New PSA guidance should serve as ‘catalyst for change’

As you know, on Oct. 7, 2011, the U.S. Preventive Services Task Force issued a statement recommending that the PSA test no longer be used for the early detection of prostate cancer. Please briefly summarize the USPSTF’s recommendation.

Bluntly, the USPSTF said using the PSA test to screen for prostate cancer was a disservice to men. The task force assigned early prostate cancer screening a grade D recommendation, meaning that it recommends against routinely providing the service in asymptomatic patients. A grade D recommendation also means the task force found at least fair evidence that screening is ineffective or that the harms outweigh the benefits. They and others in the urological community highlight the need for additional research in a number of areas.

The task force noted that we’ve seen a decrease in prostate cancer mortality with PSA testing, and this has a significant impact on that decrease. They clearly acknowledged the risk of overtreatment resulting from screening and pointed to the need for more tailored treatment. They pointed out that over time, we will develop improved approaches to early detection.

Let’s use this report to refine and improve our approaches to early detection.

PETER R. CARROLL, MD, MPH

AUA outlines framework for robotics credentialing

Responsibility for granting privileges remains with hospital, committee says

Cheryl Guttmann Krader
UT CONTRIBUTING EDITOR

Linthicum, MD—A new AUA standard operating practice document aims to help with robotic surgery credentialing for practicing urologists and those in training.

The document, developed by the AUA Laparoscopic, Robotic and New Surgical Technology Committee after 2 years of meetings and discussions, was presented during a state-of-the-art lecture at the 2011 AUA annual meeting in Washington.

“Presently, hospital credentialing requirements for urologic robotic surgery are dependent on industry-driven requirements. However, this situation could compromise patient safety because of

Please see PSA GUIDANCE, on page 32

Please see ROBOTICS, on page 35
While the focus has been on reducing androgens, **androgen receptor (AR) signaling inhibition** may be an important approach in controlling advanced prostate cancer.\(^1\)\(^2\)

- AR signaling is a key driver of disease in advanced prostate cancer (APC). Activation of the AR leads to nuclear translocation and binding to DNA, with subsequent effects that promote tumor growth and progression.\(^2\)\(^3\)
- Despite low or even undetectable levels of androgens, AR signaling remains active and continues to drive disease.\(^4\)

**Potent AR signaling inhibition may be an important approach to control advanced prostate cancer.**\(^2\)

Get the other half of the story at www.TargetAR.com

References:
Here’s to a realistic post-RP potency talk

Radical prostatectomy (RP) is the most commonly selected option for treating localized prostate cancer. The annual numbers of this procedure have grown tremendously in the last 2 decades, and the surgical technique to achieve optimal results has evolved.

RP surgeons have promulgated post-op potency preservation percentages in the range of 80% or higher for many years. Surveys of patients and their partners have found these numbers to be highly unrealistic, and results of recent studies, such as one from Memorial Sloan-Kettering Cancer Center, are closer to reality (see article, page 5). Was the idea to promote the surgeon’s good nerve-sparing technique, or was it a marketing ploy?

Another recent study, this one from Mayo Clinic, shows that the erectile dysfunction present after RP is due mostly to arterial insufficiency or venous leakage, not neural impairment (see article, page 6). This operation, by its nature, is detrimental to erections even when performed by the most skilled surgeons using optimal nerve-sparing technique. Those with good erectile reserves (ie, younger patients and those with no prior ED and few vascular risk factors) will likely have the best chance of potency preservation or adequate erections with the assistance of medications.

Those with pre-existing, pre-op erectile difficulties or older patients will very likely experience poor erections after surgery.

Patients contemplating prostate ablation wish to have their cancer eradicated. Erections can be restored very nicely afterwards with penile rehabilitation or, if this is unsuccessful and the patient is motivated, with a penile implant, which yields satisfaction rates in the range of 90% among both patients and partners.

Post-treatment potency preservation rates with brachytherapy and external beam radiation are similar to those after RP, so patients are not better served by switching from RP to radiation to achieve better potency outcomes.

The urologist performing RP should give realistic expectations in his pre-op discussion. The patient will likely choose the treatment he thinks will be best for cancer control, not the best for preserving his erections, as that problem can be very adequately dealt with later if the problem arises. Post-op, patients should be encouraged with penile rehabilitation protocols to be proactive in restoring the blood flow to the penis, and the positive aspects of a penile implant should be presented.
Tips for managing urolithiasis in women

Not only is stone disease becoming more common, but it is increasing at a faster rate in women than in men. This article discusses the pathophysiology, management, and prevention of urolithiasis in women, and includes a video of co-author Manoj Monga, MD, performing shock wave lithotripsy.

For the article and video, see: urologytimes.com/uroolithiasisinwomen

Best business pearls for your urology practice

When you were in residency, there never seemed to be enough hours to learn all there was to know about being a clinician. Once you were out in the real world, it probably didn’t take long to realize that the one thing you weren’t taught was how to be a businessperson. *Medical Economics* has assembled a string of valuable practice management pearls that will help you fill in the gaps. Read tips on staff management, cash flow operations, patient relations, personal finance, and more at: urologytimes.com/pearls

Post-retirement career requires careful planning

Looking for a post-retirement career that does not involve practicing medicine? Here are some helpful resources, including books, that you shouldn’t overlook. Learn about them at: urologytimes.com/retirementresources

FDA effort aims to combat unsafe Internet drugs

The FDA and other regulatory and international partners have completed a cooperative effort to curb online sales of counterfeit and illegal medical products, including drugs marketed as treatments for erectile dysfunction. Read about it at: urologytimes.com/unsafedrugs
Post-RP erectile function recovery lower than reported
Findings stress importance of patient counseling prior to procedure

Mac Overmyer
UT CONTRIBUTING EDITOR

New York—Post-radical prostatectomy erectile function recovery is much lower than physician-reported rates, a study from the Memorial Sloan-Kettering Cancer Center, New York, indicates.

Sexual Dysfunction

Acting on anecdotal evidence, the authors assessed the erectile function of 250 men (average age, 59±8 years) pre- and post-radical prostatectomy. The authors found that only 18% of the entire sample reported penile rigidity sufficient for penetration at 24 months post-op. Only 13% with penetration-sufficient rigidity at baseline reported a similar rigidity at 24 months post-op.

“These figures are significantly lower than most reported erectile function recovery rates, and men pre-radical prostatectomy should be educated as to the meaning of erectile function recovery,” wrote the study’s authors: Christian J. Nelson, PhD, Peter Scardino, MD, and John P. Mulhall, MD.

Some reports suggest recovery rates greater than 90%, noted Dr. Nelson, assistant attending psychologist in the Memorial Sloan-Kettering department of psychiatry and behavioral sciences.

In addition, 186 men (74%) had a baseline erectile function domain (EFD) score ≥24. At 24 months post-op, 60 (32%) of these men attained an EFD score of ≥24. Well over half (60%) of these men used phosphodiesterase type-5 inhibitor therapy to achieve results. Only 24 men (13% of the initial study cohort) with a baseline EFD ≥24 returned to that score at 24 months post-op without therapeutic intervention.

“I think there are two aspects to the study,” Dr. Nelson told Urology Times. “In terms of data, the take-home message is that only a small percentage of men are going to get back to the way they were before the surgery without therapy, especially if they are over 60.

“What is not in the data are patient expectations and the adjustments they have to make after surgery.”

Dr. Nelson explained that prior to undergoing radical prostatectomy, patients were focused on the disease itself and the effects of the surgery. Following the procedure, when the idea of cancer no longer occupied their minds, they would begin to express disappointment about their erectile function.

“This study offers an opportunity to frame the issue of ED in a way that puts it in context and allows the patient to understand it. For instance, before the procedure, the patient should be told, ‘What we need to do is cure your cancer. Unfortunately, there are some consequences that come with that and one of them is that there is going to be an impact on your erectile function,’” said Dr. Nelson, who presented the findings at the 2011 AUA annual meeting in Washington.

NewsUpdate

Panel backs active surveillance for low-risk prostate cancer

An independent panel convened in December by the National Institutes of Health concluded that many men with localized, low-risk prostate cancer should be closely monitored, permitting treatment to be delayed until warranted by disease progression. Because of the favorable prognosis of PSA-detected, low-risk prostate cancer, the panel went as far as saying that strong consideration be given to removing the term “cancer” for this condition.

The panel also recommended standardizing definitions and conducting additional studies to clarify which monitoring strategies are most likely to optimize outcomes.

“It’s clear that many men would benefit from delaying treatment, but there is no consensus on what constitutes observational strategies and what criteria should be used to determine when treatment might ultimately be needed among closely monitored men,” said conference panel chairperson Patricia A. Ganz, MD, of UCLA’s Jonsson Comprehensive Cancer Center.

Defining low-risk prostate cancer as PSA <10.0 ng/mL and a Gleason score of 6 or less, the panel estimated that more than 100,000 men diagnosed with prostate cancer each year would be candidates for active monitoring rather than immediate treatment. Important-ly, however, the panel found that active monitoring protocols still vary widely, hampering the evaluation and comparison of research findings.

FDA approves topical gel for treatment of OAB

Watson Pharmaceuticals, Inc. and Antares Pharma, Inc. recently announced the FDA approval of Antares’ topical oxybutynin gel 3% for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and frequency.

The product is a clear, odorless topical gel available in a metered-dose pump that has been shown to be an effective and safe treatment for OAB. Its approval was based on a 12-week, multicenter placebo-controlled phase III clinical study conducted by Antares.

Under an exclusive licensing agreement, Watson said in a statement that it anticipates launching oxybutynin gel 3% in 2012.
Diabetes has negative impact on function

Most post-RP ED cases have non-neurogenic etiology

Mac Overmyer
UT CONTRIBUTING EDITOR

Jacksonville, FL—The advent of nerve-sparing radical prostatectomy and its outcomes has focused attention on the etiology of erectile dysfunction following all forms of prostate cancer intervention. A study by urologists at Mayo Clinic, Jacksonville, FL, suggests that only 13.3% of cases of ED following radical prostatectomy have a primarily neurogenic etiology and that 9.1% of cases following radiation therapies have neurogenic origins.

“Nerve-sparing prostatectomy is a major step forward in the treatment of prostate cancer, and it appears from this data that it is effective at avoiding neurogenic impotence. However, vascular concerns must be considered,” first author Ryan Hutchinson, MD, told Urology Times.

“Three main points came out of this study. One is that neurogenic impotence is not the number one cause of ED following prostatectomy. The second is that ionizing radiation therapies such as external beam therapy and brachytherapy appear to be associated with a higher incidence of arterial insufficiency as the driving cause of impotence in these patients. The last would be that comorbidities, specifically diabetes, appear to have a profound negative impact on sexual function after any intervention,” said Dr. Hutchinson, a Mayo Clinic urology resident working with Gregory Broderick, MD, and colleagues. Dr. Broderick presented the results at the 2011 AUA annual meeting in Washington.

