Male patients ride online wave

Novel sites catering to men emerge, along with conflicting views about Internet-based care

Lisette Hilton
UT Correspondent

The Internet’s impact on people’s health care decision-making has long been an unsettling reality. This is especially true when it comes to men’s health, where the Internet provides privacy and immediate access to information—even services—to men who are by all accounts reluctant to seek medical care.

The Internet’s appeal and doctors’ concerns about quality make sense, researchers reported in “Health information on the Internet: Gold mine or minefield?” published in the Canadian Family Physician (2014; 60:407-8).

“Considering how easy it is to Google-search ‘bad cough,’ it is not surprising that many people make an attempt at self-diagnosis using the Internet before waiting hours in crowded walk-in clinics or emergency departments to consult professionals,” the authors wrote. “The flow of information has fundamentally changed, and physicians have less control over health information relayed to patients. Not surprisingly, this paradigm shift has elicited varied and sometimes conflicting views about the value of the Internet as a tool to improve health care.”

Having a condition like erectile dysfunction (ED) makes going to the Internet even more attractive, researchers say. Despite the availability of oral medicines to treat ED, men seeking treatment face barriers that lead to under-treatment in the U.S., including reluctance to talk about ED and other sensitive issues, high medication costs, inadequate insurance.

See ONLINE WAVE, on page 30.

MEN’S ATTITUDES TOWARD HEALTH AND THE INTERNET

- 61% have neglected visiting a physician even when they needed to go
- 56% prefer to keep health concerns to themselves
- 27% research their symptoms online when first noticing changes in health
- 27% consult a physician when first noticing changes in health

Source: Cleveland Clinic MENtion it Survey, April/May 2018
Image: Jackie Niam/Adobe Stock.com

Q&A

STONE DISEASE

Percutaneous access: Principles and best practices

In this interview, Bodo Knudsen, MD, of The Ohio State University Wexner Medical Center, Columbus outlines his step-by-process for obtaining percutaneous access, discusses the ways he reduces radiation exposure during percutaneous nephrolithotomy, and gives his thoughts on how clinicians can gain proficiency with access.

For the full article, please turn to page 18

Bodo Knudsen, MD
Prioritizing kidney preservation in upper tract urothelial carcinoma (UTUC):

Are we doing all we can?

The challenges associated with UTUC treatment have created a paradigm where up to 80% of patients with low-grade disease are treated with radical surgery.1 Yet despite the challenges, there is still plenty of clinical rationale to justify prioritizing kidney preservation whenever possible.

“As urologists, we constantly balance cancer risks with the morbidity of our surgery. At times, removing a kidney for low-grade UTUC can be overkill.”

-Brian Hu, MD, Assistant Professor of Urologic Oncology, Loma Linda University, Loma Linda, CA

UTUC PATIENTS MAY ALREADY HAVE SIGNIFICANT RENAL IMPAIRMENT AND COMORBIDITIES

A 2017 retrospective analysis of 731 patients undergoing radical nephroureterectomy (RNU) for UTUC found that 50% of patients had preoperative chronic kidney disease (CKD) stage ≥3.2

Not surprisingly, RNU only accelerates declining kidney function and progression to CKD.3,4

Additionally, many UTUC patients suffer from comorbid conditions such as cardiac disease, hypertension, diabetes, or hyperlipidemia.2,5

“UTUC typically presents later in life with many more competing risks for patients, including baseline renal dysfunction. Treatment should focus both on cancer control and on preserving long-term kidney function to prevent other risks to the patient’s survival and quality of life.”

-David Morris, MD, FACS, Urology Associates PC, Nashville, TN

ACCURATE RISK STRATIFICATION IS PARAMOUNT TO IDENTIFYING CANDIDATES FOR KIDNEY-SPARING TREATMENT

Guidelines from the European Association of Urology recommend risk stratifying UTUC to identify candidates for kidney-sparing treatment.6 But understanding patients’ baseline renal function and risk for further deterioration are also important when selecting appropriate treatment.

“The ‘best’ recommended treatment for a patient with UTUC will allow for the balance of cancer control and preserving renal function and tissue,” Morris said. “This recommendation hinges on the accurate staging and risk stratification before definitive treatment.”

The case for kidney preservation in UTUC

For more perspectives on kidney preservation in UTUC, visit: www.UTUC.info

I recently spent a few days at the Cuyahoga County Common Pleas Court in downtown Cleveland as a juror in a medical malpractice case. The experience, while brief, was enlightening.

Jury duty is a tremendous honor. For U.S. citizens, it’s a public service that’s been compared to voting and even military service. As those who have served on a jury know, it can also be tedious and, at times, stressful.

I was the last of 22 jurors chosen for this case—a wrongful death claim against a large hospital system. The plaintiff was the widow of a patient who had died while under the care of a pulmonologist at the hospital. As voir dire—the process of questioning prospective jurors—proceeded, details about our work and private lives unfolded. Some revelations raised a few eyebrows, including what I did as an employee of Urology Times.

One juror lived three doors down from the defendant physician (he was excused). Another juror was a college classmate of an attorney on the defense team (excused). A third lost her stepfather in a plane crash and noted that her family was very well compensated by the airline, a comment that drew several follow-up questions from both attorneys.

The time and effort spent on voir dire was extensive—nearly 3 full days—and involved the judge and both the plaintiff and defense attorney. In addition to personal and work-related questions, jurors were asked about their experience with the defendant hospital system, handoff of a patient from one health care provider to another, and whether they had signed an electronic signature pad in a hospital or doctor’s office.

My job as a medical editor prompted a few questions. I was asked about my knowledge of standard of care and peer review, any working relationship I had with the hospital system, and whether I could be impartial on this case. Based on their lines of questioning, it was apparent the defendant’s attorney wanted me to sit on the jury and the plaintiff’s attorney did not. I’m no mind reader, but my assumption was that the defense favored an individual with some knowledge of medicine and a working relationship with his client, and the plaintiff felt my admission that I occasionally reached out to the defendant hospital’s clinicians for manuscripts rendered me biased.

In the end, I did not make it past the voir dire phase. I was dismissed. Like my fellow jurors, I was not given a reason. But I left with a firsthand education about malpractice litigation and its lengthy, intricate process of jury selection.

Based on their lines of questioning, it was apparent the defendant’s attorney wanted me to sit on the jury and the plaintiff’s attorney did not.

From the Editor

RICHARD R. KERR

Mr. Kerr is content channel director of Urology Times.

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From the Editor

My brief stint as juror was enlightening. Another lost her stepfather in a plane crash and noted that her family was very well compensated by the airline, a comment that drew several follow-up questions from both attorneys.
Holmium, thulium lasers show similar ablative effect on stones

Cheryl Guttman Krader
UT Contributing Editor

The high-power holmium (HPH) laser with Moses technology (Lumenis Moses Pulse 120H) and the super-pulse thulium fiber laser (SPTF) have a similar ablative effect when operated at the same power, but when evaluated at maximal dusting settings, the SPTF laser seems to hold an advantage for greater efficiency, according to research reported at the AUA annual meeting in Chicago. Researchers compared the ablative effects of the two laser systems in an in vitro study using calcium oxalate monohydrate-like artificial stones and a prototype of the SPTF laser.

“Innovations in lithotripsy technologies continue to emerge. The Moses technology was developed to enhance the HPH laser lithotripter, but more recently it is being challenged by the novel SPTF laser that features a more optimal wavelength with a higher water absorption, lower pulse energy, and higher pulse rate (frequency),” said first author Laurian B. Dragos, MD, consultant urologist at Victor Babeș University of Medicine and Pharmacy, Timișoara, Romania.

“Our study shows that the [super-pulse thulium fiber] laser might increase the efficiency of laser lithotripsy, therefore decreasing operative time.”

LAURIAN B. DRAGOS, MD

“Our study shows that the SPTF laser might increase the efficiency of laser lithotripsy, therefore decreasing operative time. Still, we need to consider that these are in vitro findings, and our study did not assess other aspects of laser lithotripsy such as retroplulsion, visibility, and size of the resulting stone fragments (dust). Further clinical evaluations are required.”

The in vitro study analyzed ablation volumes created in calcium oxalate monohydrate-like artificial stones using the two laser systems.

The HPH laser was equipped with a 230-micron core-diameter fiber, and the SPTF laser, which was a prototype device, had a 200-micron core-diameter fiber. The SPTF laser can use fibers as small as 50 microns.

For both laser systems, ablation volume increased with increasing laser power and decreased as the distance between the fiber and the stone increased. Results achieved using the HPH Moses technology laser in distance and close modes showed that if power, energy, and frequency were kept constant, ablation volume was consistently greater when the laser was operated in distance mode. The differences between the two modes, however, were not statistically significant.

The ablation volumes achieved using the SPTF laser were similar to those achieved using the HPH Moses technology laser in distance mode when the two devices were operated with the same power and pulse energy settings. The two technologies also resulted in similar ablation volumes when they were operated with the same power and the HPH Moses technology was used in close mode with a very low pulse energy and very high frequency.

At each laser’s best capabilities for dusting settings that used the lowest pulse energy and highest frequency (HPH: 0.2 J and 80 Hz; SPTF: 0.05 J and 900 Hz), the ablation volume was almost threefold greater for the SPTF laser than for the HPH Moses technology laser. At stone distances of 0 mm and 1 mm, mean ablation volume was 1.28 mm² and 0.68 mm², respectively, for the SPTF laser; 0.42 mm² and 0.21 mm², respectively, for the HPH laser in close mode; and 0.48 mm² and 0.29 mm², respectively, for the HPH laser in distance mode.

In Brief
For up-to-date news, visit urologytimes.com

DR. DJORDJEVIC JOINS CENTER FOR TRANSGENDER MEDICINE AND SURGERY
Miroslav Djordjevic, MD, PhD, an internationally renowned surgeon and a world authority on surgery for transgender individuals, has joined the Mount Sinai Health System as a urogenital reconstructive surgeon at Mount Sinai’s Center for Transgender Medicine and Surgery and a professor of urology at the Icahn School of Medicine at Mount Sinai, New York.

He is one of the few urologists in the world whose scope of expertise encompasses treatment of all anomalies of the genital system regardless of sex or age, according to Mount Sinai.
INCONTINENCE / Significant quality of life improvements seen

Second-generation male sling beneficial at 5-year follow-up

Dave Levitan / UT Correspondent

CHICAGO—The second-generation AdVance XP male sling system offered good mid-term results for the treatment of post-radical prostatectomy male stress urinary incontinence (SUI), researchers reported at the AUA annual meeting in Chicago.

“Many studies have shown that the AdVance sling is effective and safe in the treatment of post-prostatectomy incontinence,” said first author Jan-Niclas Mumm, a urology intern at Ludwig-Maximilians University Munich in Germany. The AdVance XP, which has been used in Europe for several years and recently became available in the United States, features longer arms and a new anchoring mechanism, as well as a reshaped introducer needle, which Mumm said improves its ease of use.

“The AdVance XP Sling shows good and stable effectiveness and low complication rates, even in a follow-up of 5 years.”

JAN-NICLAS MUMM

The new study was a prospective trial including 115 patients; those with previous urinary incontinence surgery, previous radiotherapy, nocturnal urinary incontinence, and a functional urethra <1 cm in the preoperative repositioning test were excluded from the study. The authors used a strict definition of success for the device: A patient was considered cured if he used no pads and had 0 to <1 cm urine loss at baseline. All other results were considered failures.

The median age in the trial was 69.0 years. Most men had undergone an open radical prostatectomy (75%), with fewer numbers undergoing robotic radical prostatectomy (14%) or a laparoscopic radical prostatectomy (11%). There was an average time between surgery and sling implantation of 29 months, and the mean urine loss at baseline was 341 g (median, 272.0 g) on the 24-hour pad test.

61.1% of patients cured at 5 years

Among the 102 patients evaluable at 24 months, 66.7% were cured, 26.5% were improved, and 6.9% failed. At 48 months, among 60 patients, the cured, improved, and failure rates were 71.7%, 15.0%, and 13.3%, respectively. At the 5-year follow-up, 61.1% were cured, 19.4% were improved, and 19.4% failed. The mean urine loss was reduced substantially, to 24.4 grams (p<0.001).

There were no intraoperative or long-term complications in the trial, and there was no erosion or explantation. There were six patients (5.2%) with persistent urinary retention, and dissection of one sling arm was necessary. The investigators slightly altered their surgical approach in response, and later in the trial no such cases occurred.

“The AdVance XP sling shows good and stable effectiveness and low complication rates, even in a follow-up of 5 years,” Mumm said. “Also, our results highlight the importance of adequate preoperative patient selection.”

The study also assessed patients using the International Quality of Life Score (IQOL), the International Consultation on Incontinence Questionnaire short form (ICIQ-UI SF), the visual analogue scale (VAS) for pain, the five-item version of the International Index of Erectile Function (IIEF-5), the International Prostate Symptom Score (IPSS), and the Patient Global Impression of Improvement (PGI-I).

The mean I-QOL and ICIQ-UI SF scores improved significantly with the Advance XP (p<0.001 for both) after 5 years of follow-up. The mean VAS was 0.5, suggesting very little pain, and the mean PGI of 1.5 denotes a high satisfaction rate. There were no significant postoperative changes to the IIEF-5 or to the IPSS (p>0.05 for both).

Peyronie’s device improves length, curvature

Penile traction therapy yields benefits with 30-90 minutes of daily use

John Schieszer
UT Correspondent

Researchers at the Mayo Clinic report that they have developed a legitimate penile traction therapy (PTT) device for men with Peyronie’s disease (PD) that may work when used for just 30 to 90 minutes daily.

Investigators looked at the device (RestoreX) in a recent study, and preliminary findings suggest using it for 30 to 90 minutes daily may result in statistically significant improvements in penile length and curvature after 3 months with no significant adverse events.

“We were a bit surprised by the findings. Up until this study and the creation of this device, no traction device had shown efficacy when used for less than 3 hours a day, with many studies requiring 6 to 8 hours daily. Even then, the studies often showed very minimal or mixed results,” said study investigator Landon Trost, MD, a urologist at Mayo Clinic, Rochester, MN.

Dr. Trost and his colleagues assessed the safety and efficacy of the RestoreX PTT device in 120 men with PD, who were randomized to one of four groupings (RestoreX for 30 minutes once per day, RestoreX for 30 minutes twice per day, RestoreX for 30 minutes three times per day, or a control group). All the men were treated for 3 months and

See PD DEVICE page 6
The authors found that PTT significantly improved penile length (+1.4 cm [+9.9%] vs. +0.3 cm [2.1%], \(p<0.01\)) and helped with primary penile curvature (~9 degrees [-18.9%] vs. ~1.0 degrees [-2.4%], \(p<0.01\)) versus controls after 3 months of treatment. There were also significant improvements in the psychological/physical domain of the questionnaires for the treatment arms (PTT ~2.6 vs. ~0.5, \(p<0.01\)). Significant improvements were seen in the ability to penetrate compared to baseline, with 38% reporting restored ability to penetrate versus 0% in the controls (\(p<0.01\)). The authors also found that 19% of the PTT-treated men were able to eliminate their need for surgery.

Dr. Trost said in his practice he had not seen clinical improvements using previously existing devices, and it was nearly impossible to get men to use the older devices for 3 hours or more daily. “Although we had expected to see modest improvements in length and curve, we were surprised by the percentage of men achieving a successful result; 94% and 77% experienced length and curvature improvements, respectively. The most surprising finding of the study, though, was that it appeared to improve erectile function by a clinically meaningful amount,” Dr. Trost told Urology Times.

