The end of mesh as we know it?
FDA bans mesh kits for POP repair; support continues for sling to treat stress incontinence

ON APRIL 16, 2019, the FDA ordered the two manufacturers of surgical mesh products indicated for the transvaginal repair of pelvic organ prolapse (POP) to immediately stop selling and distributing their products in the United States. The agency said it determined that the manufacturers had not demonstrated “a reasonable assurance of safety and effectiveness for these devices,” the standard that applies since the FDA reclassified them in class III (high risk) in 2016. This FDA statement does not apply to transobturator and retropubic midurethral slings currently on the market for the treatment of stress urinary incontinence. Transabdominal mesh products such as those used for abdominal sacrocolpopexy, either through an open, robotic, or laparoscopic approach, are not affected. The directive follows a decade of notifications, warnings, and other actions taken by the FDA. It has sparked discussion in the medical literature, lay press, and on social media. In this issue of Urology Times, we take a wide-ranging look at the FDA ban of mesh for POP and what its future impact may be. Our coverage begins with a Q&A with Eric S. Rovner, MD, and continues with reaction from other experts in the field, including current leaders at the American Urological Association, Society of Urodynamics, Female Pelvic Medicine and Urogenital Reconstruction, and American Urogynecologic Society. For a full list of articles and commentary, see the box above.
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
1. LIFT study showed an IPSS reduction of 47% at 1 year. Roehrborn, J Urology 2013
2. Roehrborn, J Urology 2013
3. No instances of new, sustained erectile or ejaculatory dysfunction. McVary, J Sex Med 2014

To learn more about My Story, visit www.info.UroLift.com/UT
Check out the data at UroLift.com
From the Board

Prostate Ca study highlights complexity of ‘appropriate care’

PETER C. ALBERTSEN, MD
Dr. Albertsen, a member of the Urology Times Editorial Council, is professor of surgery and chief of urology at the University of Connecticut Health Center, Farmington.

Research by Sun et al presented at the AUA annual meeting just scratches the surface of the complexity of health care resource consumption and appropriate health care. The authors note that 5 percent of patients with newly diagnosed prostate cancer consumed 23% of health care resources utilized by men with newly diagnosed prostate cancer (page 4).

This conclusion is not surprising and is simply a variation of the well-known Pareto principle. Named for the Italian economist Vilfredo Pareto, who noted in 1896 that 20% of Italians owned 80% of the land, the 80/20 rule has proven remarkably accurate in many economic situations. Researchers have demonstrated that 20% of Medicare recipients in general consume 80% of Medicare resources. This rule is not limited to prostate cancer patients.

Health care costs continue to escalate and are becoming an increasingly important political issue in the U.S. The current financing mechanisms are no longer sustainable. Most European countries control health care costs through budgets. The NHS in the United Kingdom has a very explicit methodology to determine if new pharmaceuticals, especially anti-cancer drugs, and other new medical technologies will be funded. Most new treatments are evaluated according to their cost per life-year saved.

The U.S. has a very different model of health care delivery that depends primarily on the ability to pay. Most Americans have some form of health insurance that they use to help pay for the care they receive. More and more expenses, however, are either only partially covered or not covered at all. Furthermore, insurance companies are more frequently demanding co-pays or mandating pre-authorization before covering discretionary care.

We must all participate in this health care debate. When healthy, we are often reluctant to pay health care premiums or recent increases in taxes to cover Medicare and Medicaid services. When sick, however, we want only the best for ourselves and our family. We expect others to help us shoulder the costs of nursing home care for our parents or expensive chemotherapy for ourselves or our spouse.

The health care industry—including pharmaceutical companies, device companies, surgeons, and medical doctors—has the ability to constantly innovate. This is a good thing when new treatments lead to substantial gains in returning people to productive, healthy lives. Unfortunately, it is a bad thing when treatments simply prolong suffering and do not lead to independent living.

Deciding what care is appropriate is already extraordinarily difficult but will be a growing problem for the next generation of physicians and society.

To read more, see PCa costs: 5% of patients account for ~25% of total spending on page 4

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Clinical Updates

PROSTATE CANCER / Cost drivers include both clinical, non-clinical factors

Prostate Ca care costs: 5% of patients account for ~25% of total spending

Cheryl Guttmann Krader
UT Contributing Editor

Results of a population-based study analyzing Medicare expenditures in the first year after men are diagnosed with prostate cancer show that 5% of patients account for almost 25% of the total spending that year.

The variables found to contribute to being a high-resource patient include both clinical and non-clinical factors, reported first author Maxine Sun, PhD, MPH, at the AUA annual meeting in Chicago.

“In terms of contribution to the burden of national health care expenditures, treatment of men with prostate cancer ranks among the top five cancers. Understanding of service utilization and the factors associated with high-resource spending for this patient population is important for identifying strategies for optimizing value-based care,” said Dr. Sun, research scientist in the division of urology at Brigham and Women’s Hospital and the Lank Center for Genitourinary Oncology at the Dana-Farber Cancer Institute, Boston.

The research, which was funded by an AUA Data Grant, analyzed payment data for a Surveillance, Epidemiology, and End Results Medicare prostate cancer population. It included 12,875 men ages ≥66 years who were diagnosed with prostate cancer in 2009 and had at least 1 year of continuous follow-up.

The cohort was divided into two groups according to spending status (top 5% vs. bottom 95% resource-patients). The 646 men comprising the top 5% of spenders accounted for almost $62.5 million in the total $241 million spent in 2009.

Analyses of inpatient costs showed that the average cost for prostate cancer-related care was almost $10,000 greater for men in the top 5% of spenders than for those in the bottom 95%: $22,284 versus $13,151. Average spending for non-prostate cancer inpatient care was almost $15,000 higher for men in the top 5% of spenders compared with those in the bottom 95%: $28,767 versus $13,908.

For outpatient services, the top 5% of spenders accrued $1,417 in expenditures for prostate cancer-related care and $1,011 for non-prostate cancer-related care; corresponding expenditures for the bottom 95% of spenders were $1,297 and $770, respectively.

Advanced age among predictors of high costs

A univariable analysis of potential patient, disease, sociodemographic, and regional characteristics associated with being a high-resource user showed that compared with the men in the bottom 95% of spenders, the top 5% group was comprised of men who were significantly older, sicker at diagnosis, more likely to be African-American, less likely to be married, and more likely to have advanced-stage or metastatic disease.

A multivariable analysis found that more advanced tumor stage, metastatic disease, unmarried status, higher Charlson Comorbidity Index, and living in a high Medicare spending health service area were all independently associated with being a top 5% spender.

“We hypothesized that the top 5% resource-patients are invariably sicker and older than the bottom 95% resource-patients. Strikingly, we found that approximately one-third of men in the group comprising the top 5% of spenders died in the year after their prostate cancer diagnosis compared with just 5% of their counterparts in the bottom 95% resource-patients,” Dr. Sun said.

“We found that approximately one-third of men in the group comprising the top 5% of spenders died in the year after their prostate cancer diagnosis compared with just 5% of their counterparts in the bottom 95% resource-patients.”