The researchers arrived at these conclusions by identifying 194 patients who had undergone prostate interventions and were evaluated for ED refractory to medical therapy. The records were compiled using Research Electronic Data Capture (REDCap), a data acquisition tool developed at Vanderbilt University, Nashville, TN. Of these patients, 120 (61.9%) underwent robotic and radical retropubic prostatectomy, 22 (11.3%) underwent external beam radiation or brachytherapy, 42 (21.6%) underwent transurethral resection of the prostate, and 10 (5.2%) underwent other interventions.

“The data contained both non-nerve-sparing and nerve-sparing procedures; however, the vast majority of these were nerve sparing,” Dr. Hutchinson said.

Incidence of neurogenic etiology low

Analysis found that among surgical patients, 48.3% had refractory ED associated with cavernous veno-occlusive disease, 36.7% had ED associated with arterial insufficiency, and 13.3% had ED associated with neurogenic origins. Among those with ED following radiation therapy, more than half (54.5%) evidenced arterial insufficiency, 36.4% evidenced cavernous veno-occlusive disease, and 9.1% evidenced neurogenic etiology for their ED.

The study also found that diabetics had the lowest Erection Hardness Scores (p=.025) and that these men also exhibited lower peak systolic velocity and a lower resistive index during Doppler penile blood flow testing.

“These findings speak to the value of a good pre-operation counseling session,” Dr. Hutchinson said. “Patients should be told that a successful nerve-sparing procedure does not mean that their erectile function will be exactly the same after the procedure as it was before. Many men will experience some decline in erectile function and may require ED therapy. That said, it appears that the neurologic function is well preserved using the techniques of modern retropubic and robotic prostatectomy.”

He said that this study is probably the first of a number of such studies, some of which will examine the relationship of diabetes, hypertension, and coronary artery disease to ED. UT

Pre-RP penile length returns by 4 years post-op

Recovery of erectile function main predictor of length at long-term follow-up

Mac Overmyer
UT CONTRIBUTING EDITOR

Hannover, Germany—Post-radical prostatectomy penile length appears to return to baseline values approximately 48 months postoperatively, according to a collaborative prospective study of 105 consecutive patients at institutions in Brazil and Germany.

The researchers found that stretched penile length following radical prostatectomy for prostate cancer decreased by a mean of 1 cm at 3 months and continued to shorten at 24 months (mean, 0.9 cm) and again at 36 months (mean, 0.7 cm). At this point, the process appears to reach a nadir and reverse itself so that by 48 months, stretched length had returned to within -0.1 cm of baseline (p=.465) and appeared to be fully restored (mean, +0.3 cm) at 5 years post-op (p=.346).

The key to restoration of length appears to be recovery of erectile function following surgery. Men with no erectile dysfunction, as evidenced by an Erectile Function domain score on the International Index of Erectile Function (IIEF-EF) of ≥26, exhibited less loss of length than those with erectile dysfunction (IIEF-EF score <26). Those patients with established ED prior to the operation and continuing ED following the procedure (IIEF-EF <6) showed little to no evidence of recovery of length at the 5-year follow-up. These men were also significantly shorter at baseline than the other two groups.

Study unique for length of follow-up

“There are studies of length at 1 and 2 years, but there are no studies that evaluated penile length at longer terms, at 5 years. We found that penile length returns to baseline,” first author Juliana
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Gene panel predicts advanced prostate Ca survival
Prognostic value improves when combined with other biomarkers, data show

Cheryl Guttmann Krader
UT CONTRIBUTING EDITOR

New York—Results from testing in an initial patient cohort indicate the potential for a six-gene, whole blood RNA-based expression panel to predict survival in men with progressive metastatic castration-resistant prostate cancer (mCRPC), reported researchers from Memorial Sloan-Kettering Cancer Center, New York.

Prostate Cancer

“Recognition that men with CRPC represent a heterogeneous group whose survival time after diagnosis of progression varies from a few months to several years speaks to the need for identifying prognosticators that can accurately predict survival,” noted first author Sumit K. Subudhi, MD, PhD, a medical oncology fellow in genitourinary cancer at Memorial Sloan-Kettering, who presented the findings at the 2011 American Society of Clinical Oncology annual meeting in Chicago.

“The ability to differentiate men who will succumb early to their disease and those who will live longer is important in clinical management, where this information can help guide decisions on aggressiveness of therapy, but the ultimate goal is to be able to optimize patient stratification for enrollment into clinical trials where selection of a higher risk population can increase the efficiency and ability of the trial to determine efficacy and safety of interventions. We believe this gene panel holds promise in this regard,” said Dr. Subudhi, who worked on the research with Howard I. Scher, MD, and colleagues.

The biomarker panel was derived by analyzing RNA expression in whole blood obtained from 101 men at the time of mCRPC progression. A 2.5-mL sample of blood was collected and submitted for total RNA extraction. A total of 45 genes were selected for reverse transcriptase-polymerase chain reaction, and a biostatistical model was developed to identify genes that predicted survival in the study cohort.

Six genes were found to have prognostic significance and were combined into a biomarker panel that was shown to independently predict survival time in a multivariate analysis.

Panel displays ‘moderate’ accuracy
A concordance probability estimate (CPE) was used to determine the discriminatory power and predictive accuracy of the six-gene panel, and the six-gene panel was found to have a CPE value of 0.71, which is indicative of moderate accuracy. (A CPE of 0.5 represents a biomarker with no predictive accuracy, ie, a coin toss, whereas a CPE of 1.0 demonstrates a biomarker predicting with 100% accuracy that an event will occur.) Improved prognostic value was achieved by combining the six-gene panel with circulating tumor cell (CTC) enumeration (CellSearch Assay, Veridex, North Raritan, NJ) and lactate dehydrogenase (LDH). The CPE value of the latter biomarker model was 0.76, Dr. Subudhi reported.

“Current biomarkers for predicting survival in patients with metastatic CRPC include CTC enumeration and levels of PSA, LDH, and albumin, but each of these markers has limited clinical utility when used in isolation,” Dr. Subudhi told Urology Times.

“Our study also found that the six-gene panel has greater predictive accuracy for predicting survival in patients with progressive mCRPC than the existing biomarkers, which had CPE values ranging from 0.56 to 0.68, and the prognostic value of the combined biomarker model is reasonable enough to suggest a role in clinical practice. However, our findings first need to be validated through testing in an independent population. Such an investigation is currently under way, and if the results are positive, the next step will be to test the ability of the RNA-based gene signature to predict outcomes in a prospective clinical trial,” he said.

The six genes comprising the predictive panel are BCL2 (B Cell Lymphoma 2), CIQB (complement component 1, b subcomponent), CAV2 (caveolin 2), CD82 (cluster of differentiation 82), GAS1 (growth arrest-specific protein-1), and NFATC2 (nuclear factor of activated T cells, cytoplasmic 2). They all have different functions that regulate cancer cell growth and metastasis.

Penile length
continued from page 6

Vasconcelos, MD, a first-year resident at Hannover Medical School, Hannover, Germany, told Urology Times. Dr. Vasconcelos worked on the study with Ronaldo Damiao, MD, and researchers from Hospital Universitario Pedro Ernesto, Rio de Janeiro, Brazil.

For the study, the investigators evaluated 105 consecutive men scheduled for radical retropubic nerve-sparing prostatectomy prior to the procedure and at 3, 6, 12, 48, and 60 months postoperatively.

Dr. Vasconcelos concluded her presentation at the 2011 AUA annual meeting in Washington by saying that there was some penile shortening following radical prostatectomy but that declines in length reversed around 30 months or so and by 4 years after the procedure, most of the men with either post-procedure ED or no ED had recovered their length.

“It is important to note that no patient in this study participated in rehabilitation,” Dr. Vasconcelos told Urology Times. “This means that the next question is to find out what effect rehabilitation might have. Does a patient really need to wait for 5 years?”

She added that around the world, a great variety of rehabilitation programs are available to these patients and she suspected that a number of studies assessing recovery of function and length are likely under way at present.
**Gene fusions point to radiation resistance in prostate Ca**

**Biomarker could be target for treatment with PARP inhibitor, data suggest**

**Cheryl Guttman Krader**
UT CONTRIBUTING EDITOR

Ann Arbor, MI—Results of in vitro studies indicate that E-twenty six (ETS) gene fusions in prostate cancer may be a biomarker of radiation resistance and a potential target for reversing radioreistance through treatment with a poly(ADP-ribose)/polymerase 1 (PARP1) inhibitor, according to researchers from the University of Michigan, Ann Arbor.

“Were are very excited by our findings, considering there are several PARP inhibitors that are already being investigated in phase II and III clinical trials, and so hopefully one might become commercially available in the not-too-distant future,” said first author Felix Feng, MD, assistant professor of radiation oncology at the University of Michigan. “Now, we are in the process of planning a clinical trial to investigate the efficacy and safety of PARP inhibition using one of these investigational agents for reversing radiation resistance of prostate cancer.”

ETS gene fusions, which consist of the fusion between an androgen-sensitive promoter and a transcription factor, are considered to be driving mutations in about half of all prostate cancers. ETS Related Gene (ERG) is the prototype transcription factor in ETS gene fusions, and through their interest in investigating associations of ETS gene fusions in prostate cancer, Dr. Feng and colleagues recently discovered that ERG, as well as other ETS transcription factors, interact with PARP1 (*Cancer Cell* 2011; 17:664-78).

Recognizing that PARP1 participates in DNA repair, the researchers hypothesized that the interaction between ERG and PARP1 would be important in prostate cancer resistance to radiation therapy. They tested this hypothesis using prostate cancer cell lines (PC3 and DU145) and found that overexpression of ERG transcription factor induced by lentiviral transfection resulted in increased activity of PARP1 demonstrated by increased poly ADP-ribose formation.

Assays performed after radiation exposure showed that relative to controls, prostate cancer cells overexpressing ERG had increased efficiency of DNA repair and increased survival, both of which were reversed when radiation exposure was performed after addition of a PARP1 inhibitor to the cell cultures. The benefit of PARP1 inhibition was seen using different investigational PARP1 inhibitors as well as in PARP1 knockout cells, the researchers reported at the 2011 American Society of Clinical Oncology annual meeting in Chicago. **UT**
Findings could guide PCa screening programs

Study: Monitor subgroup of young, high-risk men

Wayne Kuznar
UT CORRESPONDENT

New York—Almost half of prostate cancer deaths occur among men with PSA levels in the top 10% when assessed at age 44 to 50 years. This small group could benefit from intense surveillance over the ensuing years, whereas in about half of men, three lifetime PSA tests appear sufficient to capture the risk of prostate cancer metastases or death 10 or more years in advance, according to American and Swedish researchers.

Their conclusions were derived from a large, retrospective, case-control study of previously unscreened men who participated in the Swedish Malmö Preventive Project, in which men were followed for up to 30 years.

“Our results appear to identify a subgroup of relatively young men at very high risk of aggressive prostate cancer who would likely benefit from close monitoring as they age.”

HANS G. LILJA, MD, PhD

Shortcomings of PSA-based screening are its modest specificity and its inability to discriminate between indolent and significant disease, said first author Hans G. Lilja, MD, PhD, attending research clinical chemist at Memorial Sloan-Kettering Cancer Center, New York.

