No stranger to legal risk
Urology practices vulnerable under False Claims Act, recent cases show
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11:15 am to 11:45 am

Combination Strategy Using the 4Kscore Test and mpMRI for Improved Accuracy in Prostate Biopsy Decisions: A multi-site study

Saturday, May 4th
11:15 am to 11:45 am

Presented by:

**Eric H. Kim, M.D.**
Assistant Professor, Urology, Department of Surgery
Washington University School of Medicine
St. Louis, Missouri

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No stranger to legal risk
Urology practices vulnerable under False Claims Act, recent cases show

Lisette Hilton / UT Correspondent

Urology practices are among the health care entities accused of violating the False Claims Act in recent years. And they've paid the price.

In February 2019, the U.S. Department of Justice (DOJ) announced Skyline Urology would pay $1.85 million to settle Medicare overbilling allegations. The government alleged that Skyline, with offices in Southern California, submitted improper claims to the Medicare program for evaluation and management (E/M) services, using modifier −25 to improperly unbundle routine E/M services that were not separately billable from other procedures performed on the same day, according to the DOJ.

Skyline Urology declined to comment when contacted by Urology Times.

Last year, FWC Urogynecology, LLC in Orlando, FL, agreed to pay the government $1.7 million to settle a False Claims Act liability for knowingly misusing Medicare billing codes with modifier −25 to receive additional payment, according to a DOJ July 2, 2018 press release.

Earlier in 2018, the DOJ announced that two California urologists agreed to pay in excess of $1 million to settle allegations that they submitted and caused the submission of false claims to Medicare for image-guided radiation therapy that was referred and billed in violation of the Stark Law and the Anti-Kickback Statute, according to a DOJ release.

Often it's not criminal behavior but ignorance or lack of oversight that causes practices to bill improperly, according to Jonathan Rubenstein, MD, compliance officer and medical director of coding and reimbursement at Chesapeake Urology Associates, an 87-physician urology group in Maryland. Dr. Rubenstein also chairs the AUA’s Coding and Reimbursement Committee.

“A lot of people are just unaware of proper coding rules,” Dr. Rubenstein said.

Lisette Hilton / UT Correspondent

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KEY PITFALLS TO AVOID
- Under-documenting, which can lead to overbilling in payers’ eyes
- Incorrect use of modifier –25
- Not ensuring your providers and employees are aware of current enforcement areas
- Failing to take corrective action if a mistake is identified
- Relying on your EHR for proper billing codes
- Relying on the billing staff exclusively to bill correctly

Sense of urgency surrounds BCG shortage

Ken Krizner / UT Correspondent

As urologists maneuver through the third shortage of bacillus Calmette-Guérin (BCG) during the past decade, there is a sense of urgency to find short- and long-term alternative treatments to the only FDA-approved BCG strain as a therapeutic agent for nonmuscle-invasive bladder cancer.

The incidence of bladder cancer is increasing worldwide. In the United States alone, there were 80,000 newly diagnosed cases in 2018, compared with 60,000 newly diagnosed cases 10 to 15 years ago.

Of these, nearly 45% of patients present with high-grade, noninvasive tumors. For these patients, intravesical immunotherapy with BCG remains the best bladder-sparing treatment, says Ashish M. Kamat, MD, MBBS, professor of urologic oncology (surgery) at MD Anderson Cancer Center, Houston.

The increase in new cases, as well as the recognition by both patients and their doctors that maintenance therapy with BCG is required, has led to an increase in demand—both in the United States and around the world—and the shortage.

Merck is the only manufacturer for the TICE strain of BCG for many countries, including the United States. Earlier this year, the company started to proportionally allocate the medicine across countries where it is the sole or primary
When treating challenging conditions in urology, urologists often face a tough choice: take their chances with organ-sparing approaches or opt for radical surgery and potentially expose the patient to complications or sequelae.

Too often, there’s no right tool for the job.

That’s why UroGen Pharma has developed a novel technology platform designed to facilitate intracavitary treatment of challenging urological conditions.

Introducing RTGel

RTGel is a sustained-release hydrogel formulation that is liquid at lower temperatures and converts to gel form at body temperature. Administered via local instillation under chilled conditions, RTGel enters the target organ as a liquid, filling and conforming to the specific anatomy. After conversion to gel form, RTGel gradually releases active drug over a period of several hours before being excreted.

Therapeutic potential

RTGel increases dwell time and exposure of active drugs, potentially improving the therapeutic effects of urological therapies.

It has the potential to increase the viability of organ-sparing techniques and give urologists a novel alternative to radical surgery.

RTGel is compatible with a number of active drug products. The technology is currently being investigated in drug formulations for the treatment of low-grade upper tract urothelial carcinoma (UTUC), low-grade non-muscle-invasive bladder cancer (NMIBC), and overactive bladder (OAB).

To learn more about RTGel, visit urogen.com/innovation

About UroGen
UroGen Pharma is a clinical-stage biopharmaceutical company focused on developing innovative solutions to address unmet needs in the fields of urology and uro-oncology.

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From the Board

Therapeutic layering in advanced PCa: Another win

Leonard G. Gomella, MD
Dr. Gomella, a member of the Urology Times Editorial Council, is chairman of the department of urology, Sidney Kimmel Cancer Center, Thomas Jefferson University, Philadelphia.

Since the pioneering work of Huggins and Hodges was first published nearly 80 years ago in Cancer Research (1941; 1:293–7), the management of metastatic prostate cancer has relied on primary androgen deprivation therapy (ADT). Reducing the circulating levels of androgens is the foundation for all treatments, from newly diagnosed metastatic hormone-sensitive prostate cancer (mHSPC) through the late stages of metastatic castration-resistant prostate cancer (mCRPC). While ADT usually slows prostate cancer progression, metastatic prostate cancer remains a fatal disease in need of improved therapies.

The phase III ARCHES trial evaluated enzalutamide (XTANDI) plus ADT in men with mHSPC (page 4). The study is its primary endpoint of improving radiographic progression-free survival versus ADT alone. ARCHES is another example of the trend in combining agents to improve outcomes, a concept known as “therapeutic layering.” Therapeutic layering, first described in the treatment of mCRPC, adds one or more agents onto an existing therapy (Urology 2017; 104:150–9). The concept is now becoming commonplace in the initial treatment of newly diagnosed metastatic prostate cancer.

Other recent examples of therapeutic layering in which agents are added to ADT in mHSPC include the CHAARTED trial (adding docetaxel), the LATITUDE trial (adding abiraterone [ZYTiga/prednisone]), and the TITAN trial (adding apalutamide [Erleada]). Results from both CHAARTED and LATITUDE demonstrated improved overall survival with the combination therapy. Preliminary results from TITAN have also shown improved survival. ARCHES has shown the benefit of delaying enzalutamide with ADT.

The recent trials using therapeutic layering are redefining how initial mHSPC is managed. Historically, the addition of nonsteroidal antiandrogens (eg, flutamide, bicalutamide) to ADT regimens represented the first therapeutic layering attempts, but only minor improvements in long-term outcome were seen with this combined androgen blockade (CAB) approach. CAB outcomes were inferior to those of recent trials that support the combined use of ADT with chemotherapy or next-genera- tion androgen receptor pathway blockers in mHSPC.

Docetaxel and abiraterone are now part of mHSPC guidelines such as those from the National Comprehensive Cancer Network. With the likely approval of enzalutamide based on the ARCHES trial, we will have one more agent available to perform therapeutic layering to improve outcomes in men with newly diagnosed metastatic prostate cancer.
Enzalutamide plus ADT improves rPFS in hormone-sensitive PCa

Wayne Kuznar
UT Correspondent

SAN FRANCISCO—Enzalutamide (XTANDI) added to androgen deprivation therapy (ADT) significantly extended radiographic progression-free survival (rPFS) compared with ADT alone in a large international phase III study of men with metastatic hormone-sensitive prostate cancer (mHSPC).

In the ARCHES study, at a median follow-up of 14.4 months, median rPFS was not reached in the enzalutamide arm compared with 19.4 months in the placebo arm, corresponding to a 61% reduction in the risk of radiographic progression or death (HR=0.39; p<0.0001), said Andrew J. Armstrong, MD, at the Genitourinary Cancers Symposium in San Francisco.

In an interim analysis of overall survival (OS), data are immature with 39 deaths in the enzalutamide arm and 45 in the placebo arm (HR=0.81; p=.3361), about one-fourth of the number of events required for final analysis. The median OS had not been reached in either arm; some 93% of patients were still alive at the interim analysis.

ARCHES was a double-blind trial of 1,150 patients with histologically verified mHSPC (both low- and high-volume disease) conducted across North America, Europe, and the Asia-Pacific region. Participants were randomized to enzalutamide, 160 mg daily, or placebo.

Patients who received recent treatment with docetaxel (Taxotere) but did not have disease progression were allowed into the trial, a departure from recently published studies in mHSPC in which men who received prior docetaxel were excluded, noted Dr. Armstrong, professor of medicine and associate professor of pharmacology and cancer biology at Duke University, Durham, NC. Patients were allowed to receive ADT <3 months prior to entry unless they received prior docetaxel, in which case they could have had ADT for up to 6 months before study entry. The primary endpoint was rPFS.

At initial diagnosis, 70% of men in the enzalutamide arm and 63% in the placebo arm had distant metastasis, about two-thirds in each arm had high-volume disease, and two-thirds in each arm had a Gleason score >8. About 18% overall had received prior docetaxel. The median duration of prior ADT was 1.6 months.

Median duration of therapy was 12.8 months for enzalutamide plus ADT versus 11.6 months for placebo plus ADT. As of the data cutoff of Oct. 14, 2018, “Nearly 76% of patients remain on the study drug for enzalutamide and 58% remain on ADT alone,” Dr. Armstrong said.

The 12-month event-free rate estimate was 84.5% for enzalutamide plus ADT and 63.7% for placebo plus ADT.

rPFS benefit seen in several subsets

Significant benefit on rPFS to enzalutamide was realized in clinically important subsets of patients stratified by low and high disease volume and prior docetaxel. A significant advantage to enzalutamide on rPFS was also observed across subgroups by age, geographic region, Gleason score, disease localization and pattern of spread, volume of disease, and receipt of prior docetaxel.

“This important—nearly 20% subset of patients—had a hazard ratio of 0.53 indicating a 47% improvement in the hazard of progression or death over time,” Dr. Armstrong said.

Other findings included:

• Enzalutamide plus ADT reduced the risk of PSA progression by 81% (p<0.0001). The median time to PSA progression was not reached in either group. The 12-month event-free rate estimate was 91.2% for enzalutamide plus ADT and 62.8% for placebo plus ADT.

• Of the patients with detectable PSA at baseline, enzalutamide plus ADT significantly increased the PSA undetectable rate compared with placebo/ADT (68.1% vs. 17.6% [difference of 50.5%]; p<0.0001).

• The time to initiation of new antineoplastic therapy was also reduced in the enzalutamide/ADT arm versus placebo/ADT (HR=0.28; p<0.0001).

• More than one-third (36.7%) of the enzalutamide arm and 23.1% of the placebo arm achieved a complete response (disappearance of all lesions on imaging). The overall response rates were 83.1% for enzalutamide and 63.7% for placebo (p<0.0001).

• The rate of adverse events was similar in each arm, as was the proportion of patients who had to discontinue study due to adverse events (enzalutamide arm and 45 in the placebo arm (HR=0.81; p=.3361), about one-fourth of the number of events required for final analysis. The median OS had not been reached in either arm; some 93% of patients were still alive at the interim analysis.

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Please see ENZA. PLUS ADT, page 5
PCa test linked to increased risk of adverse pathology

Increase in GPS corresponds with increased risk of recurrence

Wayne Kuznar
UT Correspondent

SAN FRANCISCO—A higher OncotypeDX Genomic Prostate Score (GPS) is associated with an increased risk of adverse pathology in patients who undergo delayed radical prostatectomy (RP) after a period of active surveillance.

“I think for patients with low- to intermediate-risk prostate cancer who are diagnosed on needle core biopsy, it’s very reasonable to use GPS in conjunction with clinical factors such as PSA density and clinical CAPRA score to guide patients as to whether they may or may not be suitable for AS.”

ZACHARY KORNBERG

In examining a database of men enrolled on AS at the University of California, San Francisco (UCSF), researchers led by Peter R. Carroll, MD, found that each five-unit increase in GPS was associated with a significantly increased risk of adverse pathology and a significantly increased risk of biochemical recurrence following surgery.

The data were presented at the Genitourinary Cancers Symposium in San Francisco by Zachary Kornberg, a fourth-year medical student at UCSF, working under Dr. Carroll.

“The GPS was developed for patients with low- to intermediate-risk prostate cancer who would have otherwise qualified for AS but went on to have RP, as a predictor for adverse pathology,” Kornberg said. “We studied a very similar cohort who elected for AS and then went on to have a delayed RP after a short period of AS.”

The GPS is derived from the RNA expression of 17 genes that are associated with a likelihood of having high-grade (Gleason pattern 4) and/or high-stage (pathologic T-stage 3) disease if the prostate is removed and examined. The assay can be performed on core needle biopsies.

Of 1,662 men enrolled on AS at UCSF from 1997 to 2016, the investigators evaluated 215 with Gleason score 3+3 or low-volume disease (≤33% positive cores) Gleason score 3+4 prostate cancer on diagnostic or confirmatory biopsy. All 215 men had a PSA level <20 ng/mL, clinical stage T1/2, and Cancer of the Prostate Risk Assessment (CAPRA) score <6, and all underwent GPS testing at diagnostic or confirmatory biopsy (within 24 months).

When adjusted for CAPRA, each five-unit increase in GPS was associated with a 16% increased risk (p<.01) of adverse pathology.

ENZA. PLUS ADT

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amidine: 7.2%; placebo: 5.2%). The rate of grade ≥3 adverse events was also similar (24.3% vs. 25.6%, respectively).

• The addition of enzalutamide to ADT did not have a significant impact on time to deterioration of urinary symptoms (HR=0.88; p=2.162) or the Functional Assessment of Cancer Therapy-Prostate (FACT-P) total score compared with placebo.

“While we did not show a difference in the impact on urinary symptoms or FACT-P scores, most of these patients during 14.4 months of follow-up maintained a high level of quality of life,” Dr. Armstrong said.

Following the unblinding at the end of double-blind treatment, all patients in the placebo group are being offered enzalutamide in an open-label extension protocol.

Invited discussant Ian D. Davis, MD, of Monash University and Eastern Health, Melbourne, Australia, said that the primary end-point in ARCHES, rPFS, is probably clinically meaningful, given that rPFS was correlated with OS for enzalutamide in the PREVAIL study. Another positive indicator of benefit was the PSA undetectable rate (68.1%), which was much higher than that reported with abiraterone acetate (ZYTIGA)/prednisone (47.6%) in LATITUDE and with docetaxel (32%) in CHARTED.

“If you have an undetectable PSA (≤0.2) at 7 months after commencing the treatment, this is associated with much better outcomes,” Dr. Davis said.

Until the OS data are mature, ARCHES should probably not change practice, said Dr. Davis, although topline data recently released from the TITAN study demonstrated that apalutamide (ERLEADA) showed a significant benefit in both rPFS and OS as co-primary endpoints in patients with metastatic castration-sensitive prostate cancer.

Astellas Pharma Inc. and Medivation LLC funded the study. Dr. Armstrong has several disclosures related to Astellas Scientific and Medical Affairs Inc., Medivation, Pfizer, and other pharmaceutical companies; for full disclosures, go to bit.ly/ARCHESdisclosures.
Clinical Updates

Elevated bone markers prevalent in men on ADT

Wayne Kuznar
UT Correspondent

Nearly 90% of men with hormone-sensitive prostate cancer (HSPC) who initiate androgen deprivation therapy (ADT) have at least one bone metabolism biomarker that is elevated. As expected, a high proportion of men with bone metastases had at least one bone metabolism biomarker elevated above the median, Primo N. Lara, MD, reported at the 2018 European Society of Medical Oncology annual congress in Munich.

In an earlier study, the phase III SWOG S0421, blood-based bone biomarkers were shown to be independently prognostic of outcome in men with castration-resistant prostate cancer with bone metastases, and patients with highly elevated levels of bone markers preferentially benefited from bone-targeted therapy (strontium). Atrasentan had no effect on survival or progression-free survival in the overall study cohort. The study was therefore instructive, said Dr. Lara, director of the National Cancer Institute-designated University of California Davis Comprehensive Cancer Center, Sacramento.