MAXINE SUN, PhD, MPH

Source: Maxine Sun, PhD, MPH

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<th>TABLE</th>
<th>PCA COSTS BY HIGH-RESOURCE, NON-HIGH-RESOURCE SPENDERS</th>
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<td>Top 5% of spenders</td>
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<tr>
<td>Avg. cost, prostate cancer-related inpatient care</td>
<td>$22,284</td>
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<td>Avg. cost, non-prostate cancer inpatient care</td>
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<td>Avg. cost, non-prostate cancer outpatient care</td>
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Corrections

An article in the May 2019 issue (“ED cure? Or unproven treatment?” page 1) mischaracterized GAINSWave as a medical device. According to a GAINSWave spokesperson, GAINSWave is a marketing organization that educates consumers and raises public awareness for low-intensity shock wave therapy for erectile dysfunction.

The May 2019 “Washington and You” article (“ESWL reimbursement slashed by 22%,” page 37) provided an incorrect title for Deepak Kapoor, MD. Dr. Kapoor is LUGPA chairman of Health Policy and a past president. LUGPA’s current president is Richard Gerald Harris, MD.

We apologize for any confusion these errors may have caused.
The use of enzalutamide (XTANDI) to treat men with chemotherapy-naïve metastatic castrate-resistant prostate cancer (mCRPC) is associated with better overall survival and significantly lower resource use and health care costs compared with abiraterone acetate (ZYTIGA), according to findings from a retrospective analysis of real-world data presented at the AUA annual meeting in Chicago.

“Prostate cancer is the second leading cause of cancer death for men in the United States, and it accounts for a large health care cost burden. Both enzalutamide and abiraterone combined with prednisone are approved therapies for men with mCRPC. Findings from previous retrospective analyses suggest that enzalutamide is associated with survival advantages compared with abiraterone and prednisone when used to treat men with mCRPC in both chemotherapy-naïve and post-chemotherapy patient populations,” said Daniel J. George, MD, professor of medicine and co-chair of the Duke Cancer Institute Center for Prostate and Urologic Cancers, Durham, NC.

“The results from our analysis are consistent with the prior data for overall survival. In addition, our study provides insight on the economic burden of veterans with mCRPC, revealing that treatment with enzalutamide resulted in statistically less clinic visits and hospitalizations than treatment with abiraterone.”

“Better survival, lower costs with enza vs. abi
Mean inpatient length of stay significantly shorter for enzalutamide group, data show

The research used the Veterans Health Administration (VHA) database to identify adult men diagnosed with prostate cancer between April 1, 2013 and March 31, 2017. Men were selected for the study if they had undergone surgical or medical castration for prostate cancer and then had a pharmacy claim for abiraterone or enzalutamide (index date). Men were also required to have no history of receiving a prescription for chemotherapy, abiraterone, or enzalutamide during the 12 months prior to the index date and to have continuous VHA enrollment for at least 12 months before and after the index date.

After applying the selection criteria, 1,945 men prescribed abiraterone and 1,229 patients prescribed enzalutamide were included in the survival analysis. Median follow-up after the index date was similar in the enzalutamide and abiraterone groups (18 and 19 months, respectively), and the groups were well-matched for mean age, race, and Charlson Comorbidity Index score. The proportion of men with arrhythmia, congestive heart failure, and type 2 diabetes was significantly higher in the enzalutamide group, whereas a greater percentage of men prescribed abiraterone had received a corticosteroid prior to the index date.

Median overall survival time estimated with Kaplan-Meier analysis was 29.3 months for the enzalutamide group and 26.0 months for men prescribed abiraterone. A multivariate Cox proportional-hazards regression model found the risk of death was significantly lower in men treated with enzalutamide (hazard ratio: 0.87; p<0.0073).

Health care costs lower in enzalutamide group
Prostate cancer-related health care costs for inpatient and outpatient medical care were also significantly lower in the enzalutamide group as were total prostate cancer-related health care costs, which included inpatient, outpatient, and pharmacy expenditures ($6,321 vs. $7,280; p<0.001).

Similarly, all-cause health care costs were significantly lower in men prescribed enzalutamide compared with those prescribed abiraterone considering both inpatient and outpatient medical costs, and there was a statistically significant difference of approximately $1,000 in total all-cause health care costs favoring the enzalutamide group ($8,086 vs. $9,092; p<0.001).

“Nonetheless, increased clinic visits and hospitalizations create added physical and emotional stress and fatigue on our patients and their caregivers. Awareness of the full impact these treatments have on our patients and their caregivers should factor into our decision process.”

The research was funded by Pfizer. Dr. George is a consultant to and his institution receives research support from Janssen/Janssen Oncology. He is a consultant for Pfizer/Astellas and his institution receives research support from Pfizer.

### TABLE ENZALUTAMIDE VS. ABRIRATERONE: HOW COSTS/RESOURCE USE COMPARISON

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<thead>
<tr>
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<th>Enzalutamide group</th>
<th>Abrisoterone group</th>
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<tr>
<td>Mean number of pharmacy visits</td>
<td>0.86</td>
<td>0.87</td>
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<tr>
<td>Mean inpatient length of stay (days)</td>
<td>0.45</td>
<td>0.63</td>
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<tr>
<td>Mean number of outpatient visits</td>
<td>0.86</td>
<td>1.03</td>
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<tr>
<td>Prostate cancer-related health care costs</td>
<td>$6,321</td>
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<tr>
<td>All-cause health care costs</td>
<td>$8,086</td>
<td>$9,092</td>
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Source: Daniel J. George, MD

### TELEMEDICINE USERS EXPECT SERVICES TO INCREASE

Nearly 84% of urologists who currently use telemedicine expect these services to increase within the next 3 years, according to data from the 2018 AUA Annual Census report, “The State of the Urology Workforce and Practice in the United States.”

In addition, 61% believe the use of these services offers individuals in underserved areas new opportunities for enhanced quality of care with reduced costs. To read the full report, go to www.AUAnet.org/CensusReport.
Does mpMRI have a role in predicting RP pathologic outcomes?

Modality shows minimal value in predicting non-organ-confined disease, extracapsular extension

Jeni Williams / UT Correspondent

CHICAGO—More research is needed to determine the value of using magnetic resonance imaging (MRI) to predict pathology outcomes following radical prostatectomy, according to a study presented at the AUA annual meeting in Chicago.

While the results of the study showed minimal additional value in using multiparametric prostate MRI (mpMRI) to help predict pathology outcomes for radical prostatectomy at the time of surgery, just three predictors were used: highest Prostate Imaging Reporting and Data System (PI-RADS) score, number of lesions, and appearance of lymph nodes. Additionally, the study relied on MRI registry data from a single center.

“We’re hoping we’ll see more of a difference by looking at lesion location as well as lesion size and by studying patients from more centers,” Karandeep Singh, MD, MMSc, assistant professor of medicine and assistant professor of learning health sciences at the University of Michigan, Ann Arbor, told Urology Times. “We are currently in the process of combining MRI registries from three large health systems and are looking at additional MRI predictors to address these limitations.”