“To better understand the relationship between PSA and the natural history of clinical prostate cancer, we would need not only PSA measured in the blood from men at an age typical for screening but also that these men have not been subject to PSA-based screening,” he said.

As men aged, if their PSA level remained below the median for the population in their age group, the risk of death from metastatic prostate cancer progressively declined:

- Twenty-eight percent of metastases or deaths from prostate cancer over the following 27 years occurred in men ages 44 to 50 years who had a PSA below the median in the population (0.7 ng/mL).
- For men ages 51 to 55 years with a PSA less than the median (0.8 ng/mL), the risk of metastatic prostate cancer or death was 18%.
- At 60 years of age, only 0.5% of deaths or metastases occurred in men with a PSA less than median for that age, 1.1 ng/mL.

Based on progressively declining risks, Dr. Lilja concluded that men with PSAs below the population median in each age group remain at increasingly lower risk for dying of prostate cancer as they age. As a result, testing only three times between ages 44 and 60 years could be recommended for 50% of men. The other half of men with PSAs above the median would be followed more closely.

A single PSA test at ages 45 to 51 years would not be sufficient to rule out the risk of metastasis or death at follow-up to 30 years, he added.

If confirmed in prospective trials, the screening approach developed from this study could have a significant impact on future prostate cancer screening programs, Dr. Lilja said. [1]

T breakthrough common in patients on ADT

Young age, obesity, high pretreatment testosterone level predict breakthrough

Cheryl Guttman Krader
UT CONTRIBUTING EDITOR

Vancouver, BC—Among men treated with curative radiation therapy and neoadjuvant, adjuvant, or concurrent androgen deprivation therapy (ADT), about one-fourth fail to achieve or maintain true castrate levels of testosterone suppression, according to Canadian researchers.

“I recently reported at the 2011 congress of the European Association of Urology that testosterone breakthroughs during ADT are associated with worse PSA kinetics as an early measure of outcome. Therefore, as a take-home message, testosterone levels should be monitored whenever using ADT,” said study co-author Tom Pickles, MD, professor of radiation oncology and developmental radiotherapeutics at the University of British Columbia, Vancouver.

The frequency of escape of testosterone suppression among men being treated with a luteinizing hormone-releasing hormone agonist (LHRHa) and clinical factors that predicted the breakthrough phenomenon were investigated...
using data obtained from British Columbia provincial databases, patient charts, and institutional records. Between 1998 and 2007, nearly 12,000 patients received curative radiation therapy. The analyses of testosterone breakthrough included nearly 2,200 patients who had serial testosterone data available, received ADT for at least 3 months, and were treated for no more than 12 months with neoadjuvant ADT.

“Patients who had received a long duration of neoadjuvant ADT were excluded due to concern that they had progressive castrate-resistant prostate cancer when referred in. The final sample size in this study is about 15 times larger than any other series investigating the phenomenon of testosterone breakthrough,” said Dr. Pickles.

The frequency of breakthroughs was calculated using three a priori defined levels of testosterone: ≥50 ng/dL, representing FDA criterion; ≥32 ng/dL, which is the level at which PSA fails to be suppressed; and ≥20 ng/dL, corresponding to the level achieved with orchietomy.

Analysis of testosterone breakthrough rate per patient, which takes into account that the average patient received 5.5 injections over almost 1 year, showed a 3.6% risk of having at least one testosterone level above 50 ng/dL, a 3% risk of a testosterone level in the range of 32 ng/dL to 50 ng/dL, and a 20% risk of a testosterone level of 20 ng/dL to 32 ng/dL.

“These breakthrough rates are lower than have been reported in other series, and the difference probably relates to the assay used. When measuring testosterone, it is advisable to get input from the lab in interpreting the results because many assays are inaccurate in the castrate range,” said Dr. Pickles, who presented the results at the AUA annual meeting in Washington.

Young, obese prone to breakthrough
Analyses of factors that predicted breakthrough using a logistic regression analytical model showed that men who were younger, obese, or who had a higher pretreatment testosterone level (>500 ng/dL) were most prone to breakthrough.

Patient age had the strongest predictive value. LHRHa product used was not a significant predictor of breakthrough.

Dr. Pickles proposed that breakthroughs represent two different phenomena. He described the lower level breakthroughs as a physiologic effect that may be related to age, body mass index, and pretreatment testosterone. In addition, “device failure,” in which testosterone level remains normal despite LHRHa treatment, occurs in a small, but not insignificant number of men.
RNA signature score predicts localized PCa death
Tool could help guide decision of active surveillance vs. treatment

Cheryl Guttman Krader
UT CONTRIBUTING EDITOR

London—A composite score calculated from a 46-gene RNA signature independently predicts cancer death among men with clinically localized prostate cancer managed by active surveillance, researchers from the Transatlantic Prostate Group reported.

The composite score is determined from RNA levels of 31 genes involved in cell cycle progression (CCP) and 15 housekeeper genes. Gene expression is measured by performing quantitative reverse transcriptase-polymerase chain reaction on mRNA extracted from paraffin-embedded prostate cancer tissue.

“Considering the increasing numbers of men being diagnosed with early prostate cancer through PSA screening and the limited ability of current prognostic models for predicting disease aggressiveness, we believe the composite CCP score will be an important advance for helping clinicians identify which of these patients can be safely watched and who should receive active intervention,” said first author Jack Cuzick, PhD, head of the Cancer Research UK Centre of Epidemiology, Wolfson Institute of Preventive Medicine, St. Bartholomew’s Medical School, Queen Mary University of London.

The retrospective study determined the prognostic performance of the 46-gene RNA signature in 352 men from the United Kingdom using tissue obtained at diagnosis by needle biopsy between 1990 and 1996. The group had a median follow-up post-diagnosis of 11.5 years.

Gleason, PSA add to predictive power

In univariate analysis, the hazard ratio (HR) for prostate cancer-specific death was 2.07 for each unit increase in CCP score (p=1.4 x 10^-3), Dr. Cuzick reported at the 2011 American Society of Clinical Oncology annual meeting in Chicago. In a multivariate analysis that adjusted for centrally re-reviewed Gleason score, baseline PSA, age, clinical stage, and extent of disease (proportion of positive cores), the HR for death from prostate cancer was 1.67 for each unit increase of CCP (p=1.2 x 10^-4). CCP score was a stronger independent predictor of death than Gleason score (p=2.8 x 10^-4) or PSA (p=.01).

Adding Gleason score and baseline PSA to the CCP score resulted in a model with even greater predictive power.

In analyses stratifying men by baseline PSA and Gleason score, the CCP score independently predicted death from prostate cancer for all PSA subgroups with a level >4.0 ng/mL (4.0-10.0, >10.0-25.0, >25.0-50.0, >40.0-100.0 ng/mL) as well as in men with a Gleason score >7, but not in those with a lower Gleason score.

Dr. Cuzick noted that results of a previously published study also showed the CCP score was a robust predictor of disease outcome in two cohorts of men with prostate cancer (Lancet Oncol 2011; 12:245-55). In the earlier investigation, the RNA expression signature was analyzed in one group of 366 American men using tissue from radical prostatectomy and in a second cohort of 337 men from the United Kingdom conservatively followed after diagnosis of prostate cancer by transurethral resection of the prostate.

The analyses showed the CCP score independently predicted biochemical recurrence after radical prostatectomy and prostate cancer-specific death in the men who underwent active surveillance. As in the current study, the CCP score had stronger predictive accuracy than either PSA or Gleason score in the earlier cohort of men managed conservatively after diagnosis with clinically localized disease.

“The results of the present study provide further evidence of the performance of the CCP score to predict cancer-related death in men with clinically localized prostate cancer and using a very small sample of cancer tissue obtained through needle biopsy to determine the RNA expression signature, which is important because most cases of prostate cancer are currently diagnosed by needle biopsy. Still, further validation in another independent cohort to confirm the robustness of these findings is desirable,” Dr. Cuzick said.

The study was done in conjunction with Myriad Genetics, which is developing the test for commercialization. Dr. Cuzick’s institution received funds from Myriad to conduct this study, but he does not personally receive funds from the company. Several of the study’s co-authors have an employment or leadership position with Myriad. [1]

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Study: Functional outcomes better with HoLEP vs. PVP

Improvements in urinary flow rate, PVR favor HoLEP, researchers find

Charles Bankhead
UT CONTRIBUTING EDITOR

Montreal—Men with lower urinary tract symptoms (LUTS) associated with large prostates had significantly greater improvement in functional outcomes when treated with holmium laser enucleation of the prostate (HoLEP) than with photoselective vaporization of the prostate (PVP), data from a randomized trial showed.

A year after treatment, urinary flow was 260% from baseline in the HoLEP group compared with 196% in the PVP group (p=.02). Post-void residual (PVR) improved by 96% with HoLEP and 87% with PVP (p=.02). Patients and quality of life improved to a similar degree in both groups.

Additionally, more than 20% of PVP cases had to be converted to other procedures, whereas all men allocated to HoLEP underwent the procedure, according to a presentation at the 2011 AUA annual meeting in Washington.

“HoLEP and PVP are effective modalities for treatment of LUTS secondary to a large-size prostate,” first author Hazem Elmansy, MD, a urology fellow at McGill University in Montreal, concluded in a poster presentation. “The early functional results of HoLEP appear to be superior to PVP.

“The objective functional results are more pronounced if we correct for converted cases,” he added.
The findings came from a randomized trial involving 80 men with LUTS secondary to an enlarged prostate. Prostate volume in the study population averaged about 90 mL and ranged from 62 mL to 160 mL.

Outcomes of interest included International Prostate Symptom Score (IPSS), International Index of Erectile Function (IIEF), Qmax, PVR, PSA, and transrectal ultrasound (TRUS) volume. Investigators also documented operative data and number of fibers used per procedure. Follow-up evaluations occurred at 1, 3, 6, and 12 months after surgery.

No conversion with HoLEP procedures
In eight of 37 cases, bleeding required conversion of PVP to another procedure (HoLEP with 60% in the PVP group, and TRUS-assessed prostate volume decreased by 78% with HoLEP versus 52% with PVP. Patients who required conversion to other procedures were still counted as part of the PVP group. An analysis of the results according to the treatment actually yielded larger differences in functional outcomes. The improvement in Qmax was 277% with HoLEP compared with 143% with PVP, and PVR improved by 97% with HoLEP versus 62% with PVP (p<.001 for both outcomes). IPSS and quality of life remained similar in the two treatment groups in the second analysis.

In general, IIEF scores did not differ significantly between groups following treatment. However, the PVP group had significant improvement in the orgasmic domain (p=.01) whereas the HoLEP arm did not.

Dr. Elhilali is a consultant/adviser for Lumenis and American Medical Systems.

“HoLEP and PVP are effective modalities for treatment of LUTS secondary to a large-size prostate. The early functional results of HoLEP appear to be superior to PVP.”