The study, which was presented at the AUA annual meeting in Chicago, included 117 men. The authors had 3-month data available on 85 patients (66 patients in PTT arms and 19 controls). The mean age of the men was 58.4 years, and the mean duration of PD was 45 months. The mean primary curvature was 45.7 degrees and mean stretched penile to coronal length was 11.5 (1.4) cm, which was non-significant between PTT patients and controls.

“We really wanted to know if this therapy truly worked or not. We have no tolerance for introducing another ‘snake oil’ into the men’s health arena,” said Dr. Trost.

Several roles for device
He said there are a few roles for the device. It could be used as a stand-alone therapy for PD to improve length and curvature, as an additive therapy with collagenase clostridium histolyticum (XIAFLEX) to significantly enhance curvature outcomes and increase length, or to restore length in men who have lost length due to medical conditions such as diabetes or have undergone a prostatectomy.

“Given its cost-effectiveness compared to other treatments and minimal side-effect profile, it would make sense as a first-line therapy. I think it’s too early to know if it has a role in improving erectile function or if it makes sense to use in other scenarios, such as pre-prosthesis prosthesis for example,” Dr. Trost said.

He said the benefit of penile traction therapy in general is that it is very safe, with only minor transient side effects. The downside is that it takes time to see improvements, particularly with curvature.

Edward Cherullo, MD, a urologist at Rush University Medical Center, Chicago, said with many of these patients, the management of scar tissue is the major issue.

“I think it has some utility in the properly selected patients,” Dr. Cherullo told Urology Times. “I think it is promising. It is not surgical or a pharmacological approach. The surgery and injections are not without risks,” said Dr. Cherullo, who was not involved with the study.

The technology behind the aforementioned device was developed by Dr. Trost in cooperation with Mayo Clinic Ventures. To mitigate potential conflicts, Dr. Trost elected not to invest in the licensing company in order to be able to perform research studies evaluating its efficacy.
Novel US ablation therapy shows significant PSA effect

Richard R. Kerr
Content Channel Director

CHICAGO—A pivotal phase II trial of a novel MRI-guided ultrasound ablation treatment exceeded its primary efficacy endpoint of PSA decline in men with organ-confined prostate cancer.

In the prospective, open-label study of MRI-guided transurethral ultrasound whole-gland ablation (TULSA-PRO), 96% of men had a PSA decrease of at least 75% at 1 year. Approximately 80% of the men who entered the study with Gleason grade group 2 (Gleason score 7) prostate cancer no longer had evidence of Gleason grade group 2 disease at 1 year. Nearly two-thirds of men had a complete histologic response based on biopsy, principal investigator Scott Eggener, MD, reported at the AUA annual meeting in Chicago.

Rates of severe treatment-related toxicity were low, said Dr. Eggener, director of the Prostate Cancer Program at the University of Chicago.

The phase II study, conducted at 13 centers in the United States, Canada, and Europe, included 115 men with a median age of 65 years. Median pre-treatment PSA was 6.3 ng/mL and maximum PSA was 15.0 ng/mL. All men had Gleason grade group 2 or lower prostate cancer. Two-thirds of study participants had intermediate-risk disease, and the remainder had low-risk disease. More than 80% of men had Gleason grade group 2 or high-volume Gleason grade 1 cancer, which is generally considered to be clinically meaningful disease, Dr. Eggener noted.

The intent of treatment was whole-gland ablation with sparing of the urethra and urinary sphincter. The procedure is performed entirely within the MRI suite under general anesthesia to eliminate motion. An ultrasound device, placed transurethrally under MRI guidance, continuously rotates and robotically delivers ultrasound waves peripherally to a predetermined contour around the prostate. Colorimetric feedback indicates when the target temperature of approximately 57 degrees Celsius is reached.

Following treatment, an MRI is provided to confirm the ablation margin. A suprapubic tube is placed for 2 weeks.

The procedure is capable of treating all sizes of prostates, Dr. Eggener said. It is not a form of high-intensity focused ultrasound, which is performed transrectally and has a different mechanism of applying ultrasound energy, he pointed out.

**Primary endpoint met**

In the current study, the primary endpoint of PSA reduction ≥75% was achieved in 110 of 115 men (96%). The FDA-approved protocol’s pre-established definition of success was a PSA decrease of ≥75% in 50% of patients.

“The trial] oversaw the PSA-based primary endpoint of what was considered success or failure,” Dr. Eggener said.

The median reduction in PSA was 95%.

“Impressively, the median PSA nadir was 0.34 ng/mL. There was dramatic gland reduction,” Dr. Eggener said, with the pre-treatment median perfused prostate volume of 41 cc declining to 4 cc at 1 year following treatment—a 90% decrease.

In terms of safety, nine of 115 men (8%) experienced a grade 3 adverse event, with infection (4%) being the most common. One case each of urinary retention, urinoma, ileus, deep-vein thrombosis, urethral stricture, and urethral calculus was reported.

Of 112 patients on whom continence data were available at 1 year, 1% were incontinent (more than one pad per day). At 1 year, 3.8% of men had a new increase in their daily leakage of urine.

At 1 year, 20% of men had grade 2 erectile dysfunction, and 69 of 92 (75%) who were potent prior to treatment were potent at 1 year.

**TABLE**

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<thead>
<tr>
<th>Endpoint</th>
<th>Result</th>
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<tr>
<td>PSA reduction ≥75%</td>
<td>Achieved in 96% of patients</td>
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<tr>
<td>Median PSA reduction</td>
<td>95%</td>
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<tr>
<td>Median PSA nadir</td>
<td>0.34 ng/mL</td>
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<tr>
<td>MRI median perfused prostate volume decrease</td>
<td>From 41 to 4 cc (90%)</td>
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Source: Scott Eggener, MD

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**Clinical Updates**

**TECHNOLOGY FOCUS**

**PROSTATE CANCER / PSA drops >75% in 96% of men at 1 year**

**See US ABLATION page 8**
Race does not affect docetaxel/prednisone response

PSA/objective responses similar among cohorts, researchers report

Cheryl Guttman Krader
UT Contributing Editor

CHICAGO—Race does not affect oncologic response to treatment with docetaxel (Taxotere)/prednisone in men with metastatic castrate-resistant prostate cancer (mCRPC), according to research presented at the American Society of Clinical Oncology annual meeting in Chicago.

Results of the study that included data from patients enrolled in nine phase III randomized clinical trials showed that the likelihood of achieving either a PSA response or an objective response was similar among African-Americans and Asians compared with their Caucasian counterparts.

“Data reported from the National Cancer Institute (NCI) show that the mortality rate from prostate cancer is higher among African-Americans and Asians compared with their Caucasian counterparts. However, the NCI National Clinical Trials Network studies were reasonably successful in enrolling black men and Asian patients,” said Dr. Kelly.

“Understanding possible differences in treatment response among Asian men is an important issue because Asians represent a growing segment of the population and considering evidence showing differences in drug metabolism in Asians versus whites,” he told Urology Times.

The analysis for PSA response included 7,375 evaluable patients and identified men who achieved a ≥50% PSA decline from baseline defined by the PSA Working Group 2. It found that the proportion of patients who achieved the PSA endpoint was similar across the African-American, Asian, and Caucasian racial groups (58%, 62%, and 64%, respectively).

Race not independent predictor of PSA response

Results of a logistic regression analysis adjusting for established prognostic variables (treatment arm, performance status, age, PSA, hemoglobin, alkaline phosphatase, and site of metastases) found that race did not independently predict PSA response.

Objective response was defined as complete or partial response, and was analyzed for 2,760 evaluable men. The results showed that similar proportions of African-Americans, Asians, and Caucasians achieved an objective response (31%, 34%, and 39%, respectively). The logistic regression analysis found that race was not independently associated with objective response.

The research was supported by the U.S. Department of Defense. Dr. Kelly has received honoraria from Constellation Pharma and Janssen Oncology; has served as a consultant/adviser to Foundation Medicine and Sanofi; has received institutional research funding from Bayer, Endocyte, Exelixis, Janssen Oncology, Novartis, Sanofi, and Seattle Genetics; and has received travel, accommodations, and expenses from Janssen Oncology. For full disclosures, see bit.ly/5021disclosures.

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US ABLATION
continued from page 7

or to treatment maintained erections suitable for penetrative intercourse.

Among 68 men with pre-treatment intermediate-risk Gleason grade group 2 disease, 54 (79%) were free of Gleason grade group 2 disease on 1-year biopsy. Complete histologic response was seen in 72 off 111 patients (65%). Of 39 positive biopsies, 16 (41%) were clinically insignificant.

On multivariate analysis, three factors predicted the likelihood of ongoing presence of Gleason grade group 2 disease: presence of intraprostatic calcifications at screening, MRI thermal coverage of target volume, and PIRADS ≥3 lesion at 1-year post-treatment MRI (p<.05).

With the caveat that TULSA-PRO remains investigational, Dr. Eggener was asked which prostate cancer patient he would consider an ideal candidate if the treatment was granted regulatory approval.

“I would argue that it’s a guy who’s otherwise healthy, has Gleason 7 cancer, and understands the pros and cons of this approach,” he said. “Similar to other management options, it is not the ‘holy grail’; however, this could potentially be a nice addition to the menu of options for a guy that needs treatment, a menu that is getting larger and larger. Considerably more follow-up, trials, and data are required to better understand the long-term implications of this novel treatment modality.”

Profound Medical, the maker of the TULSA-PRO device, announced in May 2019 that its 510(k) application for premarket clearance cleared the FDA’s acceptance review. Follow-up will continue for 5 years.

Dr. Eggener is a paid consultant to Profound Medical.
Prostate cancer imaging agent detects regional/distant metastases

Sensitivity, positive predictive value ‘excellent’ regardless of metastasis site

Cheryl Guttman Krader
UT Contributing Editor

CHICAGO—¹⁸F-DCFPyL PET/CT imaging demonstrated excellent performance in identifying regional or distant metastases in men with prostate cancer in the prospective OSPREY study.

In an analysis that included data for 93 men who underwent image-guided biopsy for suspected locoregional recurrence of their cancer or distant metastasis, ¹⁸F-DCFPyL positron emission tomography/computed tomography imaging had an overall sensitivity of 96% and an overall positive predictive value (PPV) of 82%. The sensitivity and PPV remained excellent regardless of the site of metastasis, and the imaging agent was safe and well-tolerated, reported Michael J. Morris, MD, at the American Society of Clinical Oncology annual meeting in Chicago.

“Current imaging methods perform poorly in accurately detecting locoregional or metastatic prostate cancer. The OSPREY study is designed to provide evidence in support of credentialing the tracer for FDA approval of ¹⁸F-DCFPyL PET/CT imaging for prostate cancer in the United States,” said Dr. Morris, OSPREY scientific committee chair and clinical director of the Genitourinary Medical Oncology Service at Memorial Sloan Kettering Cancer Center, New York.

“PET/CT scan fused image (coronal view) is from a 68-year-old man with high-risk prostate cancer (Gleason grade 9 [4 + 5]) and a PSA level of 4.6 ng/mL prior to planned radical prostatectomy and pelvic lymph node dissection with no adverse events following ¹⁸F-DCFPyL administration. (Image courtesy of Progenics Pharmaceuticals)

“The results from the cohort of men with suspected recurrent or metastatic disease indicate that a positive scan is highly likely to represent pathologically proven distant disease. The findings support the potential of ¹⁸F-DCFPyL as a PET imaging agent to favorably influence treatment planning.”

¹⁸F-DCFPyL is a small molecule radiopharmaceutical PET imaging agent targeting prostate-specific membrane antigen (PSMA), a dimerized type II transmembrane glycoprotein that is mainly expressed extracellularly in primary and metastatic prostate cancer tissue. The radiopharmaceutical binds selectively to PSMA with high affinity, and it is associated with relatively low radiation exposure to all organs (<50 mGy).

The 93 men included in the OSPREY arm investigating ¹⁸F-DCFPyL PET/CT imaging for detecting local recurrence or metastases had evidence of disease outside the confines of prior treated site(s) or new or progressive metastatic disease demonstrated by CT/magnetic resonance imaging, ultrasound, or whole-body bone scan. They received a single intravenous injection of ¹⁸F-DCFPyL 9±1 mCi 1 to 2 hours prior to PET/CT imaging and then underwent image-guided biopsy of at least one amenable lesion.

The ¹⁸F-DCFPyL PET/CT imaging results were evaluated independently by three blinded, central readers, and the performance of the technique was analyzed using findings from pathology review of the biopsied tissue.

The 93 men included in the performance analysis had a median PSA of 11.3 ng/mL. Approximately three-fourths of the patients had undergone prostatectomy, almost two-thirds had received radiation, and two-thirds had received systemic therapy.

The sensitivity rates of ¹⁸F-DCFPyL PET/CT imaging for bone, lymph node, and visceral/tissue metastases were 97%, 97%, and 100%, respectively; the PPV values for the three sites of metastases were 82%, 81%, and 90%, respectively.

The performance of the imaging technique was also analyzed with men stratified into six groups according to PSA (<0.2, 0.2 to <1, 1 to <2, 2 to <5, 5 to ≤20, and >20 ng/mL). Results showed that the ¹⁸F-DCFPyL PET/CT scan maintained good performance in detecting disease in men with low PSA.

OSPREY included another cohort of patients who had high-risk prostate cancer at diagnosis. Previously reported outcomes evaluating the performance of ¹⁸F-DCFPyL PET/CT imaging for detecting pelvic lymph node metastases compared to surgical pathology showed that the technique had 40% sensitivity, 98% specificity, 87% PPV, and 83% negative predictive value.

The safety review, which included data for 385 men who received ¹⁸F-DCFPyL in OSPREY showed that 27 men (7%) experienced at least one treatment-related adverse event, the most frequent of which were dysgeusia (2.1%) and headache (2.1%). There were no serious adverse events judged related to ¹⁸F-DCFPyL injection.

Dr. Morris is an uncompensated consultant for Progenics, Astellas, Bayer, and Endocyte. He has received compensation as a consultant for Advanced Accelerator Applications, Blue Earth Diagnostics, Tokai, Tolmar, and Orci. For full disclosures, see bit.ly/ospreydisclosures.

COMPLICATIONS MORE LIKELY WITH SURGEONS REPORTED FOR UNPROFESSIONAL BEHAVIOR

Patients of surgeons with higher numbers of reports from co-workers regarding unprofessional behavior are significantly more likely to experience complications during or after their operations, researchers from Vanderbilt University Medical Center, Nashville, TN reported in JAMA Surgery [June 19, 2019] (Epub ahead of print).

The authors found that patients whose surgeons had one to three reports of unprofessional behavior were at 18% higher estimated risk of experiencing complications, and those whose surgeons had four or more reports were at nearly 32% higher estimated risk compared to patients whose surgeons had no reports.
Adding enzalutamide (XTANDI) to androgen deprivation therapy (ADT) significantly improves outcomes for men with metastatic hormone-sensitive prostate cancer (mHSPC) regardless of whether they received prior chemotherapy.

That new finding is from the phase III ARCHES (Androgen Receptor Inhibition with ChEmohormonal Therapy in Men with Metastatic Hormone-Sensitive Prostate Cancer) study, which was presented at the American Society of Clinical Oncology annual meeting in Chicago.

The research showed that men randomized to enzalutamide had a statistically significant improvement in radiographic progression-free survival (rPFS) compared with the placebo-treated control group whether or not they received prior docetaxel (Taxotere). Statistically significant between-group differences favoring the enzalutamide group versus placebo were also seen in the subgroups of patients with and without prior docetaxel in key secondary endpoint analyses, and the benefits of treatment with the androgen receptor-targeted therapy were achieved without any compromise in quality of life.