The study was conducted by the Michigan Urological Surgery Improvement Collaborative (MUSIC), a consortium of 45 urology practices looking at additional MRI predictors to address registries from three large health systems and are currently in the process of combining MRI data from the MUSIC registry and identified 392 men who underwent an mpMRI between 2015 and 2018 prior to undergoing radical prostatectomy. The team then developed random forest models to predict the presence of non-organ-confined disease (NOCD), extracapsular extension (EPE), seminal vesicle invasion (SVI), or lymph node involvement (LNI) at the time of surgery.

Next, the authors evaluated the ability to predict pathology outcomes in these men using:

• traditional predictors (clinical T-stage, PSA levels, biopsy Gleason score, and the number of positive and total cores detected on the biopsy)
• mpMRI predictors (highest PI-RADS score, number of lesions, and appearance of lymph nodes)
• both traditional and mpMRI predictors.

The authors used a 10-fold, cross-validated area under the curve to assess model discrimination.

Ability to predict lymph node involvement worsens with mpMRI

The results showed little difference between MRI and traditional predictors in predicting pathology outcomes. The authors also found only slight improvement in predicting NOCD, EPE, and SVI when traditional predictors and MRI predictors were combined. The ability to predict LNI, on the other hand, slightly worsened when MRI and traditional predictors were combined.

As expected, traditional predictors exhibit excellent discriminative ability for predicting pathologic outcomes, they found.

Until more than three mpMRI predictors are examined, “If you have an MRI, the only thing you might be able to provide greater information on is who to dissect,” Dr. Singh said.

Low T could hasten time to post-RP biochemical recurrence

Higher free T levels do not further progression of prostate cancer, findings confirm

Jeni Williams / UT Correspondent

CHICAGO—Men with low levels of free testosterone 3 months after undergoing radical prostatectomy could face increased chance of early recurrence of prostate cancer, according to researchers from the University of California Irvine.

It’s a finding that could point to the benefit of testosterone replacement therapy in men with low free testosterone and total testosterone.

“We didn’t expect free testosterone to be an independent predictor of recurrence,” co-author Linda M. Huynh, MS, clinical research coordinator and assistant specialist in the department of urology at University of California Irvine, told Urology Times during the AUA annual meeting in Chicago.

The study confirms that higher levels of free testosterone do not further the progression of prostate cancer, the authors say. Meanwhile, low levels of free testosterone may hasten time to biochemical recurrence following radical prostatectomy.

The relationship between testosterone and prostate cancer has long been a source of controversy. For years, researchers believed testosterone replacement therapy increased men’s chances of developing prostate cancer. Now, some new studies are exploring whether testosterone replacement therapy could reduce the risk of aggressive prostate cancer. A study presented at the European Association of Urology annual congress in Barcelona found a 53% reduction in recurrence of prostate cancer among patients treated with testosterone therapy following robot-assisted radical prostatectomy.

See LOW T, page 8

“We didn’t expect free testosterone to be an independent predictor of recurrence.”

LINDA M. HUYNH, MS
PCa agent evaluated by PSA progression status

Enzalutamide reduces MFS event risk in men with, without PSA progression, phase III data show

Cheryl Guttman Krader
UT Contributing Editor

Post-hoc analyses of data collected in PROSPER, the prospective phase III randomized placebo-controlled trial of enzalutamide (XTANDI) treatment for nonmetastatic castration-resistant prostate cancer (nmCRPC), show that a significant proportion of men who progress radiologically while on the androgen receptor inhibitor do not meet standard criteria for PSA progression, reported Fred Saad, MD at the AUA annual meeting in Chicago.

“Many clinicians rely on PSA along with physical examination to monitor prostate cancer patients for therapeutic response and disease progression,” said Dr. Saad.

MFS event incidence higher in men with PSA progression

At the data cut-off date, 22% of patients being treated with enzalutamide and 69% of patients in the placebo group met the criteria for PSA progression. In both the enzalutamide and placebo treatment arms, the proportion of men with an MFS event was higher within the subgroup of patients who had PSA progression than in those who did not. Compared to the placebo group, treatment with enzalutamide reduced the risk of an MFS event by 43% within the subgroup of men with PSA progression and by 81% in the subgroup without PSA progression, Dr. Saad reported.

Comparisons between the two treatment arms also showed that at the time of an MFS event, men in the placebo group had a higher median maximum PSA than men being treated with enzalutamide (38.5 ng/mL vs. 6.0 ng/mL), a higher median maximum increase from nadir (193.2 vs. 81.3%), and a higher median maximum absolute increase from nadir (25.6 ng/mL vs. 1.4 ng/mL).

In addition, among men who experienced an MFS event, PSA was unchanged or decreased by 71% (p<.0001). Subgroup analyses showed that enzalutamide maintained its statistically significant benefit for reducing the risk of radiographic progression or death in both men with and without PSA progression (p<.0001 for both subgroups), as defined by Prostate Cancer Working Group 2 (PCWG2) guidelines (≥25% increase and an absolute increase of ≥2 μg/L above the nadir confirmed by a second consecutive value obtained at least 3 weeks later).

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“Most patients in the study who had a radiographic progression event in the absence of PCWG2-defined PSA progression still showed some increase from nadir PSA.”

FRED SAAD, MD
Clinical Updates

First-line therapy for advanced RCC remains controversial amid new approvals

Combination treatment of choice for intermediate-, poor-risk disease not clear, according to expert

Christina Bennett, MS
UT Correspondent

In April of this year, the FDA approved pembrolizumab (KEYTRUDA) plus axitinib (Inlyta) as a first-line treatment for patients with advanced renal cell carcinoma (RCC). The approval, however, comes at a time of considerable progress in the first-line treatment of advanced RCC and means pembrolizumab plus axitinib may not necessarily be the new standard of care for this patient population.

The approval comes 1 year after the FDA approval of nivolumab (Opdivo) plus ipilimumab (Yervoy) for the same treatment line and very similar population of patients. In addition, the pivotal trials—that is, the phase III KEYNOTE 426 trial of pembrolizumab plus axitinib and the phase III CheckMate 214 trial of nivolumab plus ipilimumab—behind each approval used the same comparator arm: sunitinib (Sutent), which was the standard of care at the time. Without a head-to-head trial, it’s unclear which combination treatment is better.

During an interview with Urology Times sister brand Cancer Network, Kai Tsao, MD, medical director of the Ruttenberg Treatment Center at The Tisch Cancer Institute, New York, offered perspective on which combination therapy could be used upfront among patients with advanced RCC. But first, he cautioned that given the dozens of factors that must be considered to arrive at a treatment decision, “there’s no one right answer.”

Approved indications differ
That said, Dr. Tsao noted that the approved indications are different. Pembrolizumab plus axitinib is indicated for favorable-, intermediate-, and poor-risk disease, whereas nivolumab plus ipilimumab is indicated for only intermediate- and poor-risk disease, not favorable-risk disease. He asserted that the standard of care should be pembrolizumab plus axitinib for favorable-risk disease because ipilimumab plus nivolumab did not show an overall survival (OS) benefit for favorable-risk disease in CheckMate 214.

“The bar has been raised high now in 2019. Overall survival is the new gold standard for the first-line setting.”