HAZEM ELMANSY, MD

The baseline Qmax averaged 8 mL to 9 mL, and PVR averaged about 270 mL. Operative time, catheterization time, and hospital stay were similar between treatment groups. However, total energy used was significantly higher with PVP (257.8 kJ vs. 162.5 kJ for HoLEP, p<.0001), and median fiber use was 1.0 with PVP (range of 1 to 3) and 0.05 with HoLEP (p<.0001). The higher energy requirement would probably rule out PVP as the first choice for treatment of a large prostate, according to Dr. Elmansy, who worked on the study with Mostafa Elhilali, MD, and colleagues.

### Functional outcomes: HoLEP vs. PVP

<table>
<thead>
<tr>
<th></th>
<th>HoLEP</th>
<th>PVP</th>
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</thead>
<tbody>
<tr>
<td>Urinary flow improvement from baseline</td>
<td>260%</td>
<td>196%</td>
</tr>
<tr>
<td>PVR improvement from baseline</td>
<td>96%</td>
<td>87%</td>
</tr>
<tr>
<td>Total energy used</td>
<td>162.5 kJ</td>
<td>257.8 kJ</td>
</tr>
<tr>
<td>Median fiber use</td>
<td>0.05</td>
<td>1.0</td>
</tr>
<tr>
<td>Procedures requiring conversion</td>
<td>0</td>
<td>8</td>
</tr>
<tr>
<td>Reduction in mean PSA</td>
<td>88%</td>
<td>60%</td>
</tr>
<tr>
<td>Decrease in TRUS-assessed prostate volume</td>
<td>78%</td>
<td>52%</td>
</tr>
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Source: Hazem Elmansy, MD
PCNL: Tricks and tips for access and stone removal

Although percutaneous nephrolithotomy (PCNL) comprises only 4% to 6% of all stone surgeries (*J Urol* 2005; 173:848-57), it behooves the urologist with an interest in stone disease to be facile in this treatment modality in order to offer patients the most appropriate and effective treatment for their stones. This article focuses on the technical details of our approach to PCNL, from preoperative imaging to postoperative care.

Preoperative imaging

Thorough delineation of the location and extent of the stone as well as of the intrarenal and relational anatomy of the kidney is critical to successful PCNL. Intravenous urography (IVU) and non-enhanced computed tomography provide complementary information that together provide an accurate assessment of stone burden and location within the collecting system as well as establish the position of the kidney in relation to surrounding visceral organs such as the pleural space and colon (figure 1) (*Urol Clin North Am* 2006; 33:353-64; *J Urol* 2003; 170: 45-7).

Positioning, retrograde catheter placement

The anesthetized patient is placed prone in the split-leg position to enable simultaneous access to the flank and perineum (figure 2). A retrograde ureteral catheter is placed to opacify the collecting system and prevent antegrade migration of fragments. We use a 7F, 11.5-cm occlusion balloon catheter (Boston Scientific, Natick, MA) passed through a 22F Councill catheter, as it provides optimal occlusion of the ureteropelvic junction (UPJ) and maximal distension of the collecting system for access. The occlusion balloon catheter is carefully inflated just above the UPJ with 1 cc of dilute contrast.

Opacification of the collecting system with air or contrast allows identification of the optimal calyx for percutaneous puncture. We prefer an air pyelogram, as contrast may obscure the stone and extravasated contrast can obscure the calyces. Gentle injection of 5 to 15 cc of air will preferentially delineate the posterior calyces as the air rises (figure 3). Rare cases of air embolism have been described with both

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*This detailed description outlines the authors’ approach, from pre-op imaging to post-op care*

Margaret Pearle, MD  •  Stephen Faddegon, MD

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**UT Figure 1**

Retrorenal colon (yellow arrow) in a horseshoe kidney requiring CT-guided access. Red arrow: left kidney.

**UT Figure 2**

Prone positioning for PCNL. A table with spreader bars enables simultaneous access to the flank and perineum.
Selecting the optimal calyx for puncture

Percutaneous puncture directly into a posterior polar calyx (upper or lower) generally provides optimal access to the collecting system and minimizes the amount of parenchyma traversed by the tract. Guidewire access from an anterior calyx to the renal pelvis and ureter is more difficult because of the unfavorable acute angle. Access via an upper pole posterior calyx risks transgression of the pleural space, although it provides optimal access for staghorn stones occupying the entire collecting system, for stones occupying multiple lower pole calyces, and for large UPJ or proximal ureteral calculi. Because the upper pole of the kidney lies more posterior than the lower pole, access to the renal pelvis follows a less acute angle, thereby necessitating less torque on the nephroscope. Mid renal access is generally avoided as access to both the upper and lower pole calyces can be challenging from this location.

Percutaneous access

Percutaneous puncture into the selected calyx is accomplished with an 18- or 22-gauge Chiba needle. We prefer a 22-gauge needle to minimize trauma in the event that multiple puncture attempts are required. The smaller-gauge needle can accommodate a 0.018-inch platinum-tip guidewire, which is used to gain access to the ureter or collecting system. An exchange coaxial dilator (Jeffrey introducer set, Cook Medical, Bloomington, IN) provides transition from the small 0.018-inch guidewire to a standard 0.035- or 0.038-inch guidewire.

Needle puncture. With the patient prone, the table is tilted 10° to 15° away from the operator to align the posterior calyces vertically. The calyx should be entered directly through the tip of the papilla, in line with the infundibulum, in order to avoid the interlobar arteries. Posterior calyces can be distinguished from anterior calyces by rotating the C-arm away from the operator. Fluoroscopically, the posterior calyces will elongate and move laterally while the anterior calyces shorten and move medially. The most posterior calyx of the lower pole can often be correctly identified on AP fluoroscopy as the second most inferior calyx in more than 90% of cases (J Endourol 2009; 23:1621-5).

A simple, reliable method for percutaneous access is the “eye-of-the-needle” approach, by which the hub of the needle is aligned over the tip, directly in line with the calyx, giving the appearance of a bull’s-eye (figure 4). For upper pole calyces, the C-arm is positioned AP, in line with the vertically oriented posterior calyces. For inferior calyces, we initiate the needle puncture approximately 2 cm inferior to, and in line with, the lower pole infundibulum to provide a less acute angle of entry into the calyx, and the C-arm is aligned to look “down the barrel” of the needle. Rotating the C-arm away from the surgeon determines the proper depth of the needle. The needle is aspirated for air or urine to confirm proper positioning within the calyx.

Securing the access. With successful puncture of the calyx, a guidewire is advanced into the collecting system and preferentially down the ureter. If necessary, a 0.035-inch angled hydrophilic guidewire, in conjunction with an angled angiographic catheter (Kumpe Access Catheter, Cook Medical), is “steered” in the direction of the UPJ and down the ureter. The slippery hydrophilic guidewire is then replaced with a more secure superstiff guidewire and a second safety guidewire.

Tract dilation. Dilation of the tract is most efficiently performed with a balloon dilator over a stiff guidewire. The balloon should be advanced over the guidewire just until the radio-opaque mark reaches the calyx. Over-advancing the balloon may cause splitting of the infundibulum and excessive bleeding. The working sheath is advanced over the balloon no further than the radio-opaque mark, as the mark indicates the distal extent of the full diameter of the balloon; beyond that point, the balloon tapers and the working sheath can potentially shear the infundibulum.

Stone fragmentation

After removal of the balloon, the rigid nephroscope is advanced through the working sheath into the collecting system. There are a number of devices available for stone fragmentation through the rigid nephroscope, including ultrasonic and pneumatic devices. For hard stones, it may be advantageous to fragment the stones into pieces that can be removed with grasping forceps. For softer stones, fragmentation and aspiration of the entire stone may be more expedient.

Excessive torquing of the nephroscope and forceful maneuvers through tight infundibula should be avoided as this can cause infundibular injury and bleeding. Flexible nephroscopy, in conjunction with Holmium:YAG laser lithotripsies and nitinol stone retrieval devices, can be used to access moderate-sized stones that are located remote from the nephrostomy tract and are not accessible with the rigid nephroscope.

If a stone can be visualized fluoroscopi-
Ureteroscopic access likewise provides an alternative to additional percutaneous access for difficult-to-reach stones. The flexible ureteroscope, passed retrograde, can be used to fragment and/or basket inaccessible stones, which can then be “delivered” to the flexible or rigid nephroscope for removal.

Before exiting the kidney, complete stone removal should be confirmed both endoscopically and fluoroscopically (with injection of contrast). Opacification of a calyx that was not visualized endoscopically will help direct entry of the nephroscope into the calyx using fluoroscopy. Finally, the occlusion balloon catheter is removed and the ureter is inspected for stones or injury either endoscopically or by injection of contrast at the UPJ.

 Exiting the kidney
A 10F locking loop nephrostomy tube is used for routine cases with no significant bleeding and an expectation that the patient is free of stones. A large-bore nephrostomy tube (22F Councill catheter), passed over a 5F angiographic catheter and secured with a Tuohy Borst adapter, is used when significant bleeding occurred, obvious residual stones remain, or the patient is morbidly obese. The large-bore catheter facilitates secondary flexible nephroscopy in the event that residual stones are identified on postoperative imaging.

“Tubeless” PCNL is reserved for patients in whom stones were removed intact and there was no significant bleeding or collecting system injury. In this case, the working sheath is withdrawn under vision until it sits at the cut edge of the calyx. The occlusion balloon catheter is advanced over a through-and-through guidewire until the balloon is positioned just at the end of the working sheath where it is inflated to occlude the tract. Using a laparoscopic applicator, Floseal Hemostatic Matrix (Baxter Inc., Deerfield, IL) is injected through the working sheath into the renal parenchyma while simultaneously withdrawing the sheath (J Endourol 2005; 19:614-7; discussion 617). A ureteral stent is placed in retrograde fashion, and after a few minutes of observation and no signs of bleeding, the guidewire is removed and the skin incision is closed.

Because of the risk of violating the pleural space, particularly with supracostal access, fluoroscopy is performed over the chest to identify a hydropneumothorax, which can be drained while the patient is anesthetized (figure 6) (Urology 2003; 62:988-92). A 22-gauge Chiba needle is inserted just over a rib into the pleural space and the needle is withdrawn while aspirating with a syringe. Once fluid is obtained, a J-wire is advanced through the needle into the pleural space, over which a 10F locking loop nephrostomy tube is passed (Urology 2002; 60:1098-9). The thoracostomy tube should be the last tube removed, after the nephrostomy tube and when there is no further accumulation of pleural fluid.

Postoperative care
Non-enhanced CT of the kidneys and an antegrade nephrostogram are obtained on postoperative day one to ensure antegrade drainage prior to nephrostomy tube removal and to identify residual stones. If no stones are demonstrated and there is good antegrade drainage, the nephrostomy tube is removed and the patient is discharged home. If residual stones >2 mm are identified, the patient undergoes second-look flexible nephroscopy, 48 hours after initial PCNL, through the same nephrostomy tract. Replacement of a small Amplatz working sheath (22F) at the time of second-look flexible nephroscopy is required for supracostal access.