“It is unclear whether prognostic or predictive value of bone metabolism biomarkers applies to the earlier HSPC state,” he said. Therefore, Dr. Lara and colleagues prospectively assessed bone metabolism biomarkers in men enrolled in the S1216 trial, a National Institutes of Health-funded phase III study of ADT with or without a novel CYP17 inhibitor (orteronel). The main purpose of S1216 is to compare overall survival in patients with newly diagnosed metastatic prostate cancer randomly assigned to ADT plus orteronel or ADT plus bicalutamide (Casodex). S1216 is still collecting events, with the first read-out anticipated next year, he told Urology Times.

“We’re hypothesizing that maybe the same observations we saw in castration-resistant disease will be seen in this different, earlier population of men with HSPC,” he said. “We hope to see that the patients with the highest levels of bone biomarkers are the ones who benefit preferentially from orteronel.”

The data presented at the ESMO annual congress were the distribution of baseline bone metabolism biomarkers from S1216 and their relationship to other baseline clinical variables. Median baseline PSA level of the study cohort was 29.16 ng/mL. Of the 799 men with baseline serum assessable for bone metabolism biomarkers, 305 (50.5%) had bone metastases, 305 (50.5%) had elevations in one to three bone markers.

Among the 604 patients with bone metastases, 305 (50.5%) had elevations in one to three bone markers.

“Expectedly, if you have bone metastases, your bone turnover biomarkers will be elevated. Elevated bone biomarkers tend to track with clinical features, such as tumor grade, lower performance status, and disease extent.”

PRIMO N. LARA, MD

C-terminal collagen propeptide and bone alkaline phosphatase were measured.

Median levels of bone metabolism markers at baseline in the overall cohort and the patients with bone metastases were as follows:

- Bone alkaline phosphatase, 1.66 U/L and 2.09 U/L, respectively
- C-terminal of type I collagen, 116.39 ng/mL and 125.28 ng/mL, respectively
- C-telopeptide, 0.46 ng/mL and 0.49 ng/mL, respectively
- Pyridinoline, 1.68 nmol/L and 1.74 nmol/L, respectively

A bone marker was considered elevated if it was above the median or in the upper quartile. Men were grouped as having all four, one to three, or no bone metabolism biomarker elevated.

53.7% of patients have 1-3 markers elevated

A total of 429 patients (53.7%) had one to three bone markers elevated, and 28 (3.5%) had all four bone markers elevated. At least one bone metabolism biomarker was above the median in 87% and in the top quartile in 57%.

Among the 604 patients with bone metastases, 305 (50.5%) had elevations in one to three bone markers, 25 (4.1%) had all four bone markers elevated, and 513 had at least one bone metabolism biomarker elevated above the median.

The distribution of bone metabolism biomarker elevation above the median differed significantly within groups defined by baseline PSA (p<.0001), Gleason score (p<.0001), performance status (p<.0001), and disease extent (p<.0001). For example, in 292 patients with serum PSA level >29 ng/mL, 30% had all four bone metabolism biomarkers elevated, whereas in those with serum PSA <29 ng/mL, only 6% had all four elevated.

“Expectedly, if you have bone metastases, your bone turnover biomarkers will be elevated,” said Dr. Lara. “And that’s what we see. Elevated bone biomarkers tend to track with clinical features, such as tumor grade, lower performance status, and disease extent.”

Bone metabolism biomarker distribution in the entire cohort did not differ within race/ethnicity, age, and bisphosphonate/denosumab groupings. Millennium Pharmaceuticals provided funding for the study.

Inflammatory bowel disease may raise prostate Ca risk

Further validation required before considering IBD a risk factor, researcher says

Wayne Kuznar
UT Correspondent

SAN FRANCISCO—Inflammatory bowel disease (IBD) increases the risk of any and clinically significant prostate cancer, according to an examination of data from a large, single medical network.

On adjusted analyses, IBD was associated with four- to five-fold increased risk of any and clinically significant prostate cancer over 10 years, Shilajit Kundu, MD, reported at the Genitourinary Cancers Symposium in San Francisco.

“It has long been thought that chronic gut inflammation and cancer are related,” said Dr. Kundu, chief of urologic oncology, Robert H. Lurie Comprehensive Cancer Center, Northwestern University, Chicago. “Gut inflammation increases the risk of colon cancer, liver cancer, and cholangiocarcinoma, but the link between gut inflammation and prostate cancer...
IBD AND PCa
continued from page 6

is not well established. Data linking IBD and prostate cancer are limited and come mostly from the era before PSA screening was widely practiced.”

Dr. Kundu and colleagues examined a cohort of 1,033 men with IBD and prospectively matched them on the basis of race and age to 9,306 men without IBD. All men had at least one screening PSA test between 1996 and 2017 and none had a history of prostate cancer. The median age at first PSA test was 53 years in both cohorts, and 74% in each cohort were Caucasian. The median number of PSA tests per man over 5 years was two.

The median follow-up was 4.7 years for the controls and 6.5 years for the men with IBD. At 5 years of follow-up, there were 50 cases of prostate cancer and 16 cases of clinically significant prostate cancer (Gleason grade group >1) among the men with IBD and 29 cases of prostate cancer and 17 cases of clinically significant prostate cancer among the controls.

4.4% incidence of PCa observed

The 10-year incidence of any prostate cancer was 0.65% among controls and 4.4% among men with IBD. When adjusted for age, race, number of PSA tests, baseline PSA level, and history of abnormal rectal examination, the hazard ratio (HR) for any prostate cancer among men with IBD compared with controls was 4.84 (p<.001).

The 10-year incidence of clinically significant prostate cancer was 0.42% among controls and 2.4% among men with IBD. The adjusted HR for clinically significant prostate cancer among men with IBD compared with controls was 4.04 (p<.001).

At 10 years of follow-up, the incidence of metastatic prostate cancer was 0.03% for controls and 0.19% for men with IBD (p=.60). When assessing IBD characteristics and prostate cancer incidence among the men with IBD, use of biologic medications, duration of IBD, history of bowel resection, and ulcerative colitis versus Crohn’s disease did not affect prostate cancer incidence. Prednisone treatment for IBD was protective of any prostate cancer (adjusted HR=0.22; p<.019), but not of clinically significant prostate cancer (p=.5).

After age 60 years, PSA values were higher among patients with IBD compared with controls (p<.004), and the difference widened with increasing age.

The findings need to be further validated to consider IBD as a risk factor for prostate cancer and to optimize screening for this population, said Dr. Kundu.

“My main message would be to consider prostate cancer screening in men with IBD, and we may want to consider them potentially as a higher risk group for developing prostate cancer than men without IBD.”

SHILAJIT KUNDU, MD

“ ’My main message would be to consider prostate cancer screening in men with IBD, and we may want to consider them potentially as a higher risk group for developing prostate cancer than men without IBD,’” he said. “Second, from a practical standpoint, if a man comes in with an elevated PSA and he has a history of IBD, don’t assume that the elevated PSA is from inflammation. It may be truly prostate cancer. I would pursue it a bit more rigorously, with a consideration for imaging or having a discussion about biopsy, as their risk may be increased.”

“...”
Clinical Updates

AS increasing in African-Americans

Wayne Kuznar
UT Correspondent

SAN FRANCISCO—Active surveillance (AS) rates among African-American men with low-risk prostate cancer tripled over a 5-year period in the United States beginning in 2010, which suggests that AS is viewed as a safe management option regardless of race.

An examination of the Surveillance, Epidemiology, and End Results (SEER) Program Prostate with Active Surveillance/Watchful Waiting (WW) Database found that AS became the favored management approach in patients with ≤2 positive cores, regardless of race, with more than half of African-American and non-African-American patients receiving AS by 2015, researchers from Brigham and Women’s Hospital, Boston, reported at the Genitourinary Cancers Symposium in San Francisco.

“The concern has been that African-American men with prostate cancer have a high risk for underlying biologically aggressive disease not apparent on initial biopsy. Some providers and clinicians use race as a risk stratification tool in order to make decisions about AS versus definitive treatment, with the thought in mind that if there was missed underlying disease with the biopsy, that it might be a safer route to do definitive therapy as opposed to AS,” Butler told Urology Times.

This thinking prompted the authors to look at trends in AS, since AS in the low-risk setting became part of a guideline released by the National Comprehensive Cancer Center (NCCN). In the low-risk setting, the rates of conservative management were lower with African-American men compared with non-African-American men, a difference of about 7%.

The SEER Prostate with AS/WW database identified 50,302 men, 5,218 of whom were African-American diagnosed with localized NCCN low-risk prostate cancer from 2010 to 2015. The primary endpoint was rates of AS/WW utilization over time, stratified by race and number of positive biopsy cores (≤2 vs. ≥3).

The rate of AS/WW use increased from 12.6% to 36.4% among African-American men over the 6-year study period (p < 0.001). Among non-African-American men, the rate increased from 14.8% to 43.3% (p < 0.001). This 7% difference may be due to provider hesitancy to treat these populations uniformly in the context of their historically disparate outcomes, Butler said.

Among the men with ≤2 positive biopsy cores, AS/WW increased from 19.2% to 52.0% among African-American men (p < 0.001) and from 20.2% to 57.3% for non-African-American men (p < 0.001).

African-American men with ≥3 positive cores were the least likely to receive AS/WW, with only 22.9% receiving conservative management by 2015, and were also the only subgroup to experience a plateau in the rate of AS/WW use over the course of the study, after tripling between 2010 and 2013.

The rates of radical prostatectomy and radiation therapy each decreased between 2010 and 2015 for both African-American and non-African-American men.

DDR mutations linked to improved urothelial Ca outcomes

Wayne Kuznar
UT Correspondent

SAN FRANCISCO—Alterations in DNA damage response (DDR) genes, excluding ATM, correlate with improved outcomes in relapsed/advanced urothelial cancer (UC).

Across three independent cohorts totaling 301 patients, overall survival (OS) was longer in patients with DDR mutations than in those without DDR mutations, and a trend was observed for longer OS with an increasing number of DDR mutations, reported Monika Joshi, MD, at the Genitourinary Cancers Symposium in San Francisco.

DDM gene defects play an important role in UC tumorigenesis. A plethora of DDR mutations exist, each of which has potentially distinct implications on the functional impact of DDR proteins, she said. However, the prognostic and predictive roles of DDR gene alterations in patients with advanced UC remain unclear.

“Previously, we pooled a dataset between three institutions and looked at survival, and found that mutations in ATM and Rb1 were negative prognostic indicators,” said Dr. Joshi, associate professor of medicine and genitourinary oncologist at Penn State Cancer Institute, Hershey. “We performed this study because we wanted to expand our knowledge and further validate outcomes in patients with relapsed or advanced UC who have DNA damage repair gene defects excluding ATM abnormality.”

The investigators used 81 patients from the City of Hope, Cleveland Clinic, and Penn State who had FoundationOne tumor tissue genomic sequencing as a discovery cohort. Findings were validated in two separate cohorts, one consisting of 91 patients from The Ohio State University with FoundationOne testing and another cohort of 129 patients with relapsed/refractory UC from The Cancer Genomic Atlas. OS was measured from time of initial UC diagnosis to death or last follow-up.

A panel of 32 DDR genes, excluding ATM, was selected for further study. Please see DDR MUTATIONS, on page 9.
used for analyses. Most of the patients in all three cohorts had relapsed UC.

DDR mutations were present in 76.5% (62/81), 40.7% (37/91), and 51.2% (66/129) of patients in the three datasets. DDR mutations were associated with longer OS in all three datasets.

In the discovery cohort, median OS was 50.8 months for those with DDR mutations and 22.7 months in those without DDR mutations, corresponding to an adjusted hazard ratio (HR) for death of 0.39 (95% CI: 0.21–0.73, p=.01).

In validation cohort 1, median OS was 60.7 months versus 30.7 months in patients with and without DDR mutations, respectively, translating to an adjusted HR for death of 0.51 (95% CI: 0.26–1.03, p=.06) in those with DDR mutations.

In validation cohort 2, median OS was 21.8 months versus 19.4 months in patients with and without DDR mutations, respectively, corresponding to an adjusted HR for death of 0.62 (95% CI 0.39–0.97, p=.08).

Across the three cohorts, the OR for death was 0.61 (95% CI: 0.38–0.98) for any DDR mutation compared to no DDR mutation.

Patients with DDR mutations were more likely to have an objective response to platinum-based treatment than those without DDR mutation, and the odds increased with more DDR mutations. Among 144 patients pooled from the three cohorts who received any platinum-based treatment, the objective response rates were 29% in those without a DDR mutation, 39% in those with one or two DDR mutations, and 60% in those with three or more DDR mutations. For any DDR mutation, the odds ratio for objective response was 1.81 (95% CI: 0.85–3.92) compared with no DDR mutation, and for those with three or more DDR mutations, the OR for an objective response was 3.65 (95% CI: 0.91–14.7) compared with no DDR mutations.

Similarly, the risk of death was lowest among patients with three or more DDR mutations (OR: 0.49, 95% CI: 0.19-1.27) compared with no DDR mutations.

The findings suggest that presence of DDR mutations is correlated with improved outcome in relapsed/advanced bladder cancer.

“Our results from a separate retrospective study... suggest that patients with DDR mutations have better outcomes with immunotherapy. However, the presence of ATM alteration was again suggestive of poor prognosis in that study.

“Hence, one way to possibly treat this particular patient population would be to think about targeting the ATM pathway with an inhibitor,” Dr. Joshi said.

Dr. Joshi’s institution has received funding from AstraZeneca, and several of her co-authors have disclosures with Foundation Medicine and one or more pharmaceutical companies.

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**TABLE** DNA Damage Response Gene Mutations and Urothelial Ca Outcomes

<table>
<thead>
<tr>
<th>Cohort</th>
<th>Median OS, patients with DDR mutations (months)</th>
<th>Median OS, patients without DDR mutations (months)</th>
<th>p value</th>
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<tbody>
<tr>
<td>Discovery cohort</td>
<td>50.8</td>
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<td>.01</td>
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<tr>
<td>Validation cohort 1</td>
<td>60.7</td>
<td>30.7</td>
<td>.06</td>
</tr>
<tr>
<td>Validation cohort 2</td>
<td>21.8</td>
<td>19.4</td>
<td>.08</td>
</tr>
</tbody>
</table>

Source: Monika Joshi, MD
Cabozantinib (Cabometyx) demonstrated consistent improvement in progression-free survival (PFS) and overall survival (OS) over everolimus (Afinitor) and sunitinib (Sutent), irrespective of PD-L1 status, across two randomized controlled clinical trials in patients with metastatic clear cell renal cell carcinoma (mRCC).

In addition, using the patient populations from the METEOR and CABOSUN clinical trials, PD-L1 expression in tumor cells was found to be associated with shorter PFS and OS in both trials, reported Toni K. Choueiri, MD, at the 2018 European Society of Medical Oncology annual congress in Munich.

“These data support use of cabozantinib in a PD-L1 unselected population and, possibly, in combination with checkpoint blockers irrespective of PD-L1 status,” concluded Dr. Choueiri, director of the Lank Center for Genitourinary Oncology, Dana-Farber Cancer Institute, Boston, in his poster presentation.

The CheckMate 214 study had previously demonstrated that PD-L1 expression in tumor cells correlates with improved outcomes with assignment to nivolumab (Opdivo) and ipilimumab (Yervoy) compared with sunitinib in patients with previously untreated advanced renal cell carcinoma.

In a trial of patients with metastatic renal cell carcinoma who were treated with sunitinib or pazopanib (Votrient), however, high expression of PD-L1 in tumor cells correlated with shorter survival.

Dr. Choueiri and colleagues explored whether PD-L1 expression could serve as a prognostic and/or predictive biomarker for cabozantinib efficacy, using formalin-fixed paraffin-embedded baseline tumor tissue obtained from 110 patients from CABOSUN and 306 patients from METEOR. They assessed PD-L1 expression in both tumor cells and immune cells by performing immunohistochemical (IHC) double-staining for PD-L1 and CD45/CD163, two immune cell markers. Novel digital image analysis algorithms were used to allow scoring of PD-L1.

Twenty-nine percent of METEOR and 23% of CABOSUN tissue samples contained PD-L1-positive tumor cells.

In the comparison between cabozantinib and everolimus (Afinitor) in METEOR, the median PFS per Independent Review Committee (IRC) was 8.5 versus 5.6 months (p=0.027) in favor of cabozantinib, and the median OS was 21.3 versus 15.1 months (p=0.003). In patients with tumor cell PD-L1 expression <1%, median PFS was 8.5 months with cabozantinib versus 4.1 months with everolimus (HR: 0.46; 95% CI: 0.32-0.66).

In patients with PD-L1 expression ≥1%, median PFS was 5.6 versus 3.7 months in the cabozantinib and everolimus arms, respectively (HR: 0.66; 95% CI: 0.40-1.11).