“The inclusion of men with prior docetaxel therapy in ARCHES is important considering that current NCCN guidelines recommend the use of docetaxel for men with high-volume mHSPC. The results from ARCHES provide the first evidence of efficacy of enzalutamide in this important high-volume/risk patient subgroup and also provide further support for considering enzalutamide plus ADT as a treatment option in men with lower volume/risk mHSPC,” said lead author Andrew J. Armstrong, MD, professor of medicine and associate professor of pharmacology and cancer biology at Duke Cancer Institute Center for Prostate and Urologic Cancers, Durham, NC.

“Overall survival data from ARCHES remain immature. So, now we are waiting for longer follow-up to determine whether triple therapy also leads to better survival versus double therapy with docetaxel and ADT. However, recently published data from the phase III ENZAMET trial (N Engl J Med June 2, 2019 [Epub ahead of print]) suggest that these improvements in these early endpoints will lead to an improvement in overall survival with further follow-up.”

Men were eligible for enrollment in the ARCHES study if they had mHSPC with metastasis confirmed by bone scan, computed tomography scan, or magnetic resonance imaging, and an ECOG performance status of 0 or 1. Enrolled patients were stratified prior to randomization based on disease volume (low or high) and history of prior docetaxel therapy (none, 1-5 cycles, or 6 cycles). Existing ADT had to have been started no more than 3 months earlier in patients who had not received docetaxel or no longer than 6 months earlier in men who had been on chemotherapy.

“In contrast to the ENZAMET trial conducted largely in Australia and New Zealand that investigated enzalutamide given concurrently with or without docetaxel as first-line therapy in metastatic prostate cancer, ARCHES is investi- gating enzalutamide as ‘maintenance therapy’ to prevent the development of castrate-resistant disease. ENZAMET established a survival advantage with the early use of enzalutamide, predominantly in men with metastatic disease who did not receive docetaxel,” Dr. Armstrong told Urology Times.

“Additional studies, longer follow-up of existing studies like ARCHES, ENZAMET, and TITAN, and new studies like PEACE are needed to understand whether combination or sequential approaches with androgen receptor-targeted therapies are preferred,” Dr. Armstrong added.

In ARCHES, a total of 1,150 patients were randomized 1:1 to enzalutamide 160 mg/day plus ADT or placebo plus ADT. The two study groups were well balanced at randomization. Median patient age was 70 years, approximately three-fourths of men had ECOG performance status 0, just over one-third of men had low-volume disease, 82% had not received prior docetaxel, and 91% of men were on ADT or had undergone orchiectomy.

Median follow-up at the time of the analysis was 14.4 months. At the cut-off, 76% of men randomized to enzalutamide and 58% of control group patients were still on treatment.

Progression risk reduced by 61% vs. placebo

The primary endpoint analysis for the overall study population showed that the addition of enzalutamide to ADT reduced the risk of radiographic progression or death by 61% compared with placebo (p<0.0001). The addition of enzalutamide to ADT in men with a history of prior docetaxel reduced the risk of radiographic progression or death by 47% (p=0.0077), and it had an even greater benefit among men who had no prior docetaxel in whom there was a 64% delay in progression or death (p<0.0001).

“The men who had not been given chemotherapy typically had low-volume disease, and perhaps their prostate cancer is more androgen receptor dependent,” Dr. Armstrong said.

Similarly, adding enzalutamide to ADT had a statistically significant benefit for improving rPFS regardless of previous use of ADT or orchiectomy.

The secondary endpoint analyses showed that in the overall population, treatment with enzalutamide had statistically significant benefits for delaying time to PSA progression (p<0.0001), time to initiation of new antineoplastic therapy (p<0.0001), time to first symptomatic skeletal event (p=0.0026), and time to castration resistance (p<0.0001).

In addition, a significantly greater proportion of men treated with enzalutamide compared with placebo achieved undetectable PSA (45.3% vs 17.6%) and an objective response (83.1% vs. 63.7%) (p<0.0001 for both comparisons). Analyses in the subgroups of patients with and without a history of docetaxel use showed that enzalutamide maintained its statistically significant benefit in all of the outcomes in both subgroups, with one exception. Although time to first symptomatic skeletal event was delayed in the enzalutamide-treated patients with prior docetaxel treatment, the effect was not statistically significant.

See ENZA PLUS ADT page 14
Clinical Updates

ENZA PLUS ADT

continued from page 13

Baseline QoL maintained over time

Quality of life was evaluated using the FACT-P questionnaire. Median total score at baseline was approximately 115 and it remained stable among men treated with enzalutamide in analyses of the overall population and regardless of prior docetaxel.

“The baseline quality of life of men enrolled in this study was high, and it was maintained over time in both treatment groups,” said Dr. Armstrong. “In addition, data collected with the Brief Pain Inventory-Short Form showed that low levels of pain were maintained throughout the study in both the overall population and prior docetaxel subgroups.”

The safety review showed that the incidence of grade 3-4 adverse events was nearly the same in the enzalutamide and placebo groups (24% and 25%, respectively). Known side effects of enzalutamide include fatigue, hot flushes, fracture risk, hypertension, and falls and were increased in the ARCHES trial.

<table>
<thead>
<tr>
<th>TABLE</th>
<th>OUTCOMES OF ENZALUTAMIDE + ADT IN MEN BY CHEMO STATUS</th>
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<tbody>
<tr>
<td>Reduced risk of radiographic progression or death</td>
<td>p value</td>
</tr>
<tr>
<td>Overall study population</td>
<td>81%</td>
</tr>
<tr>
<td>Men with history of prior docetaxel</td>
<td>47%</td>
</tr>
<tr>
<td>Men with no prior docetaxel</td>
<td>64%</td>
</tr>
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</table>

Source: Andrew J. Armstrong, MD

Dr. Armstrong receives honoraria from, is a consultant/adviser to, and/or receives travel expenses from Astellas, Pfizer, Janssen, and Bayer, and is on the speakers’ bureau for Dendreon, Bayer, and Sanofi. For full study disclosures, see bit.ly/ARCHESdisclosures19.

[LETTER]

WEALTH OF RESOURCES ADDRESS TRANSGENDER HEALTH

TO THE EDITOR:

I always enjoy reading articles Urology Times offers and had an opportunity to read about transgender education for urologists in the recent issue (“Speak Out: How are you educating yourself on transgender issues?” May 2019, page 33). I would like to offer some comments in that regard.

The AUA Office of Education has been offering and providing education and curriculum guidelines on the subject of transgender care to medical students, residents, and practicing urologists for over 3 years. The AUA has been providing a course on transgender medicine (“What a general urologist should know about gender-affirming surgery”) annually since 2017. In addition, there are webcasts as well as an AUA Update offering education on transgender health and gender-affirming surgery.

At the last AUA annual meeting in Chicago, there was an 8-hour/full-day session organized by Society of Genitourinary Reconstructive Surgeons (GURS) and a 2-hour didactic course offered by AUA on the topic of transgender care. In the last 3 years, the Society of Urodynamics, Female Pelvic Medicine & Urogential Reconstruction, Sexual Medicine Society of North America, GURS, and many regional societies like the AUA Western Section AUA have educated their members and conference attendees on a broad variety of topics in gender-affirming surgery and transgender health.

Terminology of transgender health care is well defined, and while the field is dynamic and rapidly evolving, the current and updated terminology can be easily accessed at World Professional Association for Transgender Health (www.wpath.org/publications/soc) or UCSF guidelines (https://transcare.ucsf.edu/guidelines). There are plenty of other reliable sources of information and one does not have to rely on “lay press” to get proper information. We don’t go to lay press to learn about prostate cancer treatment, do we? We attend national meetings and read articles in scientific journals.

A comment from the article, “What are the definitions? Where are the fine lines drawn between transgender versus transsexual versus homosexual and how much crossover is there?” surprised and upset many of us providing urologic care and gender-affirming surgery. Transgender and homosexual have no crossover, as gender identity and sexual orientation describe different aspect of a person. These terms are very clearly defined:

Gender identity: A person’s internal sense of self and how they fit into the world, from the perspective of gender.

Transgender: A person whose gender identity differs from the sex that was assigned at birth. May be abbreviated to trans. A transgender man is someone with a male gender identity and a female birth assigned sex; a transgender woman is someone with a female gender identity and a male birth assigned sex. A non-transgender person may be referred to as cisgender.

Sexual orientation: Describes sexual attraction only and is not directly related to gender identity. The sexual orientation of transgender people should be defined by the individual. It is often described based on the lived gender; a transgender woman attracted to other women would be a lesbian, and a transgender man attracted to other men would be a gay man.

And to the question, “Where do you put an XY female who is attracted to men?” ideally you put this person into a clinic room and ask about preferred pronouns (i.e how this person would like to be addressed) and what is their reason for seeing you in clinic today.

The comment, “What is the science behind transgender? I’ve found the evidence-based information is really lacking,” is simply baseless. Has the individual you interviewed looked? If one searches PubMed with “transgender,” 5,186 citations come up, and narrowing the search to “transgender surgery” gives 742 results. (For comparison, “vaginal mesh” generates 2,489 results.) So there is a very large body of scientific literature looking at many aspects of transgender care.

Transgender persons have been part of our world for a long time. Historical references go back to 900 BC. As a medical and surgical community, we have ostracized this population for a long time. We are now slowly gaining the trust of the transgender community (estimated 1.6 million in the U.S. by 2015 census) and systematically developing knowledge in transgender and gender non-binary health care.

We truly appreciate Urology Times looking into transgender education and surveying the general audience. I hope you will be able to give broader, scientifically sound, and up-to-date information to readers.

Polina Reyblat, MD / Los Angeles Medical Center/Kaiser Permanente
Renal mass biopsy safe, but when is it necessary?

Complication risk low, even with low platelets, elevated INR, or continued aspirin use

The risk of bleeding complications is probably the most concerning adverse event following renal mass biopsy, which is further amplified by the common use of anticoagulant and antiplatelet medications in the general population. According to a recent study conducted by Posielki et al, the risk of such complications following renal mass biopsy is quite low, even in the presence of low platelets, mildly elevated international normalized ratio (INR), or continued use of aspirin (J Urol 2019; 201:1080-7).

The study authors retrospectively analyzed 1,155 renal mass biopsies performed in 965 patients at a single institution from January 2000 to December 2017 to determine the diagnostic yield and complication rate. Non-diagnostic biopsy result was defined as all cases in which histologic diagnosis of cancer could not be made due to insufficient tissue, necrosis or fibrosis, or normal tissue. Their institutional guidelines allowed biopsy in patients with an INR of 2.0 or less or a low platelet count (25,000-160,000) or continued use of aspirin.

Mild coagulopathy (INR 1.2-2) was present in 5%, low platelet count (<160,000) was noted in 15%, and aspirin was continued in 38% of patients at the time of biopsy. A total of 745 patients (64.5%) were diagnosed with cancer. Presumably, the other 35% had either non-diagnostic biopsy or benign tumors. The authors do not report the incidence of benign tumors or the indications for biopsy of the larger tumors (4-7 cm).

Biopsy-related complications seen in 2.2%

Of the 965 patients who underwent renal mass biopsy, 24 patients (2.2%) were identified with biopsy-related complications within 30 days, including symptomatic hematoma (0.5%), gross hematuria (0.7%), pain requiring intravenous narcotics (0.3%), urinary tract infection (0.3%), and hypotension, pseudoneuropathy, and urinary retention in one patient each. Hospital readmission was required for 11 patients (1.0%), and major complications requiring a secondary procedure were identified in five patients (0.4%). Selective renal arterial embolization was needed in two patients and percutaneous abscess drainage was required in one patient. Two patients were admitted to intensive care for urosepsis. The complication rate for biopsy with three or more needle cores and one needle core was 3% and 1.3%, respectively, but it was statistically insignificant. The use of aspirin (38.1%), mild elevation of INR (4.9%), and somewhat low platelet count (<160,000 (15.2%) were not associated with increased risk of hemorrhagic complications. Of note, the dose of aspirin (81 mg or 325 mg), which has a definite impact on risk of bleeding, was not reported.

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The complication rates among the 12 radiologists—who each performed at least 50 biopsies—ranged from 0% to 3.6%, which was statistically insignificant.

However, there was a significant variation in the rate of non-diagnostic biopsies among these radiologists, especially for masses <4 cm, ranging from 8.5% to 27.5% (p=.02).

Overall, non-diagnostic biopsies were noted in 145 cases (14.6%). The non-diagnostic biopsy rate was highest for cystic versus solid lesions (40.8% vs. 10.6%, p<.001).

For lesions ≤2 cm in size, about 21% of the biopsies were non-diagnostic. Interestingly, in 80 patients who underwent repeat biopsy due to initial non-diagnostic biopsy, there was no increase in the cancer detection rate in the second biopsy and the non-diagnostic rate also did not change.

What’s missing from most renal Bx studies

The oft-stated reason to perform renal mass biopsy is to obtain actionable information that can potentially affect the clinical management (ie, surgery versus surveillance). Yet, most studies showing the safety and accuracy of renal mass biopsy do not give any details about which, if any, actions were modified by the biopsy results.

For small renal masses, should the default position be extirpation unless a clearly benign tumor is detected? Can the small renal masses not be observed without a biopsy? Should a mass with a non-diagnostic biopsy be viewed as being free of cancer and be placed under surveillance? Often, there are important patient-related factors (age, comorbidities, etc.) that supersede the biopsy results during the clinical decision-making process.

While the safety and feasibility of the renal mass biopsy procedure has been established, if or when to obtain the biopsy remains a topic for active discussion.
Impact of poor sleep quality on urologic disease

Recent evidence shows significant effect of impaired sleep on ED, low T, nocturia.

O
n average, humans spend one-third of their lives asleep. Sleep is a restorative physiologic state and is a vital factor in physical and mental health maintenance, memory consolidation, and immune defense enhancement (Ann N Y Acad Sci 2010; 1193:48–59). Although sleep quality is difficult to precisely evaluate, it is a widely used construct measured subjectively by validated questionnaires and objectively by polysomnography or actigraphy. Sleep duration is commonly used as a proxy for assessment of sleep health. Adults typically require 7 to 9 hours of sleep per night, but over 35% of adults report sleeping less than 7 hours per night, and nearly 30% sleep less than 6 hours (Sleep 2015; 38:829-32).

Poor sleep has been associated with a number of serious adverse health effects, including obesity, type 2 diabetes, cardiovascular disease, and mortality (Sleep 2010; 33:585–92). Recent evidence has further linked impaired sleep with urologic disease, notably erectile dysfunction (ED) and lower testosterone levels (table). Insomnia has repeatedly been associated with poor sleep quality, and evidence suggests this relationship is bidirectional.

Targeted counseling regarding sleep hygiene improvements may positively affect several urologic disorders while also facilitating a host of overall health benefits. Here we discuss the significant impact of sleep on men with urologic disease.

Sleep and erectile function

The link between ED and sleep disorders is well established. Numerous studies have reported an increased incidence of ED in men with obstructive sleep apnea (OSA) ranging from 47% to 80% (World J Mens Health Aug 14, 2018 [Epub ahead of print]). In a recent study, men working nonstandard shifts who reported poor sleep quality had higher rates of erectile dysfunction than men who subjectively slept better (Urology 2017; 102:121-5).

Both restless legs syndrome and periodic limb movements are associated with an increased prevalence of ED (World J Mens Health Aug 14, 2018 [Epub ahead of print]), although as with other sleep disorders the underlying relationship remains unclear. Given the high incidence of poor sleep in the overall population, increased attention has recently turned to the impact of poor sleep on erectile function in men without specific sleep disorders.

In a survey study, 377 men with a mean age of 46 years completed validated sleep and erectile function questionnaires and were queried about comorbidities, smoking status, shift work status, and caffeine and medication use (J Urol 2018; 199(4S):e560, abs. PD27-08; World J Urol Sept 17, 2018 [Epub ahead of print]).