KAI TSAO, MD

For patients with intermediate- or poor-risk disease, however, the choice is less clear. Dr. Tsao said the choice is “controversial” because both combinations showed an OS benefit against sunitinib. In addition, the overall response rate was higher for pembrolizumab plus axitinib (59%) compared with ipilimumab plus nivolumab (42%), but ipilimumab plus nivolumab had a higher complete response rate (9% vs. 5.8%). “In terms of efficacy, nobody really knows which one is better in the overall sense,” he said.

When considering tolerability, ipilimumab plus nivolumab appears to be better tolerated by patients compared with pembrolizumab plus axitinib. Grade 3 or 4 adverse events occurred in 46% of patients who received ipilimumab plus nivolumab, whereas 76% of patients who received pembrolizumab plus axitinib had a grade 3 or higher adverse event; this included 2.6% of patients who died.

“What either one versus the other is better, we don’t know at this point,” summed up Dr. Tsao. He said that on the basis of tolerability and complete response rate, ipilimumab plus nivolumab is a combination that “a lot of us feel is a very good choice for the patients.” He added, “Although they both should be considered the standard of care.”

“The bar has been raised high now in 2019,” said Dr. Tsao. “Overall survival is the new gold standard for the first-line setting.”

Additional combinations are currently being evaluated in the same space, and one—avelumab (Bavencio) plus axitinib—received FDA approval in May, on the basis of the phase III JAVELIN Renal 101 trial for first-line treatment of advanced RCC, but OS benefit has not yet been seen against the comparator arm sunitinib, only improvement in progression-free survival.

LOW T
continued from page 6

Meanwhile, literature supports the protective role that high levels of free testosterone play in preventing cardiovascular disease, diabetes mellitus, and other types of metabolic disorders, the University of California Irvine researchers say. They also point to recent data that show low levels of testosterone could be an independent risk factor for high-grade prostate cancer.

The authors sought to examine the relationship between free testosterone and biochemical recurrence in radical prostatectomy patients.

Under the direction of senior author Thomas Ahlering, MD, the group studied 800 patients who underwent robot-assisted radical prostatectomy from December 2009 through June 2018 for primary treatment of localized prostate cancer. Each patient was treated by a single surgeon, and cases from four surgeons were analyzed.

The authors measured patients’ total testosterone and free testosterone levels prior to surgery as well as 3 months after surgery. They also measured PSA levels, the pathologic stage of the cancer, and the pathologic grade. Only patients for whom each of these values was available were included for analysis.

The primary and secondary outcomes measured were biochemical recurrence (defined as two consecutive PSA values of 0.2 ng/dL or greater) and time to biochemical recurrence, respectively. Median follow-up time was 3.2 years following radical prostatectomy.

1 in 5 patients experience recurrence
About one in five patients (20.8%) experienced biochemical recurrence. Among these patients, preoperative free testosterone as well as free testosterone levels after 3 months were significantly lower than those of other patients in the study.

After adjusting for age, lower levels of free testosterone 3 months after radical prostatectomy independently predicted time to biochemical recurrence as well as the pathologic stage of the cancer.

The study is a precursor to another study presented during the AUA annual meeting, “The Predictive Effect of Free Testosterone on Sexual Function Increases with Age.”

“We’re currently looking at a randomized controlled trial for free testosterone therapy to see if it improves sexual function and oncological outcomes,” Huynh told Urology Times.
Study: 5-ARI use associated with delayed PCa diagnosis

Higher PCa-specific mortality rate also observed in patients on 5-ARIs

Dave Levitan / UT Correspondent

The use of 5α-reductase inhibitors (5-ARIs) to treat BPH was associated with a delay in the diagnosis of prostate cancer, according to a recent study.

Men also had poorer cancer-specific outcomes, highlighting a need for awareness of PSA suppression with these agents. The data were published in JAMA Internal Medicine (May 6, 2019 [Epub ahead of print]).

5-ARIs, including finasteride and dutasteride, can reduce prostate volume and relieve urinary outflow obstruction, and they also depress serum PSA concentrations by approximately 50%.

“Randomized trials have shown that PSA screening remains effective for prostate cancer detection among men taking 5-ARIs if the observed PSA level is adjusted to obtain the true PSA level,” wrote study authors led by Reith R. Sarkar, MAS, of the University of California, San Diego. “However, anecdotal evidence has led to speculation that 5-ARI-induced PSA suppression is not routinely addressed in the general medical community.”

The authors tested whether pre-diagnostic 5-ARI use would be associated with delayed diagnosis and more advanced disease at diagnosis in a population-based cohort study using the Veterans Affairs Informatics and Computing Infrastructure linked to the National Death Index. They included a total of 80,875 men diagnosed with prostate cancer between 2001 and 2015, followed until death or until the end of 2017.

A total of 8,587 men (10.6%) were prescribed 5-ARIs for a minimum of 1 year prior to a prostate cancer diagnosis; most of these (8,406 patients) received finasteride. The median 5-ARI treatment duration before the diagnosis was 4.85 years.

The authors found that 5-ARI users had a significantly higher prostate cancer-specific mortality, which was the study’s primary endpoint, with a hazard ratio (HR) of 1.39 (95% CI, 1.27-1.52; p<.001). They also had a higher all-cause mortality, with an HR of 1.10 (95% CI, 1.05-1.15; p<.001).

“The authors are correct in stating that we need to establish very clear guidelines for cancer detection, which was absent in the VA cohort.”

E. David Crawford, MD

Users of 5-ARIs also had worse cancer characteristics at the time of diagnosis. They were more likely to have Gleason grade 8 disease or higher (25.2% vs. 17.0%; p<.001), as well as clinical stage T3 or higher, node-positive disease, and metastatic disease.

“These data suggest that adjustment for 5-ARI-induced PSA suppression was not routinely incorporated in this population,” the authors concluded. “Although these results are hypothesis generating, they highlight a continued need to raise awareness of 5-ARI-induced PSA suppression, establish clear guidelines for prostate cancer detection, and motivate systems-based practices to facilitate optimal care for 5-ARI users.”

E. David Crawford, MD, of the University of Colorado Anschutz Medical Campus, who was not involved with the research, said many “black clouds” have hung over the use of 5-ARIs, including a potential risk for inducing high-grade cancers. He said that once a man is on a 5-ARI for 4 to 8 months, the new PSA level could be considered the new baseline.

“If the level elevates, then this is a red flag to trigger evaluation,” Dr. Crawford said. “The authors are correct in stating that we need to establish very clear guidelines for cancer detection, which was absent in the VA cohort.”

GENITOURINARY CANCERS / Treatment may obviate need for kidney removal in select patients

UTUC agent linked to high rate of disease eradication

John Schieszer / UT Correspondent

An investigational mitomycin formulation for the non-surgical treatment of low-grade upper tract urothelial cancer (LG-UTUC) is continuing to show promise. The latest data from the OLYMPUS Trial suggest that a minimally invasive chemoablation approach utilizing UGN-101, a novel reverse thermal hydrogel containing mitomycin, may result in a high rate of initial disease eradication, possibly obviating the need for kidney removal in select patients.