In CABOSUN, the median PFS per IRC was 8.3 months in the cabozantinib arm versus 5.5 months in the sunitinib arm (p=0.059); and median OS was 28.1 versus 20.8 months, respectively (p=0.05). Median PFS with cabozantinib versus sunitinib in patients with PD-L1 expression <1% was 11.0 versus 5.0 months (HR: 0.47; 95% CI: 0.26-0.86). Median PFS in patients with PD-L1 expression ≥1% was 8.4 months in the cabozantinib arm versus 3.1 months in the sunitinib arm (HR: 0.46; 95% CI: 0.18-1.21).

Consistent survival advantage

The PFS advantage with cabozantinib in both trials was consistent according to PD-L1 expression and across PD-L1 measures, including immune cell PD-L1, combined PD-L1 score, and using different PD-L1 cut-offs.

By univariate analysis, patients with PD-L1 levels <1% on tumor cells had superior PFS and OS compared with patients with PD-L1-positive tumor cells in both trials, independent of therapy.

The association between PD-L1 expression on tumor cells and OS was statistically significant in the multivariate analysis when combining the two trials. “In the univariate analysis, PD-L1 expression was associated with shorter PFS and OS in both the METEOR and CABOSUN trials,” said invited discussant Cristina Suárez, MD, PhD, of Hospital Universitari Vall d’Hebron, Barcelona, Spain. “In the multivariate analysis, adjusting by IMDC prognosis, treatment, and bone metastases, PD-L1 was associated with poorer OS but not with PFS.”

Dual-IHC staining is a robust and efficient manner to characterize PD-L1 status on tumor cells and immune cells, she added.

She noted that in all cases, cabozantinib was associated with improved OS and PFS compared to everolimus and sunitinib irrespective of PD-L1 expression.

Exelixis provided funding for the study. Dr. Choueiri’s institution receives research funding from Pfizer, Novartis, Roche, Exelixis, BMS, Merck, Tracon, and AstraZeneca. For a full list of disclosures, see bit.ly/cabozantinibdisclosures.

### Consistent improvement in PD-L1 expression

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<th>METEOR trial</th>
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<th>Everolimus arm</th>
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<tr>
<td>Median PFS per Independent Review Committee (months)</td>
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<tr>
<td>Median OS (months)</td>
<td>21.3</td>
<td>15.1</td>
</tr>
<tr>
<td>Median PFS, patients with tumor cell PD-L1 expression &lt;1% (months)</td>
<td>8.5</td>
<td>4.1</td>
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<td>Median PFS, patients with PD-L1 expression ≥1% (months)</td>
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<table>
<thead>
<tr>
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<th>Cabozantinib arm</th>
<th>Sunitinib arm</th>
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<td>Median PFS, patients with PD-L1 expression ≥1% (months)</td>
<td>8.4</td>
<td>3.1</td>
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Chemo/RT regimens provide bladder-sparing options in bladder Ca

Gemcitabine-, cisplatin-based treatments both met prespecified DMF3 benchmark

**Dave Levitan**
**UT Correspondent**

Two bladder-sparing regimens involving chemotherapy plus radiotherapy yielded good distant metastasis-free survival rates at 3 years (DMF3) in patients with muscle-invasive bladder cancer (MIBC), according to a new phase II study. A regimen involving gemcitabine and once-daily radiation may offer more convenience and less toxicity than a cisplatin-based regimen with twice-daily radiation.

“Selective bladder preservation using trimodality therapy is an established treatment of MIBC with outcomes that are comparable to those of radical cystectomy,” wrote study authors led by John J. Coen, MD, of 21st Century Oncology in Providence, RI. Previous research has incorporated cisplatin-based chemotherapy along with twice-a-day radiation, and subsequently a regimen involving gemcitabine and radiation once per day has also been shown to be effective. The new study compared these two approaches with regard to DMF3.

The trial included a total of 66 patients with cT2-4a MIBC, randomized to receive either fluorouracil plus cisplatin and radiation twice per day or gemcitabine plus radiation once per day (33 patients in each group). Half the cohort was aged 60 to 69 years, with 33.3% older than that and 16.6% aged 59 or younger. Most of the patients were male (75.8%), and most were Caucasian (89.4%). The median follow-up period was 4.3 years; results were published in the *Journal of Clinical Oncology* (2019; 37:44-51).

The DMF3 rate in the cisplatin-based regimen group was 77.8%, compared with 84.0% in the gemcitabine and once-daily radiation group. A post-hoc analysis showed no significant difference between these groups (*p*=.73), and both regimens met the prespecified benchmark of 75%.

There were similar rates of treatment completion in the two groups, with 56% of the cisplatin group and 55% of the gemcitabine group completing the adjuvant chemotherapy treatment following induction and consolidation therapy. A cystectomy was performed in three of four patients without a complete response in the cisplatin group, and in five of seven such patients in the gemcitabine group.

In the cisplatin/fluorouracil and twice-daily radiation group, 64% of patients had a treatment-related grade 3 or 4 toxicity during the treatment; there was one death due to an intracranial hemorrhage likely related to the treatment in that group. In the gemcitabine and once-daily radiation group, 55% had treatment-related grade 3 or 4 adverse events, and fewer patients experienced hematologic events than in the other group (42% vs. 55%).

**Authors: Both regimens worthy of additional study**

“Both [regimens] could be considered for additional study,” the authors concluded. “Concurrent low-dose gemcitabine is a reasonable alternative to a cisplatin-based regimen. Once-per-day radiation is a reasonable alternative to accelerated twice-a-day radiation, which may allow for the wider adoption of bladder preservation.”

Michael Glodé, MD, of the University of Colorado School of Medicine in Denver, who was not involved in the research, called this “an important step in the ongoing efforts... to develop bladder-sparing chemotherapy/radiotherapy protocols.”

He noted that the trial was not designed to directly compare the two regimens, though both clearing the prespecified benchmark is encouraging.

“The gemcitabine plus once-daily radiotherapy regimen is more convenient for patients and less toxic, providing a basis on which to incorporate versions of this treatment into future immunologic approaches with checkpoint inhibitors,” he said.

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**Delaying neoadjuvant chemo confers risks**

Timing of treatment associated with upstaging risk in bladder cancer patients, study finds

**Dave Levitan**
**UT Correspondent**

Delaying neoadjuvant chemotherapy 8 weeks or more after diagnosis of urothelial carcinoma increases the risk of upstaging after radical cystectomy, according to a new study. Several factors, including race, insurance, and type of facility, were associated with such delays in treatment.

Previous research showed that delaying radical cystectomy can decrease overall survival (OS). “One of the hesitations in recommending neoadjuvant chemotherapy is that it may delay definitive therapy with radical cystectomy, which may compromise patient outcomes,” wrote study authors led by François Audenet, MD, of the Icahn School of Medicine at Mount Sinai in New York. “However, it is unclear if the effect of delays on patient outcomes still holds true in the setting of neoadjuvant chemotherapy utilization.”

The authors used the National Cancer Database (NCDB) to examine delays in treatment and the effect on outcomes in a cohort of 2,227 patients who underwent neoadjuvant chemotherapy and radical cystectomy for cT2-T4aN0M0 urothelial carcinoma of the bladder between 2004-2017.

Please see DELAYING CHEMO, page 17
Testicular Ca germline variant may raise risk of later cancers

Christina Bennett, MS / UT Correspondent

Researchers identified two germline pathogenic variants in checkpoint kinase 2 (CHEK2) that may account for a minority of men diagnosed with testicular germ cell tumors.

Men with aberrations in CHEK2 have an increased risk for developing prostate, colorectal, and breast cancer, and this finding could not only help inform these men of their increased risk for later cancers, but also their family members who may harbor the aberration. The study results were recently published in JAMA Oncology (Jan. 24, 2019 [Epub ahead of print]).

Scott Tagawa, MD, MS, medical director of the Genitourinary Oncology Program at Weill Cornell Medicine and NewYork-Presbyterian, told Urology Times sister brand Cancer Network that he was “impressed” with the study design. The authors not only tested their hypothesis in additional patient populations. He said the association he was “impressed” with the study design.

In the discovery cohort, 20 of 205 cases (9.8%) ed a discovery, validation, and high-risk group. The authors identified 8 weeks as a cutoff point: from surgery alone studies, as long as radical cys-

FRANÇOIS AUDENET, MD, ET AL

“Given the aggressiveness of the disease, we should expedite referral of patients for neoadjuvant chemotherapy initiation as soon as possible and no more than 8 weeks after diagnosis.”


The median time from diagnosis to initiation of neoadjuvant chemotherapy was 39 days, while the median time to radical cystectomy was 155 days; the median time between the start of neoadjuvant chemotherapy and radical cystectomy was 112 days. After a median follow-up period of 45.7 months, the OS rate at 2 years was 69%; at 5 years, the OS rate was 49%. Taken as continuous variables, the time to neoadjuvant chemotherapy and to radical cystectomy were not significantly associated with OS, and no cutoff point was found that could predict poorer OS.

However, the timing of treatment was associated with upstaging risk. A total of 916 patients (41%) were upstaged after radical cystectomy, including 485 patients (22%) with positive lymph nodes. On a univariate analysis, the time to neoadjuvant chemotherapy taken as a continuous variable was significantly associated with a higher risk of upstaging, with an odds ratio (OR) of 1.003 (95% CI, 1.00–1.005; p = .034).

8 weeks identified as cutoff point

The authors identified 8 weeks as a cutoff point: Those whose neoadjuvant chemotherapy began at least 8 weeks from diagnosis had an OR for upstaging of 1.24 (95% CI, 1.03–1.50; p = .021).

This held on a multivariable analysis, where the OR for upstaging was 1.27 (95% CI, 1.02–1.59; p = .031).

A total of 552 patients in the cohort (25%) started neoadjuvant chemotherapy at least 8 weeks after diagnosis. A multivariate analysis revealed that African-American race was significantly associated with such a delay, with an OR of 2.10 (95% CI, 1.37–3.19; p < .001). The same was true for having Medicaid or other government insurance, with an OR of 1.53 (95% CI, 1.00–2.30; p = .046), and for treatment in an academic facility, with an OR of 1.24 (95% CI, 1.00–1.54; p = .047).

“Given the aggressiveness of the disease, we should expedite referral of patients for neoadjuvant chemotherapy initiation as soon as possible and no more than 8 weeks after diagnosis,” the authors concluded. “There is no evidence to support avoiding neoadjuvant chemotherapy due to concerns of delayed treatment that was generated from surgery alone studies, as long as radical cys-

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Clinical Updates

Testis Cancer / CHEK2 aberrations linked with risk of developing prostate, other cancers

DELAYING CHEMO

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DELAYING CHEMO

continued from page 11


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Clinical Updates
New ERSPC data reveal benefits of repeated PSA screening

Relative risk of prostate cancer mortality reduced by as much as 35%

Dr. Mian is professor of surgery in the division of urology at Albany Medical College, Albany, NY.

The benefits and potential risks of PSA screening have remained one of the most studied and debated subjects in urology. One of the largest trials, the European Randomized study of Screening for Prostate Cancer (ERSPC), had previously demonstrated that PSA screening can reduce the mortality rate from prostate cancer, but with a high risk of overdiagnosis. In the most recent update from the ERSPC, Hugoson et al report on the effect of repeated screening rounds on mortality rate and the number of men requiring PSA testing or biopsies to achieve the mortality benefit after 16-year follow-up (Eur Urol Feb. 26, 2019 [Epub ahead of print]).

Of the 182,160 men who were randomized for the study, 162,389 were 55 to 69 years old. PSA test interval ranged from 2 to 7 years. The primary endpoint was prostate cancer mortality, which was analyzed first starting at randomization to screening and secondarily from cancer diagnosis while on study. Of the men randomized to screening (112,553), only 64% had at least one screening test, but the data presented are based on intention to screen analysis. Of those randomized, 17% (19,308 men) had a positive test, of whom 83% (15,994) had at least one prostate biopsy.

Cumulative prostate cancer incidence at 16 years was 13.3% in the screening arm and 10.3% in the control arm. The prostate cancer incidence in the control arm compared with the screening arm increased during longer follow-up but still remained lower than the screening group. The relative risk of prostate cancer mortality between the arms remained at 0.80 (95% CI: 0.72–0.89, \(p<0.001\)). However, the absolute difference between the arms increased from 0.14% at 13 years to 0.18% at 16 years. The relative risk of prostate cancer mortality was significantly lower in the screening arms at certain centers; ie, Sweden (RR: 0.63, 95% CI: 0.44–0.88, \(p=0.008\)) and the Netherlands (RR: 0.67, 95% CI: 0.53–0.85, \(p=0.001\)).

**PCa-specific survival improves with more testing**

The number of prostate cancer cases needed to be diagnosed with screening to avoid one prostate cancer death improved from 48 cases at 9-year follow-up to 18 cases at 16 years. Of note, in the Swedish arm of the study, this number is as low as seven cases with longer follow-up. Prostate cancer-specific survival improved during subsequent rounds of PSA testing when compared to first round. This is likely due to the prevalence of a large number of high-risk or advanced-stage cancers in the population as evident from the fact that during the first PSA round, 10% of men had PSA >20 ng/mL and only 3.2% in round three.

The ERSPC is a multicenter randomized trial of screening for prostate cancer in eight European countries, which joined the trial at different times between 1993 and 2003. Consequently, the screening frequency and intervals, as well as length of follow-up from randomization, are not uniform across all centers.

While the relative reduction in mortality for the entire study population was steady at 20%, the relative reduction in mortality in the Netherlands and Sweden was about 35%. With extended follow-up, the number of new cases needed to diagnose to avert prostate cancer death will likely continue to decrease. Despite improvements in the diagnostic markers and imaging, overdiagnosis and particularly overtreatment continue to pose a challenge for the urologic community.

**TABLE**

ERSPC 16-YEAR FOLLOW-UP: 16-YEAR DATA

<table>
<thead>
<tr>
<th>Description</th>
<th>Data - 16 Years</th>
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Source: Eur Urol Feb. 26, 2019 [Epub ahead of print]
The expanding role of immunotherapy in urologic cancers

Checkpoint blockade offers a new therapeutic source across GU malignancies

Urologic malignancies including prostate, kidney, and bladder cancer are common diseases. Despite advances in traditional treatment modalities for these malignancies, sequential cellular mutations often lead to resistance against therapeutic measures and eventual disease progression. An important factor in this process is the ability of cancer cells to evade the host immune system.

Under normal circumstances, the immune response provides a desirable profile for combating malignancy. T cells have excellent specificity due to their ability to recognize major histocompatibility complexes on the surface of cells. This allows for recognition of both intracellular and extracellular peptides. Additionally, T cells are able to produce memory, which allows for rapid and targeted response in the event of future recurrence.

Finally, T cells have the ability to adapt to the changing antigen profile of recurrent cancer cells. This is held in check by a series of stimulatory and co-inhibitory signals to prevent excessive immune activation, autoimmunity, and non-selective tissue destruction.

Cancer cells, as we have learned, often adopt a number of strategies to evade the host immune response. Upregulation of co-inhibitory signaling molecules such as programmed cell death ligand-1 (PD-1) inhibits cell killing when interacting with programmed death 1 (PD-1) receptors on effector T-cells (figure 1).

Similarly, upregulation of cytotoxic T-lymphocyte-associated protein 4 (CTLA-4) leads to T-cell tolerance and evasion of the immune system (figure 2). The ability to restore immune recognition through antibody mediated checkpoint blockade has provided an appealing therapeutic target in the treatment of cancer and ushered FDA approval of several novel agents.

This article explores the current and potential future use of immunotherapy in prostate, kidney, and bladder cancer.

Prostate cancer
Immunotherapy has enjoyed success in the treatment of prostate cancer over the last decade. Sipuleucel-T (Provenge), which received FDA approval in 2010, remains a first-line treatment for metastatic hormone-refractory prostate cancer. Sipuleucel-T is a patient-specific treatment in which a patient’s peripheral blood mononuclear cells are removed and then activated in the presence of a recombinant fusion protein and prostatic acid phosphatase (figure 3).

The IMPACT trial, which is the basis for the use of sipuleucel-T, demonstrated a 4.1-month improvement in overall survival in men with metastatic castrate-resistant prostate cancer despite no obvious change in overall disease burden (N Engl J Med 2010; 363: 411-22).

Following the IMPACT trial, several randomized trials have been conducted regarding the use of sipuleucel-T in biochemically recurrent patients. The PROTECT trial randomized biochemically recurrent patients to receive either sipuleucel-T or placebo following 4 months of androgen deprivation therapy (ADT). Patients who received sipuleucel-T were found to have a nearly 50% prolongation in PSA doubling time when compared to controls (Clin Cancer Res 2011; 17:4558-67).