Nocturia has repeatedly been associated with poor sleep quality, and evidence suggests this relationship is bidirectional.

Targeted counseling regarding sleep hygiene improvements may positively affect several urologic disorders while also facilitating a host of overall health benefits. Here we discuss the significant impact of sleep on men with urologic disease.

TABLE EFFECTS OF POOR SLEEP QUALITY ON UROLOGIC DISEASE

<table>
<thead>
<tr>
<th>Erectile dysfunction</th>
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<tbody>
<tr>
<td>• ED is associated with a number of sleep disorders, including obstructive sleep apnea, insomnia, restless legs syndrome, and shift work disorder</td>
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<tr>
<td>• Recent evidence shows poor sleep quality is independently associated with ED, indicating importance of sleep even in healthy men</td>
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<tr>
<th>Low testosterone</th>
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<tr>
<td>• Impaired sleep associated with lower serum testosterone levels (decrease of 5.85 ng/dL in serum T for each hour of sleep lost)</td>
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<tr>
<th>Nocturia</th>
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<tr>
<td>• Nocturia is a known independent predictor of sleep disturbance</td>
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<tr>
<td>• Relationship between nocturia and sleep disruption may be bidirectional</td>
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<tr>
<td>• Sleep apnea identified as potentially causing some cases of incident nocturia</td>
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<table>
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<tr>
<th>Non-urologic conditions</th>
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<tbody>
<tr>
<td>• Poor sleep associated with obesity, type 2 diabetes, cardiovascular disease, mortality</td>
</tr>
<tr>
<td>• Some conditions, such as diabetes and cardiovascular disease, can also be contributing factors in urologic symptoms</td>
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Source: Hudson Pierce and Bilal Chughtai, MD
Let’s Talk Men’s Health

Sleep and testosterone levels
Numerous studies in humans and animals have reported an association between impaired sleep and lower serum testosterone levels (J Urol 2018; 199[4S]:e560, abs. PD27-08). Low testosterone has been associated with a number of adverse health effects, including decreased libido, depressed mood, sexual dysfunction, and poor concentration (J Clin Endocrinol Metab 2006; 91:4335–43).

In a recent study, serum testosterone levels in 9,756 men aged 16-80 years were analyzed utilizing a multivariable regression model controlling for comorbidities and baseline demographics (World J Urol Sept 17, 2018 [Epub ahead of print]). The authors found an association between lower serum testosterone levels and impaired sleep, showing a decrease of 5.85 ng/dL in serum testosterone for each hour of sleep lost (World J Urol Sept 17, 2018 [Epub ahead of print]). Although it is unlikely that a decrease of 5.85 ng/dL in testosterone levels per hour of sleep lost will dramatically affect overall health, sleep improvement should still be an important part of the treatment algorithm to maintain or increase testosterone levels.

Sleep and nocturia
Nocturia is a widely prevalent condition that increases with age. Nocturia is associated with lower quality of life and has been associated with a number of comorbidities, including falls and fractures, diabetes, obesity, coronary artery disease, depression, and increased risk of all-cause mortality (Nat Rev Urol 2016; 13:573–83). Although numerous studies have identified nocturia as an independent predictor of sleep disturbance (J Urol 2011; 185:2223–8), there is evidence suggesting that the relationship between nocturia and sleep disruption is not necessarily unidirectional. It is generally supposed that nocturia causes patients to awaken, but studies have suggested that poor sleep itself results in patients waking up and realizing they need to urinate.

On one hand, successful treatment of nocturia and overall lower urinary tract symptoms (LUTS) has been shown to lead to improvement in sleep quality, while another study reported that poor sleep quality was associated with incident LUTS, including nocturia alone (J Urol 2011; 185:2223–8; J Urol 2012; 188:2288–93). Sleep apnea in particular has been identified as potentially playing a causal role in some cases of incident nocturia, but even healthy adults may suffer from sleep disturbance that causes them to awaken and then void.

A broader consideration is the potential multidirectional association among sleep, urologic symptoms, and non-urologic disease. Conditions known to be negatively affected by poor sleep quality, such as diabetes and cardiovascular disease, have also been identified as contributing factors in urologic symptoms (Eur Urol 2007; 52:407–15). Ultimately, assessment of sleep should be considered an essential aspect of care for patients with urologic disease, which includes providing counseling and appropriate referrals for sleep evaluations.

Conclusion
As leaders in men’s health, urologists can offer appropriate initial counseling on improving sleep hygiene. This includes practices such as routine exercise, avoiding stimulant use such as caffeine or nicotine before bedtime, following a regular bedtime routine, exposure to natural light during the day, and ensuring a good sleep environment (Sleep Med Rev 2015; 22:23–36). Good sleep hygiene can have a significant positive impact on health, both globally and urologically.

Feel the difference.
Make softness a priority for your patients.
Percutaneous access: Principles and best practices

One of the key elements of successful percutaneous nephrolithotomy (PCNL) surgery is obtaining percutaneous access. In this interview, Bodo Knudsen, MD, outlines his step-by-process for obtaining access, discusses the ways he reduces radiation exposure during PCNL, and gives his thoughts on how clinicians can gain proficiency with percutaneous access.

Q: Please discuss the principles of percutaneous access.
A: At The Ohio State University, we do a lot of PCNL procedures and have gone through a series of evolutions over the years. The basic principle is to have precise, clean access into the kidney that permits easy access to the stone(s) and minimizes bleeding. The goal is to enable the clinician to do the case safely and effectively.

When we approach any stone patient, we always study the stone, the kidney, and the anatomy, and create a plan—usually heavily based on the CT scan—of where we’re going to go into the kidney and how we envision that operation going.

In the past, it was pretty straightforward; we did all our access antegrade prone with split-leg spreader bars. Over the years, that has evolved. Our access was always 30F in the past and now, with new options for tract sizes, we rarely utilize 30F PCNL tracts but rather favor smaller tract sizes. It is important to limit the number of punctures into the kidney to reduce the risk of bleeding and other complications, so we always try to make the first puncture as accurately as possible. If you can get it on the first shot that’s generally going to be your best opportunity. Once you have the puncture in the right spot then it is a matter of simply dilating the tract and removing the stone. With a good puncture, usually the rest of the case is fairly straightforward.

Q: Take us step by step through obtaining percutaneous access on a procedure, beginning with looking at the CT scan.
A: When we see a patient and make the decision to proceed with a PCNL, we’ll look at the imaging. Is the stone in the upper pole? Is it in the lower pole? Is it in the pelvis? Are there multiple stones? Some surgeons prefer to go in a certain location for all cases, such as the upper pole.

This is not our approach. Our approach is to pick the best calyx to get to the target. If lower pole is going to give us the best shot for a lower pole stone, that’s where we’ll go. If upper pole is better, then that is where we will go provided the CT does not show any other anatomic problems with an upper pole approach.

You have to look at the pleura and you have to look at the spleen and liver and make sure that they’re not going to be in a problem with your choice of tract location. That’s where getting the CT scan is very valuable.

What are the pitfalls and complications of percutaneous access?

Surgeons do worry about complications from PCNL, and when you look at some of the most devastating complications, bleeding is right at the top of the list.

Bodo Knudsen, MD

Once we pick the location of the tract, the other thing we think about is the size of the tract. That is really a function of the stone. If it’s a smaller stone—1.5 to 2 cm in size—we’re probably going to do a mini on that patient. If it’s a single stone, we’re going to lean toward a mini, even if it’s a little bit bigger. If there are multiple stones scattered through the kidney or if it’s a very large stone or branching stone, then we’re probably going to do a larger tract. But for us now, a large tract is 24F rather than 30F.

Q: Please discuss radiation exposure with regard to PCNL.
A: That’s something we’ve been very concerned about, not only for our patients but also for the surgeon and the staff in the operating room who are there every day doing multiple cases. We actually recently published a paper on reducing radiation during PCNL by looking at certain steps of the procedure and the ways we can reduce it (J Endourol 2019; 33:369-74).

There are a lot of simple things that can be done to reduce the amount of radiation. Number one is just being aware of radiation: alerting the staff, alerting your residents, having a discussion with your x-ray technologist in the room. All of these are important. There are other simple steps to take: using a low dose mode on the C-arm, using pulse modes, coming-down and collimating the C-arm image, use last image hold, using spot rather than continuous imaging, and employing a foot pedal will all reduce the amount of radiation exposure. We have been able to reduce fluoroscopy use to under a minute in many cases by employing these simple steps.

There’s no question that incorporating ultrasound can bring down your radiation as well. There are some barriers to learning ultrasound; it depends on your comfort level with it and also on your patient population as obesity can increase the challenge of ultrasound. However, it is now something that we are currently employing during all our PCNL procedures. We will visualize the kidney and determine if we are comfortable proceeding with an ultrasound guided puncture. We still have the C-arm on hand and often use it to check things if we are not certain with ultrasound alone. This “hybrid” approach is a great way to become more comfortable with ultrasound.

Q: What are the pitfalls and complications of percutaneous access?
A: Surgeons do worry about complications from PCNL, and when you look at some of the most devastating complications, bleeding is right at the top of the list. The more sticks you have into the kidney with a needle, the more opportunity there is for bleeding. By
being competent at gaining access effectively, you can reduce that risk. Remember to always try and make the first puncture as accurately as possible.

Q: How would you counsel the patient on their risks before a given procedure?
A: I walk every patient through the surgery. I explain that we are going to create the tract at the time of the operation and that I need to get up into the kidney through a tract to do the operation. I would say we are 99% successful at getting access.

I don’t spend a lot of time telling them that I don’t expect to be successful unless there is some complicating factor such as an altered anatomy, but in a normal, routine patient, access usually isn’t the problem. I quote them about a 1% risk of major bleeding requiring transfusion and possible embolization, and that’s been our consistent experience over many years at our center. I tell them we are not planning to transfuse them; we are not going to group and match them for blood. We don’t do that routinely. I do counsel them on the risks of delayed bleeding when they go home and that if they do have bleeding, they need to come back and alert me.

Q: What type of drainage do you use post-stone removal?
A: It depends, but we have moved away from nephrostomy tubes for the most part. We will only use nephrostomy tubes if we believe we need to go back in percutaneously, such as for a planned second-look nephroscopy or a staged procedure, on that patient. If the patient absolutely does not want a stent under any circumstances, then we might also leave a nephrostomy tube after the procedure.

We’ll leave stents in the majority of patients, but we’ll often leave them on a string exiting via the urethra and take them out the next morning. A lot of times, we’re stenting just overnight and monitoring for bleeding and/or fevers. If the patient is stable in the morning, the stent comes out before discharge. If there are issues, then we simply leave the stent in longer. With mini-PCNL procedures, and occasionally 24F procedures, we will do them totally tubeless with no stent at times, usually when there is very little bleeding and no edema around the ureteropelvic junction.

Q: Do you put the stent in in the prone split-leg position?
A: You certainly can, both antegrade or retrograde. We did this for many years. However, we have now moved to doing about 80% of our PCNLs in the supine position. Supine also facilitates both antegrade or retrograde stent placement. When we place them retrograde, we watch the coil in the kidney deploy with the nephroscope, thereby reducing the use of fluoroscopy.

Q: As you know, a minority of urologists do percutaneous stone removal. Do you think you need a fellowship to do this?
A: You don’t need a fellowship, but there are a couple of important things that need to happen. One is you must get the training in your residency if you’re not going to do it in a fellowship. There are a lot of residencies where the residents come quite competent to do their access. At Ohio State, our residents graduate being able to do access and this is certainly the case for other programs as well.

Then, you need that critical volume of cases once you start. That’s been a little bit of a barrier for some individuals where they didn’t have the volume when they started their practices. In this situation, you can lose your skills and/or confidence pretty quickly and then give up doing the procedure altogether. I suspect this happens a lot.

Do you believe that urologists should do all access?
STEPHEN Y. NAKADA, MD

If you aren’t doing the access yourself, then working with someone who understands the surgery and the goals of the operation is very important.

Q: How many cases do you think you need to do to be trained, and then how many cases per year do you need to do to keep up?
A: There have been a few studies that have looked at learning curves, but I would say 20 to 30 cases in a 1-year period to be trained. You’re going to need probably about 20 cases a year to maintain skills in the future. That being said, learning is a lifelong endeavor; even today after more than a thousand procedures, I feel there is always something new to learn, to optimize, and to make the procedure better. This is why performing PCNLs is such a rewarding experience.

Q: Do you believe that urologists should do all access?
A: There are different models that work. The key is, if you aren’t doing the access yourself, then working with someone who understands the surgery and the goals of the operation is very important. If you and your radiologist work together and plan the tract together, that’s a perfectly fine and very reasonable approach. Certainly, the model of having a radiologist that you work with closely can be very successful and may help you through that learning curve too.

Q: How would you recommend that someone learn PCNL access and PCNL if they’re already done with their training?
A: There are some good training courses now. The AUA sponsors a pretty robust training course on percutaneous access that’s run multiple times a year. There are centers that do a lot of PCNLs where you can gain that expertise from a visit. We are always open to having visitors at OSU to see procedures. For residents who are interested in endourology, there are many very good fellowship programs including our program at OSU. Once in practice, having a surgeon with you in the OR who is an expert in access look over your shoulder for a few cases may also be beneficial. You can also partner with somebody at your own institution if you have a colleague who has some expertise with this.
Working with a co-surgeon: How should procedures be billed?

Be sure your documentation supports use of multiple surgeons.

Q: I plan to work with a friend of mine in an unaffiliated urology group to perform a cystoprostatectomy, ileal loop, and lymph node dissection. How should I code for the following two scenarios? First, if I perform the prostatectomy and charge for the prostatectomy and then assist on the rest of the surgery; and second, if I perform the lymph node dissection and then assist on the rest of the surgery.

A: The codes available to report the primary procedure of cystectomy, 51590 (Cystectomy, complete, with ureterointestinal conduit or sigmoid bladder, including intestine anastomosis) and 51595 (Cystectomy, complete, with ureterointestinal conduit or sigmoid bladder, including intestine anastomosis; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes), include by description cystectomy and loop. As one can see from the description, the primary procedure can be reported with or without nodes.

When we check the National Correct Coding Initiative bundling edits, prostatectomy codes 55840 (Prostatectomy, retropubic radical, with or without nerve sparing) and 55845 (Prostatectomy, retropubic radical, with or without nerve sparing; with bilateral pelvic lymphadenectomy, including external iliac, hypogastric, and obturator nodes) are not included in either 51590 or 51595 and can therefore be reported separately. However, lymphadenectomy can only be reported once, so code combination is important. Based on the scenarios you have provided, we see two potential coding options.

It should be noted that payer policies and payment for assistant at surgery will vary if you are paid as primary surgeon during the same encounter.

For scenario 1, in which you perform the prostatectomy and assist on the remainder of the surgery, Surgeon 1 would bill 51595 and 55840–80 or –82. You would bill 55840 and 51595–80 or –82 as appropriate. Modifier –80 specifies an “Assistant Surgeon.” According to CPT, surgical assistant services may be identified by adding modifier –80 to the usual procedure number(s). Modifier –82 specifies an “Assistant Surgeon” (when qualified resident surgeon not available). The unavailability of a qualified resident surgeon is a prerequisite for use of modifier –82 appended to the usual procedure code number(s) as appropriate.

It should be noted that payer policies and payment for assistant at surgery will vary if you are paid as primary surgeon during the same encounter. Also, you should consider that payment may allow the payer to review records to determine if the reason you are split-billing the procedure is appropriate clinically or is being provided simply for financial gain. As always, documentation should be clear on what is performed and should include medical support for the use of two surgeons as well as the appropriate diagnosis.