The findings, which were presented at the AUA annual meeting in Chicago, showed that 41 out of 68 patients (60%) for whom primary disease evaluation (PDE) data were available achieved a complete response after induction therapy. The authors found that 33 of the patients (48.5%) were initially characterized by the treating physician as having endoscopically unreatsectable tumor at baseline, and 19 patients (58%) achieved a complete response at the PDE.

“I believe UGN-101 has the potential to improve quality of life and lower morbidity by helping some patients avoid nephroureterectomy. Renal pelvis cancer typically presents in an elderly patient population with innately reduced kidney function, and UGN-101 would be an alternative to the potential morbidity of a major surgery, as well as the downstream deleterious effects from kidney removal,” said study investigator John L. Gore, MD, MS, a urologic oncologist at the University of Washington in Seattle.

In the current analysis, only three of 41 patients who achieved a complete response had relapsed. One patient relapsed at 3 months following PDE, and two patients relapsed at 9 months. UGN-101 is designed to enable longer exposure of mitomycin to urinary tract tissue, and it is delivered using standard ureteral catheters. Currently, only 30% of UTUC patients receive endoscopic, nephron-sparing treatments.

The standard of care for endoscopically unresectable LG-UTUC is nephroureterectomy. However, this predisposes patients to renal insufficiency and increases the risk of requiring hemodialysis.

Treatment well tolerated

“UGN-101 appeared to be associated with complete chemoablation in 60% of patients. It was well tolerated, with most treatment-related adverse events characterized as mild or moderate and transient. The common side effects included ureteral narrowing, ureteral stricture, hydronephrosis, urinary tract infection, flank pain, and creatinine elevation,” Dr. Gore told Urology Times.

See UTUC page 10
Mutation profiles may aid in treatment of non-clear-cell RCC

13% of tumors harbor potentially actionable somatic mutations

John Schieszer / UT Correspondent

Somatic mutation profiles of metastatic non-clear-cell renal cell carcinoma (nccRCC) vary by subtype, and analyzing somatic and germline mutations and microsatellite instability (MSI) may reveal clinically actionable mutations in a proportion of patients with advanced disease, according to a recent report published in JCO Precision Oncology (2019; 3:1-18).

Among all RCC cases, approximately 20% are nccRCC, which includes subtypes that are highly heterogeneous. Since nccRCC has limited sensitivity to conventional agents targeting vascular endothelial growth factor and mammalian target of rapamycin, a strong need for better therapies exists, and characterizing genomic variations may aid in this quest.

For the study, the authors retrospectively analyzed tumor tissue from 116 patients with metastatic nccRCC. Among these patients, 57 had de novo metastatic disease (49%), and 59 had localized disease that later metastasized (51%). The subtype classifications were highly varied (35% unclassified, 22% papillary, 15% chromophobe, 11% translocation associated, and 16% other).

The authors used OncoKB classification to annotate individual mutations for their therapeutic potential and found that 13% of all tumors harbored potentially actionable somatic mutations. They also explored the efficacy of targeted therapies in patients who received treatment, and found that 33% of patients had an objective response and an additional 25% achieved stable disease. These are very promising findings and point toward more personalized medicine in these subtypes of nccRCC, the authors noted.

The identified alterations included ALK translocation, MET amplifications, and TSC1 or TSC2 alterations. A total of five patients had tumors with level 3 alterations; most alterations were level 4, which are hypothetical biomarkers based on preclinical data.

**Alterations could be biomarkers**

“Although these are not considered clinically actionable, they may be biomarkers and may be used as eligibility criteria for early-phase clinical trials.”

JCO Precision Oncology 2019; 3:1-18

Among 45 patients who had germline testing, the authors found 11 (24%) harbored mutations (24%). Among the 115 available tumors for analysis, the investigators found two tumors (1.7%) had high MSI status and six tumors (5%) had intermediate MSI status.

The study is limited because it is a single-institution experience, and prevalence of RCC subtypes may vary by geography or ancestry.

“While it is unclear how the current findings will impact patient management, it certainly paves the way for additional investigations into the role of the identified alterations in the pathogenesis of this disease and the development of targeted therapeutic strategies,” he added.

UTUC

continued from page 9

He said urologists are limited by the current options available for treating UTUC. The endoscopic options are inadequate and available instilation adjuncts lack the needed dwell time to have benefit.

“The repeated procedures also risk injury to the upper urinary tract, and patients are prone to a high recurrence rate. The other alternative is nephroureterectomy, which is overkill for many low-grade upper tract cancers. UGN-101 was devised to address this unmet need and has the potential to change practice for patients with low-grade renal pelvis cancer,” said Dr. Gore.

As part of this international trial, 71 patients with biopsy-proven LG-UTUC received six weekly instillations via retrograde catheter of UGN-101 (maximum volume, 15 cc; concentration of 4 mg mitomycin/mL) to the renal pelvis and calyces. All the patients had measurable tumor at the time of treatment (minimum lesion size, ≥0.5 cm), and following the last instillation (4 to 6 weeks), each patient underwent a PDE including ureteroscopy and wash cytology. The authors defined a complete response as negative ureteroscopic evaluation and negative cytology.

The company developing this product (UroGen Pharma Ltd.) intends to seek regulatory approval of UGN-101 in LG-UTUC based on data from all 71 patients. It initiated its rolling submission of the New Drug Application to the FDA in December 2018.

“This is a very positive update,” Mark P. Schoenberg, MD, chief medical officer of UroGen, told Urology Times. He said it is possible that approval could occur within the next 12 months.

Adam S. Feldman, MD, MPH, of Massachusetts General Hospital and Harvard Medical School, Boston, said this is an exciting trial for a host of reasons and urologists were anxiously awaiting the latest trial update.

“We are all very excited about it,” said Dr. Feldman, who was not involved in the study.

“Our instrumentation is quite small and limited in the volume of tumor we can treat endoscopically, so this product offers us an ability to treat a tumor that would otherwise be untreatable endoscopically.”

UroGen Pharma funded the study.

“I believe UGN-101 has the potential to improve quality of life and lower morbidity by helping some patients avoid nephroureterectomy.”

JOHN L. GORE, MD, MS

“Understanding the biology of nccRCC is an important area of research given the limited data available in this space.”

SIMPA SALAMI, MD
Severe infertility may dispose males to lower cognitive function

John Schieszer / UT Correspondent

A new study is suggesting that severe male factor infertility may predispose a man to lower cognitive function.

Researchers presented data at the AUA annual meeting in Chicago that support further investigating this relationship to determine whether affected men demonstrate specific genetic defects.

Investigators at Baylor College of Medicine looked at men who either had no sperm in the ejaculate or very few (<10 million sperm/mL) and compared them to men who fathered children without difficulty. They found that men with severe infertility had an IQ score that was about 7.1 points lower than fertile controls.

“Although this was statistically significant, this is not considered to be a significant difference by most cognitive experts and would be unlikely to manifest in a day-to-day fashion,” said study investigator Jonathan Beilan, MD, clinical fellow in male reproductive medicine and surgery at Baylor College of Medicine, Houston, working with Larry Lipshultz, MD, and co-authors.

He said there is growing evidence that suggests genetics are involved in male infertility and this may be important to neural development and cognitive function. Currently, it is unknown if male infertility and lower cognitive function are due to shared genetic abnormalities.