The STAND trial also assessed the use of ADT followed by sipuleucel-T or in the opposite order. While findings of the study suggested improved anti-tumor activity when sipuleucel-T preceded ADT, the clinical impact of these findings is unclear (Clin Cancer Res 2017; 23:2451-9). Multiple ongoing trials are exploring the use of sipuleucel-T in combination with androgen receptor antagonists (NCT02456571) and with check-point blockade.

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IMMUNOTHERAPY

continued from page 19

There are currently two ongoing clinical trials exploring the expanded use of CTLA-4 inhibitors in metastatic prostate cancer. First is a phase II trial investigating the role of ipilimumab in conjunction with abiraterone acetate (ZYTIGA) chemotherapy- and immunotherapy-naïve patients (NCT01688492). Second is a phase II study investigating the role of ipilimumab in combination with hormonal therapy in those with incomplete response to hormonal therapy for metastatic prostate cancer (KEYNOTE-028). The recently published CheckMate 025 trial demonstrated partial response in some patients receiving anti-PD1 therapy (Ann Oncol 2016; 27[suppl_6], 725PD). In addition, the ongoing KEYNOTE-199 study, a nonrandomized open-label phase II trial, will also explore response rates to pembrolizumab in patients with metastatic prostate cancer whose tumors demonstrate PD-L1 expression (NCT02787005).

Additional studies exploring the use of anti-PD-L1 will shed light on its use in metastatic prostate cancer. An open-label, phase II trial evaluating the use of atezolizumab (TECENTRIQ) in solid tumors, including prostate cancer, is ongoing (NCT02438638).

Kidney cancer

Immunotherapy has been long established in the treatment of metastatic kidney cancer. For years, interleukin-2 (IL-2) and interferon alpha (IFN-alpha) remained the standard of care for metastatic renal cell carcinoma. While the explosion of tyrosine kinase, VEGF, mTOR, and MET inhibition has supplanted the use of IFN-alpha and IL-2 in more recent years, this early experience highlighted the importance of the tumor immune environment. This has provided a fertile space for the recent arrival of checkpoint blockade.

The recently published CheckMate 025 trial was the first phase III clinical trial to demonstrate benefits in overall survival and objective response rate in patients receiving nivolumab (Opdivo) when compared to everolimus in patients who had failed prior anti-VEGF therapy (Eur Urol 2017; 72: 962-71). Not surprisingly, the promising results of CheckMate 025 paved the way for increased exploration of checkpoint blockade in first-line therapy for metastatic renal cancer. The recently reported CheckMate 214 phase III trial demonstrated a significant benefit in overall survival (median survival not reached vs. 26 months) in intermediate- and poor-risk patients who received combination therapy with ipilimumab and nivolumab when compared with sunitinib (Sutent) in previously untreated metastatic renal cancer (N Engl J Med 2018; 378:1277-90). The ongoing IMmotion150 phase III trial of atezolizumab (anti-PD-L1) alone or in combination with the anti-VEGF agent bevacizumab (Avastin) compared with sunitinib in patients with untreated metastatic renal cell carcinoma will further explore the use of upfront checkpoint blockade in patients with renal cancer (NCT02420821).

The success of checkpoint blockade has also generated interest in adjuvant checkpoint therapy. This is currently being investigated as part of the ongoing PROSPER RCC trial, which aims to explore the use of adjuvant nivolumab following nephrectomy (NCT03055013).

Bladder cancer

Nonmuscle-invasive bladder cancer (NMIBC) has long benefited from localized immunotherapy in the form of intravesical bacillus Calmette-Guérin (BCG) (TICE BCG). BCG is an attenuated form of the tuberculosis bacteria that promotes...
immune infiltration and cellular cytotoxicity. While an effective treatment for NMIBC, a portion of patients will go on to develop muscle-invasive disease and eventual metastatic cancer. Despite the early successes with BCG, few new treatment options have emerged over the past 4 decades and platinum-based chemotherapy remains the standard for metastatic urothelial cell carcinoma. Fortunately, checkpoint blockade has proven to be a fertile ground for treatment of patients with metastatic urothelial cell carcinoma.

The need for new therapeutic options afforded a unique opportunity for metastatic urothelial cell carcinoma. In 2017, PD-1 blockade (pembrolizumab and nivolumab) and PD-L1 blockade (atezolizumab, avelumab [BAVENCIO], and durvalumab [Imfinzi]) received orphan designation from the FDA for treatment of metastatic urothelial cell carcinoma. This has since led to clinical trials investigating the use of single-agent and combination therapy in the metastatic setting as well as advancement into the treatment of localized disease.


While these trials have shown promise in the treatment of metastatic disease, it should be noted that the majority of patients enrolled did not respond to checkpoint blockade. This highlights the lack of understanding regarding appropriate patient selection and ideal agents in the metastatic setting. While the vast majority of trials did include some assessment of PD1 and PD-L1 expression, the clinical utility of this information as it relates to objective response or overall survival remains unclear at best.

Despite these areas of uncertainty, the use of checkpoint blockade has continued to advance. Ongoing phase II clinical trials utilizing pembrolizumab in the BCG-refractory NMIBC population will explore the role of checkpoint blockade in the non-metastatic population (NCT02625961). Additionally, a number of clinical trials are currently investigating the role of anti-PD-1, anti-PD-L1, and anti-CTLA-4 in the neoadjuvant setting for patients with muscle-invasive bladder cancer (NCT02365766, NCT02736266, NCT02989584, NCT03234153, NCT03294304, and NCT03498196).

**Summary**

The rapidly expanding role of checkpoint blockade (PD-1, PD-L1, and CTLA-4) alone and in combination with other agents has demonstrated a new source of therapeutic avenues across the breadth of urologic cancers. While the early experience demonstrates benefits in the metastatic setting, it is possible that we may soon see the emergence of immunotherapy in local, neoadjuvant, and adjuvant therapy as well. The ideal candidate for checkpoint blockade remains unclear. Further investigation into patient selection, checkpoint expression, and potential biomarkers is still needed to best implement these new therapeutic options into clinical practice.
In advance of this year’s AUA annual meeting, Urology Times asked members of our editorial board to choose the top presentations—instructional courses (IC), plenary sessions, forums, and video sessions (V), among others—in their subspecialty. They also commented on what’s hot and, in some cases what’s not, in their area of interest.

**Urolithiasis/Endourology**

**BRIAN R. MATLAGA, MD, MPH**

Among the hot trends in stone disease: opioid use, high-power lasers, and single-use ureteroscopes. “Due to the pain that accompanies a kidney stone event, opioids are commonly utilized. The urologic community is beginning to recognize this as an opportunity to improve practice patterns by decreasing reliance on opioids,” said Dr. Matlaga, professor of urology at Johns Hopkins, Baltimore.

A “dusting” approach to ureteroscopic laser lithotripsy has become increasingly popular, and among its purported benefits are shorter operative times and reduced complication rates. “We are now seeing increasing reports on the outcomes associated with this treatment approach, as well as better understanding of the physics of high-frequency laser lithotripsy,” Dr. Matlaga said.

The market for single-use ureteroscopes has evolved, and there are now multiple device companies providing single-use devices. “Concomitantly, the urologic community is working to better understand how these devices fit into present practice environments,” he said.

**Prostate Cancer**

**J. BRANTLEY THRASHER, MD**

“Areas that are hot are covered by some of my choices, such as immunotherapy in many cancers—even prostate cancer,” said Dr. Thrasher, professor of urology at the University of Kansas, Kansas City. “Another area that continues to grow in prostate cancer is imaging and genetic markers—specifically their use in diagnosis and treatment planning. Continued advances in imaging, specifically PET scanning, have helped in the targeting of biochemically recurrent prostate cancer.”

Active surveillance for low-risk prostate cancer has significantly grown in popularity. “It has been widely accepted by urologists, and the only real question left is the standardization of the approach. It’s probably the fastest growing part of my practice,” he said.

**Kidney, Bladder, and Urothelial Cancer**

**LEONARD G. GOMELLA, MD**

Our experts outline the must-see presentations in Chicago

Richard R. Kerr | Content Channel Director

**TOP PICKS**

- **031IC**: Surgical & Medical Stone Guidelines Update: A Case-Based Approach
- **026IC**: Dust or Bust: A Beginner’s Guide to Modern Day Laser Lithotripsy Strategies For Ureteroscopy
- **078IC**: Catastrophes, Complications & Corrections of Percutaneous Stone Procedures
- **019IC**: New Technology in the Management of Stone Disease: What’s New, What Works, & What to Buy
- **008IC**: Advanced Ureteroscopy: Overcoming Challenging Problems

- **023IC**: Chemotherapy and Immunotherapy Options for Genitourinary Malignancies: A Primer for Urologists and Advanced Practice Providers
- **024IC**: Prostate Cancer Diagnostics: Biomarkers, MRI, & Biopsy Techniques
- **083IC**: AUA Guideline 2019: Incontinence After Prostate Treatment
- **001IC**: Active Surveillance for Prostate Cancer: 2019 Update
- **Prostate Cancer Trends Over the Last Decade: Is the Disease Becoming More Advanced? Effect of the 2012 Task Force Recommendations (Società Italiana di Urologia lecture)
- **Panel Discussion**: Enhanced PET imaging for High Risk and Advanced Prostate Cancer: Ready for Prime Time?
- **Panel Discussion**: Biomarkers in Prostate Cancer

- **010IC**: Renal Cell Carcinoma: Surgical & Medical Management of High-Risk Renal Cell Carcinoma: New Paradigms for Treatment
- **072IC**: Management of NMIBC: Practical Solutions for Common Problems

Please see AUA 2019, on page 24

Image (above): jeremyreds@Shutterstock.com
True Bipolar Technology
Available exclusively with the UH 400 Surgical Generator from KARL STORZ

• Energy is precisely delivered at the electrode tip
• Greatest control of the surgical effect
“Nonmuscle-invasive bladder cancer is an area of intense interest in part to the worldwide shortage of our gold-standard BCG,” said Dr. Gomella, professor and chairman of urology at Thomas Jefferson University, Philadelphia. “Newer intravesical agents are critically needed that may address the shortage. The concept that systemically administered immuno-oncology agents can impact nonmuscle-invasive bladder cancer is revolutionary and is being tested in a variety of clinical trials.

In kidney cancer, Dr. Gomella said robot-assisted surgery for partial nephrectomy has entered the mainstream of surgical care, but the same cannot be said for muscle-invasive bladder cancer. “We continue to be conflicted concerning the risks and benefits of robotic surgery in the management of muscle-invasive bladder cancer compared to traditional open surgery,” he said.

DR. NITTI: 32 NEW COURSES ON TAP THIS YEAR

With the AUA annual meeting quickly approaching, Victor W. Nitti, MD, chair of the AUA Office of Education, provided a snapshot of new course offerings and other AUA educational opportunities. He was interviewed by Barry A. Kogan, MD, of the Urology Times Editorial Council.

The AUA Office of Education courses are among the highlights of the AUA annual meeting for many of us. Can you tell us about any new courses this year? This year the Office of Education will be offering 85 2-hour Instructional Courses, of which 30 are brand new. New courses will be available in all major areas of urology, including sexual and reproductive medicine, female pelvic medicine, reconstructive urology, lower urinary tract dysfunction, endourology, geriatric urology, public policy, new technologies, and urologic oncology. In addition, will be offering two new Hands-On Courses on office-based transperineal prostate interventions (including biopsy) and flexible ureteroscopy, for a total of six Hands-On Courses.

I imagine you repeat the courses that have had the most interest over the years. Which courses have attendees found to be most popular? The most popular courses by number of attendees are in endourology (especially stone management), testosterone therapy, infertility update, prostate cancer (including treatment options and active surveillance), and robotic technologies.

The meeting is always pretty jam packed. What are the options for those who have conflicts for a given course? In 2019, we will have several ways to access the AUA Instructional Courses.

“Certainly as we continue to make strides in female sexual dysfunction and consider what approaches we may bring to those presenting with female sexual dysfunction problems, we need to be more versed in the area,” he said.

Dr. Burnett was particularly enthusiastic about a panel discussion on novel therapies for ED and Peyronie’s disease. “I think it’s important that we do have a good discussion from experts highlighting what’s new but also help urologists be guided on what is proper therapy, what is effective therapy, what is therapy that they should know is likely to be of benefit to patients. This is all the more important in the past year or so with therapies that are getting a lot of attention, such as stem cell therapy and shock wave therapy, that at this time remain incompletely understood.

“The other trend that I see is that urology practices are trying to not let some of their potential practice and revenue go out to [non-urologists]. They’re sensing that this is their source of revenue and their domain [and that] if we don’t do it, these other will do it, so we better do it.”

The Live Course Pass is our traditional option, providing access to all 85 Instructional Courses. One can also choose the Course Pass Bundle that gives the same access to all live courses plus all online webcasts. Lastly, we will be offering a single-course ticket for those attendees who want to go to just one course. Access to the Instructional Courses can be purchased with meeting registration, through the mobile app, or at registration upon arrival in Chicago.

Not everyone can make the meeting. For those stuck on call back home, are they able to access the information presented at the courses? Content from the annual meeting will be available on AUAUniversity following the meeting. Some content will be open to everyone, while other content like the Surgical Video Library will be available to our members. The entire meeting content can be accessed through the AUA2019 Virtual Meeting product, which will be available for purchase within a week of the meeting.

Given the expense and time commitment of travel, many urologists are unable to attend many meetings. In addition to Self-Assessment Study Program and the Update series, can you tell us about some of the newer offerings of the Office of Education? The AUAUniversity is an invaluable source of educational opportunities. In addition to those products you mentioned, the University offers the AUA Urology Core Curriculum, webcasts and podcasts that are constantly updated, surgical videos, and access to online materials from our annual meetings. In 2018, we completely revamped our online platform, giving our members easier access to all of the educational opportunities that we have to offer. The new AUAUniversity allows for easy search of materials by topic or by ABU lifelong learning categories.
“In general, the Practice Management Conference provides an up-to-date, cutting-edge, nuts-and-bolts summary of what practitioners need to know to successfully bill in 2019,” said Dr. Kaufman, who is in private practice in Santa Ana, CA. “If members attended one health policy course at the conference, this would be it.

“The AUA has an agenda according to which we lobby and educate Congress and private payers on our patients’ behalf to get appropriate coverage. Understanding why we hold the opinions we do weaponizes individual urologists to argue locally or get involved in national advocacy. Every AUA member— in private practice, academia, or training—should attend.”

Trauma/Reconstruction/ Diversion
BRADLEY A. ERICKSON, MD, MS

“We armamentarium of the reconstructive urologist continues to expand. Many centers around the country have begun to offer gender-affirming genital surgery for our transgender patients and this year’s AUA will offer a course, co-sponsored by the Genitourinary Reconstruction Society (GURS), on how to incorporate transgender care into your practice,” said Dr. Erickson, associate professor of urology at the University of Iowa, Iowa City.

“Cancer survivorship continues to be a popular topic at the meeting, especially after the treatment of prostate cancer. We continue to get better at prolonging the life of genitourinary cancer patients; the focus now turns to how improve their quality of life after treatment.

“The benefits of robot-assisted surgery for reconstruction of the urinary tract continue to be explored, with the ureter being the most obvious organ of benefit, but also in the management of post-prostatectomy anastomotic strictures,” Dr. Erickson said.

Health Policy
JEFFREY E. KAUFMAN, MD

Infertility
JAMES M. HOTALING, MD, MS

Female Urology
PRIYA PADMANABHAN, MD, MPH

TOP PICKS
16th Annual AUA Urology Practice Management Conference (2-day event)
AUA Public Policy Council Liaison Update

“Research examining surgical or medical outcomes in male infertility prospectively from multi-institution databases will continue to drive the field forward,” said Dr. Hotaling, assistant professor of surgery (urology) at the University of Utah, Salt Lake City. “Translational work that allows refinement of the male infertility phenotype through molecular diagnostics in order to provide personalized care will also be a key theme. Finally, work that begins to apply the tools of health services research to male infertility will also be featured.”

What’s not hot? “Single-surgeon case series, work that further validates existing series in varicoceles, and work that looks at the impact of single genes on male infertility is fading in importance,” Dr. Hotaling said.

“Past meetings have had much focus on the implications of mesh complications in female pelvic medicine and reconstructive surgery [FPMRS], robotic apical prolapse repairs, and the role of obesity in incontinence management,” said Dr. Padmanabhan, associate professor of urology at the University of Kansas, Kansas City. “Tertiary OAB treatment is now abuzz with applications in atypical populations, trending of alternative and future options of neuromodulation (ie, implantable tibial nerve stimulation and improved batteries).