For the second scenario that you have listed in which you perform the lymphadenectomy and assist on the rest of the procedure, Medicare does not have a great option but private payers may.

For private payers, follow CPT definitions and use 51595 and 55840 and apply modifier –62 to 51595 and 55840–80 (or –82) (“Two Surgeons”). Per CPT, when two surgeons work together as primary surgeons performing distinct part(s) of a procedure, each surgeon should report his/her distinct operative work by adding modifier –62 to the procedure code and any associated add-on code(s) for that procedure as long as both surgeons continue to work together as primary surgeons. Each surgeon should report the co-surgery once using the same procedure code. If additional procedure(s), including add-on procedure(s), are performed during the same surgical session, separate code(s) may also be reported with modifier –62 added.

For all claims, Medicare requires that the two surgeons working together as primary surgeons be of different specialties. As you are both urologists, use of –62 would not be allowed when reporting the service to Medicare. As such, coding for Medicare should be 51595 and 55840 for the other urologist and 51595–80 and 55840–80 (–82 if you are in a teaching facility and a qualified resident).
HHS program collects data on malpractice, adverse actions

NPDB: Failure to diagnose is most common allegation resulting in med mal payment

TABLE 1 TOP ALLEGATIONS AGAINST MDs AND DOs BY PAYMENT YEAR

<table>
<thead>
<tr>
<th>Allegation</th>
<th>2014</th>
<th>2015</th>
<th>2016</th>
<th>2017</th>
<th>2018</th>
</tr>
</thead>
<tbody>
<tr>
<td>Failure to diagnose</td>
<td>1,837</td>
<td>1,788</td>
<td>1,793</td>
<td>1,752</td>
<td>1,742</td>
</tr>
<tr>
<td>Improper performance</td>
<td>1,660</td>
<td>1,555</td>
<td>1,437</td>
<td>1,522</td>
<td>1,437</td>
</tr>
<tr>
<td>Delay in diagnosis</td>
<td>847</td>
<td>759</td>
<td>642</td>
<td>724</td>
<td>700</td>
</tr>
<tr>
<td>Improper management</td>
<td>647</td>
<td>614</td>
<td>626</td>
<td>625</td>
<td>619</td>
</tr>
<tr>
<td>Failure to recognize a complication</td>
<td>379</td>
<td>357</td>
<td>369</td>
<td>348</td>
<td>383</td>
</tr>
<tr>
<td>Failure to treat</td>
<td>327</td>
<td>310</td>
<td>278</td>
<td>401</td>
<td>381</td>
</tr>
<tr>
<td>Failure to monitor</td>
<td>287</td>
<td>256</td>
<td>272</td>
<td>276</td>
<td>316</td>
</tr>
<tr>
<td>Improper technique</td>
<td>324</td>
<td>297</td>
<td>271</td>
<td>251</td>
<td>243</td>
</tr>
<tr>
<td>Delay in treatment</td>
<td>311</td>
<td>251</td>
<td>254</td>
<td>229</td>
<td>258</td>
</tr>
<tr>
<td>Failure to order appropriate test</td>
<td>152</td>
<td>184</td>
<td>142</td>
<td>188</td>
<td>155</td>
</tr>
<tr>
<td>Wrong or misdiagnosis (eg, original diagnosis is incorrect)</td>
<td>144</td>
<td>128</td>
<td>154</td>
<td>156</td>
<td>170</td>
</tr>
</tbody>
</table>

Source: Adapted from NPDB data by Robert A. Dowling, MD

What must be reported

The NPDB is overseen by the Department of Health and Human Services and implemented through federal regulations (45 CFR Part 60). The law requires the following actions to be reported by an eligible entity within 30 days to the NPDB and any similar state authority: malpractice payments; licensure and certification actions; negative actions or findings by a federal or state licensing or certification authority, peer review organization, or private accreditation entity; health care-related civil judgments; exclusions from federal or state health care; and other adjudicated actions or decisions (bit.ly/pdphdata).

NPDB records are broadly categorized as malpractice payments or adverse actions. In addition to reporting requirements, the law also defines when and how health care entities (chiefly hospitals) must request information (chiefly when a health care practitioner applies for a position on the medical staff and every 2 years thereafter). Finally, the regulations describe which subsets of information are available upon request to other persons, entities, or agencies. Statistical information on deidentified data is available on the NPDB website and forms the basis of some of this article (bit.ly/npdbdatafile).

Physicians who find themselves the subject of a report to the NPDB will be notified and given an opportunity to dispute the accuracy of the information in a process defined in regulations. The ultimate decision about the accuracy of the report and whether it should be removed or altered rests with the Secretary of Health and Human Services.

Large urology practices that have a formal process for peer review may meet the definition of an eligible reporting entity and should be familiar with the definitions of adverse actions and clinical privileges in order to understand whether they have a duty to report group member physicians to the NPDB; very few records in the NPDB are unfounded: 222,859 allopathic physicians (MDs) and 17,204 osteopathic physicians (DOs) have records in the NPDB for all years. In 2016, there were 953,695 actively practicing MDs and 102,137 DOs; for the 5-year time period (2014-’18) surrounding 2016, there were 47,847 unique MDs (about 5% of 2016 census) in the NPDB. That prediction has, so far, proven unfounded: 222,859 allopathic physicians (MDs) and 17,204 osteopathic physicians (DOs) have records in the NPDB for all years. In 2016, there were 953,695 actively practicing MDs and 102,137 DOs; for the 5-year time period (2014-’18) surrounding 2016, there were 47,847 unique MDs (about 5% of 2016 census) and 4,557 DOs (about 4.5% of 2016 census) in the NPDB (bit.ly/physiciancensus; bit.ly/ompdata).

It appears the risk of allopathic and osteopathic physicians being reported in the NPDB is still low. Reporting peaked for MDs in 2000 and since then has gradually decreased; DO reporting has been relatively flat. The NPDB does not collect information on specialty.

What are the most common reasons allopathic and osteopathic physicians are reported to the NPDB? For the years 2014–’18, malpractice payments (44,373) outnumbered adverse action reports (38,139). The NPDB offers unique detail See NPDB, page 22.
NPDB
continued from page 21

on the incidence and economics of malpractice payments in this country. The most common allegations resulting in malpractice payments are shown in table 1. Failure to diagnose is the most common allegation resulting in a malpractice payment for the years 2014-18, totaling almost $4 billion for that 5-year period.

Failure to monitor is also a common allegation resulting in payment; urologists may recognize this as a potential risk presented by patients lost to follow-up, missed lab and radiology results, and other implied duties of the physician/patient relationship.

Settlement payments are far more common than judgments resulting from trial (table 2). The NPDB also offers detail on the outcome of cases in which there were payments: For MDs and DOs, the most common outcome was death, followed by significant permanent injury (table 3).

Adverse actions taken against MDs and DOs, the second type of report in the NPDB, are slightly less common than malpractice payments. These actions are most commonly reported by a Health Care Practitioner Licensing Board/Authority or State Composite Board (71%), a hospital or acute care facility (6.7%), the Drug Enforcement Agency (5.6%), and others (16%). Group Medical Practices are among the least common reporting entities.

in the NPDB, with only four reports (0.1%) of adverse actions over a 5-year period (2014-2018). Most of the adverse actions reported for physicians are categorized as indefinite (55%) or permanent (24%).

Bottom line: The NPDB is near its 30th anniversary of operation, and a minority of practicing physicians are recorded in the data. Hospitals are the main consumer of this information and use it for routine credentialing purposes. The publicly available malpractice payment data can aid urologists and others in understanding the incidence and type of malpractice events resulting in payment and the importance of risk management in the contemporary practice of medicine.

TABLE 2 ALLEGATIONS AGAINST MDs AND DOs: METRICS BY PAYMENT TYPE

<table>
<thead>
<tr>
<th>Payment type</th>
<th>Unique physicians</th>
<th># records</th>
<th>Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Settlement</td>
<td>32,219</td>
<td>42,716</td>
<td>$16.1 billion</td>
</tr>
<tr>
<td>Judgment</td>
<td>876</td>
<td>958</td>
<td>$655.9 million</td>
</tr>
<tr>
<td>Unknown</td>
<td>582</td>
<td>589</td>
<td>$224.3 million</td>
</tr>
<tr>
<td>Before settlement</td>
<td>109</td>
<td>110</td>
<td>$30.1 million</td>
</tr>
</tbody>
</table>

Source: Adapted from NPDB data by Robert A. Dowling, MD

TABLE 3 ALLEGATIONS AGAINST MDs AND DOs: METRICS BY OUTCOME

<table>
<thead>
<tr>
<th>Outcome</th>
<th>Unique physicians</th>
<th># records</th>
<th>Payments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Death</td>
<td>12,515</td>
<td>14,061</td>
<td>$5.3 billion</td>
</tr>
<tr>
<td>Significant permanent injury</td>
<td>6,389</td>
<td>6,920</td>
<td>$3.2 billion</td>
</tr>
<tr>
<td>Major temporary injury</td>
<td>4,748</td>
<td>5,124</td>
<td>$1.2 billion</td>
</tr>
<tr>
<td>All others</td>
<td>16,016</td>
<td>18,268</td>
<td>$7.3 billion</td>
</tr>
</tbody>
</table>

Source: Adapted from NPDB data by Robert A. Dowling, MD

CO-SURGEON
continued from page 20

There are many examples that state that you should follow payer rules if there is a conflict between CPT and the payer.

Q: What are the documentation requirements for code 51798? Is documenting the residual amount enough, or do we have to have the printout from the bladder scan? Some of the machines do not have the capability to print out the scan. We have been requesting that medical assistants scan the printout but would like to know if entering the postvoid residual is enough.
A: Code 51798 reads: Measurement of post-voiding residual urine and/or bladder capacity by ultrasound, non-imaging.

As such, the code is not treated the same as other ultrasound codes with regard to documentation requirements. Documentation should include the reason the postvoid residual (PVR) was obtained that day, the postvoid amount, should indicate that ultrasound was used and how it was used in medical decision-making. Documentation of how PVR is used in medical decision-making can be explicit or implicit in the documentation for the visit and is not required to be documented in the same place as the postvoid amount and reason for PVR.

Q: Can we bill for an orchiopexy (54640) and an inguinal hernia repair (49495-49525) together, when the hernia repair is also performed through the one orchiopexy incision?
A: Excellent question, because the answer is not black-and-white. The rules are somewhat confusing in many areas and often inconsistent. Typically, CPT is the foundation for coding and reimbursement and rules for payment take into account CPT descriptions and included services.

CPT code 54640 (Orchiopexy, inguinal approach, with or without hernia repair) clearly states that hernia repair is included.

However, payer rules (in this case NCCI edits that can be viewed in AUACodingToday) show that the two codes, if billed for the same date of service, would be allowed. Payer rules usually trump CPT rules. There are many examples that state that you should follow payer rules if there is a conflict between CPT and the payer.

As CPT and payer rules are in conflict for this situation, we have implemented a general rule for coding these cases: Respecting what we believe is the intention of the CPT description, if the hernia repair is incidental, we will recommend not coding for the hernia repair. If documentation indicates that significant additional work to repair the hernia is required for the patient, as NCCI rules allow reporting of the hernia repair code in addition to the orchiopexy, we recommend reporting both codes instead of using modifier –22 on the orchiopexy code.

As you have heard many times before, private payer rules may vary, including the adoption of edits using the CPT language to deny payment for both. Follow the rules and your contract.
Avoid these six mistakes that can hinder your financial goals

Procrastination, lack of investment strategy can jeopardize long-term success

**Q:** What are some common mistakes physicians make when it comes to financial planning?

**A:** Not every physician is financially successful. It takes planning and execution to achieve your financial goals. However, success is not always dictated by what you do right as much as by what you may do wrong. Time and time again, we see physicians make avoidable mistakes that hinder or delay their ability to reach their financial goals.

These common mistakes include: **Procrastination.** The number one reason we see physicians fail financially is procrastination. Whether from educational programs, self-research, or working with a financial professional, physicians know what they need to do to become financially successful. However, too often we hear physicians say, “Life gets in the way.” Work, family, and hobbies prevent physicians from devoting the time necessary to get their financial lives in order. The longer the wait, the more difficult it is to get on track.

**Lack of clearly defined goals.** Vague goals often result in vague plans, and when you have a vague plan, it is easy to deviate from that plan and get off track. It is important to be specific about your goals so you can design a detailed plan for reaching them. For example, when thinking of your retirement goal, at what age do you what to retire? What level of income do you want in retirement? What sources are your savings coming from? What rate of return will you need to earn on your investments? Be specific so you can design a plan for reaching your goals.

**Not saving and investing early.** Compounding interest is a powerful tool for growing wealth, and the key is saving and investing early so the investment has more opportunity to compound. The cost of waiting is substantial. If you wanted to save $1,000,000 by age 66 (assuming an 8% rate of return), you would have to save $671 per month if you started at age 35, $1,698 per month at age 45, and $5,466 per month at age 55. Many physicians wait too long and don’t have the resources to save large amounts due to other financial obligations.

**An investment strategy holds a physician accountable to what types of investments they will purchase, when they will get in and out of the market, and what their asset allocation will be.**

**No investment strategy.** An investment strategy holds a physician accountable to what types of investments they will purchase, when they will get in and out of the market, and what their asset allocation will be. The investment strategy protects physicians from themselves so they don’t react emotionally when markets are performing very well or performing poorly. It keeps them steady, so they are not tempted to do something not in their own best interest.

**Failing to prepare for the unexpected.** Simply put, many physicians don’t have enough disability and life insurance. Without adequate coverage, your financial goals and the goals of your family are at risk in the event of a long-term disability or your premature death. Protect yourself so you and your family can still reach financial goals even if you are unable to work or if you die early.

**Lifestyle creep.** Frequently, we see physicians start splashing the cash right out of their residency or fellowship. They buy a big home or new car, eat at fancy restaurants, and generally start living an extravagant lifestyle. This often comes at the expense of saving for financial goals later in life. The realization that their focus needs to change comes too late, and there isn’t enough time or money available to catch up. Be careful about how you spend your money, especially early in your career.

All of the above mistakes are avoidable. If you want to be financially successful, avoiding these mistakes while executing your financial plan is critically important.

**Q:** Do I need an umbrella insurance policy? If so, how much should I get?

**A:** An umbrella insurance policy covers the same things as your home and auto policies, plus some additional items, including lawsuits. Umbrella coverage picks up where the liability limits of your homeowner and auto policies leave off. Most insurers cap the home and auto liability coverage they will sell you at $500,000 or $1 million. If you have assets valued above what your home and auto policy cover, an umbrella policy can cover those assets. Umbrella policies are usually sold in increments of $1 million, so determining an appropriate amount will require that you calculate the value of your assets not covered by your home and auto policy.

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**MONEY MATTERS / Business**

Mr. Witz is education- al program director at MEDIQUS Asset Advisors, Inc. in Chicago. He welcomes readers’ questions and can be reached at 800-883-8555 or witz@mediqus.com.

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**FINANCIAL TIPS**

- It is important to be specific about your financial goals, so you can design a detailed plan for reaching them.
- Physicians must be cautious about extravagant spending early in their career, as this often comes at the expense of saving for financial goals later in life.
- An umbrella insurance policy covers the same things as your home and auto policies, plus some additional items, including lawsuits.
How independent docs can combat hospital consolidation

Survey shows Americans associate independent physicians with more patient-focused care

Independent physicians across the country continue to experience changes to the way we practice. While the public might think the most significant changes are driven by new medicines or technologies, the increasing rate of hospital consolidation is perhaps the most pressing threat we face today.