“Further understanding this potential link could aid in counseling couples and direct future treatment plans for affected men,” wrote the authors.

This current study is an update to the research team’s previous series exploring the association between male infertility and cognitive function, anxiety, and depressive symptoms. Dr. Beilan et al prospectively identified and enrolled 70 men (mean age, 38.5 years) presenting to a single academic andrology practice. More than half of the men (N=42) presented with non-obstructive azoospermia or severe oligospermia (<5 million sperm/mL) and 28 had proven fertility (control group).

For this investigation, all the men completed the validated Patient Health Questionnaire-9 (PHQ-9), Generalized Anxiety Disorder-7 (GAD-7) questionnaire, and Test of Nonverbal Intelligence, 4th edition (TONI-4) IQ evaluation under the supervision of a trained technician. The authors analyzed patient occupations and they used U.S. Census Bureau statistics to estimate incomes by occupation. A psychologist in blinded fashion analyzed the TONI-4 results to determine final IQ scores.

When the authors compared the test and questionnaire results between the two groups, they found the mean estimated income in the infertile group was $76,474 compared to $97,340 for the control group (p=.14). Slightly more of the men in the infertile group (22 of 41, 53.7%) had at least a bachelor’s degree compared to the control group (14 of 28, 50.0%) (p=.77). The mean IQ for the infertile cohort was 99.2 points compared to the mean IQ of 106.3 for the control group (mean difference: 7.1 points; p=.001). The mean PHQ-9 scores and the mean GAD-7 scores were similar between both groups and these test results ensured that other psychological factors did not impact the IQ findings.

“It’s important to remember that our study focused on men with only the most severe forms of infertility and that our findings cannot be extrapolated to all men with infertility,” said Dr. Beilan.

“We found an average difference of 7.1 IQ points between the infertile and control groups. While statistically significant, the clinical or real world implications of this are less profound.”

He said this difference represents roughly 0.5 standard deviations from the mean, so clinically it is unlikely to change practice patterns. However, it does point to the potential and interesting connection between fertility and cognitive function.

“Dr. Beilan said in recent years fertility in men has emerged as a measure of health. Individuals with very low sperm counts are not as healthy as those with normal semen counts, as evidenced by increased cancer risk, lower testosterone levels, and increased morbidity/mortality rates, according to Dr. Beilan. He noted that many of these men may have genetic defects that explain their low sperm counts, but these same defects can affect more than just the reproductive system.

“Although our study was not designed to elucidate the mechanism behind this connection, it reaffirms that there is an intrinsic relationship that deserves further investigation,” said Dr. Beilan.

Focus groups shed light on male partner’s experience of infertility

Both men and women report frustration with lack of information on male-factor infertility

John Schieszer / UT Correspondent

Male partners of infertile couples experience substantial emotional and psychological distress, which is often unrecognized, according to new data presented at the AUA annual meeting in Chicago.

The authors reported that men experience female-factor infertility differently from male-factor infertility.

“See INFERTILITY, page 12
Laser lithotripsy: Is there a saturation point for frequency?

Cheryl Guttman Krader
UT Correspondent

Increasing the frequency setting on a holmium:YAG laser increases stone fragmentation, but determining the saturation point at which efficiency plateaus will require further study, researchers from the University of Michigan reported at the AUA annual meeting in Chicago.

“Previously available holmium laser lithotripsy systems were limited to a maximum frequency of 20 Hz. With their higher power, newer generation lasers can achieve frequencies of 80 Hz, which led to the advent of the dusting technique using low pulse energy and high frequency. In theory, increasing the frequency would be expected to increase stone fragmentation, but it is not known if there is a level above which there is no additional gain from raising the frequency,” said first author Ali Aldoukhi, MD, MS, research fellow in urology at the University of Michigan, Ann Arbor.

“Our research was designed to answer this question, and based on our findings, we believe that a saturation point for efficiency may be reached when the frequency is 80 to 100 Hz. However, confirmation of our prediction will require additional study.”

The laboratory study was comprised of two sets of experiments that were done using a 120W holmium:YAG laser (Moses P120) with a 230-μm core fiber (Moses 200) and pulse energy setting of 0.5 J. The first experiment investigated the effect of frequency on fragmentation of a flat BegoStone at a fixed location. It was done with the fiber fixed in contact with the stone.

Crater volume was measured using 3-D laser confocal microscopy after delivery of 1, 5, 10, 15, 20, 25, 30, 35, and 40 pulses. Five trials were done at each pulse level, and averaging of the results showed that crater volume increased only minimally with delivery of more than 20 pulses.

Of greater clinical relevance, the second experiment investigated the relationship between increasing frequency and fragmentation when the fiber was moving. Here, the fiber was attached to a 3-D positioner and used to make 10 20-mm lines, simulating a painting technique, while the fiber was moved at a rate of 1 or 3 mm/second. Five trials each were done at each speed for frequencies of 20, 40, and 60 Hz. Fragmentation was calculated as the difference in stone mass before and after treatment.

At the 1-mm/second speed, increasing the frequency from 20 to 40 Hz resulted in 38% greater fragmentation. Fragmentation approximately doubled when using a frequency of 60 Hz compared with the 20-Hz setting.

At each of the three frequencies, absolute fragmentation was significantly greater at 1 mm/second than at the faster speed of 3 mm/second. However, when considering time as a factor, fragmentation was more efficient at a faster speed when the outcome was measured in mg/second.

Several caveats to consider

Senior author Khurshid R. Ghani, MD, said that the clinical implications of this work suggest there might be a saturation point for frequency when using the holmium:YAG laser for stone fragmentation, especially when performing a dusting technique. He mentioned, however, that there are several caveats to consider.

“One limitation of our work is that we did not assess how using higher pulse frequencies can affect vision quality during dusting technique. Higher frequencies might result in more debris that could hinder optimal visualization and cause the surgeon to slow down, thereby leading to lower efficiency. This problem might be addressed in the future by suction systems or devices during lithotripsy,” Dr. Ghani said.

“In addition, we do not know how fast surgeons are moving the fiber when executing a dusting technique during ureteroscopy. Understanding this is important, especially since robotic platforms for ureteroscopy are currently being developed.”

Dr. Ghani is a consultant to Lumenis and Boston Scientific.

INFERTILITY

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has been mainly geared toward female partners. That needs to change, according to Dr. Mehta and her co-authors. They conducted a study with exploratory focus groups involving 13 male and 14 female participants affected by infertility. The focus groups, which were run by trained facilitators, documented comments via audio recordings and written summaries.

The focus groups discussed individual experiences with male-factor and female-factor infertility, and the availability and quality of education materials pertaining to the diagnosis and treatment of male factor infertility. The authors found that feelings of grief and loss related to the inability to have a family were common. Dr. Mehta said men reported problems communicating with their partners, and this often led to emotional isolation.

“There are very little data on what the male partner’s experience is, and what they go through in terms of diagnosis,” Dr. Mehta said in an interview with Urology Times. “This was a well-educated group and they had no idea they could have a problem and they completely rejected that notion and that really surprised me.” She also was surprised by how uneducated the men were health wise.