Conclusions
Effective and safe percutaneous access requires three-dimensional understanding of renal anatomy, facilitated by axial imaging and multiview urography. The optimal access site should provide the greatest chance for complete stone removal through a single percutaneous puncture. Liberal use of flexible nephroscopy, both at the time of initial PCNL and at second-look flexible nephroscopy, improves the likelihood of achieving a stone-free state and reduces the need for multiple percutaneous tracts.
Coverage agreements: How they affect billing

Don’t charge for seeing another urologist’s patient if reciprocal arrangement is in place

Q Can I charge for hospital visits if I see another urologist’s post-surgical patient who is still in the global period (for instance, when they’re on call and round on many of these patients)? Or is it considered part of the surgery?

A We will have to give you two answers to this question. The first answer is no, if you are in a reciprocating coverage arrangement with the other urologist—in other words, the other urologist sees your patients postoperatively when you are out of town and you see the other urologist’s patients when he/she is out of town. Even if the coverage agreement is not a formal, signed agreement, we would not charge for the visits.

The second answer is yes, if you are not in a coverage arrangement with the other urologist. For example, if a patient was operated on by another urologist and you were asked to see the patient for any reason, then you can charge for that hospital visit. Or, if the patient had been operated on by a urologist elsewhere and you were seeing the patient postoperatively in the hospital or in the office, you should charge for your services and no modifier is needed.

Q What code would be used for image fusion regarding prostate magnetic resonance imaging and transrectal ultrasound for targeted biopsy? This is currently available under an Institutional Review Board approval only. When and how will it be available for general clinical use and for reimbursement (for use with the Artemis prostate imaging instrument [Eigen, Grass Valley, CA])?

A As with any new technology, we often have to wait for CPT to adopt new codes that accurately describe the services provided, wait for a value to be assigned that will reimburse for the services, and/or wait for the coverage policies to be adopted. Although the system is designed to follow a step method, we have all seen that coverage and payment may precede the establishment of a code and value.

We did not locate a code or coverage policy that clearly applies to the use of image fusion with prostate biopsy ultrasound guidance. In today’s health care environment, coverage, coding, and payment for new technology are not automatic. Any new technology has to demonstrate clinical efficacy supported in peer-reviewed literature and have FDA approval, if applicable, to be included in CPT.

Additionally, with many new technologies, payers are beginning to demand cost efficiency for a new procedure or service before they will cover it. We assume the manufacturer and those interested in the service you are describing are pursuing these goals.

In the short term, the following codes may be applicable to the service you describe:

- 76942: Ultrasonic guidance for needle placement (eg, biopsy, aspiration, injection, localization device). Imaging supervision and interpretation
- 76376: 3-D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality; not requiring image post processing on an independent workstation
- 76377: 3-D rendering with interpretation and reporting of computed tomography, magnetic resonance imaging, ultrasound, or other tomographic modality; requiring image post processing on an independent workstation
- 77021: Magnetic resonance guidance for needle placement (eg, for biopsy, needle aspiration, injection, or placement of localization device) radiological supervision and interpretation.

if a patient was operated on by another urologist and you were asked to see the patient for any reason, then you can charge for that hospital visit.

Without further information on the system and its use, we cannot comment directly on whether the codes above are applicable and/or paid for when using the device.
Market dips: Now may not be time to get out

Asset allocation can help you weather uncertain markets

Q With economic uncertainty surrounding the markets, is this a good time to get out?

A Investor concern about economic uncertainty is indeed very prevalent, not just in the U.S., but on a global basis. During periods of economic uncertainty, financial markets are often characterized by wide swings in market value. Movements (in either direction) of 200 to 300 points in the Dow Jones Industrial Average are no longer unique or surprising. Such market volatility, with prices sharply rising and falling, is a reflection of changeable investor sentiment as well as more substantive economic or political events. Even during more stable times, financial markets will fluctuate, although price movements tend to be more moderate. By their very nature, financial markets rise and fall constantly, with an ever-present potential for gain or loss.

It is important during these periods for investors to avoid emotional responses to investing. When markets fall sharply, some investors will sell all or part of their holdings and shift into what they perceive to be “safer” investments. Such emotion-based selling after a market decline simply turns paper losses into real ones and limits any possible gains should the market recover. These same investors also respond emotionally and buy when the markets are “hot” and values are rising. The result is frequently a pattern of buying high and selling low, with the investor consistently losing money.

Money Matters

Joel M. Blau, CFP, Ronald J. Paprocki, JD, CFP, CHBC

Joel M. Blau, CFP, (top) is president and Ronald J. Paprocki, JD, CFP, CHBC, is chief executive officer of MEDIQUIS Asset Advisors, Inc. in Chicago. They can be reached at 800-883-8555 or blau@mediquis.com or paprocki@mediquis.com.

Dollar cost averaging offers the advantage of buying more shares when the price is low and fewer shares when the price is higher.

Other investors attempt to time the markets: buying when the market is thought to be low and then selling when the market is considered to be high. The problem is that it’s never clear just when the market has reached a trough or a peak. Market timing is a concept that, in theory at least, seems logical. In practice, however, no one has yet devised a system for consistently and accurately identifying market tops and bottoms. Many have sold prior to the market moving lower but just can’t find the low point to buy back in, and often buy after prices have risen, just like the emotion-based investor.

Although the market cannot be reliably timed, there are ways for investors to cope with fluctuations. Asset allocation modeling is an investment strategy that seeks to reduce investment risk by spreading an investor’s portfolio over a number of different asset types or classes. “Dollar cost averaging”—investing an equal dollar amount at regular intervals—allows investors to buy more shares when the price is low and fewer shares when the price is higher.

Financial Tips

- Emotion-based selling after a market decline simply turns paper losses into real ones and limits any possible gains should the market recover.
- Asset allocation modeling is an investment strategy that seeks to reduce investment risk by spreading an investor’s portfolio over a number of different asset types or classes.
- “Dollar cost averaging”—investing an equal dollar amount at regular intervals—allows investors to buy more shares when the price is low and fewer shares when the price is higher.
- The Social Security Administration no longer mails annual statements to individuals; to check your account, go online at www.ssa.gov.

and cash (or cash equivalents) are the investments normally used. Tangible assets, such as real estate or gold, may also be included for further diversification.

The asset allocation process normally begins with an analysis of the historical levels of risk and return for each asset type being considered. These historical values are then used as a guide to structuring a portfolio that matches the investor’s individual goals and overall risk tolerance level. It’s crucial that an investor’s portfolio allocation reflects factors such as their investment goal, time frame, need for liquidity, risk tolerance, and income tax bracket. As time passes, and as market and economic conditions change, it is likely that an investor’s goals, and the optimal portfolio mix to reach those goals, will also change. Adjusting the asset allocation by rebalancing is a regular part of good investment management in both up and down markets.

Market volatility also impacts the implementation of an investment strategy. Rather than making a single, lump-sum investment, some investors feel more comfortable investing an equal dollar amount at regular intervals. This process is often referred to as “dollar cost averaging.” It offers the advantage of buying more shares when the price is low and fewer shares when the price is higher. Dollar cost averaging does not assure a profit and does not protect against losses in a declining market. Dollar cost averaging requires an investor to make continuous investments regardless of the fluctuating price levels. Investors should therefore consider their financial ability to continue purchases through periods of low price levels.

Q I used to receive an annual statement from Social Security detailing my historical earnings and my projected benefits. I read that these are no longer mailed. Is this correct?

A The Social Security Administration (SSA) no longer mails annual statements to individuals. To verify your annual wages and confirm that your salary was properly posted to your account, go to the Social Security Web site at www.ssa.gov. If there is any discrepancy, you need to contact the SSA directly to make adjustments.

Send us your questions
Send your questions about estate planning, retirement, and investing to Joel M. Blau, CFP, c/o Urology Times, at UTL@advantestar.com.

Questions of general interest will be chosen for publication. The information in this column is designed to be authoritative. The publisher is not engaged in rendering legal advice.
Hiring a friend: Why it’s a bad idea for your practice

Perception of favoritism can adversely affect staff morale

Hiring staff can be one of the most stressful aspects of managing a urology practice. Often, you’re not looking just for qualifications; you need someone you can trust to act in your stead and represent your practice—represent you, really—to prospective and existing patients, the medical community, and the general public.

With so much riding on the decision, it’s not surprising that physician owners and practice managers sometimes turn to friends and relatives to fill open positions. After all, isn’t a known ally—a friend or relative who you know has your best interests at heart—more trustworthy than a complete stranger?

This thinking seems to fit with intuition, and it sure makes things easier in the short term to fill that employment gap with a friend. But it’s usually not a good idea, because it can cause more problems in your practice than it solves.

What’s more, you’re putting a valued relation—someone you trust—undermining that trust, productivity could not be at risk. This article will explain why hiring a friend is often not the best move.

Favoritism issues inevitable
Perceived favoritism is one of the most common sources of staff bickering and dysfunctional communication that we see in practices. It’s exceedingly difficult to avoid this problem when friends and relatives are hired into the practice—especially if one friend is supervising another. Sometimes, we encounter practice managers who have truly done everything to act in your stead and represent your practice—especially if one friend is supervising another. Sometimes, we encounter practice managers who have truly done everything possible to avoid the appearance of favoritism—even overcompensating—but the other staff members are nonetheless suspicious and assume they’ll get an unfair shake in the event of a conflict with the “favored” newcomer.

Whether the favoritism is actual or imagined, the effect on the practice is very real. To perform at their best, your employees must believe what they contract for: that employees could decide to leave the practice altogether.

Please see FRIEND, page 28

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Don’t let no-shows erode your practice’s revenue

Staff must be motivated to keep the physician’s schedule full

Every urology practice is concerned about decreasing reimbursements and increasing overhead costs. These problems translate to an erosion of the bottom line. There is little we can do to increase reimbursement; however, there is a lot we can do to improve our practices’ efficiency and productivity. One of the simplest methods is to decrease the no-show rate, a problem that affects most medical practices.

In this article, Elizabeth Woodcock, an expert on this topic, explains the financial impact of no-shows and how to minimize them. Woodcock, who is president of Woodcock and Associates in Atlanta, is one of the nation’s leading authorities on practice management.

Changing the practice culture

According to Woodcock, each missed appointment costs the practice approximately $140, and that’s a conservative estimate based only on the office visit. That amount quadruples—or more—if that missed appointment represents a surgery. If you have multiple no-shows each day, you don’t need an MBA to calculate the lost income that can impact your practice. Woodcock estimates that the missed opportunity rate is 7% to 10%.

Fixing problems with scheduling requires a cultural shift, Woodcock says. Instead of focusing on barriers to access—including celebrating when the patient doesn’t keep an appointment (said tongue in cheek, but often a reality)—physicians need to motivate staff to keep the schedule completely full. The staff has to understand that open time slots are lost income and that a full, robust schedule improves productivity and profitability. When the staff keeps the schedule full, the physician needs to compliment the entire team and say, “Thank you for giving me a full day.”

How to prevent no-shows

No-shows can be prevented. Begin by requesting three phone numbers for each patient: home, work, and cell phone number. If three is too many, ask for the “best” number.

There are automated systems that can be used to contact patients, but these are not as effective as a human being contacting a patient. Also, programs are available that provide patients with an automatic text message to remind them of their appointment. Increasingly, practices are taking advantage of reminding patients through an automated, text-based service.