As the health care landscape evolves, challenges to our daily practices include frequent government-mandated changes, insurer intrusions, and ever-changing marketplace dynamics. Currently, we are being confronted with the ongoing monopolization of health care by hospital systems aggressively acquiring independently run physician practices. For those of us who are committed to treating patients in our communities, these mergers are occurring at an alarming rate.

I’ve seen—and felt—the impact of hospital consolidation firsthand as a practicing independent urologist. Many of my colleagues could no longer compete. They felt they had no choice but to agree to be purchased by a hospital system.

This problem is not unique to urology. Hospitals across the country are purchasing private practices in all specialties to extend their service areas.

LUGPA commissioned a survey that demonstrated a majority of Americans (65%) trust independent physicians in general and associate us with more personalized and patient-focused care compared to physicians employed by hospitals.

Hospital systems’ continued purchase of independent practices is making my patients nervous. Nearly one-third of older Americans (31%) worry they won’t get the care they need at a location they choose for a price they can afford. Their concern comes as no surprise given that hospitals are usually more expensive than independent practices.

It’s simple economics that pricing increases when a player monopolizes the market. A review by the Health Care Cost Institute showcased where the price differences are particularly stark, including:

- chemotherapy infusions, where hospitals are reimbursed $281 versus $136 for independent practices
- cardiac imaging, where hospitals are reimbursed $2,078 versus $655 for independent practices
- colonoscopies, where hospitals are reimbursed $1,383 versus $625 for independent practices.

As a result of unchecked hospital monopolization, patients are left with fewer options and higher costs—contrary to the benefits hospitals claim mergers offer. Data from LUGPA also revealed more than two-thirds of Americans want a solution to the growing trend of hospital purchases of independent practices. They also want payers to compensate all medical practices equally, a concept known as site-neutral payments.

Patients want to be in control of their health and have the ability to choose the best option for their care. They want to receive care at a site that’s most convenient and comfortable for them. Patients do not want to be forced to rely on large, impenetrable, and much more expensive hospital systems that are gobbling up the local family practices they’ve been visiting for decades.

The care we offer as independent physicians is incredibly valuable to patients. Likewise, it is both a reward and a privilege to care for them. But an equally important role for independent practices, though largely unseen by our patients, is that our very existence protects them from hospitals’ monopolistic activities.

Independent physicians have a major role to play in shaping health policy. As such, we must continue to advocate on behalf of all patients to ensure they receive the highest quality care possible and at the location of their choice.

We can care for our patients by championing legislation that levels the playing field between hospitals and independent practices. We can call for more aggressive Federal Trade Commission review and enforcement of hospital mergers and acquisitions. I invite you to join us in making our collective voice heard. [11]
It’s urologists’ turn to do something about the opioid crisis in America

Practitioners must implement alternative strategies for pain control

It is rare that a single lecture radically alters my practice. I’ve been on my own long enough to have developed some habits (good and bad), and more importantly I know what works for me. As a result, it surprised me and the people I work with when I came home after hearing Dr. Nicole Miller’s Rocky Mountain Urological Society talk on the opioid crisis and changed how I use narcotics.

This message was reinforced at the AUA annual meeting and is the single most important message I took home from Chicago.

That there is an opioid crisis in America is not a surprise. It is truly an American problem, with Americans accounting for 99.7% of hydrocodone consumption in the world. Why? Simply because other countries don’t prescribe these drugs to the extent that we do.

Further, I knew that opioid deaths are increasing (47,600 deaths in 2017 alone), but I didn’t understand the context of that until I realized that more Americans died in 2017 from opioids than from car accidents. I also knew that the number of opioid deaths from heroin and fentanyl was spiking, but I didn’t realize that >75% of all patients who use heroin started off by using prescription opioids and that 6% to 8% of all opioid users transition to heroin.

Where do people get the vast majority of their opioids? From us.

What can we do? This may be simplistic, but for the most part we need to follow Nancy Reagan’s advice from many years ago and “just say no” to prescribing narcotics. I am in no way advocating that we not treat our patients’ pain; I understand that surgery hurts. What I am advocating is that we do it in a smart and proactive manner to limit both the quantity and duration of the narcotics we use.

How do we accomplish this? Find alternatives. Let me give you two examples. We’ll start with post-ureteroscopy pain control. Dr. Miller presented a wonderful poster at this year’s AUA (MP39-12 Enhanced Recovery After Surgery Protocol for Ureteroscopy: A prospective Comparative Study Evaluating a No Opioid Versus Standard Protocol) describing a method to almost eliminate the need for opioids following routine ureteroscopy. Her strategy includes both acetaminophen and gabapentin preoperatively, a belladonna and opioid suppository, and ketorolac intraoperatively combined with a no-narcotic anesthesia protocol.

Where do people get the vast majority of their opioids? From us.

On discharge, patients receive oxybutynin, tamsulosin, and scheduled ibuprofen and acetaminophen. Interestingly, Dr. Miller stressed that she wrote out prescriptions for both ibuprofen and acetaminophen and gave those scripts to her patients, as there is something almost magical about getting a prescription versus going to Walmart and buying medication off the shelf. Her protocol worked: She found no difference between her standard narcotic group and her no-opioid group in postoperative patient phone calls, requests for more pain medicines, or emergency room visits. This truly is amazing, and if I may be so bold, I would argue that we all need to start implementing strategies like this today.

My second example is for the critics who say this may work for surgeons who do “little” cases, but for those who make real incisions, we need real medicine. Actually, you don’t. You just need to be creative with your regional blocks. Drs. Anthony Anderson and Francis McGovern presented amazing work on the use of creative regional blocks in their AUA instructional course, 051IC: Opioid-Sparing Analgesia for Enhanced Recovered after Urological Surgery. They showed that by working with our anesthesia colleagues, it is possible to basically eliminate the need for opioid-based pain medicine after even the biggest urologic case.

We’re not the only people thinking about this. While the federal government has yet to take any meaningful steps, many states have legislation in place. As of this year, almost two dozen states have passed laws setting restrictions on the quantity and/or duration of opioid prescriptions. Interestingly, one of the toughest is in Tennessee, Dr. Miller’s home state, where there is a 3-day, 60-morphine equivalent limit in most opioid-naïve patients.

If truly implemented, think about how this would change our daily lives. Thirty-year-old man walks into the ER with nausea, vomiting, and 10/10 right flank pain. CT shows a 5-mm mid-ureteral stone. No fever and no evidence of infection. ER gets his pain controlled with IV morphine. Now what? Current management is to send him home with pain medicine and medical expulsive therapy with outpatient urologic follow-up. In my world, I usually would have given him 3-4 weeks to pass the stone before intervening.

Is that appropriate if he needs opioids during that 3-4 weeks? How does the risk of immediate surgical intervention weigh against his risk of chronic opioid use if he needs a month worth of opioids to pass the stone on his own? I don’t know the answer to that one, but if we start early intervention on most stone patients, that’s going to mean even more late nights in the OR.

Unfortunately, in the short term, things will likely get worse before they get better. The data is pretty clear that as prescription opioids are withdrawn, a certain fraction of patients will move to street drugs such as heroin and fentanyl. But this tide will pass and things will get better. As surgeons, our first step toward improving the situation is to become significantly better at controlling postoperative pain using opioid-sparing protocols.
Embracing change in health care: How to get your team on board

Follow these steps to facilitate the change process in your practice

STEVE GORDON, MD, AND KEELY KILLPACK, PhD

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Change is a fact of life. Yet the degree to which change is occurring in health care is astounding. From Affordable Care Act requirements to the array of medical research and new treatment options, providers have been overwhelmed by the pace of transformative change. So, when change needs to occur at an organization or medical practice, how should leaders approach it?

Whether that change requires embracing new technology or the adoption of new policies, leaders must communicate the reasons behind the change and connect people to strategy in order to help them assimilate the change and understand the benefits and impact on the business. Implementing change management best practices facilitates this process and helps staff more easily and quickly make a personal transition from a current to a future mindset.

Change efforts among physicians and providers falter when leadership stumbles into some common pitfalls including:

• failure to describe and communicate the problem; its personal impact on physicians, providers, and staff; and what exactly individuals are being asked to change within their daily workflow
• failure to determine the root cause of the problem before working to solve it
• delaying engagement with providers until after the solution has been decided
• solution bias and over-confidence in the chosen approach
• inadequate support through the change; failure to address the communication and training needs and provide at-the-elbow experts during implementation and additional staffing to maintain productivity
• failure to recognize the personal investments made by physicians and providers and their successful adoption of the change benefitting the organization or practice

Your messages are resonating with the right team members who can help drive change.

Forming the strategy

Identify the specific problem you are trying to solve. Frame it in a way in which people will understand and agree on the problem and convey what will happen if the problem goes unaddressed.

Engage physician and provider leaders. Create open dialogue and show empathy. Affirm that you understand the myriad challenges they face and ask for their advice and partnership in trying to solve this issue. Solicit their engagement in finding the solution, becoming experts in it, helping the rest of their colleagues adopt the change as it happens, and understanding resourcing needs afterwards.

Choose solutions wisely. Use proven data-informed techniques, such as Lean or 6-Sigma, to guide improvement and thoroughly review technology products with a large group of physicians, providers and other relevant end user staff. All time spent choosing the right solution to the problem is invaluable and saves your organization exponentially down the road.

Planning for the change

Clarify each person’s role in the change process. Prepare an inventory of roles and customize a change plan for each. Participants without workflow change can nevertheless be impacted secondarily, so awareness matters.

Select which changes to bring to physicians and providers for input or decision-making. Develop a tailored approach, focusing on how much and what information to bring forward, and each specific audience group.

Identify change champions. Seek out individuals who have the most influence and ensure your messages are resonating with the right team members who can help drive change.

Create checklists for change. Provide specific action item lists that inform staff of what will be needed, and when. Custom checklists for leaders, physicians, and other staff roles are helpful to support each employee through the change experience for their job.

Plan for success. Break large initiatives into smaller projects that are most likely to succeed. Any plan should be achievable from start to finish in 3 years or less.

Determine how success will be measured. Success measurements should be agreed on by all impacted group leaders and transparent to everyone. Adjustments to the solution may be needed, so set expectations to be flexible and to monitor and track performance as the change processes and becomes the new normal.

Get support from others. Align and partner around change with other individuals and groups inside and outside your practice, as well as with professional societies and advocacy groups with similar values. Consider investing in expert change management support for larger, complex initiatives and when change fatigue or physician burnout is a risk.

Making the change

Remind others that change is the new normal. Regardless of your specialty, position, or function, changes frequently emerge in health care, especially with external market forces such as MACRA or adopting new value-based payment models. Emphasize that these programs are likely to change over time but are not going away.

Acknowledge the uncertainty with any change. Shadow people in their daily work, solicit their reactions to the experience, understand their pain points, and offer assistance or support when you can.

All progress is good and should be recognized. Don’t assume that every physician or group can or should be a top performer right away. Pushing too hard or too fast may jeopardize long-term success. Focus on short-term goals and be sensitive to overlapping demands for change.
How online ratings can affect your practice’s bottom line

Maintaining positive online reputation key to drawing new patients

AARON CLIFFORD
Mr. Clifford is the senior vice president of marketing for the Binary Fountain, a cloud-based provider of patient feedback and reputation management solutions.

Health care practices, like any business, need to constantly pursue new customers as well as work to retain existing ones.

As the cost of health care continues to rise in the United States, currently a $3 trillion business, many patients are beginning to reassess their visits. Was the promised service delivered, was it delivered with quality and was it delivered at a fair price? If the standard of care does not meet patients’ expectations, they are more likely to switch practices.

In today’s experience economy, health care practices need to concentrate on two things: providing excellent customer service and operating a profitable business. These two seemingly disparate clinical and business goals are interconnected through reputation management, patient engagement, and value-based care.

The need for reputation management

In the past, a health care provider’s reputation was based primarily on word-of-mouth recommendations from friends, family or another provider. However, online reputation management is something health care practices can no longer afford to overlook.

Today, searching and selecting a physician is more than just verifying a physician is experienced and qualified. Patients are actively seeking and reading online ratings and review sites. They’re evaluating a physician or practice based on a myriad of components, such as cleanliness, bedside manner and parking.

A recent consumer survey found:

- 95% of respondents say online ratings and reviews are “somewhat” to “very” reliable
- 70% of Americans say online ratings and review sites have influenced their decision when selecting a physician
- 41% of consumers still check online ratings and reviews of physicians/specialists even when referred by another physician.

Therefore, maintaining a positive online reputation is key to promoting a successful business.

With this in mind, medical practices need to monitor and track what is being said about them online. Although many physicians are skeptical of online reviews—particularly negative reviews—more health care providers are using this data as a means of benchmarking their performance.

In fact, online ratings and reviews enable physicians to better understand and make operational improvements to the patient experience. In today’s competitive health care market, online reputation could be what distinguishes one physician apart from another, especially when cost of care and location are similar.

The role of patient engagement

Medical practices want to build trust, loyalty, and a rapport with their patients. Therefore, practices and their providers need to be vigilant about asking patients to leave online ratings, reviews, and recommendations.

Reputation monitoring and management is most effective when a large percentage of patients and caregivers are participating. The more feedback captured via Consumer Assessment of Healthcare Providers and Systems surveys, ratings and review sites, or social media, the better the patient experience will be for future patients.

Today, more and more consumers are providing unfiltered, public-facing feedback to help others make an informed decision about whether a practice is worth a visit. It’s equally important for practices and providers to request patient feedback and respond to all online reviews, even the negative ones. In doing so, practices and providers will show they care about improving the patient experience.

The shift toward value-based care

The health care industry is currently operating mostly on a fee-for-service payment model. However, the industry may soon be heading toward a value-based reimbursement payment model.

Regardless of how a provider is paid, improving the patient experience and closing gaps in care should be top of mind for all providers. Patients already have high expectations for the level of customer service that they wish to receive.

OnePoll conducted a survey of more than 1,000 U.S. adults with a physician. They found that 48% of Americans believe “a friendly and caring attitude” is the single most important factor for patients when rating or evaluating a physician, closely followed by “ability to answer all my questions” (47%) and “thoroughness of the examination” (45%).

If practices want to increase their number of repeat patients, it is imperative they create professional, personable, and valuable experiences for their patients.

Patient experience is the common thread that ties reputation management, patient engagement, and value-based care together. The experience is the catalyst for driving patient retention, referrals, and revenue for physician practices. After all, without satisfied patients, there is no business.

EMBRACING CHANGE

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Celebrate progress and express your appreciation. Recognize individuals not just for the change at hand, but also for providing compassionate, high-quality care every day.

Above all else, always keep your eye on the patient. Virtually all providers and staff can agree on a change when the benefit to patient care is clear.

Change is a predictable component of health care delivery. Developing and refining an effective approach to managing change is an essential leadership skill. Recognizing common pitfalls, planning accordingly, and course correcting effectively will help to inspire others, ensure success, and minimize adverse impact.
How to avoid the legal risks of telemedicine

Obtaining license among several considerations when adding virtual visits

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Judd Hollander, MD, holds a medical license in Pennsylvania, where he practices, but to ensure that he could legally treat his patients virtually, even when they’re traveling out of state, he sought out medical licenses in an additional 18 states.

Dr. Hollander obtained those credentials after surveying 3,500 of his patients and asking about their travel showed that obtaining licenses in those 18 states, along with Pennsylvania, would allow him to see his patients nearly any time they needed him.

Dr. Hollander, who in addition to practicing is a senior vice president of Healthcare Delivery Innovation at Jefferson Health, a regional health care system based in Philadelphia, says this step allows him treat his patients without worrying about whether he is legally out of bounds.

Dr. Hollander says that it takes time and effort to manage the requirements associated with all those licenses.