The authors found that with female-factor infertility, men viewed their primary role as problem solvers. However, that was not the case when it was a male-factor infertility issue. The men reported frequent self-blame, loss of manhood, and feelings of guilt and isolation.

“There is a stigma around infertility for men and women. It has been thought of as a female problem, but for men who are supposed to be the stronger sex, for them to find they are impotent, that is a big blow to their psyche sometimes, and that is something they don’t necessarily want to discuss,” said Dr. Mehta.

The focus groups also indicated that there are significant barriers to treatment for men, and all participants reported frustration with the lack of information about male infertility. They also complained about difficulty in finding reputable websites pertaining to male reproductive health. Another issue cited was a scarcity of male reproductive health specialists.

The study showed there were significant differences in the types of information men wanted and how they wanted it presented compared to their female counterparts. Men wanted easy-to-understand, centralized information about male infertility. Women were interested in getting comprehensive, detailed materials with links to additional resources. Both men and women said there is a need for mental health resources geared to couples with infertility.

“This is a good start and we hope to build on this onward,” said Dr. Mehta. “It needs to be discussed more. When they go in for an infertility visit after 1 year of trying, they are going to see a reproductive endocrinologist. Ideally, they need to refer the men to urologists, but that happens less than 10% of time.”

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**GUIDELINES** / Clinicians should evaluate whether patients have evidence of intraductal carcinoma

**NCCN PCa guideline update includes genetic testing, genomically informed therapies**

Wayne Kuznar / UT Correspondent

**ORLANDO, FL**—Integration of tumor genetic testing and genomically-informed therapies into clinical practice for patients with advanced prostate cancer are featured in updated National Comprehensive Cancer Network (NCCN) guidelines on the management of prostate cancer (version 2.2019).

In addition, populations for whom germline testing is recommended as part of an initial prostate cancer diagnosis or initial risk stratification for clinically localized disease have been updated.

In 2018, a positive family history of prostate cancer was updated to include careful interrogation of the presence of germline mutations. In version 2.2019, “We’ve given a lot more detail to this, where we now are helping practitioners and patients to know what they’re supposed to be investigating about as part of the careful history,” said James L. Mohler, MD, professor of oncology, Roswell Park Comprehensive Cancer Center, Buffalo, speaking at the NCCN annual conference in Orlando, FL. “So we want to take a more careful genomic family history. We’re really asking the question, do our patients have evidence of, in their families, Lynch syndrome or homologous recombination [HR] gene abnormalities?”

“**We want to take a more careful genomic family history. We’re really asking the question, do our patients have evidence of, in their families, Lynch syndrome or homologous recombination gene abnormalities?”**

James L. Mohler, MD

In the update, which was published in the *Journal of the National Comprehensive Cancer Network* (2019; 17:479-505), a positive family history for prostate cancer constitutes having a brother, father, or multiple family members who were diagnosed with prostate cancer at <60 years of age or who dies from prostate cancer; being of Ashkenazi Jewish ancestry; or having ≥3 cancers on the same side of the family, especially when diagnosed at ≥50 years of age.

“The next thing that we recognized since the last guideline that represented a change is the importance of paying attention to as to whether patients have evidence of intraductal carcinoma,” said Dr. Mohler. Intraductal cancer is commonly confused with ductal cancer, he said, but intraductal cancer demonstrates a higher incidence of gene mutations.

In the updated guidelines, for initial risk stratification and staging work-up for clinically localized disease, germline testing is recommended in very low-, low-, and intermediate-risk groups if they have a positive family history or intraductal histology, and in all patients in the high- and very high-risk groups.

Germline testing can be performed using next-generation whole-genome sequencing or targeted exomic gene testing. Although targeted sequencing is the less expensive option, the cost of next-generation sequencing continues to decline.

“Obviously, by reducing cost by doing targeted sequencing, you could miss mutations that might affect the patients’ course of disease later, and their treatment,” said Dr. Mohler, who is chair of the NCCN’s Prostate Cancer Guidelines Panel.

**MMR mutations in 3%-5% of mCRPC**

The MMR pathway is the most important single-stranded DNA repair mechanism. The genes that control the MMR pathway are *MSH2, MSH6, MLH1*, and *PMS2*. The prevalence of all MMR mutations in metastatic castration-resistant prostate cancer (mCRPC) is 3% to 5%.

HR genes are responsible for fixing double-stranded DNA damage, such as that induced by ionizing radiation. Within this category, the most famous genes are *BRCA1* and *BRCA2*, but also include *ATM, PALB2, RAD50, RAD51, NBN, MRE11, BLM*, and *ATR*. HR mutations occur in 15% to 25% of patients with mCRPC, noted Emmanuel S. Antonarakis, MD, associate professor of oncology and urology, Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins University, Baltimore.

In one study, bi-allelic DNA repair defects are found in 21.3% of patients with mCRPC.

“Interestingly, the unusual histologic types, including ductal carcinoma and separately intraductal, are greatly enriched for all of the DNA repair mutations.”

Emmanuel S. Antonarakis, MD

In patients with regional spread or metastatic prostate cancer, the updated guidelines recommend consideration of tumor testing for HR gene mutations and for microsatellite instability (MSI) or mismatch repair deficiency (dMMR).

MSI deficiency informs therapy; PD-1 inhibition with pembrolizumab (KEYTRUDA) has been found to improve outcomes in any type of cancer with dMMR compared with MMR-proficient tumors. On this basis, pembrolizumab was approved by the FDA for the treatment of metastatic MSI-high or dMMR cancer.

In the updated prostate cancer guidelines, pembrolizumab is recommended as second-line or beyond for the treatment of M1 mCRPC with MSI-I or dMMR. The level of evidence for the use of pembrolizumab in this setting is category 2B “simply because there’s no prospective data yet,” said Dr. Antonarakis. The indication for pembrolizumab treatment of MSI-II/dMMR prostate cancer is based on clinical studies that included only two patients with prostate cancer, he observed.

Inhibitors of poly (ADP-ribose) polymerase [PARP] are capable of inducing synthetic lethality in tumors with deficiencies in HR-mediated DNA repair, such as those harboring *BRCA1* mutations. PARP inhibitors are not included in the most recent guidelines for the management of patients with prostate cancer and germline or somatic HR gene mutations, but they can be considered for such patients, he said. The FDA granted olaparib Breakthrough Therapy designation for the treatment of *BRCA1/2- or ATM-mutated mCRPC*, andrucanib for the treatment of *BRCA1/2-mutated* mCRPC with at least one prior androgen receptor-directed therapy and taxane-based chemotherapy.
PSA adjustments are required in men taking 5-ARIs

5-ARI use associated with delayed PCa diagnosis, worse cancer-specific outcomes

The use of 5-alpha-reductase inhibitors (5-ARIs) for voiding symptoms from enlarged prostate and PSA screening for early detection of prostate cancer are among the most frequent urologic interventions in men. When using 5-ARIs (finasteride, dutasteride), the observed PSA level should be adjusted (by a factor of 2) to obtain the representative PSA level.