“Some other hot topics include: gender disparity patterns in FPMRS, the questioning of our practices in screening and prevention of UTIs, the clinical significance of vaginal lasers, and basic research advances in stress urinary incontinence.”

TOP PICKS
Forum: Gender-Affirming Genital Surgery
032IC: Management of Complicated Urinary Dysfunction after Prostate Cancer Treatment
002IC: Robotic Upper Urinary Tract Reconstruction: A Top to Bottom Approach

This year’s meeting will continue to highlight an association between metabolic factors and the onset of lower urinary tract symptoms secondary to BPH. In addition, data on maturing technologies as well as new investigational methods to treat BPH will be presented,” said Dr. Kaplan, professor of urology at Icahn School of Medicine at Mount Sinai, New York.

“Finally, updated data on surgical therapies for BPH will be presented as well.”

“Reconstructive and robot surgery remain of great interest this year in the presentations. On the other hand, diagnosis and treatment of reflux is of lesser interest, as is (surprisingly) antenatal hydronephrosis,” said Dr. Kogan, chief of urology at Albany, Albany, NY.

“The older generation of pediatric urologists keep trying to bury robotic procedures that seem to have few benefits over open surgery, but they keep coming back. [The Crossfire session] should be a great debate.

“There is also a session on whose hypospadias repair is better. There is constant evolution in this area, so this should be an informative and fun session,” Dr. Kogan said.

Keep up to date on Urology Times’ coverage of the AUA annual meeting at www.urologytimes.com/aua-annual-meeting.
How to evaluate, implement new technology in your practice

This 8-step action plan will help you efficiently establish new lines of service

We recommend that projections on income be based on realistic and conservative outlooks, which is often difficult for the optimistic practice.

We are commonly asked our opinion on new technology. Questions range from “How do we get paid or code for a new technology?” to “Does this new technology make sense for my practice?” The answers with regard to payment and coding vary from technology to technology and are an important part of the equation, and we will address these issues in future articles. In this article, we attempt to provide a way for a practice to consider the question, “Does this new technology make sense for my practice?”

As you consider new technology in the practice, we encourage you to remember that a urology practice is a complex ecosystem with many moving parts. Introducing a new service line may initially appear easy; others may not be so straightforward. As you consider new technology and procedures for your practice, we encourage a broad look at the practice impact.

First and foremost, as a urology caregiver, you need to consider the clinical aspects of the technology. Will the new technology improve patient care or your efficiency? Will the new technology drive utilization? If it does not make sense to the practice clinically, you should move on for now and revisit the technology only when the data support the service clinically.

Once you are able to determine clinical relevance and there is support among at least a few of the providers in the practice for the new technology, you will need to consider the financial and practical requirements to support the introduction of new technology to your practice. The length of this article will not allow us to include every aspect you must consider, so we will focus on those items that are deemed the most relevant.

The following action plan will provide a guide to the evaluation and adoption of new technology.

Step 1. Define where the practice is today and where you need to be downstream. Is the technology directed toward a population that you currently serve, or is the service targeted to a new group of patients? New patient groups can be defined in many ways: self-pay patients, gender- or age-specific patients, or disease group-related patients—in short, any way to identify patients who are currently not served or are underserved by your practice.

Knowing your long-term planning is a must as you look at new technology. You should be able to articulate your goals for any new technology as it relates to your existing service lines. Make no mistake: New technology requires an investment. Time and capital will be committed.

Step 2. Align core practice data with robust analytics. If the new technology is directed toward your existing patient population, you will need to consider both the new revenue generated and the cost to your practice from the services that will no longer be provided. Being able to review your data to project the impact on your existing practice will help build a realistic pro forma (a spreadsheet with 24-month projected income and expenses for the new product based on your practice assumptions), develop marketing plans, and implement measurable goals to analyze the results of your decisions.

Step 3: Define actionable data and plans (business pro forma). Ideally, new technology will be of immediate financial benefit to the practice, adding revenue to the bottom line as a profit center. However, some lines of business may not provide a true bottom-line bump in the short term but will become profitable over time, return benefits to the practice by attracting new patients that will generate revenue beyond the new technology, improve overall outcomes and performance on value-based care, or free up the practice to see other patients that provide revenue through other services. All of these may result in the decision to adopt a new technology that others may not adopt. Again, this requires data from the practice that can be used for projections.

You will also need to make realistic revenue projections for the new technology. New technology with codes, payment, and coverage for a majority of your major payers will make this easier. New technology with uncertain reimbursement pathways is more difficult to project. We recommend that projections on income be based on realistic and conservative outlooks, which is often difficult for the optimistic practice. For most of our groups, we also produce a “low-use” scenario, discounting our realistic projections by 25%.

Finally, it is important to look at the market pressure and influence surrounding the technology. If profits are high and uptake in the market is swift, payers are likely to attempt to decrease reimbursements for the service. The market tends to shift slowly, but projecting decreased income per service after a 2- to 3-year window is appropriate in some cases.

Step 4. Develop effective top-down com-

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Mr. Painter is CEO of PRS Urology SC in Denver.

Business / CODING AND REIMBURSEMENT
munications to support practice team buy-in. This is arguably the most difficult step. Successful communication is often more art than science. Identifying the people in your practice who will work with the technology and setting up strong feedback pathways will help to ensure success. Providers, clinical support staff, administration, and billing will need to communicate routinely to provide the practice with real data once the technology is added to the practice. From patient coverage to time in the room and patient experience, the staff and physicians will need to make sure that any projections are accurate once implemented.

Based on feedback adjustments, modifications should be incorporated into the business plan. Do not forget outcomes; patient communication after the experience will serve both internal and external marketing for the practice.

Step 5. Align practice assets for future profitability. If all goes as planned, you can follow the business plan. If your business plan is well developed, you have incorporated the use of profits from some investment in the future. The market is changing and new opportunities will continue to arise. Good planning will not only invest in the present but will also save for future investment.

If the new technology is not going as planned, your projections and planning should also include an exit strategy for the technology.

If the financial benefit of the new technology is not going as planned, your projections and planning should also include an exit strategy for the technology. These exit plans should have clear milestones and time lines. Making sure that you provide enough time to allow your practice to incorporate and market the new technology is important. It is also important that you look at all aspects of the implementation. In the end, however, some technology may not work as a line of business; if your milestones are not met and the problems identified are not rectified, walk away.

Step 6. Reengineer the practice to meet targeted goals and supporting objectives. Some new technology introduces a new approach to practicing medicine. For example, some of the new BPH technologies will move patients from a pattern of repeat visits and follow-up once or twice per year to several years. The practice will then need to change its marketing and service focus to new patient services with the now-empty time slots that established patients once occupied.

Marketing and interaction with outside referral sources will need to be increased or other service lines pursued. The practice must change with the times.

This may require only small changes or it may require the addition of new support for the practice that will require reallocation of personnel and time. Keep looking forward.

Step 7. Implementation. Planning for success must be followed by execution. Communication, as noted, is key to all aspects of the practice and is vital to any new service line. We have found that in order to execute any plan, the practice must identify a leader who will act to implement a successful new service line. Assign a person to communicate and review the processes and procedures that were identified in the plan.

Lack of leadership can come in the form of a true leadership void (ie, no one is monitoring the plan), or it can come from too many leaders who are focusing on different parts of the plan without coordination. The implementation plan must include both processes and procedures for all staff and a designated leadership structure to monitor the implementation.

Step 8. Review, monitor, and adjust as needed. This is not a static business. Autopilot is not a setting that can be used with organizations made of human beings. Plans, procedures, and protocols must be monitored routinely. Even the well-oiled machine should be reviewed to avoid the pitfalls of complacency. New lines of business are no exception. Build review points and milestones into the business plan that continue beyond the implementation phase of the new service line. Ask the question, “Is this aligned with our practice goals?” at least once per year.

Finally, do not ignore data, your personnel, or your patients. If the information points to needed change, then plan to change.

Summary

Evaluating and implementing new lines of business is not easy (figure). In today’s environment, new practice business services must offer quality, value, and profitability. Doing the math and extensive homework really does matter. Effective due diligence is required to define value and overall impact on the practice. Also, remember that you are asking people to leave their comfort zone and that you are committing operating capital.

Building an effective practice infrastructure and implementing new services requires leadership and a skilled team. Focus on the core financials and clinical issues. When considering new business services and committing practice capital, in-depth due diligence is required. Understand that while the numbers may appear positive, it only works if the procedure can be efficiently provided and accurate payment collected. In closing, we understand the challenges and critical pressure points confronting today’s successful practice, as well as the stress and time constraints of evaluating and onboard successful new business services. For a few examples of high-level financial business case studies, please visit bit.ly/PRSassetstudies.

The information in this column is designed to be authoritative, and every effort has been made to ensure its accuracy at the time it was written. However, readers are encouraged to check with their individual carrier or private payers for updates and to confirm that this information conforms to their specific rules.

HEMATURIA EVAL.: EVIDENCE FOR OPTIMAL PRACTICE?

“Hematuria is a major reason for a clinic encounter, and the most efficient way to evaluate the condition is not always straightforward,” writes Adele M. Caruso, DNP, CRNP. In her most recent blog post, Ms. Caruso summarizes current evidence and guidance for hematuria evaluation as it pertains to clinicians, including advanced practice providers. Read the full post at www.urlogytimes.com/hematuria-eval.
In 2019, the Quality Payment Program (QPP) introduced eight new episode-based measures in the Cost category of the Merit-based Incentive Payment System (MIPS). None of these eight existing episodes are triggered by diagnoses or procedures that are likely to affect urologists, but that is expected to change. In this article, I offer a preview of what is to come in this area, including a new stone disease episode.

How measures are developed

In 2018, the Centers for Medicare & Medicaid Services began the process of developing 11 new episode-based cost measures for eventual inclusion in the Cost category of MIPS. The general process of measure development works like this: With the guidance of committees representing a wide range of stakeholders—physicians, other providers, technical experts, patients and caregivers, and others—a draft list of high-priority, high-impact clinical areas is developed for possible measure development. Then, clinical subcommittees composed of relevant physician stakeholders in the specialties that are responsible for care and cost are created and convened; their first task is to choose one or more measures from a draft list to develop.

A smaller working group of physicians is then tasked with working out the details of the measure—for example, what events will trigger an episode, what is included and excluded from the episode, how long the episode should last, etc. Once the specifications for the episode are drafted, the measure is “field tested” on actual past claims data and analyzed for statistical significance. The measure can be further refined after field testing if necessary.

Ultimately, the measure and its specifications are advanced to an endorsing body (such as the National Quality Foundation) with a recommendation for inclusion in the QPP. If endorsed, the measure would be proposed for inclusion during the typical rule-making process for payments to physicians under the QPP; after a comment period, a final rule would be issued.

In 2018, a Urologic Disease Management Subcommittee was convened according to the above process, consisting of urologists (plurality), radiologists, radiation oncologists, and representatives from anesthesiology, pathology, gynecology, and geriatric medicine. With guidance from actual claims data, consultants, and analysts, the committee chose to develop a measure for kidney stones. This measure was chosen from a list of possibilities because it is a common condition, is treated with a finite number of procedures, and had the most impact on urologists, patients (Medicare beneficiaries), and cost.

A smaller working group of urologists (majority) and others then determined the codes that would trigger an episode, subgroups of patients for comparison, and rules for including or excluding costs during the episode. The measure was field tested during October 2018 based on 2017 data, and minor modifications were made. The measure was sent to and approved by the National Quality Foundation’s Measure Application Partnership, and it is expected to be included in future rulemaking—perhaps in time for implementation in 2020.

So how will this actually work? When you perform and bill for one of the trigger procedures (ureteroscopy with treatment, percutaneous nephrolithotripsy, or extracorporeal shock wave lithotripsy), an “episode” will be created in the claims data. Based on the detailed specifications of the measure, costs (Medicare Part A and B claims) for some procedures and treatments within a window of time before and after the procedure will be aggregated to a total observed cost for that single episode. Other costs will be excluded (for example, cardiac surgery 15 days post-op). The expected costs for the episode including risk, age, geographic, and measure specific adjustments will be similarly calculated.

The average ratio of all your episodes’ observed to expected cost will then be benchmarked against all of the other episodes in the national data. Ureteroscopy episodes will be compared to ureteroscopy episodes, ESWL to ESWL, etc.

Then, your tax ID performance on this measure relative to every other tax ID will be used to assign you a performance score using a decile methodology. Your episode score will be weighted equally with the other cost measures in the category (such as Total Per Capita Cost and Medicare Spending per Beneficiary). The performance and weight of the Cost category will contribute to your final MIPS composite score.

What ‘field test’ revealed

This measure was field tested last year on 2017 data—so how did everyone do? There were almost 94,000 episodes created using these specifications, and almost all were attributed to urologists, as expected (4,425 NPI). The average individual provider had 21 episodes assigned for the year, and the average tax ID entity had 62 episodes.

For field testing, the benchmark used was the average national observed cost per episode. The mean score in this exercise was $6,706, and there was a wide enough range in costs to predict this

**STONE MEASURE FIELD TEST: A CLOSER LOOK**

For an in-depth breakdown of the results of the kidney stone measure field test, go to www.urologytimes.com/stone-measure.
measure can discriminate in a significant fashion. Mean costs for percutaneous nephrolithotripsy were almost twice that of mean costs for ureteroscopy and ESWL. There was no obvious difference in mean costs when stratified by setting (urban vs. rural), region of the country, or volume of episodes/provider.

How can you use this information to prepare for the day when this episode measure is live? First, remember that your costs are going to be scored at the tax ID level. If you are in a group that shares a tax ID, now is the time to understand if there are standards and address outliers in the way your associates treat kidney stones. In a future article, I will present an example of how to examine “utilization” as a predictor of outliers in an episode-based environment. Regardless of how you are compensated individually, in the QPP as currently configured, you will share your cost performance (including episode measures) with other providers in your tax ID entity.

Second, start to think about being accountable for some of the costs you direct. For example, other episode-based payment models have suggested that the best way to decrease costs is to keep patients out of the ER and the hospital. Reducing unnecessary ER visits and repeat computed tomography scans after stone procedures is something you can probably influence.

Third, consider where you perform your stone procedures. Medicare and other payers often pay more to hospital outpatient departments than ambulatory surgery centers for the exact same procedure. Those costs will now be attributed to episodes, which in turn will be attributed to the urologist who triggered the episode.

Finally, don’t change your best practices or try to “game” the system. Everyone is going to be scored in the same way, and it is the big-ticket items—like unnecessary hospitalizations—that will contribute the most to your episode costs and performance.

Bottom line: Episode-based payments are live in the Quality Payment Program in 2019, and the Renal and Ureteral Stone Episode is expected to be implemented as soon as 2020. The measure is based in claims data, and there is no reporting requirement—episodes will be assigned to urologists if they perform a triggering procedure and according to rules that have been developed with input from urologists and tested on past data.

Urologists can prepare for succeeding in episode-based scoring by adhering to standards and best practices, keeping people out of the ER when clinically reasonable, and shifting procedures to lower cost sites of care. UT
Why you should resist the urge to sell in a down market

Selling during decline reduces ability to make up losses in subsequent rally

Q: My account really fluctuated during the last 3 months of 2018. Should I have been more proactive about protecting my investments from losses?
A: The fourth quarter of 2018 did not reward equity investors. The S&P 500 (Large Cap Index) was down 13.52%, the Russell 2000 (Small Cap Index) was down 20.20%, and the MSCI EAFE (International Index) was down 12.54%.

When markets are down significantly, investors commonly feel a sense of panic or fear they are losing everything they have accumulated. They obsess over the financial news and are tempted to sell to preserve what is left. However, these moves typically provide short-term comfort at the expense of long-term goals.

Selling after the markets are down may significantly reduce your ability to make up those losses in the rallies that historically occur after a sharp decline. For example, after the 2008-09 financial crisis, in which the S&P 500 was down as much as 51%, the following rally lasted 118 months and was up over 300%. Following the dot-com crash in 2000, when stocks were down 45%, the following rally lasted 61 months and was up over 100%.

In fact, every sustained downward slide, whether it is because of panic or fear they are losing everything they have accumulated, it is nearly impossible things to predict, and guessing wrong can negatively impact your investment success.

When markets are down significantly, investors commonly feel a sense of panic or fear they are losing everything they have accumulated.