“It's a half-time job keeping up with them,” he jokes, but he says physicians need to take such steps if they want to offer telemedicine services and be compliant with administrative rules and legal regulations.

Patients are increasingly seeking out virtual medical care, while more physicians are working toward providing increased telemedicine services.

However, as physicians add such services to their practices, experts say they need to consider legal and compliance issues around providing such care, from telemedicine-specific regulations to state licensure requirements and even malpractice-related questions.

“You do have to be careful. You can be successful if you're meticulous, use good resources, have risk managers looking at policies and procedures, and have good technology selection, appropriate documentation, and training around telemedicine.”

NEAL SIKKA, MD

“Multiple state licenses might be required

Technology now enables physicians to deliver a range of medical services virtually. Experts group these services into two categories: telemedicine, which is when the physician delivers care via telecommunications to a patient located at another site, and telehealth, which includes technology-related health services such as remote patient monitoring.

A leading consideration when implementing telemedicine is state licensure, experts say. Telemedicine adds a complication to licensure needs, because the technology enables physicians to see patients who are located in a state where the doctor is not licensed to practice.

As such, physicians and other clinicians will likely need a license to practice in multiple states if they want to treat their patients virtually.

Experts advise physicians to examine their patient panel to determine if they have patients living out of state—for example, in a neighboring state if their practice is near a state line. Physicians may want to determine if they have a significant number of patients who re-locate for part of the year—such as retirees who head to warmer climates during the winter—or if a large percentage of their patients travel extensively.

Thus, a physician seeing a patient via video link needs to know where that patient is located at the time of the visit—known as the "originating site”—and understand that state's licensure requirements.

Some states are making it easier for physicians to practice in other states. The Interstate Medical Licensure Compact (IMLC), which encompasses 28 states and the territory of Guam and their 38 medical and osteopathic boards, offers an "expedited pathway to licensure for qualified physicians" seeking to practice in multiple states.

It also offers reciprocity, with the members recognizing each other's licensing requirements so physicians don't have to review and meet each state's requirements to obtain a license, says Steven E. Waldren, MD, MS, vice president and chief medical informatics officer for the American Academy of Family Physicians.

Dr. Waldren notes that although physicians still need to apply and pay license fees for each member state where they want to practice, the IMLC offers a more efficient way for physicians to obtain additional state licenses.

However, physicians seeking licenses in states that aren't part of the compact will have to meet the requirements of each of those, Dr. Sikka says.

Rules vary by state

Physicians also need to understand the differences in state regulations governing telemedicine, experts say.

Some require physicians to see patients in person before offering any type of telemedicine service, while some have additional regulations that could apply to physicians billing patients located in those states. Some states have restrictions on asynchronous visits—interactions where the clinician and patient do not interact in real time—while others allow both synchronous and asynchronous visits as well as a broader range of telemedicine services.

States vary in their regulations in other ways, says Rachel Dixon, a consultant and telemedicine expert with the Medical Group Management Association (MGMA). For example, some states allow physicians to prescribe certain controlled substances via telemedicine visits under certain circumstances. Such rules, she says, require physicians to understand such
regulatory differences if any of their patients are out of state.

Furthermore, she says, states generally require physicians to obtain consent from patients before treating them, but some states have specific requirements around consent that others do not.

California, for instance, requires the originating site provider to obtain and document patient consent, according to the Center for Connected Health Policy, while Kentucky says the treating physician who delivers or facilitates the telemedicine services is responsible for obtaining consent.

Jitendra Barmecha, MD, MPH, who chairs the American College of Physicians’ newly formed Digital Health Advisory Group, says physicians should seek to ensure compliance with the varying state rules and regulations by building them into their telemedicine workflows.

For example, he says, just as most practices have front-office workers automatically obtain consent as part of the check-in process, the telemedicine application can include the appropriate consent documents based on the state rules where the patient is located at the time of the visit.

Medicare rules add another layer of complexity for physicians expanding into telemedicine, says Mollie Gelburd, JD, associate director of government affairs at MGMA.

For example, Gelburd explains, both the originating site and the physician providing the service are expected to submit documentation of the visit. Failure to meet that extra requirement would mean noncompliance with the federal rules.

Security, privacy risks

Telemedicine must also meet all HIPAA requirements.

“The rules are no different for telemedicine than for [in-person visits],” said Ronald Weinstein, MD, founding director of the Arizona Telemedicine Program.

This means physicians need to ensure they’re in a location where no one can overhear the virtual visits, which would violate HIPAA’s privacy and confidentiality requirements. Additionally, physicians must use technology that’s compliant with HIPAA rules. The technology should have fully encrypted data transmission and provide secure connections. Experts stress that consumer videoconferencing platforms, such as Apple’s FaceTime application, do not offer those features.

Physicians that opt to work with another business or a technology provider to offer telemedicine services to patients must ensure that those partners are compliant with HIPAA regulations, too, Dr. Weinstein says.

“You should have contractual assurances that third parties will follow all the rules around HIPAA,” he added.

Malpractice concerns?

Experts say physicians offering virtual services don’t face new malpractice rules or risks.

“Telemedicine isn’t really high risk, but you do want to make sure you’re practicing under the board of medicine for the state where the patient is located, and practicing under the terms of your licensure and the standards of care for the conditions and for your practice focus,” Dr. Sikka said.

Physicians who comply with licensing rules, who document appropriately, and who follow the same standards of care they would for in-person treatments don’t create additional malpractice risks just because they’re offering their services virtually.

Still, there are risks if physicians don’t diligently adhere to the rules. For example, Dr. Waldren says, physicians could face a loss of malpractice insurance coverage if they treat a patient located in a state where they aren’t licensed to practice—even if that error was inadvertent.

As a result of the potential for such situations, Dr. Waldren advises physicians to consult with their attorney and malpractice insurance company before starting to offer telemedicine services.

Telemedicine training a must

Technology can help physicians adhere to the various regulations and laws that govern telemedicine services.

Some telemedicine applications, for example, allow physicians to incorporate into their telemedicine workflows the appropriate consent forms and checks on patient locations thereby helping them follow the rules applicable to their practice.

Additionally, experts advise physicians to seek out training in delivering telemedicine services to ensure that they’re not only following the applicable rules, but also that they’re delivering the best possible care in this new setting.

Institutions that offer training in telemedicine services for physicians include the American Telemedicine Association, the American Medical Association, the Arizona Telemedicine Program, and Thomas Jefferson University.

Experts say physicians shouldn’t let complicated regulations over licensure, rules, and regulations stymie their adoption of telemedicine, because patients will increasingly seek out virtual visits and other technology-enabled care.

At the very least, Dr. Hollander says, physicians should offer telemedicine service to their existing in-state patients if they want to remain relevant in health care. “You have to figure out how to do it.”

EHR SYSTEMS CARRY RISK OF MEDICAL ERRORS

Originally heralded as a tool that would make health care more efficient and effective, EHRs have revealed themselves to be a mixed blessing.

In addition to frustrations over badly designed interfaces and interoperability issues, physicians are coming to realize that the software they rely on to manage their practices can be putting their patients at risk of medical error and themselves in danger of medical liability.

The problems were highlighted in a recent joint Kaiser Health News and Fortune investigation that showed that EHRs are not living up to their promise, but they have been blamed for everything from incorrect prescriptions to patient deaths and serious injuries.

And while many practices have come to working terms with their EHRs, they might be unaware of the malpractice dangers they can pose.

“It’s definitely on our radar,” said Robert Hanscom, JD, vice president, business analytics at Coverys, a medical liability insurer. “We are urging [physicians] to pay more attention.”

Three years ago, Coverys created a code to flag EHR-related malpractice claims. The number of cases rose from 21 in 2013 to 63 in 2017 and continues to climb, Hanscom says.

In the Medical Economics 2018 EHR Scorecard, dozens of practicing physicians commented on how their EHR systems made them more prone to errors.

“I make more prescription errors with the EHR than I ever did with paper charts,” said one respondent.

For more, see the full article from Medical Economics at bit.ly/ehrrisks.
coverage, and in some cases failure to respond to phosphodiesterase type-5 (PDE-5) inhibitor therapy (J Sex Med 2014; 11:2546–53). In addition, research shows that reimbursement policies for ED lack transparency and keep men from pursuing appropriate care (Urology 2017; 102:126–9).

These psychosocial and fiscal barriers, in turn, encourage patients to turn to the online marketplace to research and obtain alternative medical therapies for ED.

Ripe for Internet startups
Sexual medicine is a subspecialty that’s ideal for Internet startups. That’s because male patients tend to suffer with embarrassment, humiliation, and poor self-esteem, and men are notorious for avoiding the doctor. A Cleveland Clinic survey conducted in 2018 showed that 61% of men have neglected visiting a physician even when they needed to go, and more than half (56%) prefer to keep health concerns to themselves. The survey, conducted annually as part of Cleveland Clinic’s MENtion It campaign, also found that 27% of men research their symptoms online when first noticing changes in their health, which is the same percentage who would consult a physician.

And doctors, even urologists, get little training in sexual medicine, so providers might offer little help in addressing patients’ issues, according to Irwin Goldstein, MD, a urologist who practices sexual medicine in San Diego and is president and director of The Institute for Sexual Medicine, a nonprofit agency dedicated to education and basic science research in the field.

Businesses are swooping in to meet the unmet demand in men’s health. Enter web startups, like Hims and Roman, which are promising quick access to treatment and raising concerns about care quality, according to an article published last month in USA Today.

Arthur L. Burnett, II, MD, MBA, professor of urology at Johns Hopkins University School of Medicine, Baltimore, said he has mixed feelings about certain business models that provide urologic care. He understands that men may have psychological and other challenges that make them hesitant to visit the doctor’s office.

What urologists can do to educate male patients
Urologists should be open minded that more people are turning to the Internet for health care advice or services and should consider reaching patients where they live and work by implementing telemedicine, when it makes sense, or in their own online communications, according to Aaron Spitz, MD, of Orange County Urology Associates in California.

Urologists can help set the record straight by dispelling rumors and myths and shuttling patients to reliable sources, according to Ryan P. Smith, MD, of the University of Virginia.

“My reservation has to do with whether [online businesses] are actually taking up these medical issues in patients well in terms of addressing medical diagnoses or management issues that deserve medical attention.”

ARTHUR L. BURNETT, II, MD, MBA

“It’s no use hoping online direct-to-consumer care will go away. Digital tools are here to stay in health care and urology, and access to them is growing,” Balasubramanian said.
“My reservation has to do with whether [online businesses] are actually taking up these medical issues in patients well in terms of addressing medical diagnoses or management issues that deserve medical attention,” Dr. Burnett said.

The concerns, when it comes to Hims at least, are more a prevailing misperception than reality, according to Peter Stahl, MD, clinical director of Men's Sexual Health at Hims, which launched in 2017.

Direct-to-consumer digital health care companies like Hims have the power to transform men's health and urology, Dr. Stahl told Urology Times in an email.

First, Hims and similar companies facilitate access to care by reducing or eliminating financial, logistical, and emotional barriers to clinical care, according to Dr. Stahl, who is director of Male Reproductive and Sexual Medicine at New York-Presbyterian Hospital/Columbia University Medical Center and assistant professor of urology at the Columbia University College of Physicians and Surgeons.

“Financial barriers are reduced through affordable pricing strategies and independence from third-party payers. Clinical encounters occur remotely through a digital interface that is accessible via mobile devices and personal computers, which dramatically reduces the time and logistical burdens that are typically associated with traditional, in-person physician visits. And some men who would otherwise not seek care because of embarrassment about sexual dysfunction may feel more comfortable engaging a physician digitally from the privacy of their home,” Dr. Stahl said.

Second, the direct-to-consumer health care industry has brought an infusion of financial capital and marketing expertise to the men's health space, according to Dr. Stahl.

“Hims and similar businesses have the resources and expertise to engage a heretofore unprecedented number of affected patients,” he said. “Rather than feeling threatened by [direct-to-consumer] digital health care companies such as Hims, as urologists we should recognize the opportunity to partner with such companies.”

Urologists could benefit because these companies will find patients who are too complex for treatment on their platforms or who don't respond to the first-line therapies offered, he added.

Third, Hims and companies like it in the direct-to-consumer space have the opportunity to improve the quality of care for men's health conditions that are at risk for suboptimal clinical management during in-person visits with non-specialized care providers, Dr. Stahl wrote.

Only about 1% of urologists have integrated telehealth into their practices, according to Dr. Stahl, so many are unaware of asynchronous telehealth services, how they function, and the potential benefit they offer both patients and physicians.

“The consultation process is designed to ensure that the health care provider has the necessary information to make an informed and appropriate decision about diagnosis and treatment plans in conformance with the standard of care, and if not, the patient is not treated and is advised to seek care outside of the platform,” he said. “As part of the consultation process, the provider initiates an online dialogue with the patient to address any...”

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risks and contraindication, gives the patient the opportunity to ask questions, and if appropriate, recommends treatment. If at any point the provider believes a patient is more appropriately treated in person or does not believe a prescription is the best path forward, the patient is referred out.”

Online searches good for urologists

Some urologists agree the Internet can be a good thing for men’s health.

“I think overall the Internet is a good thing for urologists because what studies are showing is that the majority of men are going to the Internet first when they have concern about their health. The Internet is allowing them to do this privately and, without this access, it’s likely that a lot of these men will just not seek help in the first place,” said urologist Aaron Spitz, MD, a partner in Orange County Urology Associates in Laguna Hills, CA, voluntary assistant clinical professor of urology at UC Irvine, and co-chair of the AUA Telemedicine Taskforce.

After many of those men learn they have a treatable medical condition, chances are good that they’ll go to a doctor, potentially a urologist. The Internet also can disseminate information to a lot of people simultaneously and, in the case of telemedicine, could even help streamline treatment if it complies with licensure and follows sound medical practices, according to Dr. Spitz.

But even Dr. Spitz worries about potential abuse and patient harm that could result when men turn to the Internet instead of a urologist.

In-person exam lacking

Here’s where the bad news comes in: the Internet is giving people access to self-management, including prescription medicine, without having ever had a face-to-face examination, according to Dr. Goldstein. “No prostate exam; no determination if there are masses near the prostate, no PSA examination, no testosterone assessment, no physical examination to see if there’s numbness in the penis or if there’s penile cancer,” Dr. Goldstein said.

The Internet enables patients to procure potentially dangerous substances, such as steroids, tainted PDE-5 inhibitors, and unvalidated nutraceutical supplements, according to Adithya Balasubramanian, a fourth-year medical student at Baylor College of Medicine in Houston. Balasubramanian and Dr. Spitz debated Internet pros and cons during “The New Wild West: Men’s Health and the Internet” session at this year’s AUA annual meeting in Chicago.

“There are many underground websites that sell anabolic androgenic steroids (AAS) directly to consumers. These websites have been noted to tout the benefits of AAS without presenting the potential risks.”

ADITHYA BALASUBRAMANIAN

“Patients have also been known to procure PDE-5 inhibitors that are manufactured by non-validated vendors via online websites. Subsequent analyses of these pills have revealed that they are composed of inappropriate dosages of active drug compounds. Online marketplaces like Amazon also feature nutraceutical supplements for erectile dysfunction and hypogonadism.”

Balasubramanian and colleagues authored papers recently published in the Journal of Sexual Medicine analyzing these supplements and demonstrated that human studies evaluating the efficacy of supplement ingredients are limited (J Sex Med 2019; 16:203-12; J Sex Med 2019; 16:843-52).

Urologist Ryan P. Smith, MD, said online prescription services for medications like testosterone often fall dangerously short of providing comprehensive care. Dr. Smith, assistant professor of urology at University of Virginia, Charlottesville, said he commonly sees young men who are prescribed testosterone online for complaints including low energy but aren’t told that the testosterone might affect their fertility. One of his recent patients adopted a child because he and his wife didn’t think they could conceive.

