m listening.</td>
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<td>Doctor: Great. Thanks. As we get older, the risk of developing any number of conditions gets higher... whether it’s heart disease, diabetes or cancer.</td>
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<td>Jason (nodding): Right. I’m with you so far.</td>
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<td>Doctor (smiling): Ok good. Thanks for following along. So one of the things that is important to watch out for among older men is prostate cancer. It’s the most common cancer and the second most-common cause of cancer-related death, behind lung cancer, among Canadian men.</td>
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<td>Jason: Ok. So, you think I might have cancer?</td>
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<td>Doctor: No, you actually have a very low risk of having prostate cancer right now. What we want to do is run a test now, while you’re in your 40s that will help us detect prostate cancer as soon as possible if it develops later in life. That’s important, because prostate cancer has a very high survival rate when it’s identified early.</td>
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<tr>
<td>Jason: What kind of test?</td>
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<td>Doctor: It’s a simple blood test called the PSA test. When the levels go up, it is a sign that you might have prostate cancer. You see, if we don’t know what your PSA number is now, when you’re healthy, it makes it harder to put the numbers in perspective later, when you’re older. If we do the test now, we can enter it into your medical record and it becomes part of your medical profile.</td>
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Jason: Oh, ok. What about the rectal exam? I thought that was how you looked for prostate cancer.

Doctor: You’re talking about the digital rectal examination. That test could come in handy if anything about the PSA values suggests that we need to evaluate further. It’s not a big deal: your prostate gland can be felt with a finger inside the rectum, so I would put on a rubber glove, lubricate a finger and feel your prostate gland to see if it is abnormal in any way. It takes less than a minute. In any case, that would be later. For now, we’ll just be measuring your PSA, which is simply a blood test.

Jason: OK. So I go get the test. Then what?

Doctor: We would enter your result into your medical record and it becomes an important part of your overall risk profile. We would then discuss the results and your overall risk of prostate cancer and decide together when you should get tested again. It’s important that we have that discussion no matter what your PSA result turns out to be.

Jason: Okay

Doctor: So here is the lab requisition form. I encourage you to do the test in the next couple of weeks. You can have it done at any lab—and they’ll send the results to me. If you don’t hear from us, it means that everything is within normal parameters. But if there’s anything that I’d like to investigate further, the office will call you to set up an appointment. If the results are within regular limits for you, I still want to see you on a more regular basis to be reviewing your overall health. Plus we can talk about how we’re going to use the PSA information and reach a decision about when you should get tested again. How does that sound?

Jason: That sounds good. I can do that.

Key Learning Points

PCC’s recommendations for PSA testing state that:

- Men at high risk for prostate cancer should talk to their primary care provider before age 40 about prostate cancer;
- Men should get a PSA test in their 40s to establish their baseline for identification of prostate cancer;
- At or over age 70, the decision to end PSA testing should be based on individual factors.

Practice Tips

- Prostate cancer is a very common disease that occurs in men.
- Clinical course ranges from indolent to lethal.
- Looking for prostate cancer and testing for it does not necessary lead to treatment.
- Many men can simply be followed but others with seemingly no baseline risk factors may harbour significant disease.
- Be vigilant and be prepared to uncouple diagnosis from treatment of prostate cancer. In this manner we can hopefully look after those that need to be treated and save others from the harm of overtreatment.
Discussion Forum

1. Do you perform DREs with the same approximate frequency as PSA tests? Why or why not?
2. What factors do you discuss with patients to help determine the appropriate frequency of PSA testing?
3. In what circumstances would you recommend assessing the free:total PSA ratio?
4. What factors help you decide when to stop PSA testing in older men?
References