Surviving a down market requires some key behaviors: faith, patience, and discipline. You need to have faith that markets will turn and, over the long term, move in an overall positive direction. Patience means not chasing the hottest trends and trusting that your investment strategy will produce the results you desire long term. Discipline means continuing to adhere to an asset allocation strategy and diversified investment mix that can help you reach your financial goals.

Q: How big of an impact can selling when the markets are going down and buying back in have on my account balance?
A: If we look at an example from the 2008-09 financial crisis, we see that selling and then guessing when to get back in the market had a negative effect. Assume someone with a $1 million diversified portfolio panicked and sold in March of 2009, at the bottom of the market crash. After the markets started recovering, they bought back in after 3 months with the same portfolio. Today, their account would be worth approximately $2.64 million. If they had waited a full year to get back into the market, their account value today would be only $2.20 million.

But if they had stayed invested throughout, their account today would be worth $3.28 million. Panicking and selling, then trying to guess when to get back in the market, is not something most investors are regularly successful at.

References
1. Morningstar Dec. 31, 2018 data. All indices referenced are unmanaged indices of various asset classes within the investment markets. None are available for direct investment.
2. S&P data copyright 2018 S&P Dow Jones Indices LLC, a division of S&P Global. All rights reserved.
3. Dimensional Funds. Benchmarks used in calculation; S&P 500 (30%), Russell 2000 (20%), Dow Jones Select REIT (10%), MSCI EAFE (18%), Barclays US Agg Bond (12%), Barclays Global Agg Bond (7%), Cash (3%). S&P data are provided by Standard & Poor’s Index Services Group; Russell data © Russell Investment Group 1995-2019, all rights reserved; Dow Jones data by Dow Jones Indexes; Barclays indices © Bloomberg Barclays 2019; MSCI data © MSCI 2019, all rights reserved. Referenced indices are not available for direct investment. This is a hypothetical illustration only, and its performance is not indicative of any particular investment. Investments with potential for higher returns carry greater risk of loss.
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How to position your newly hired clinician for success

Setting clear expectations, providing administrative support among key steps

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Whether you’re hiring a physician or a non-physician provider, odds are you’ll spend a great deal of time (and probably money, too) attracting the right clinician candidate to your practice. If that new hire ultimately doesn’t work out, your practice will face the costs of going back to square one—as well as lost revenue while that job remains unfilled. Effective onboarding can help ensure your new hire knows what is expected and become productive more quickly. Yet despite the high stakes involved, getting new hires off to a good start often gets much less attention than recruiting does.

Protect that big recruitment investment by getting your new clinicians off to a strong start. Here are some quick tips for how to do it.

Be realistic about ramp-up time. It’s natural to be excited about the productivity a new clinician can bring to your organization. It will take a while, though, for your new hire to ramp up to full capacity.

Plan more accurately for the ramp-up by considering the individual’s training and prior experiences. A nurse practitioner (NP) or physician assistant (PA) may need a lot of training and oversight for many months, especially if they’ve just graduated or are coming from a different specialty. (Remember that less-experienced clinicians will likely be counting on your training—and not providing it could severely affect their morale.)

Even experienced physicians will need time to get acclimated to your systems, protocols, and work flows. And if you expect a newly hired physician to attract new patients, keep in mind that creating a reputation and building a network also take time.

Be clear from the start about expectations. When employed clinicians fall behind on unspoken expectations, resentments may fester—and relationships can fray if both sides come to feel deceived. Before you even recoup your investment in recruiting, your new hire could end up leaving your practice. Unfortunately, it’s a sad pattern we’ve seen too often in our consulting work.

The first step to avoid such costly misunderstandings is to be as clear as possible about what you expect. Invest time to document a full year’s productivity goals in advance of your new hire’s arrival—then share the specifics once he/she starts.

Productivity may be the most important area where misunderstandings can occur, but it’s not the only one. You may also be making work flow and work style assumptions that don’t align with your new hire’s.

If you expect a newly hired physician to attract new patients, keep in mind that creating a reputation and building a network also take time.

For example, do you consider it “standard” that charts be completed within a certain time frame? Will you be disappointed if your new physician does not personally meet with primary care doctors or present at local hospitals? Are NPs and PAs expected to network with their peers in your local area? Are there unwritten rules for how to work with staff? Try to be as specific as possible about all of the things that could undermine your new hire’s ability to fit in and thrive—don’t just assume they already know.

Make sure you’re prepared to give specific, objective feedback as your clinician ramps up, too. For example, make sure your physicians have access to reports detailing their productivity, new patient visits, and other key metrics.

Give them the administrative support they need to adapt quickly. Every workplace has everyday “stuff” that new employees have to learn: how to use company email, where the bathroom is, where to park, how and when salaries are delivered. Preparing a document that covers all of these sorts of basics, then sending it to all new hires before they start, can help new employees feel welcome and ready for work.

Learning new software can make getting up to speed harder for new physicians, NPs, and PAs. Staff can help by making access to system training available and helping new providers learn your practice’s clinical and billing documentation policies.

Your practice management team can also help new physicians bring revenue in fast by getting started on credentialing as soon as possible. The complete process might take months—so starting well ahead of the physician’s first day of work is a good idea. Make sure your team has already planned for the documents and data they’ll need from the physician to complete the process.

Marketing support is also critical to a strong start. One of the easiest and most valuable first steps is to be sure your new hire is listed properly in online payer and reviews directories. If getting your physician out into the community is part of your marketing approach, make sure staff is also ready to help with contacts, introductions, and planning.

RECRUITING AND RETAINING YOUNG PHYSICIANS

With the physician shortage remaining a major concern, a 2018 study from medical employment firm CompHealth identified ways young physicians find their first positions, what they want in a job, and why they leave.

While the survey found that young physicians want good compensation, Lisa Grabl, president of Midvale, UT-based CompHealth, says facilities should be aware that young physicians also want to work in a place that has a great culture and offers a good work/life balance. To read the full article, originally published by Urology Times sister brand Medical Economics, go to bit.ly/recruitretaindocs.

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supplier, including the United States, based on historical averages.

The company is producing between 600,000 and 870,000 vials annually, which is considered full capacity, but it cannot keep up with the increased demand.

“People need to know we’re doing all we can possibly do,” he said. “We’re working with regulatory agencies to understand what options we can pursue.”

Alternative therapies

Dr. Kamat said patient care has not been impacted by the shortage because steps were taken ahead of time in the form of alternative therapies.

One step includes better risk stratification of patients, with more appropriate use of BCG—for example, limiting its use in low-grade patients who have other alternative therapies available. Another step is for patients with high-risk disease but limited tumors to stop BCG after one year of maintenance therapy. Additionally, studies have shown that reduced-dose BCG (one-third dose) has similar efficacy to full-dose BCG.

If BCG is not available, the AUA recommends mitomycin (induction and monthly maintenance up to one year) as an alternative. Gemcitabine, epirubicin, docetaxel, valrubicin, or sequential gemcitabine/docetaxel or gemcitabine/mitomycin may also be considered with an induction and possible maintenance regimen.

Long-term strategies

One long-term hope is to introduce foreign

strains of BCG into the United States. While there are BCG strains in Germany, India, and Russia, it is the Tokyo strain that is currently being studied.

“As far as the foreseeable future, Merck will continue to produce TICE BCG.”

TYRONE BREWER

MERCK

“The trial [comparing the Tokyo and TICE strains of BCG] is a good idea, but I’m not sure it will solve any of the problems related to the manufacturing and financial ramifications and the ability to scale BCG.”

JATHIN BANDARI, MD

“When patients and doctors realize we can’t offer BCG, I hope and expect changes in the regulations to give a dispensation for BCG in the clinical arena.”

STEVEN WAHLE, MD

COMPLEXITY IN PRODUCTION COMPLICATES MATTERS

One issue that has led to the shortage of the TICE strain of bacillus Calmette-Guérin (BCG) is the way it is produced.

While it is the first-line therapy for nonmuscle-invasive bladder cancer, BCG is a difficult medicine to produce and there is little financial incentive. BCG is derived from a bacteria that has to be cultured in facilities that cannot be utilized for other drugs in discovery or manufacturing. It takes a minimum of 3 months to obtain a supply from the original culture.

“That certainly adds to the complexity of production,” said Tyrone Brewer, vice president of global oncology marketing for Merck. “BCG is not something we can produce overnight.”

BCG is priced at between $100 and $200 per dose, far less than the average price per dose of a cancer-fighting drug.

“BCG grows slowly, and it is an expensive proposition,” said Edward Messing, MD, professor of urology and oncology at the University of Rochester Medical Center. “It takes time to culture.”

In response to the shortage, the SWOG Cancer Research Network is conducting a randomized control trial, S1602, which compares the Tokyo and TICE strains of BCG. The trial is ongoing, meaning it will be some time before results can be forwarded to the FDA for approval. Even if the Tokyo strain is approved for use in the United States, there still needs to be a company that commits to manufacturing and distribution.

“The trial is a good idea, but I’m not sure it will solve any of the problems related to the manufacturing and financial ramifications and the ability to scale BCG,” said Jathin Bandari, MD, a urologist at the University of Pittsburgh.

Bladder cancer options used in Israel and Italy make mitomycin more effective therapy, including electromotive mitomycin-C or the use of a microwave device to heat the drug, says Edward Messing, MD, professor of urology and oncology at the University of Rochester Medical Center, Rochester, NY. In clinical studies, both treatments have looked promising when compared with BCG.

However, the studies are small, they don’t include maintenance treatments, and side effects are greater, Dr. Messing cautions. The treatments are also not being actively pursued in the United States, although Dr. Messing says that could change with another TICE strain shortage and if no new strain is approved.

Michael O’Donnell, MD, professor and director of urologic oncology at the University of Iowa Carver College of Medicine, Iowa City, is studying a combination protocol of sequenced gemcitabine and docetaxel. In his research, Dr. O’Donnell has found excellent responses as an alternative to treat carcinoma in situ (CIS) when BCG cannot be administered.

Gemcitabine and docetaxel are FDA-approved individually but not FDA-approved as a combination. Dr. O’Donnell is close to publishing a multi-institutional retrospective report of the gemcitabine/docetaxel combination’s utility in BCG-naïve patients, and he is working through academic circles to develop a prospective clinical trial.

The Urology Care Foundation recently awarded a grant to evaluate the impact of the BCG shortage and determine whether it has caused any change in mortality or cancer-specific outcomes. The research will also examine alternative treatment strategies, Dr. Bandari says.

Worst-case scenario

There is little hope that the current BCG shortage will be the last because the fundamentals of production are not expected to change. What if Merck comes to the same decision arrived at by Sanofi in 2017—that financial considerations force Merck to permanently halt production of the TICE strain?

“From our standpoint, that could be catastrophic,” Dr. Bandari commented. “Who
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Some basics
There is a distinction between fraud and a False Claims Act violation, according to David J. Zetter, a certified healthcare business consultant and founder and lead consultant with Zetter Healthcare, Mechanicsburg, PA.

A false claim is a service that is billed incorrectly, and practitioners in most cases are not aware that they’ve billed incorrectly. Urologists and others who commit fraud know what’s right and intend to bill incorrectly to get paid, Zetter said.

Urologists can prevent False Claims Act violations but often don’t take the proactive steps to do so. That’s the case even though taking these steps is law and documented in the Federal Register, according to Zetter.

“Most medical practices that are seeing Medicare or Medicaid patients—even if they’re seeing managed care Medicaid or Medicare Advantage plan patients—are required by law to have a compliance plan in place. Most practices either aren’t aware of this requirement, ignore this requirement, or just feel it is an expense that the practice cannot afford. Either way, it is non-compliant behavior,” Zetter said.

Improper billing
The Centers for Medicare & Medicaid Services cites five major categories of improper billing: no documentation, insufficient documentation, lack of medical necessity, incorrect coding, and other, according to a Dec. 12, 2018 article in Medical Economics.

Mark Painter, CEO of PRS, LLC, in Denver, said documentation and coding problems are not uncommon at urology practices. Bad billing patterns can become systemic and compounded errors add up.

“The rules are complex enough so that you can probably find mistakes in just about every practice,” Painter said.

It’s not just over-coding but under-documenting that’s a problem, Painter said.

Under-documenting can lead to overbilling in payers’ eyes and under-earning for the practice, according to Zetter. There is always money to be found in a chart review.

“When you bill a level 4 office visit and only document for a level 3, that is overbilling. Your documentation does not support the level of service which was billed,” Zetter said.

A physician might do work and neglect to put it in the record. There are plenty of elements that a practitioner receives credit for completing, but many do not know what these elements are, according to Zetter.

“Here’s an example: A doctor sees a patient for the first time and the patient brings in previous imaging or records from either their old practitioner or another physician, and the doctor reviews those old records. Doctors get credit for doing that, but a lot of times doctors won’t note they reviewed previous imaging or a previous record,” Zetter said.

Pitfalls of modifier −25
Practices have long struggled to correctly use modifier −25.

The Department of Health and Human Services Office of Inspector General’s (OIG’s) report “Use of Modifier 25,” released in November 2005, found that more than one in three claims using modifier −25 that Medicare allowed in 2002 did not meet program requirements. The result: $538 million in improper payments, according to the report.

Modifier −25 can be difficult to interpret, according to Dr. Rubenstein.

The bottom line is, a zero-day global procedure payment includes everything related to the procedure—preoperatively, intraoperatively, and postoperatively.

“The only time in which an evaluation and management service can be billed on the same day of a procedure with a 0-, 10-, or 90-day global period is if the service is unrelated to the procedure itself, which typically but not always would require a separate diagnosis code. It would have to be truly separate and identifiable. I believe that is where some of the confusion arises,” Dr. Rubenstein said.

“A lot of people are just unaware of proper coding rules.”
JONATHAN RUBENSTEIN, MD

Among the more common zero-day global procedures in urology that are impacted by modifier −25: instillation of cancer therapy, such as bacillus Calmette-Guerin or mitomycin into the bladder; urodynamics; posterior tibial nerve stimulation; injection of hormone therapy; injection of antineoplastic therapy; and intramuscular intravenous injections, according to Dr. Rubenstein.

Remember these false claims truths
Former OIG lawyer Brian Bewley, who today is a health care fraud and abuse attorney and partner at Bass, Berry and Sims in Nashville, TN, said physicians must ensure that the services they’re providing are medically necessary and properly billed and coded according to the reimbursement regulations.

Urologists and their staffs should become familiar with the OIG’s Work Plan, according to Bewley. The Work Plan is available online (see bit.ly/OIGWorkPlan) and is regularly updated, he said.

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Brewer says there are no plans for Merck to halt production.

“As far as the foreseeable future, Merck will continue to produce TICE BCG,” Brewer stressed.

Steven Wahle, MD, a urologist with Physicians Clinic of Iowa in Cedar Rapids, believes future shortages or onerous proposed regulations that obstruct the use of BCG will spur action from every impacted constituent.

“When patients and doctors realize we can’t offer BCG, I hope and expect changes in the regulations to give a dispensation for BCG in the clinical arena,” he said.

“Most medical practices that are seeing Medicare or Medicaid patients… are required by law to have a compliance plan in place. Most practices either aren’t aware of this requirement, ignore this requirement, or just feel it is an expense that the practice cannot afford.”

DAVID J. ZETTER

“The rules are complex enough so that you can probably find mistakes in just about every practice.”

MARK PAINTER
“The general position of the government, particularly the OIG, is that you need to be proactive and be aware of high-risk areas for your particular organization or practice,” Bewley said.

“This includes paying attention when the Department of Justice, including the various U.S. Attorneys’ offices, announce settlements or cases. Notable settlements are published annually in the annual Bass, Berry and Sims Healthcare Fraud & Abuse Review (www.fraudinhealthcare.com).”

“Being aware of current enforcement areas, and the corresponding risks, is not sufficient. You need to be proactive and make sure that your employees and other providers and practitioners in the practice are also aware of them. Make sure everyone knows the rules and regulations surrounding what’s appropriate and what isn’t,” Bewley said.

“Then pressure-test that. Take a look and make sure you’re billing properly and are only providing services when necessary and are properly documenting these services. If you identify mistakes or errors, then implement corrective action, including making appropriate refunds of overpayments and training and education for those who made the mistakes or errors. And re-educate and train.”

The worst thing that you can do as a health care provider is put your head in the sand, according to Bewley.

“It’s risky business to intentionally try to beat the system and overbill because Medicare and other payers look for patterns and eventually many of the outliers who try to take advantage of the system stand out, get audited, and find themselves making DOJ headlines, according to Painter.

Dr. Rubenstein thinks about his level of coding before he closes each chart. He said he asks himself: If the chart he is about to close ever gets audited, has he documented appropriately to support the level of the code?