Studies demonstrate that longer time intervals between appointments significantly increase the no-show rate. For example, patients who are given an appointment 10 days of their last office visit, the no-show rate is as much as 30%. In another study in which patients who had an appointment within 10 days of their last office visit, the no-show rate was less than 5%. Woodcock suggests that you target patients who are likely to miss their appointments with a “warm” confirmation. Such patients include those who have been given an appointment in excess of 150 days, those who previously have canceled appointments, those who are scheduled for a procedure, new patients, or certain demographics or payer types who have a history of not keeping appointments.

Another option for reducing the no-show rate is to consider accepting electronic appointment requests. There are programs on many practice management systems that allow patients to request an appointment, after which you contact them to confirm a date and a time.

Please see NO-SHOWS, page 29
NO-SHOWS
continued from page 28

Make it easy for a patient to cancel an appointment, Woodcock advises, noting that it’s difficult for patients to cancel in most practices. If a patient cancels an appointment, be sure to follow up and give him an opportunity to reschedule. Also, let the patient know that you appreciate the notification about the cancellation.

Another effective method of reducing the no-show rate and keeping the schedule full is to maintain a list of patients who would like an earlier appointment. Consequently, when openings occur, the scheduler or receptionist can go to the waiting list and contact patients who could potentially fill those open slots.

Of course, it is necessary to carefully document all no-shows in the patient’s chart or electronic medical record. Woodcock cautions that no-shows are a significant liability for the practice, and consulting with your malpractice carrier about protocols is recommended.

To charge or not to charge no-shows

There are advantages and disadvantages to charging a penalty to no-show patients. Charging them may provide them with an opportunity to change their behavior. We think it’s a good idea to let patients know that the physician was expecting them, held a time slot for them, and their cancellation or not keeping their appointment resulted in an opportunity to fill that slot with another patient who needed your services.

Woodcock only recommends charging patients who are second-time offenders. Patients should receive a warning for a first-time offense. Reasons not to charge patients include difficulty collecting the no-show fee as well as creating a source of negative publicity for your practice.

Woodcock suggests requiring the repeat offender to prepay in order to “hold” the slot. The receptionist informs the patient that the appointment will be held for them; however, a credit card number is required to hold the appointment. Then, if the patient cancels, you can submit a fee using their credit card.

As of 2007, Centers for Medicare & Medicaid Services policy allows physicians to charge Medicare patients for missed appointments as long as the practice also charges for non-Medicare patients who miss appointments. The guidelines also state that the charges for missed appointments for both Medicare and non-Medicare patients are the same. For more information, go to www.urologytimes.com/noshowguidelines.

On occasion, you might come across chronic no-show patients, but you don’t want to remove them from your practice. For example, if a relative or friend brings a patient and their ability to be on time is out of their control, then we suggest giving them the last appointment of the day. That way, if they miss the appointment, they won’t wreak havoc with your schedule.

Bottom line: It doesn’t require rocket science to reduce the no-show rate. Attention to detail, looking at no-show patterns, and motivating staff to keep the schedule full are simple solutions to solving this common problem.

Practice Pointers

- The cost of one missed appointment is approximately $140, according to one conservative estimate.
- Practice staff need to be motivated to keep the doctor’s schedule completely full.
- No-shows are a significant liability for a practice and should be carefully documented.
- Reasons not to charge no-shows include difficulty in collecting the fee and creating negative publicity for a practice.
FDA warning on mesh held little surprise for urologists

Karen Nash | UT COLUMNIST

Last summer, the FDA issued a strong warning about the dangers of complications from using mesh for the repair of pelvic organ prolapse and treatment of stress urinary incontinence. Between 2008 and 2010, the FDA said it received more than 2,800 reports of complications associated with surgical mesh devices, generally placed transvaginally, when used for these indications.

The agency urged physicians to be thoroughly trained, to watch carefully for complications, and to make sure their patients are fully informed about procedures and their risks. In September, an FDA advisory panel concluded that the clinical benefits of using transvaginal mesh for prolapse repair have not been proven, but that available data support the safety and efficacy of first-generation suburethral slings for treating stress incontinence.

Has your approach to prolapse and stress incontinence changed since the FDA issued a warning about the use of transvaginal mesh?

**Respondents**

Michelle Aspera, MD
Honolulu

Gregory Bales, MD
Chicago

Tomi Bortolazzo, MD
Mammoth Lakes, CA

Brian Cohen, MD
Asheville, NC

Howard Goldman, MD
Cleveland

_Urology Times_ wanted to know if urologists have changed their approach to prolapse and stress incontinence treatment as a result of the FDA’s statement. Urologists say they aren’t surprised at the warning, and it hasn’t affected what they do, either because they weren’t using mesh in the first place or because mesh can be used safely in the hands of the right surgeon.

_Brian Cohen, MD_, in Asheville, NC, has never used synthetic mesh for prolapse repairs.

“I use all absorbable products, some Vicryl mesh, and Tutoplast by Coloplast, a product which is cadaveric fascia lata,” Dr. Cohen said. “That’s the way I learned in my residency and fellowship, and I’ve had good results. You don’t have the worries you have with a synthetic mesh. I’ve seen plenty of patients with dyspareunia afterwards. There’s no way to really deal with it.”

In practice for 4 years, Dr. Cohen doesn’t think the mesh should be banned, but he does think the risks outweigh the potential benefits.

“I just had an 85-year-old woman who had a prolapse repaired five years ago. I had to do a partial cystectomy in order to get the mesh out of her bladder,” he said. “I take care of the problems, I’m not interested in dealing with them.”

In Mammoth Lakes, CA, _Tomi Bortolazzo, MD_, agrees with that sentiment.

“The FDA warnings haven’t affected me,” Dr. Bortolazzo said. “I work in a rural setting now, but when I worked downtown, I used to take care of all the complications from the gynecologists and other doctors doing all the TVTs with mesh. I even had a young, healthy patient spit mesh from her vagina. A lot of people just don’t seem to react well to mesh, so now I use a Mylar sling that has pigskin.”

Dr. Bortolazzo, a practitioner for 17 years, says she didn’t like what she was seeing with the mesh long before the FDA came out with its statements, so she decided to avoid what she thought would be problems down the road.

“Now, I live in an area where everyone is an athlete and active. People don’t like to put something foreign in their bodies,” Dr. Bortolazzo said. “So I’ve been doing more and more autologous slings over the last 10 years.”

Although both Dr. Bortolazzo and Dr. Cohen are experienced with the complications, neither thinks the mesh should be banned.

“I’m sure there are places for it, perhaps in an older woman who is not sexually active,” Dr. Cohen said. “You’ll get a longer-lasting repair.”

“There are pros and cons,” Dr. Bortolazzo added. “I occasionally use it, but I just don’t think it’s the best thing.”

Other doctors question whether the problem is the mesh, as much as it might be surgical techniques or patient selection.

**Good approach to SUI repair**

_Michelle Aspera, MD_, in Honolulu, has not stopped using mesh.

“I have a fairly strong opinion on this. I primarily use it for mid-urethral slings. I don’t use a lot of mesh for prolapse repairs except for abdominal sacral colpopexy, but it’s one of the best ways to repair stress urinary incontinence. I’ve not had mesh erosions and my complication rate is extremely low.

“The only thing I’ve really changed is my informed consent. I actually give them the AUA position statement and the FDA five-page handout on the seriousness of mesh,” Dr. Aspera said.

The chief of urology at Kaiser Permanente Hawaii, Dr. Aspera says patient selection is important in using the mesh successfully.

“I do a lot of mid-urethral slings but I’ve been fortunate,” she said. “I’ve done them here now in private practice for nine years and haven’t had to revise much exposed mesh at all.

“You have to pick the right person, because if they have very atrophic tissue and you’re trying to cover a piece of mesh, that can break down. Having healthy tissue to actually cover the mesh is important.”

_Howard Goldman, MD_, was one of six urologic pelvic floor surgeons who responded to the FDA warning with a message that all of the problems may not be completely mesh driven. He says mesh has a variety of uses, and there were no new restrictions for most of those applications.

“For me, the warning hasn’t really
changed what I do,” said Dr. Goldman, associate professor of urology at Cleveland Clinic’s Lerner College of Medicine. “I only use mesh in the anterior compartment. I don’t use it for rectoceles posterior. For years, I’ve had long and detailed discussions with my patients about all the potential risks and the pros and cons. The only additional thing I mention to them now is that the FDA has issued this warning.”

Dr. Goldman explains that the real focus is on transvaginal mesh kits.

“That’s because the industry promoted these kits a lot and there have been a fair number of reported complications, some of which have been pretty serious—and that’s without long-term data,” he explained. “Mild prolapse probably doesn’t need mesh, and the issue is that a lot of physicians who never did work in this area saw this nice little kit, and it looked easy. Companies were more than happy to send doctors to a course where they watched one procedure and went home to do it themselves.

“This is my personal opinion, but this technique is very different from our traditional techniques. I have actually seen some highly thought of surgeons doing this procedure, who aren’t doing it correctly and end up with complications. Then they get on the bandwagon and say the procedure is a horrible thing, when in fact they probably aren’t doing it the right way.”

Concerns exaggerated?
Although he knows there can be complications, Gregory Bales, MD, suggests that some of the concerns may be exaggerated for external reasons.

“At least here in Chicago-land, we have a lot of radio and television ads by attorneys, so it’s on the patients’ minds,” Dr. Bales said. “I try to be proactive and have a discussion before surgery. We don’t have an inordinate number of complications with mesh and I believe it gives some patients a better long-term outcome.”

Dr. Bales, associate professor of urology at the University of Chicago, says there are factors that do need to be considered in order to attain reliable results with mesh.

“It’s important that doctors employing these technologies have appropriate training, and that they use reputable products. In the right circumstances, the procedures do very well,” he said. “It’s also important that patients have healthy vaginal tissue. I think perhaps that’s under-appreciated. Patients with significant atrophic changes won’t do as well and those patients are at higher risk for erosion.”

The situation isn’t helped, however, by fanning the fire.

“The attorneys’ ads on TV are not helpful. I had not one, but two patients yesterday who were doing perfectly fine after surgical procedures they had a number of years ago. But they saw the ads on TV and immediately called our office thinking there was a time bomb waiting to go off.

“It’s very important that patients understand the risks and benefits of any surgery, but in this particular instance I think the pendulum may have swung too far.”

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PSA GUIDANCE
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biomarkers for prostate cancer. And lastly, they advocate a risk-based approach. That means physicians should discuss with patients the likelihood of having high-grade disease because the benefits of screening accrue to those at highest risk. I think they were relatively balanced in acknowledging the important issue of over-detection and our need to get a handle on that.

Q I think we all saw the response to the statement from Dr. Sushil Lacy, current president of the AUA. What was your take on that response?

A I think it was a reasonable response. We have to be careful that we do not demonize the people who produced this report. If you read it in detail, the report was well written and well intentioned. It highlights many of the uncertainties and problems of PSA testing. However, I would disagree strongly with the interpretation of the data and the panel’s conclusions.