“They hired me and I told them that I think this is the testosterone you’ve been on for the last 3 years. Sure enough, we took him off and gave him alternative medication, and he had completely normal fertility,” Dr. Smith said.

Disclosure: Dr. Spitz is a consultant for Foresight Imaging, a telemedicine company. He is a spokesperson for Endo Pharmaceuticals and is on the speaker’s bureau for Abbvie Pharmaceuticals.

STUDY: T-BOOSTING SUPPLEMENT CLAIMS MORE MYTH THAN REALITY

Alternatives to traditional testosterone replacement therapy, known as testosterone-boosteric supplements or “T boosters,” may not have ingredients to support their claims, according to researchers, who say men may want to think twice about using these over-the-counter products to improve their libido or build body mass.

“Many supplements on the market merely contain vitamins and minerals, but don’t do anything to improve testosterone,” said lead author Mary K. Samplaski, MD, assistant professor of clinical urology at the Keck School of Medicine of USC in Los Angeles. “Often, people can be vulnerable to the marketing component of these products, making it difficult to tease out what is myth and what is reality.”

Using a structured review approach, Dr. Samplaski and colleagues explored the active ingredients and advertised claims of 50 T boosting supplements. Their findings were published in The World Journal of Men’s Health (2019; 37:3-34).

Researchers performed a Google search with the search term “Testosterone Booster,” thus mimicking a typical Internet research for someone looking to increase testosterone levels, and then selected the first 50 products that came up in their search. The team then reviewed published scientific literature on testosterone and the 109 components found in the supplements. Zinc, fenugreek extract, and vitamin B6 were three of the most common components in the supplements.

The research team also compared the content for each supplement with the FDA Recommended Daily Allowance and the upper tolerable intake level as set by the Institute of Medicine of the National Academy of Science.

Of the 150 supplements, researchers came across 16 general claims to benefit patients, including claims to “boost T or free T,” “build body lean mass or muscle mass,” or “increase sex drive or libido.” While 90% of the T booster supplements claimed to boost testosterone, researchers found that less than 25% of the supplements had data to support their claims. Many also contained high doses of vitamins and minerals, occasionally more than the tolerable limit.
Men primarily ask me about treatments those centers offer for ED or low testosterone. Patients ask, ‘Are they offering something other than what you guys do, and who’s doing it?’

I tell patients, ‘Look on the website; see who is running those clinics.’ If they don’t have a doctor listed, I wouldn’t bother going. If doctors are afraid to put their name behind the clinic, it’s probably some place patients should avoid.

Some clinics offer shock wave therapy for ED; some offer platelet-rich plasma; some, bioidentical hormone substitution. Patients ask whether they should consider those therapies. Typically, I counsel them to avoid therapies which haven’t been proven successful through randomized clinical trials.

Some men go, then come back and say it didn’t do anything. Others go and we never see them again. It really depends. Most times, we offer patients enough alternatives that they really don’t need to go there.

The usual feedback from men who have gone is that the places were a little sketchy. They weren’t sure if the people running them were doctors or nurses or what. They didn’t get good explanations about exactly what they were doing. A lot of these places prey on men who are looking for alternative treatments they think the medical establishment doesn’t consider.

They make promises they can’t keep, like ‘we guarantee you’ll be able to get an erection,’ but when it’s not the appropriate treatment, patients end up with a priapism and have to come to us. When they find their way here, we treat them with proven treatments.”

Jason Kovac, MD / Greenwood, IN

We have one of those cash-grab clinics on every corner. They promote injection therapy, supplying patients intracorporeal injections with prefilled syringes for many months so they lose their potency. Their latest gimmick is low-intensity shock wave treatment, using shock wave therapy to treat Peyronie’s disease and ED. The AUA and Sexual Medicine Society of North America came out with similar statements that shock wave is investigational and men who are interested should sign up for a study evaluating it.

Questions come up every day from my patients. If they’re interested, I tell them to find a clinical trial because we don’t know whether it’s truly efficacious. We don’t know what intensity should be administered or how often.

Clinics are charging $500 per treatment, usually giving patients six or seven treatments for cash. Shock wave therapy was approved by the FDA for tissue regeneration, but not for tissue regeneration in the penis.

Most of the time, after I talk to men, they don’t try it. Some men already tried it and it didn’t work. They’re upset they spent a lot of cash, that wasn’t covered by insurance, and didn’t get any benefit.

None of these centers are being run by urologists. My patients who have gone haven’t even seen a physician. They have physician assistants or nurse practitioners, but none of them have seen a urologist.

If they come to me before doing the treatment, I explain our position. If they come afterwards and it didn’t work, I try to help them.”

Sheldon Freedman, MD / Las Vegas

We definitely see more patients coming to us for second opinions after they’ve been to one of those clinics. We don’t see many going the other direction. They come once they realize something’s not quite right or if they have questions that aren’t being answered.

They usually realize they’re lacking lab reports or that no one checked their hematocrit levels, their blood count, estrogen levels, or their PSA; or they weren’t satisfied with the medication. Some places use nonstandard sources for their medication.

Sometimes it’s the cost. Patients expect them to be less expensive, but actually they usually cost more than health systems.

I avoid talking negatively about other practitioners, but I will tell patients that we have a multidisciplinary approach, coordinating with cardiologists, with endocrinologists about bone density, and other practitioners with skills in different areas that can benefit patients more than just looking at an isolated area such as testosterone.

I think the standardized protocol is the key benefit missing on their side. We track patients’ labs, follow men for all aspects of health—whether it be mental health, bone density. Many health systems do, but that’s usually lacking in pop-up clinics that really just focus on one thing.

Men’s centers here are offering testosterone treatments without doing much testing beforehand. They also give little or no warning about potential comorbidities of testosterone.

Patients generally like that we follow stricter guidelines.”

Matthew Wosnitzer, MD / New Haven, CT
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Urologist – General and Reconstructive Surgeon

The University at Buffalo, in association with Western New York Urology Associates and the Erie County Medical Center (ECMC), is seeking candidates for a full-time position specializing in reconstructive surgery. Eligible candidates should be board-certified or board-eligible in urology, fellowship-trained in Reconstructive Surgery, and be eligible for a New York medical license. Additional information is available online on the Modern Medicine Career Board.

Interested candidates please email estone@maximweb.com
The Division of Urology at the University of Vermont Larner College of Medicine in alliance with the University of Vermont Medical Center, is seeking Clinical Practice Physicians who are board eligible/board certified Urologists to join the Urology service at our affiliate community medical center, 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 additional colleagues to join the dynamic Urology faculty that span the network hospitals. Specifically, the Division seeks applications from individuals seeking a community Urology employment opportunity with a collegial and collaborative setting with University support. Plattsburgh is located on the shores of Lake Champlain with easy access to the Adirondack Mountains, Olympic-Lake Placid region, Montreal and Burlington, VT.

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.

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, Chief of Urology, via Kristin Allard at Kristin.Allard@uvmhealth.org

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.
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 (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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Bipartisan bill targets prior authorization

AUA among groups urging legislation’s passage

“Of all the much-needed updates to prior authorization, none is more critical than ensuring that, for routinely approved services, health plans make prior authorization available in ‘real time’ so that physicians and their staff have more time to spend on patient care, rather than paperwork.”

REP.AMI BERA, MD (D-CA)

The hassles caused by Medicare Advantage prior authorization requirements are being targeted by a coalition of medical specialty organizations and a bipartisan group of congressional representatives who are responding to their concerns.

The key culprits are Medicare Advantage plans that have imposed increasingly onerous prior authorization requirements for medical services that are adversely affecting patient access to necessary medical care, according to the Regulatory Relief Coalition (RRC).

The coalition, which includes the AUA and seven other national medical specialty groups, contends that prior authorization requirements are worsening, patients often experience long delays before obtaining needed treatment, and physicians’ offices are overburdened with the time-consuming process of obtaining the needed approval.

“Prior authorizations are the worst,” said Robin Shaw, billing manager at Urological Associates of Savannah, PC, in Savannah, GA. “We are getting 100% of the CY Medicare fee schedule; however, the administrative burden is ridiculous. I have had to hire someone additional to do pre-certs due to the requirements they have placed on us for authorizations.”

“The preauthorization gauntlet prevents or delays patients from receiving needed diagnostic tests and therapies and adds significantly to health care provider costs and regulatory frustrations with the clear goal for enhancing profits for health care provider costs and regulatory delays patients from receiving needed diagnoses for authorizations.”

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“What proposed bill would do

According to the RRC, H.R. 3107, the bipartisan Improving Seniors’ Timely Access to Care Act of 2019, would protect patients from unreasonable Medicare Advantage plan requirements that needlessly delay or deny access to medically necessary care. It would require the Centers for Medicare & Medicaid Services (CMS) to regulate Medicare Advantage plans on prior authorization’s use. It would also require the plans to report to CMS on the extent of such use and the rate of approvals or denials by service and/or prescription medication.

The bill is sponsored by Reps. Suzan DelBene (D-WA), Ami Bera, MD (D-CA), Roger Marshall, MD (R-KS), and Mike Kelly (R-PA). It is based on a consensus statement adopted by leading national organizations representing physicians, hospitals, and health plans.

Last year, over 100 members of Congress called for such reform in a bipartisan letter to CMS.

According to Dr. Bera, the legislation would improve the prior authorization process in Medicare Advantage plans through improved transparency, electronic adoption, and an analysis on the items and services subject to prior authorization.

“Of all the much-needed updates to prior authorization, none is more critical than ensuring that, for routinely approved services, health plans make prior authorization available in ‘real time’ so that physicians and their staff have more time to spend on patient care, rather than paperwork,” Dr. Bera said.

In addition, the bill includes a surgical exception that allows the surgeon to rely on the initial authorization if he/she needs to perform additional services while the patient is in surgery.

“Physicians spend far too much time on burdensome paperwork and seeking authorization on certain items when they can be spending that time taking care of their patients. This bill modernizes the process and it is a win for physicians and patients,” Dr. Bera said.

“When seniors need critical medical care, doctors and support staff should be spending their time working with patients instead of having to haggle with insurance companies over whether they can do their jobs,” DelBene said. “This bipartisan legislation creates sensible rules for the road and will offer transparency and oversight to the prior authorization process.”

Survey outlines prior auth’s toll

In conjunction with introduction of the legislation, the RRC released results of a physician survey that details the extent to which abusive prior authorization policies are putting patients at risk and increasing burdens on physician practices.

According to the survey:

• Eighty-two percent of respondents say prior authorization either always (37%) or often (45%) delays access to necessary care.

• For most physicians (74%), it takes 2 to 14 days to obtain prior authorization, but for 15%, this process can take from 15 to more than 31 days.

• Prior authorization causes patients to abandon treatment altogether, with 32% reporting that patients often abandon treatment and 50% reporting that patients sometimes abandon treatment.

• Eight-four percent of physicians say the burden associated with prior authorization has significantly increased over the past 5 years.

• The burden associated with prior authorization for physicians and their staff is high or extremely high (92%).

• Despite gaining prior authorization, insurance companies deny payment after services are rendered, an outcome three-fifths of physicians have experienced more than once in the past year, and 16% have had this happen 20 or more times.

• Nearly three-fifths (59%) of physicians have staff members working exclusively on prior authorization, with most staff spending 10-20 hours per week on prior authorization.
Not your patient? You can still be sued for malpractice

Laws regarding curbside/formal consults vary by state

A recent state Supreme Court decision in Minnesota has cast a broad definition of when a legal duty applies to a provider, and therefore, perhaps broadened the range of circumstances under which a physician who has no patient-physician relationship might be sued.

In Warren v. Dinter, the patient sought medical care for abdominal pain, fever, and chills, among other symptoms. She was evaluated by a nurse practitioner (NP). Her lab results demonstrated an elevated white blood cell count, and the NP suspected an infectious process. The NP placed a call to the local hospital to discuss admission with the admitting hospitalist.

During this conversation, which lasted approximately 10 minutes and during which the admitting hospitalist was unable to view the patient’s medical record, the decision was made by the hospitalist to not admit the patient. Her symptoms were attributed to her diabetic condition and outpatient follow-up was recommended. The patient died 3 days later of an untreated staph infection (bit.ly/mmaarticle; bit.ly/gidasonbunterarticle).

Suit brought against NP, hospitalist

The patient’s son brought a medical malpractice action against both the NP and the hospitalist. The trial court granted summary judgment to the defendants, and the Minnesota Court of Appeals affirmed the decision, holding there was no duty of care owed by the hospitalist because there was no physician-patient relationship. The hospitalist had only spoken to the NP by phone and had not seen the patient. The Minnesota Supreme Court overturned the lower court rulings, stating in part that it had “never held that such a relationship is necessary to maintain a malpractice action under Minnesota law” (bit.ly/gidasonbunterarticle) and applying a foreseeability standard.

As it pertains to foreseeability, the Court stated: “When there is no express physician-patient relationship, we have turned to the traditional inquiry of whether a tort duty has been created by foreseeability of harm” (bit.ly/warrenvdinter).

In fact, the first line of the decision reads: “A physician-patient relationship is not a necessary element of a claim for professional negligence. A physician owes a duty of care to a third party when the physician acts in a professional capacity, and it is reasonably foreseeable that the third party will rely on the physician’s acts and be harmed by a breach of the standard of care” (bit.ly/warrenvdinter).

It is prudent for providers to know the law of the jurisdiction where they practice and any applicable policies surrounding consult and documentation.

The Court highlighted a few points in coming to its conclusion (bit.ly/gidasonbunterarticle):

- The NP did not have admitting privileges, and it was the hospitalist’s sole duty to make decisions around patient admission.
- The hospitalist knew or should have known that the decision to admit or not would have been relied upon by the NP and her patient.
- The hospitalist knew or should have known that breach of the standard of care could result in harm.
- The Court repeatedly referred to the hospitalist in this case as the “gatekeeper,” distinguishing him from a “curbside consult” in that the hospitalist was the individual with the sole authority to make a decision around hospital admission (bit.ly/warrenvdinter).

Although this case pertains in detail to primary care and internal medicine, it can easily be extrapolated to other areas of medicine, urology included, and offers a good opportunity to revisit issues surrounding curbside consults, documentation, applicable hospital and insurance carrier policies and guidance, and legal differences between jurisdictions.

‘Curbside’ vs. formal consults

For example, a small study from 2013 looked at the accuracy and completeness of curbside consults versus formal consults (J Hosp Med 2013; 8:31-5). With a sample size of 47 patients getting both curbside and formal consults, information was either inaccurate or incomplete in 24 of 47 of the curbside consultations. Management advice after formal consultation differed from that given in the curbside consultation for 28 of 47 patients. Lastly, when inaccurate or incomplete information was received, the advice provided in the formal versus the curbside consultation differed in 22 of 24 patients, a statistically significant result.

Many hospital and insurance carriers have either policies or guidance around curbside and formal consults, and documentation of these. Given that jurisdictions differ in how the physician-patient relationship arises, it is prudent for providers to know the law of the jurisdiction where they practice and any applicable policies surrounding consult and documentation.

Minnesota and a handful of other states fall into the “minority view,” in that a physician’s duty is not tied to personal contact with the patient. Despite that, and given the ever-changing communication landscape and the use of technology in medicine, close introspection of personal practice may be worthwhile to ensure your practices align with what your state and medical facility or organization permit.

Between text messaging, emails, phone calls, and electronic medical record portal messaging, plenty of communication about patients occurs outside of the exam room. Protect yourself by knowing the law in the state where you practice and what your insurer or counsel’s office recommends when it comes to your duty as a consultant, whether formal or informal. UT
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.

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