“If I can say to myself, yes, if this chart got audited, it’s water-tight and is appropriate coding, I close out the chart and submit the billing,” Dr. Rubenstein said.

Practices like FWC Urology and gynecology that settle False Claims Act liabilities often pay the price and move on.

**MORE DOS, DON’TS FOR PROPER BILLING**

- **Don’t count on the EHR for billing codes.** Electronic health records have a function, which practices can turn on or off, that suggests level of service codes based on documentation. But that’s only part of what goes into proper coding. It’s difficult for an EHR to determine the impact of things like risk, according to David J. Zetter, a health care consultant at Zetter Healthcare.

- **Don’t rely on the billing department or staff to bill correctly.** “Many group practices have either an internal billing expert or use an outside billing company to help them submit bills. Some of these experts are there merely to make sure that appropriate codes go out and that they’re lined up with the proper ICD-10 codes,” said Jonathan Rubenstein, MD, of Chesapeake Urology Associates.

  “But many billing experts just don’t understand the nuances of what a doctor is or is not doing. Sometimes a billing expert will trust that a doctor is submitting bills appropriately.”

- **Do train, then train some more.** Dr. Rubenstein said he trains all new providers in proper billing and coding at Chesapeake Urology before they start practice.

  “And within the first 3 months into practice, I personally look through their charts for appropriate coding. I get monthly reports from our billing staff, which outlines our doctors’ coding patterns, and if I see an abnormality in coding patterns, I will do a specific review of a doctor who is more than one standard deviation above the mean of the practice,” Dr. Rubenstein said.

  “I have monthly meetings with our billing staff where they alert me to any problems that they might see with billing or with certain providers. And we have an internal compliance plan where we have the ability to enforce a behavior change with a provider who may be coding or billing out of the normal range or as would be expected.”

  Smaller practices can hire outside consultants or coding experts to educate practices and do chart reviews, or internal staff can attend training classes. The AUA offers yearly training, according to Dr. Rubenstein. PRS, LLC offers an online course on the topic for physicians.

- **Don’t under-code for fear of an audit.** “Medicare looks for patterns, and sometimes if you under-code, that may be sending a red flag as somebody trying to hide something that they’re doing wrong,” Dr. Rubenstein said.

- **Realize that whistleblowers, or relators, can come from anywhere.** These individuals alert the government about possible False Claims Act violations. They can work in practices. Some are patients. Others, as in the case with Skyline Urology, are practice consultants.

- **Don’t view audits as death sentences.** “Everybody is going to get audited one way or another. There’s no way to code or report things that doesn’t get you in trouble,” said Mark Painter of PRS, LLC. “Ultimately, the best way to behave is to think that you will be audited at some point in time in your practice, and as long as you approach it by supporting everything you do with documentation and medical necessity, there’s no reason to fear an audit.”

“The billing instance being referenced happened a number of years prior to the settlement, and the company cooperated in all respects,” wrote FWC spokesperson Chris Cooney in an email to Urology Times.

“The company takes its compliance responsibilities very seriously, and has the systems, processes and controls in place to accurately document and bill for services rendered on behalf of patients,” Cooney added.

Changes could be on the horizon. Late last year, CMS announced its final 2019 Physician Fee Schedule and the Quality Payment Program rule, which addresses consolidating E/M coding requirements for physician services but delayed implementation of E/M coding reforms until 2021 to allow for continued stakeholder engagement. (For more, visit “Final Policy, Payment, and Quality Provisions Changes to the Medicare Physician Fee Schedule for Calendar Year 2019” at bit.ly/CMS2019Schedule.)

E/M coding reform might result in fewer codes, less documentation, and less confusion, but that remains to be seen, Zetter said.
Locum work a refreshing break from the daily grind

Change of pace, fewer administrative concerns among advantages

About two years ago, a rural hospital, not close to my hometown but not that far either, approached my practice and asked if we would be interested in doing an outreach clinic at their hospital. It had been 15 years since the hospital’s last urologist retired, and the closest practicing urologist was almost 2 hours from them, on the other side of a mountain pass. Welcome to Colorado.

We did a bit of due diligence and quickly learned that hospital’s payer mix and patient volume was typical of a small rural hospital, and it likely didn’t make financial sense for us to start an outreach clinic. So we declined.

But the town, its citizens, and its obvious need for a urologist appealed to this small-town plumber. We proposed a salaried physician model, similar to a locum tenens model, and the hospital accepted. The arrangement has worked out very well. As locum work was something I did not think I would ever do, I wanted to share my experience, as I’m sure everyone else receives the same almost daily deluge of emails from the locum recruiters. I’m sure too at least a small share of us are curious about what this type of work entails.

What is locum tenens work? The phrase is Latin for temporary work, and the concept is to allow a hospital to temporarily fill a position while it searches for a long-term solution. It doesn’t mean, of course, that some doctors don’t use a locum position as a way to test-drive a job, but the positions should not be understood to have any guaranteed longevity and most (including mine) have contracts with very short, very broad termination clauses. I’m pretty sure I could be let go on a 1-week notice for no other reason than the administrators don’t like one of my blue button-down shirts, and I wear a lot of blue button-down shirts.

What are the advantages and disadvantages of locum tenens work? First, it pays well. These jobs exist because by definition the hospital has a need and has been unable to find a long-term solution. On the other hand, there are certainly better long-term options. Many partners in suburban single-specialty urology groups make far more than you would as a locum doctor, and honestly, work in much more desirable locations. On the other hand, the long-term salary of most hospital-employed urology positions pales in comparison to the money that can be made doing locum.

Work is patient focused

Another potential advantage is that you can avoid the hassles that come with running an office. In my day job, there are days I spend more time worrying about the administrative fire of the day than I do worrying about patients. Conversely, when I go to my locum job at the hospital, I worry about is seeing patients. If the computer system is running slow, I don’t worry about calling the IT guy to figure things out. If the copier stops working, that’s someone else’s problem. However, if I don’t like the computer system, too bad; I really don’t have a voice in any potential replacement. If I think my clinic would be a bit smoother with another medical assistant, well, not my decision.

Further, it’s interesting to look at these jobs from a recruiter’s perspective. Given the number of companies that try to match doctors with hospitals, they clearly do well. I understand that if you go through one of these recruiters, they will likely pay for housing and travel and even malpractice, but they clearly make a profit on top of that. I was lucky. The hospital I work for directly approached my group, and as a result, we were able to negotiate a nice contract and cut out the middle man.

This also allowed me the opportunity to tailor the contract to my needs. If anyone is considering such a position, it’s worth simply calling the local hospitals to see if they would be willing to talk to you directly, as most likely this will earn you a higher contracted rate and the hospital will pay less overall!

Locum work also helps with burnout

Lastly, don’t underestimate the psychological advantages of this kind of work. The patient population I see is incredibly kind and grateful. Many are thrilled to not have to drive 2 hours to see a doctor and they let us know that. Further, for me, the change of pace associated with this kind of work has relieved some of the sensation of burnout associated with going to the same clinic and dealing with the same office politics every day.

While I love my partners and my staff, the chance to work with a new group of nurses and to interact with a new group of local doctors is in many ways invigorating. When I talk to other physicians who do locum work, the number one reason they chose it is the flexibility it affords. You have a great deal of control over your hours and your location. Further, you are paid well from day one with no requirement to make partner and no requirement to invest in ancillary income. What you gain in flexibility you certainly lose in predictability, but for some, that is a trade-off worth making.

I love my day job and have every intention to finish my career right here in Colorado Springs, so please don’t read too much into this article. I am lucky to have great partners and wonderful staff, but traveling to my locum position in a truly rural part of Colorado and interacting with patients and local physicians there has been a great addition to my monthly routine and something that I highly recommend everyone consider.
**PCa agent phase III data show significantly improved survival**

Results from the pivotal phase III ARAMIS trial in patients with non-metastatic castration-resistant prostate cancer showed a statistically significant improvement in metastasis-free survival (MFS) with the investigational agent darolutamide plus standard of care (ADT) compared to placebo plus ADT (HR=0.41, 95% CI: 0.34–0.50; p<.001). This translates to a 59% reduction in the risk of metastasis or death, according to a report from Orion Corp. and Bayer. The median MFS was 40.4 months in the darolutamide arm compared with 18.4 months for the placebo arm—an overall improvement in median MFS of 22 months. A positive trend in overall survival was also observed (HR=0.71, 95% CI: 0.50–0.99; p=0.45), and all other secondary endpoints demonstrated a benefit in favor of darolutamide. Importantly, the incidence of treatment-emergent adverse events with ≥5% frequency or of grade 3-5 was comparable between darolutamide and placebo arms; only fatigue occurred in more than 10% of patients (darolutamide plus ADT resulted in 12.1% vs. 8.7% in patients with placebo plus ADT). Quality of life outcomes were similar between the treatment groups. The data were presented at the Genitourinary Cancers Symposium in San Francisco and published in the *New England Journal of Medicine* (2019; 380:1235–46).

**Advanced RCC combo Tx significantly improves OS**

Merck recently announced the presentation of the full results from the pivotal phase III KEYNOTE-426 trial investigating the anti-PD-1 therapy pembrolizumab (KEYTRUDA), in combination with the tyrosine kinase inhibitor axitinib (Inlyta), for the first-line treatment of advanced renal cell carcinoma (RCC). The data were presented at the Genitourinary Cancers Symposium in San Francisco and simultaneously published in the *New England Journal of Medicine* (2019; 380:1116–27). This is the first combination regimen to significantly improve overall survival, progression-free survival, and objective response rate compared to sunitinib (Sutent), according to Merck. Results were consistent across all International Metastatic Renal Cell Carcinoma Database Consortium subgroups, including favorable-, intermediate-, and poor-risk groups, and regardless of PD-L1 expression. As previously announced, the FDA has granted priority review for a supplemental biologics license application for pembrolizumab in combination with axitinib for the first-line treatment of patients with advanced RCC based on the results of KEYNOTE-426, and has set a Prescription Drug User Fee Act, or target action, date of June 20, 2019. Look for additional coverage of this study in an upcoming issue of *Urology Times*.

**Overactive bladder agent meets primary endpoint in phase IIb study**

Velicept Therapeutics’ next-generation beta-3 adrenoceptor agonist solabegron met the primary endpoint in VEL-2002, a phase IIb study in patients with overactive bladder. In the study, twice-daily administration of solabegron demonstrated a statistically significant improvement compared to placebo at week 12, as measured by the mean change in number of micturitions per day, the study’s primary endpoint. Solabegron also demonstrated statistical significance across multiple secondary endpoints, including percent reduction of urge urinary incontinence episodes, dry rate, and urgency episodes. The 12-week placebo-controlled VEL-2002 study enrolled 435 women ages 18 to 80 years suffering from OAB. Solabegron was generally well tolerated. Treatment-emergent adverse events and serious adverse events were infrequent and comparable between the solabegron- and placebo-treated groups.

**Ligation tech to be integrated into robotic surgical system**

Titan Medical Inc. and Teleflex Inc. have announced a collaboration under which Teleflex’s market-leading polymer ligation technology will be integrated into Titan’s development-stage, single-port robotic surgery system. Teleflex’s Weck Hem-o-lok polymer ligation system is used for vessel sealing and has enhanced clip security features. Titan Medical is developing the SPORT Surgical System, a single-port robotic surgical system comprised of a surgeon-controlled patient cart that includes a 3-D high-definition vision system comprised of a surgeon-controlled patient cart that includes a 3-D high-definition vision system and multi-articulating instruments for performing minimally invasive surgical procedures, and a surgeon workstation that provides an advanced ergonomic interface to the patient cart and a 3-D endoscopic view inside the patient’s body. Titan Medical says it intends initially to pursue focused surgical indications for the SPORT Surgical System, which may include one or more of gynecologic, urologic, colorectal, or general abdominal procedures.

**Phase III trial to evaluate OAB Tx in men on BPH treatment**

UroVant Sciences has initiated COURAGE, an international phase III trial to evaluate the safety and efficacy of vibegron for symptoms of overactive bladder in men who are receiving pharmacologic treatment for BPH. Vibegron is an investigational beta-3 agonist that has previously been evaluated in phase I/II and phase III studies in patients with OAB. The COURAGE study is a randomized, double blind, placebo-controlled trial in men with BPH who are also taking BPH medications but continue experiencing OAB symptoms. The study will be conducted in two phases, with the first phase focusing on safety and the second phase assessing efficacy and safety. Approximately 1,000 patients who meet eligibility requirements will be randomized to receive either 75 mg of vibegron or placebo daily for 24 weeks. The co-primary efficacy endpoints will be measured at 12 weeks and include change from baseline in the average number of micturitions per 24 hours and change from baseline in the average number of urgency episodes per 24 hours.

**Positive interim phase II data reported for CAH treatment**

Neurocrine Biosciences, Inc. recently announced positive interim results from a phase II proof-of-concept study evaluating the safety, tolerability, pharmacokinetics, and pharmacodynamics of NBI-74788, a proprietary corticotropin-releasing factor type 1 receptor antagonist, in adult patients with classic congenital adrenal hyperplasia (CAH). Results from this ongoing phase II open-label study demonstrated a reduction of at least 50% from baseline in 17-hydroxypregosterone and adrenocorticotropic hormone levels in more than 50% of CAH patients treated with NBI-74788 for 14 days. Meaningful reductions were also observed in other biomarkers, including androsterenedione. NBI-74788 was shown to be well tolerated with no serious adverse events reported to date. The company says it plans to meet with the FDA to discuss the registration program for NBI-74788 in adult and pediatric patients with CAH.

**Antibiotic for prostatitis granted QIDP designation**

Iterum Therapeutics plc recently announced that the FDA has granted Qualified Infectious Disease Product (QIDP) designations to the oral and intravenous formulations of sulopenem in four new indications: acute bacterial prostatitis, community-acquired bacterial pneumonia, gonococcal urethritis, and pelvic inflammatory disease. These new designations augment Iterum’s existing QIDP designations for oral and IV sulopenem for the treatment of uncomplicated urinary tract infection (uUTI), complicated urinary tract infection (cUTI), and complicated intra-abdominal infection (cIAI), which the FDA granted in 2017. The company is currently conducting three pivotal phase III clinical trials in uUTI, cUTI, and cIAI, and expects to report top-line results in the second half of 2019. Fast Track designation for all seven of these indications in both the oral and intravenous formulations has also been granted, according to the company.
Who should own medical records—the doctor or patient?

That’s a good question. Clearly, the doctor has to. Then the question is, does the patient own the records as well? I would say the patient owns the record too—so I would say both.

Patients get an after-visit summary that has the salient points discussed during our office visit. In our institution, they’re also encouraged to sign up for an online service called ‘MyChart,’ where they can get into their medical records electronically and remotely.

That has more detail than the after-visit summary, information like laboratory tests another doctor ordered—things outside of our specific appointment.

If a doctor wants to make notes for himself, the chart isn’t the place to put them. The chart can be subpoenaed and so forth, so if a physician wants to leave private comments, that should be a separate location.

Some systems provide the opportunity to make notes in part of the chart that are not literally part of the patient’s medical records. Patients can’t get into that. It’s not part of the after-visit summary, but it’s part of the records that doctors leave for themselves. I don’t use those. Everything I think about, I share with the patient, and therefore it goes into my notes. I may say things like, ‘Bring the patient back in 6 months to talk about these other issues, and I introduced the first two concepts today.’

It helps you to know what’s going on, and obviously the health care team needs to know everything to provide the best possible care. That’s pretty self-explanatory. In today’s world, patients are demanding increased participation in the process… and secrets don’t really help anybody.”

Steve Bernstein, MD / Edina, MN

The medical record itself, in my opinion, is the possession of the patient. The responsibility for maintenance of that record would fall on us as providers obviously. But the rights of access, without question, belong to the patients.

As far the contents of the records, the onus comes back on us as providers to be able to communicate in a way patients understand, which in certain circumstances might require us to use terminology that is slightly more layman’s language. Are there always going to be situations where there is a misunderstanding and will further communication be required? Yes, without question. It’s an imperfect system, but patients should have full access to those records.

If doctors want to remind themselves of something, they need to be willing to clarify those comments to the patients. If they’re not willing, then obviously they have to develop a different means of self-reminding than medical records.

Whether we like it or not, we’re legally required to make the information available. So if we’re willing to put it in the medical record, we need to be ready to give full disclosure, interpretation, and explanation to the patient.”

Phillip Fuller, MD / Ada, OK

State laws vary throughout the country, so sometimes it’s not our choice.

In my opinion, medical records are the work product of the doctors, and if employed by an institution, a combination of the doctor and the institution. That doesn’t mean that patients shouldn’t have complete access.