Q What is the AUA’s current position on prostate cancer screening, and how should the average urologist make sense of the data currently available?

A The AUA recommendations on prostate cancer screening were last updated in 2009 and are currently being revised. That best practice statement states that when it’s interpreted appropriately, the PSA test provides important information for the diagnosis, pre-treatment staging, and monitoring of prostate cancer patients. It also clearly states that the decision to proceed to treatment or surveillance is one that men should discuss with their urologist.

My sense is that there will be some important changes in the AUA guidelines based on new evidence. This should be a living document. We shouldn’t wait several years to refine such documents because new data is coming out very rapidly.

I think it’s important to make three points about the data on prostate cancer screening with the PSA test. First, we do have more current data now from the best-quality studies. The best-quality studies show a significant reduction in the risk of prostate cancer mortality with screening. You could argue that risk reduction is anywhere between 22% and 44% and likely to grow with time. Some new data coming out very shortly will show, in fact, that the risk reduction has grown.

Unfortunately, the USPSTF looked at all the screening trials and meta-analyses instead of focusing on the highest-quality, best-performed screening studies—those that had the best pow-

The long-standing controversy over the value of prostate cancer screening heated up last fall when the U.S. Preventive Services Task Force issued a recommendation against routine screening. In this exclusive interview, Peter R. Carroll, MD, MPH, discusses the positive and negative aspects of the recommendation and provides a unique perspective on how the urology community should respond. Dr. Carroll is professor and chair of urology at the University of California, San Francisco, and served as chair of the AUA’s 2009 PSA best practice statement update panel. He was interviewed by Urology Times Editorial Consultant J. Brantley Thrasher, MD, professor and chair of urology at the University of Kansas Medical Center, Kansas City.

Do you see this as a bit of a wake-up call for urology?

J. BRANTLEY THRASHER, MD

I think it’s a tremendous wake-up call. We should be using it as a catalyst for real change to demonstrate the benefits of PSA testing in those at highest risk, clearly acknowledge the risk of overtreatment associated with screening, and get a handle on how we can both decrease overtreatment and save lives.

PETER R. CARROLL, MD, MPH
were offered active surveillance, and the trials still showed a mortality decline. That’s an important point that is frequently missed in these debates: Randomized trials show that you can decrease mortality without treating all patients.

The third point, however, is that we cannot over-estimate the impact of PSA testing. We frequently talk about risk reduction of 22% to 44%. That sounds like a very big reduction in risk, but when you look at the absolute reduction—the number of lives saved per 1,000 men—that number appears much smaller. By using a pictogram, we can probably better show the actual absolute benefits of screening.

Lastly, the AUA will continue to advocate for a risk-based approach focusing on the use of PSA in conjunction with other predictors. In other words, don’t use PSA alone, but use PSA in combination with other factors: family history, ethnicity, digital rectal examination, etc. Some very good biomarkers will become available and better refine risk assessment. We can tailor screening to those with the highest risk of prostate cancer and the highest risk of more advanced disease. The most profound risk reductions occur in such men.

Q You mentioned that there are new data on the benefits of PSA screening. Do you have particular data that the task force may have overlooked or downplayed?

A This is data that is not available to the task force as yet, but I understand the screening trials are updating their results with more follow-up. In the screening studies, what we saw is that the risk of metastatic disease declined more quickly and had a greater fall than the reduction in mortality. Metastatic disease is a harbinger of prostate cancer-specific death, so over time, you’ll actually see a greater decline in mortality rates as well.

Q In the ERSPC and Prostate, Lung, Colorectal, and Ovarian Cancer Screening Trial (PLCO), the greatest benefit was seen in the younger patients, a finding that has been underplayed in the USPSTF report. Would you not agree that higher-risk patients and those patients with a longer life expectancy are the ones where we should be concentrating the effort?

A Certainly, younger, healthier patients will accrue benefit. This was seen in a subset analysis of the PLCO trial. Again, this was a subset analysis and all the caveats of such an analysis must be considered, but the authors were able to show a mortality decline in young, healthy patients whereas the entire study did not. On the other hand, I don’t want people to think that every young patient with cancer needs to be treated immediately because in this population of younger, healthy, well-insured men, you actually see a lot of repeat screening with the consequence of over-detection. At UCSF, we currently think that some young patients with very low-risk, well-quantitated disease may be candidates for active surveillance.

Q Are you using an active surveillance protocol that is similar to Dr. Laurence Klotz’s protocol in Canada?

A Yes, it’s very similar. The world literature on active surveillance shows that it’s safe. In over 2,500 patients followed for over 5 years from U.S., Canadian, and European centers, this appears to be feasible and associated with what appears to be a very low risk. The main challenge is determining just what that risk is so we can advise patients with real numbers about what risks they’re taking with regard to both over- and under-treatment.

Q Are there particular markers that hold promise and that might become commercially available in the next 5 years?

A I think we’ll see some interesting data on a variety of biomarkers in the coming months both at the 2012 AUA annual meeting and the ASCO Genitourinary Cancers symposium. These include tests such as PCA3 and the TMPRSS2:ERG gene fusion product. In terms of imaging, 3 Tesla MRI and multiparametric MRI may have benefit. There are also new forms of gene expression profiling that appear to offer value. In the initial studies, these markers look interesting, but they need to be validated prospectively in larger populations.

There’s no question that new technology in one form or another is going to play a role in the future. My sense is that in the near term, it won’t replace PSA but likely will be used in conjunction with PSA. We need to move forward quickly and develop registries and the clinical trials to validate new markers as well as the risks and benefits of both surveillance and treatment. There are already some great examples of this type of work happening now. For example, the Canary Foundation’s Prostate Active Surveillance Study (PASS) is a consortium of multiple academic institutions participating in a prospective registry of men on active surveillance. A specific focus of this consortium is to develop and validate new biomarkers of risk and progression.
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Q Can you explain exactly what a “draft recommendation” from the USPSTF is, and might the recommendation change? We saw the USPSTF change its earlier recommendation about screening mammography. Might we see something similar with PSA screening?

A This statement is in draft form, which means the USPSTF issued a draft and gave the public 30 days to respond to it. I don’t know if the recommendation will change extensively, but I think it will be modified. We’ve all seen the outcry in response to this, so even when recommendations are made, frequently they’re not followed.

I want to point out that there’s a middle ground here that we have to reach. On one hand are those who say don’t test anyone, and on the other hand are those who say test everyone. There’s a middle ground that we need to get to. It consists of selective early detection, refined risk assessment, and selective treatment. We just need to keep focus on that middle ground because I think that’s where it’s going to benefit our patients.

My hope is that we’ll push hard for the benefits of early detection and, at the same time, expose the risks of over-detection. It’s a two-pronged approach. If we manage both of those well—showing the benefits of early detection and treatment in some patients and the risk associated with early detection and overtreatment in others—we will come out in a very principled position.

Q As you know, the task force had no urologists or prostate cancer experts among its members. Does that concern you?

A It’s a concern to some extent, but we have to remember that the task force is making recommendations to primary care providers. It has a primary provider perspective and always has. The physicians who served on the task force may not be urologists, radiation oncologists, or medical oncologists, but they are experts in evidence-based medicine who are very familiar with the literature on PSA.

I do think it would have been helpful in one form or another to have an experienced, well-published, well-funded expert in the field at least working with the committee on this subject.

Q You indicated that the AUA is preparing a new clinical guideline on early detection of prostate cancer. Do you know what that guideline will address, how it might answer some of the questions raised by the task force, and when it will be released?

A I don’t know when it will be released, but my hope is they’re moving very quickly on this. My sense is that it will include a lot of the things that were included in the 2009 report but update the data. I think it will look more carefully at other tools that we can use in addition to PSA or should not use. The issues of how often to screen, how to screen, and when to stop screening could be better addressed because there’s some new data on all of these subjects.

Q The AUA guidelines department has made the determination that they’re going to get away from best practice statements and focus on guidelines only with very strong evidence. Do you think there’s been enough new level I evidence about prostate cancer screening to make appreciable changes in what the AUA guidelines stated previously?

A There will be in some areas and not in others. When trying to make a guideline evidence-based, the guidelines committee has to comment on the level of evidence that they use. For some aspects of prostate cancer screening, it may be used quite commonly, and in other areas, the evidence for or against may be less robust. I certainly think the updated results of the screening trials will be included, and that alone will be helpful.

Q I’m concerned that the task force is linking PSA screening to treatment when one doesn’t automatically require the other. What are your thoughts on this?

A One of the things to remember is we as urologists are responsible, to some extent, for the problems related to prostate cancer detection and treatment. Urology as a community has linked them too tightly. The task force commented on this. I think to some extent we got ourselves in this position by not addressing this issue many years ago when it started to surface.

My feeling is that if we can’t manage the issue of over-detection, we shouldn’t be screening. If we manage the issue of over-detection, then screening becomes more valuable. This is our responsibility as urologists, and I think we need to acknowledge and pursue the issue aggressively. There are many reasons for overtreatment. It could be the way physicians are trained, it could be the patient’s request for treatment, or it could be the strong financial incentives to treat one way or another. We need to better study this and come to a consensus on what is appropriate and what may be inappropriate. My hope is the AUA and other organizations like it will tackle this. It won’t be easy, but I think it’s one of the things we have to do if we expect to maintain our position as the primary providers of care to men who seek guidance both on early detection and treatment, if they are found to have prostate cancer.

Q Is that best done through AUA guidelines or some other means?

A First, I think we need to more formally acknowledge the risk of over-detection and the automatic overtreatment of many patients. One good thing about this task force recommendation is that it has galvanized the specialty into acknowledging this problem. Any new guidelines have to make that statement clearer and more in the forefront. It will come from many sources, including the leaders in urology and from dissemination of new data on active surveillance.

Second, I want to caution urology in general that we will be judged on how we manage this disease. If we don’t manage it well, someone else is going to step up and become the primary purveyor of prostate cancer care.

Q What do you think the response from third-party payers will be if the USPSTF recommendation stands? Do you think they’ll stop paying for the test?

A I don’t think so. It’s too controversial. I think what insurers and payers are looking for is quality, appropriateness, and efficiency, and they can demand such things without banning the PSA test.

Q Do you have any final comments on what practicing urologists should take from these new recommendations?

A Again, let’s use these recommendations in a positive way. Let’s use them as a catalyst for change and a catalyst for a deeper understanding of the benefits of PSA testing as well as the risks. Let’s push to get to the middle ground where we can save lives while not having to treat every patient. As I mentioned, the goals are selective screening, refined risk assessment when a patient is found to have cancer, and selective treatment. That’s the middle ground we need to reach.
competing interests among the hospital, physicians, and industry,” said Chandra P. Sundaram, MD, chair of the Laparoscopic, Robotic, and New Surgical Technology Committee.

“The standard operating practice document provides a broad framework to assist with robotic surgery credentialing of urologists in training and already in practice. The responsibility for granting privileges will remain with the hospital and medical staff committee,” added Dr. Sundaram, who is professor and program director of urology at Indiana University School of Medicine, Indianapolis.

The AUA Core Curriculum for urology residencies now includes a section on laparoscopic and robotic surgery that must be followed in the residency program, whereas training of fellows will be governed by the respective society.

Dr. Sundaram pointed out that a minimum number of procedures for establishing a resident’s competency in robotic surgery was not established by the AUA Residency Review Committee. The AUA standard operating practice document recommends that at least 20 cases be performed for a resident to become credentialed in robotic surgery, apart from approval by the residency program director.

In the document, it is recommended that urologists who did not receive robotic surgery training during residency or a fellowship should successfully complete the manufacturer’s 90-minute online training module (www.daVinciSurgeryCommunity.com) and undergo hands-on training and proctoring by experienced surgeons.

Other learning resources include the AUA Handbook of Laparoscopic and Robotic Fundamentals, which is being updated with a test and curriculum, and an online course in robotic surgery that, at press time, was being finalized before release. Dr. Sundaram is the director of the course, which consists of nine sections covering fundamentals for commonly performed procedures. Mani Menon, MD, and Elspeth McDougall, MD, have also been actively involved with the development of the course.

Recognizing that acquisition of surgical skills requires more than cognitive training, it is also recommended that surgeons be observed by a urologist experienced in robotic surgery and gain hands-on experience with system set-up and docking in a laboratory setting, practicing both upper and lower tract approaches. Further skills training may be acquired using inanimate simulation models, animals when available, and virtual reality simulation.

“The AUA realizes there is no validated robotic skills curriculum similar to the fundamentals in laparoscopic surgery for general surgeons. Basic virtual reality skill simulation training has undergone initial validation and may be used widely in the future,” Dr. Sundaram said.

Initial cases should be performed in the presence of an experienced proctor who will judge when the newly trained surgeon can perform the specific operation independently. Proctors must have performed more than 50 robotic cases, of which at least 20 are similar to the one that is being proctored.

“The informed consent for the proctored procedures should include information about the proctor and his or her role and responsibilities during surgery. The proctor should have temporary privileges to take over in case of a complication, but legal liability of the proctor should be minimized,” Dr. Sundaram said.

Granting, denying privileges
Initially, a surgeon may be granted provisional privileges to operate independently, but early cases should still include the presence of another urologist and appropriate biomedical support. The appropriate hospital committee may determine the period of time and number of cases needed before granting unrestricted privileges.

Once unrestricted privileges are granted, the surgeon’s clinical performance, volume, and complications may be monitored by a hospital peer review committee to assure optimal patient care. However, after gaining unrestricted privileges for robotic surgery, urologists may perform procedures different from the type for which privileges were initially granted if the surgeon has privileges to perform the same type of surgery via an open or laparoscopic approach.

If an institution denies or restricts privileges to a physician, there should be an unbiased mechanism for appeal involving a three-person expert panel comprised of one expert selected by the urologist, one by the institution, and the third chosen jointly by the other two experts.
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Reimbursement fights to intensify in 2012

Committee’s failure to cut deficit is bad news for physicians

Washington—Urologists and other physicians across the country now find themselves in the midst of a high stakes game of “chicken” on Capitol Hill, with their level of compensation for treating Medicare patients at stake.

At press time, the House of Representatives had rejected a Senate-passed bill to extend a payroll tax cut for American workers for 2 months, legislation that also included a physician payment freeze until Feb. 29. Without action by Congress, a 27.4% reduction is mandated under current law. The House was pushing for a full year’s extension of the payroll tax cut, and its bill provided for a 2-year “doc fix” and a 1% payment update for 2012 and 2013.

Meanwhile, the Centers for Medicare & Medicaid Services notified physicians that Medicare claims would be held for the first 2 weeks of 2012 to give Congress time to act.

The Obama administration promised that such deep cuts would not be allowed to take place.

“We have not and will not let deep cuts to doctors’ payments occur,” said Health and Human Services Secretary Kathleen Sebelius. “The Obama administration is 100% committed to fixing the flawed Medicare payment system and protecting Medicare beneficiaries and doctors.”

Since the bipartisan Joint Select Committee on Deficit Reduction (the “super committee”) established by Congress in last year’s Budget Control Act failed to agree on a plan to slash $1.2 trillion from the U.S. budget as required by law, it did not deal with reforming the Medicare payment system and left in place a fallback maximum 2% across-the-board cut that is slated to take effect in 2013.

The legislation exempted Medicare patient benefits from being affected by the automatic spending cuts, leaving health care providers “on the chopping block,” in the words of a press release from the American Medical Association.

However, unless a sharply divided Congress can overcome election-year politics and find a way to cover the estimated $300 billion cost of replacing the sustainable growth rate (SGR) formula used to determine Medicare physician fees, still further reductions will be threatened again for next year under that system.

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Meanwhile, physician groups, including the AUA and the American Association of Clinical Urologists (AACU), oppose a proposal by the Medicare Payment Advisory Commission (MedPAC) that would eliminate the SGR but slash the conversion factor for specialist services by 5.9% each year for 3 years, or a total of almost 18%, followed by a 7-year freeze. For primary care physicians, Medicare payments would simply be frozen over 10 years.

The AUA endorsed a November 2011 letter to the House of Representatives leadership signed by some 80 House members from both parties opposing MedPAC’s recommendations. Lawmakers said the proposal “would threaten the ability of seniors and disabled Americans to access care from qualified physicians and providers when faced with a potentially life-altering or even life-threatening illness.”

“We are committed to finding a legislative solution that addresses the shortcomings of the current Medicare payment system, but we believe we must do so in a way that improves access to care—not in a manner that makes an already tenuous situation worse,” said the letter, initiated by Reps. Michael C. Burgess, MD (R-TX), and Gene Green (D-TX).

Another letter on Nov. 10 to Rep. Jeb Hensarling (R-TX), co-chair of the Deficit Reduction Committee, and signed by the AUA and AACU, among other physician groups, pleaded with the panel to resolve the SGR issue, noting that “even as physicians are facing draconian cuts, they are being required by Medicare legislation to make significant changes to their practices that involve both financial investments and a series of workflow changes that affect their productivity.”

Committee failure could help IPAB backers

The letter, of course, was to no avail, and the failure of the committee to find a budget solution, specifically with respect to Medicare, could make it more difficult for those who oppose creation of the Independent Payment Advisory Board (IPAB) by the health care reform law now being challenged before the U.S. Supreme Court.

Some observers believe that failure may bolster the argument of supporters of the IPAB, which the AUA, AACU, and most other physician groups oppose and have been urging Congress to repeal.

The IPAB’s recommendations for reducing Medicare spending will take effect unless Congress passes and the president signs alternative proposals to save the same amount of money, or unless the Senate votes with a three-fifths majority to reject the proposals. Further, IPAB’s changes cannot be overruled by the administration or the courts. Currently, MedPAC’s recommendations must be approved by Congress in order to take effect.

While the challenge of the health care law now before the Supreme Court centers on the mandate for health care coverage, the IPAB provision would be eliminated should the law be declared unconstitutional. If left intact, the IPAB’s first recommendations for cuts must be submitted to Congress by Jan. 15, 2014 and will become effective—unless Congress overturns them—by the following January.

How Congress and the White House respond to all of these issues in this 2012 election year remains to be seen. Urologists, whose practices rely heavily on Medicare patients, have a great deal at stake.

Fast Facts

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- cannot be overruled by the administration or the courts
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Feedback

Send your comments to Bob Gatty c/o Urology Times, at UTA@advanstar.com
CBS News

**Wi-fi radiation from laptop usage may lead to sperm damage**

New evidence is linking the electromagnetic radiation emitted by wi-fi-enabled laptops to sperm damage.

In a study from Argentina, researchers obtained semen from 29 healthy men and measured the swimming ability of the sperm cells after they were exposed to wi-fi radiation. After 4 hours, 25% of the sperm were no longer swimming. However, 14% of the sperm that were kept at the same temperature and not exposed to wi-fi were also no longer swimming.

“Keeping a laptop connected wirelessly to the Internet on the lap, near the testes, may result in decreased male fertility,” said the authors, led by Conrado Avedaño, MS, of Nascentis Medicina Reproductiva, Córdoba. Their findings were published online in *Fertility and Sterility* (Nov. 22, 2011).

**Association found between erectile dysfunction, peripheral neuropathy**

Men with severe peripheral neuropathy frequently report having erectile dysfunction, as well as failure with phosphodiesterase-type 5 inhibitors, according to a report in *BJU International* (2011; 108:1855-9).

First author Consuelo Valle Antuna, MD, of Hospital Universitario Central de Asturias, Oviedo, Spain, and colleagues recruited 90 men for the study. The average patient age was 54 years. Subjects underwent a battery of neurophysiologic tests and filled out the five-item version of the International Index of Erectile Function and the Neuropathy Symptom Score.

Pelvic floor electromyography revealed signs of chronic axonotmesis in 48% of the participants, and was bilateral in 20%. Polyneuropathy was found in about 38% of the patients. In addition, 9% had small fiber neuropathy and 14.4% had pudendal neuropathy.

“Up to now, the impact of peripheral neuropathy on the pathogenesis of ED has been underestimated,” the authors concluded. “Day-to-day clinical practice should, in the future, optimize the assessment of pelvic small fiber function.”

**Lung resection laser may find new use in outflow obstruction**

A laser normally used during lung resection is a good modality for relieving bladder outflow obstruction, according to a report in the *Journal of Urology* (2011; 186:1967-71).

Researchers led by Lukas Lusuardi, MD, of Paracelsus Medical University, Salzburg, Austria, compared Eraser laser enucleation of the prostate (ELEP [Rolle and Rolle, Salzburg]) to bipolar transurethral resection of the prostate (TURP) in 60 men with symptomatic bladder outflow obstruction.

In the randomized trial, total operative time was 9 minutes longer with ELEP than TURP, while enucleation time was significantly shorter than resection time. Mean blood loss with ELEP was significantly less than with TURP. In addition, ELEP patients had postoperative catheters for about half the time the TURP patients did.

“Due to the hemostatic properties of the laser, we believe that further studies are needed to evaluate whether this novel minimally invasive surgical technique could achieve durable functional results equivalent to those of holmium laser enucleation with superior hemostasis and shorter catheter time and hospital stay,” the authors wrote.

**President undergoes PSA test, despite task force recommendation**

President Obama underwent a PSA test during his most recent physical exam last October, not long after a government panel recommended that men no longer undergo routine prostate cancer screening.

Obama, who turned 50 last August, was screened for prostate cancer using a PSA blood test. Earlier, the U.S. Preventive Services Task Force recommended against having the test because many tumors it finds are too slow growing to be a threat. However, the White House report of the president’s physical shows there was an “informed patient request,” and Obama was screened. Following the test, his PSA was found to be low.

Obama has improved his health since his last physical. This includes having quit smoking entirely and lowering his cholesterol.

**Diffusion-weighted MRI may help detect lymph node metastases**

Diffusion-weighted magnetic resonance imaging can be used to detect pelvic lymph node metastases in normal-sized lymph nodes and may help improve prostate and bladder cancer staging, according to research presented at the 2011 Radiological Society of North America annual meeting in Chicago.

**Associated Press**

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