There could be issues, however, for which doctors must be prepared. ‘Complete’ is probably the definitional issue. Sometimes it’s complete access to an ‘edited’ record. That may be better for some patients because of the confusing nature of the information.

It might be better, and less confusing, if patients had access to a layman’s edited record, rather than the current system where they have complete access to the unedited record.

We have a web portal where patients can access their records. They can request copies of office and operative notes, but don’t actually have complete access. They have open records except for specific areas, like psychiatric reports or HIV testing. Patients can get that information, but not immediately through the portal.

In Pennsylvania, all x-ray abnormalities have to be reported directly to the patient with a recommendation to call their doctor. That becomes a huge burden because although you’ve told a patient about a benign cyst on his kidney, he thinks something else is wrong because the letter reported an abnormality. You spend significant time educating patients about the practice of medicine.

I’m not professing having secrets from the patients. Transparency is good, but when information is delivered without editing, it can be more confusing than helpful.

Editing information means extra work, but when interpretation of the information is necessary, the record is not designed for the patient. We may have to dictate like our patients will read it, as opposed to dictating for a doctor. That may be the solution.”

Peter Lund, MD / Erie, PA

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General Urologist Surgeon
Plattsburgh, NY

The Department of Surgery at the University of Vermont College of Medicine is seeking a Clinical Practice Physician in the Division of Urology to join the Champlain Valley Physicians Hospital (CVPH) in Plattsburgh, New York. CVPH is a progressive medical center with nine state-of-the-art OR’s and Ambulatory Surgery Center. This position offers the unique opportunity to work in a community setting while having an active affiliation with Vermont’s only Academic Medical Center; the only ACS verified Level 1 trauma center in the state providing tertiary care to patients from Vermont and Northern NY. Serving the patients from Upstate New York for decades, the local urologic surgery practice recently joined the faculty at the University of Vermont and are now seeking an additional colleague to join the dynamic Urology faculty that span the network hospitals. Specifically, the Division seeks applications from individuals seeking a community Urology practice employment opportunity with a collegial and collaborative setting with University support.

Applicants must be board certified or board eligible and eligible for medical licensure in the state of New York. This is a full-time, 12 month, salaried position.

Plattsburgh is located on the shores of Lake Champlain, near the Adirondack Mountains, Olympic-Lake Placid region, Montreal and Burlington, VT.

The University is especially interested in candidates who can contribute to the diversity and excellence of the academic community through their research, teaching, and/or service. Applicants are requested to include in their cover letter information about how they will further this goal.

The University of Vermont is an Equal Opportunity/Affirmative Action Employer. All qualified applicants will receive consideration for employment without regard to race, color, religion, sex, sexual orientation, gender identity, national origin, disability, protected veteran status, or any other category legally protected by federal or state law. The University encourages applications from all individuals who will contribute to the diversity and excellence of the institution.

Interested individuals should apply online at https://www.uvmjobs.com/postings/31529 (position number 00024781).
Inquiries may be directed to Mark Plante, MD, FRCS(C), FACS, Division Chief, via Kristin Allard Kristin.Allard@uvmhealth.org
The Division of Urology at the University of Vermont College of Medicine in alliance with the University of Vermont Medical Center, is seeking a Clinical Practice Physician who is board eligible/board certified Urologist to join the Urology service at our affiliate community medical center, Central Vermont Medical Center (CVMC). This position offers the unique opportunity to work in a community setting while still being involved with an academic center. The successful applicant must have completed an American Board of Urology approved urology residency, be eligible for medical licensure in the State of Vermont and eligible to work in the United States. Duties will include general urologic patient care (adult and minor pediatric) with potential opportunities for the teaching of medical students and urology residents. This is a full-time, 12 month, salaried position with attending staff privileges at Central Vermont Medical Center.

The University is especially interested in candidates who can contribute to the diversity and excellence of the academic community through their research, teaching, and/or service. Applicants are requested to include in their cover letter information about how they will further this goal.

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Interested individuals should apply online at http://www.uvmjobs.com/postings/33676 (position number 00023212). Inquiries may be directed to Mark Plante, MD, FRCS(C), FACS, Chief of Urology, Via Kristin Allard Kristin.Allard@uvmhealth.org
Marketplace
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**PEDIATRIC UROLOGIST**

The Department of Surgery at the University of Vermont College of Medicine and its affiliated medical centers, the University of Vermont Medical Center and Vermont Children’s Hospital, is seeking a Pediatric Urologic Surgeon. The University of Vermont Medical Center and Vermont Children’s Hospital, along with the university, offers a full spectrum of pediatric medical and surgical specialties. The institution has a Level III NICU, a fully staffed PICU, and serves as the regional adult and pediatric regional trauma center. The Division of Urology holds a long-standing reputation as a premier urologic surgery practice for the surrounding communities’ pediatric and adult patients with urologic care needs and enjoys an excellent relationship with the Department of Pediatrics. With a highly respected residency training program with a robust compliment of dynamic faculty across the network hospitals, the Division seeks applications from individuals seeking an academic career in a collegial and collaborative setting.

Applicants must be BE/BC in Urology and Pediatric Urology, eligible for licensure in the State of Vermont, and eligible to work in the United States. They must have experience in the teaching of medical students and surgical residents, and the clinical and research activities of an academic division of Pediatric Surgery.

This is a full-time, 12-month salaried faculty appointment in the Clinical Scholar Pathway at the rank of Assistant or Associate Professor and carries with it attending staff privileges at University of Vermont Medical Center, a level 1 trauma center that serves as a tertiary care facility serving Vermont and northern New York State. Salary is competitive and commensurate with ability and experience.

Burlington, is located on the eastern shore of Lake Champlain between the Adirondack and Green Mountains, is consistently ranked one of the top places to live and work. Numerous recreational and cultural opportunities across four seasons are available, with Vermont considered to be an outstanding environment to practice medicine.

_The University is especially interested in candidates who can contribute to the diversity and excellence of the academic community through their research, teaching, and/or service. Applicants are requested to include in their cover letter information about how they will further this goal._

_The University of Vermont is an Equal Opportunity/Affirmative Action Employer. Applications from women, veterans, individuals with disabilities and people from diverse racial, ethnic, and cultural backgrounds are encouraged._

Interested individuals should apply online at [https://www.uvmjobs.com/postings/30302](https://www.uvmjobs.com/postings/30302) (position number 00024730).

Inquiries may be directed to Mark Plante, MD, FRCS(C), FACS, Division Chief, via Kristin Allard Kristin.Allard@uvmhealth.org

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AUA lobbies Congress on PCa, prior auth

More funding urged for urologic research

Members of the urology community who participated in the Annual Urology Advocacy Summit in Washington early last month urged lawmakers to support initiatives to improve patient care, including in minority populations, increase support for urologic research, and ease regulatory burdens.

More than 200 members of the urology community participated in the Summit, which included educational sessions on advocacy topics such as work force issues, urologic care for veterans, and other critical access-to-care concerns.

Attendees participated in meetings with lawmakers from 112 House districts and 74 Senate offices and discussed three primary concerns: prostate cancer screening in high-risk populations, increased funding for urologic research, and the regulatory burden of prior authorization and its impact on urologic practices and patients.

“The AUA Summit confronts and obliterates the myth that physicians can’t make a difference in Washington. It offers an opportunity for urologists to use their intelligence, problem-solving skills, insight, and passion for patient care to shape and redirect health care legislation and regulations in our and our patients’ favor,” said Thomas Rechtschaffen, MD, chair of the AUA’s Legislative Affairs Committee.

“During our meeting this year, we discovered new avenues to access research funds and roll-backs on harmful regulations. We were a loud voice, added to other physician groups, to rally against prior authorization burdens. Congress is hearing us and paying attention. We obtained support to direct funding to research how prostate cancer affects people of color more specifically and for renewal of PCORI [Patient-Centered Outcomes Research Institute] legislation, which is another source of research funding that our academic urologists and trainees depend upon.

A call for more research on PCa in African-Americans

Lawmakers were urged to encourage the National Cancer Institute to direct additional research efforts toward better understanding prostate cancer among African-American men and other populations at high risk for the disease.

The AUA pointed out that in 2018, after being pressed for years by the urologic community, the U.S. Preventive Services Task Force (USPSTF) released upgraded recommendations for prostate cancer screening but was unable to make specific recommendations for African-American men, citing a lack of available research evidence of the benefits to these patients.

The USPSTF has called for additional studies “to explore the optimal screening frequency and whether beginning screening before age 55 years provides additional benefits to African-American men.” The AUA’s clinical practice guidelines on early detection of prostate cancer support this statement, the association said in a briefing paper provided to members of Congress.

Summit attendees urged Congress to support increased funding in fiscal year 2020 for the Department of Defense Congressionally Directed Medical Research Programs, which since 1992 has funded 16,350 research grants and projects totaling $11.6 billion.

In FY 2019, prostate cancer research in the program received $100 million and kidney cancer research received $20 million, and since FY 2016, Congress has provided bladder cancer funding through the program as well.

The AUA also urged lawmakers to support pending legislation to reauthorize the PCORI to avoid a lapse in its research efforts. Created in 2010 by the Affordable Care Act, the Institute is an independent, non-profit research agency that facilitates comparative clinical effectiveness research to help patients make informed decisions about their care.

Since 2017, the Institute has invested nearly $2.4 billion in more than 600 research-related projects, including more than $32 million for nine different urologic disease research initiatives. Congressional authorization for the program expires in 2019 unless the program is extended.

In addition, the AUA joined with the Ad Hoc Group for Medical Research Funding in requesting that Congress provide $14.6 billion for the National Institutes of Health, a 6.4% increase over current funding.

“NIH funding has already improved the lives of Americans with urologic diseases, including those with [BPH],” the AUA said in its congressional briefing paper.

In addition, the AUA said, NIH research has shed light on potential health care savings with better treatment options for urinary incontinence, which costs more than $7.5 billion annually to evaluate and treat.

Prior auth legislation urged

Summit attendees encouraged members of Congress to support the introduction of bipartisan legislation to address prior authorization issues and include consensus recommendations by the AUA and other leading national physician organizations.

The AUA noted that on Feb. 5, the American Medical Association released the results of a survey indicating more than one-quarter of physicians said the prior authorization process has led to serious or life-threatening events for their patients.

The AUA and more than 100 other health care organizations have endorsed the “AMA Prior Authorization and Utilization Management Principles,” intended to “ensure that patients receive timely and medically necessary care and medications and reduce the administrative burdens.”

The AUA also has joined with the Regulatory Relief Coalition, which includes specialty provider organizations, in working with key lawmakers to address the issues physician organizations and patients face because of prior authorization.

— BOB GATTY

Mr. Gatty, a former congressional aide, covers news from Washington for Urology Times.
Failure to consult urologist at heart of case
Negligence established by plaintiff, but is it enough?

A 56-year-old male retired truck driver presented to the ER with a chief complaint of fever, chills, and body aches for 2 days. His prior medical history was positive for a urethral stricture for which he began receiving treatment when he was 24.

Prior to his urethral injury, the patient underwent several procedures to dilate his urethra and had been seen in the ER on numerous occasions for urinary tract infections. On presentation to the hospital, he reported to the ER physician that he had had trouble catheterizing himself at home. The ER nursing staff made several attempts to catheterize the patient, but to no avail. A urologist was consulted, who recommended that if the patient was able to void, there was no need to place a catheter in the ER.

The patient was subsequently given IV fluid and was able to void; however, he began to demonstrate tachycardia and hypotension. An internal medicine doctor then admitted the patient for a suspected UTI and to rule out sepsis. Urine and blood cultures were ordered and the patient was started on antibiotics for possible sepsis.

The man was seen for the first time by the internal medicine doctor the day after his admission. After testing, the patient was discharged 4 days later with instructions to continue on his antibiotic therapy for 7 days and follow up with his primary care physician. Later that day, the patient presented to the ER again with a chief complaint of hematuria and difficulty voiding. He was advised to make an appointment with a urologist.

Soon after, the patient was seen by a urologist. The urologist attempted to perform a cystoscopy, but he was unable to pass the scope beyond the stricture due to the presence of multiple false passages. The urologist opted to place a suprapubic catheter under general anesthesia. The plan was to leave the suprapubic catheter in place as long as necessary to allow for decreased swelling and healing of the urethra.

The patient later sued the hospital, the internal medicine physician, and nursing staff. The case proceeded to trial against the internal medicine doctor only.

The plaintiff claimed that because of the defendant-doctor’s negligence, he had to undergo placement of a suprapubic catheter, which remained in place for 7 months. He claimed that he presented to the ER with a chief complaint of a UTI and did not request to be catheterized. He argued that because of the multiple attempts at catheterizing him in the ER, he suffered injury to his urethra.

Plaintiff’s expert internist opined that the defendant fell below the standard of care due to his failure to be aware of the nature and extent of the urethral injury the plaintiff had suffered by the time he was admitted. The expert found that the defendant failed to adequately take a history of the urethral injury and did not perform a genitourinary exam at any time during the plaintiff’s hospital stay, negligently failed to request a consultation with a urologist while the plaintiff was an inpatient, and at discharge did not refer the plaintiff to a urologist.

Plaintiff’s expert urologist testified that the failure to consult a urologist while the plaintiff was an inpatient resulted in a lost opportunity to avoid suprapubic catheter placement. The expert noted that, due to the urethral injury, the plaintiff was not voiding well.

The expert concluded that the defendant’s opinion regarding urinary retention was supported by the findings of the renal ultrasound, which revealed a distended bladder, and had a urologist been consulted, additional attempts at placing a Foley catheter using a guidewire would have been made in an effort to relieve the retention and thereby avoid the need for the suprapubic catheter that remained in place for 7 months.

The defendant claimed that his inpatient care and treatment of the plaintiff was well within the standard of care and that nothing he did or failed to do caused the need for the suprapubic catheter placement.

The defense’s expert internist opined that the defendant complied with the standard of care throughout the plaintiff’s hospitalization. The expert professed that the primary reason for hospital admission was a life-threatening UTI that was adequately treated, and that the standard of care did not require a urology consult under the circumstances because any further catheterization attempts would have been contraindicated due to the plaintiff’s serious infection.

The defense’s urologist opined that the plaintiff had a chronic problem with a urethral stricture. The expert concluded that nothing that the defendant did or failed to do caused the need for the suprapubic catheter. In addition, on exam 3 years after discharge, the plaintiff had no residual problem with his ability to urinate.

Following a 7-day jury trial, the jury deliberated for 1.75 days. Ultimately, the jury returned a defense verdict, finding that although the defendant-doctor was negligent, his negligence did not cause the plaintiff harm.

LEGAL PERSPECTIVE: To succeed in a malpractice claim, a plaintiff must establish, by the greater weight of the evidence, both negligence and causation. In this case, plaintiff succeeded in establishing the defendant-doctor’s negligence, but failed to establish causation by the greater weight of the evidence.

PERKO, ESQ.
Malpractice Consult

ACACIA BRUSH PERKO, ESQ.
Ms. Perko is an attorney in the Columbus, OH office of Reminger Co., LPA, where she specializes in medical malpractice defense litigation and transactional matters. She welcomes your feedback at APerko@reminger.com.
Filling the Gap in BPH CARE

Last year, the AUA updated its guidelines for benign prostatic hyperplasia (BPH). The update includes a recommendation for urologists to consider prostatic urethral lift (PUL) for the treatment of some patients with BPH.

Six experienced providers of PUL joined a panel to examine the AUA’s new guidelines, the current status of the UroLift System® within the standard of care for BPH, and how to improve the care pathway for BPH.

read this supplement at urologytimes.com/bphcare
The UroLift System procedure is FDA-cleared for the treatment of symptoms due to urinary outflow obstruction secondary to BPH, including lateral and median lobe hyperplasia, in men 45 years of age or older. Results and patient experience may vary. Most common adverse events reported include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence. Most symptoms were mild to moderate in severity and resolved within 2 to 4 weeks after the procedure. Consult the Instructions for Use (IFU) for more information.

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Peter J. Walter, M.D., F.A.C.S.  Western New York Urology Associates and UROLIFT® SYSTEM PATIENT

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The UroLift System procedure is FDA-cleared for the treatment of symptoms due to urinary outflow obstruction secondary to BPH, including lateral and median lobe hyperplasia, in men 45 years of age or older. Results and patient experience may vary. Most common adverse events reported include hematuria, dysuria, micturition urgency, pelvic pain, and urge incontinence. Most symptoms were mild to moderate in severity and resolved within 2 to 4 weeks after the procedure. Consult the Instructions for Use (IFU) for more information.

*Dr. Walter is UroLift faculty and a paid consultant for NeoTract|Teleflex