While 5-ARIs have been used as a preventive measure (based on the PCPT and REDUCE trials) to reduce the risk of prostate cancer, a new report by Sarkar et al suggests that the clinical use of 5-ARIs resulted in delayed biopsy, worse pathology, and increased mortality from prostate cancer (JAMA Intern Med [published online May 6, 2019]).

The authors used the Veterans Affairs (VA) electronic platform that provides access to patient-level electronic health and administrative data for all veterans within the VA health care system, including tumor registry data. There were 80,875 men with prostate cancer and PSA level known at diagnosis between Jan. 1, 2001 and Dec. 31, 2015 who met the inclusion criteria. Prostate biopsy date and prebiopsy PSA level were available for 62,165 patients.

PSA elevation was defined as PSA >4.0 ng/mL for men without 5-ARIs and 2.0 ng/mL for those men who had been prescribed 5-ARIs (then adjusted by multiplying it by 2). There were 19,065 all-cause deaths and 4,513 due to prostate cancer. A total of 8,587 men (10.6%) were prescribed 5-ARIs at least 1 year before prostate cancer diagnosis.

The authors reported that 5-ARI users had longer delays from first “adjusted” elevated PSA to prostate biopsy (3.60 years) than patients taking alpha-blockers alone (2.11 years) or patients who did not use either medication (1.17 years). While the “unadjusted” PSA at the time of biopsy was similar among the groups (6.8 ng/mL, 6.4 ng/mL, 6.4 ng/mL), the “adjusted” PSA level for 5-ARI users (13.5 ng/mL) was significantly higher compared to other groups (p<.001) at biopsy.

At diagnosis with prostate cancer, 5-ARI users were noted to have significantly worse disease characteristics compared to those not using 5-ARIs, including Gleason score ≥8 (25.2 % vs. 17%), stage T3–4 (4.7% vs. 2.9%), lymph node-positive disease (3.0% vs. 1.7%), and distant metastatic disease (6.7% vs. 2.9%).

This report brings to light an often-suspected but previously undocumented clinical issue in great and alarming detail.

Prostate cancer-specific mortality was significantly higher than those using an alpha-blocker alone (8%) or who used neither (8%). Similarly, all-cause mortality was worse in 5-ARI users than other groups (45% vs. 42% vs. 36%; p<.001). Using different multivariable analyses, the use of 5-ARIs was associated with 10% to 39% increased risk of prostate cancer-specific mortality.

Clearly, these findings are concerning. Are patients’ cancer diagnoses being delayed due to 5-ARIs? Since patients who were prescribed a 5-ARI were older and with additional comorbidities, one might speculate that they were not considered ideal candidates for PSA-based early detection and/or treatment. But the longer interval from PSA elevation to biopsy and the higher adjusted PSA level were noted even in patients who were less than 60 years of age.

In our personal communication about these unintended consequences of 5-ARI use, Patrick C. Walsh, MD, professor emeritus at Johns Hopkins, stated that he has seen some tragic outcomes from delayed diagnosis in younger men receiving finasteride for voiding symptoms (or for hair loss). Dr. Walsh emphasized the fact that any rise in the PSA level in men being treated with 5-ARIs increases their risk of being diagnosed with high-grade prostate cancer by several folds, as evidenced by the published data from the PCPT. Thus, it is essential for patients and health care providers to understand that regular PSA measurements should continue in these men for as long as 5-ARIs are being used.

On its surface there may appear to be conflict between this report and the previously published reports from the PCPT (see, “5-ARI use reduces prostate Ca risk for up to 16 years,” October 2018, page 10), but those two must not be conflated. This report is based on clinical use of 5-ARIs (likely for BPH and voiding symptoms) without any set protocol for PSA test or follow-up intervals, while the PCPT participants were monitored under a well-controlled protocol that included PSA, digital rectal exam, and/or biopsies. It appears that the very well-described association between 5-ARI use and PSA level (requiring multiplication of the lab-reported value of PSA by a factor of 2) may have been overlooked, and that omission may have resulted in increased mortality from prostate cancer.

This report brings to light an often-suspected but previously undocumented clinical issue in great and alarming detail. There is a clear and urgent opportunity to re-educate prescribers (both primary care physicians and urologists) about appropriate adjustments to the PSA level when using 5-ARIs in order to avoid unnecessary morbidity and mortality from prostate cancer.\[1\]
Are physicians faced with burnout? Or ‘moral injury’?

Burnout suggests a problem with providers themselves; a new term may be needed.

One of the most commonly used research definitions of job satisfaction is by Locke, a psychologist who defined it as “a pleasurable or positive emotional state resulting from the appraisal of one’s job or job experiences” (Locke EA. The nature and causes of job satisfaction. Handbook of industrial and organizational psychology. Ed. M.D. Dunnette. Chicago: Rand McNally, 1976. 1297-349). This positive emotional state can stem from many factors, including work-life balance, compensation, growth opportunities, job security, and work environment.

As physicians, we deliver quality care to both the patient and public and often possess a passion to use one’s mind and hands. More recently, a growing duality between professional reward and the lambentable and impersonal business of medicine has placed undue pressure on physicians. Excessive paperwork, declining incomes, decreased independence, and commoditization have worsened in part due to government- and insurance-related burdens. Uncertainty, constant change, and growing pressures in the practice of medicine can degrade job satisfaction and contribute to overall unhappiness.


Table 1: Burnout vs. Moral Injury: Key Differences

<table>
<thead>
<tr>
<th>Burnout</th>
<th>Moral Injury</th>
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<tbody>
<tr>
<td>Described by the Maslach Burnout Inventory as a three-dimensional syndrome consisting of symptoms for emotional exhaustion, depersonalization, and reduced personal accomplishment</td>
<td>As first used by Shay et al, term involves 3 elements: 1) It is present when there has been a betrayal of what is morally right, 2) by someone who holds legitimate authority, and 3) in a high-stakes situation*</td>
</tr>
<tr>
<td>Implies providers are feeling overwhelmed by the demands of being a physician</td>
<td>Describes the sense that one has fallen below what they think their own standards should be in ways that make them feel uncomfortable from the perspective of optimal patient care</td>
</tr>
<tr>
<td>Implies that the phenomenon is a condition that is the doctor’s own responsibility to fix</td>
<td>Points to a deeper injury that is the result of systemic failure</td>
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Source: Raj S. Pruthi, MD, MHA

By focusing on existing symptoms of physicians and not underlying causes, the term ‘burnout’ may overlook real potential solutions.

Arch Surg 2011; 146:54-62; Am J Prev Med 2000; 19. The rate of physician suicide is three to four times higher than that of the general population with almost 400 physician suicides per year—a number similar to losing almost three medical school classes each year (Arch Surg 2011; 146:54-62; Am J Prev Med 2000; 19).

What is burnout?

Burnout has been a useful term to describe the set of symptoms associated with this growing phenomenon. The term burnout was first used in 1974 to describe the symptoms related to occupational stress, and psychologist Christina Maslach developed the first widely used instrument for assessing burnout (Maslach C, Jackson S, Leiter M. Maslach Burnout Inventory Manual. Palo Alto, CA: Consulting Psychologists Press 1996). The Maslach Burnout Inventory operationalizes burnout as a three-dimensional syndrome consisting of symptoms for emotional exhaustion, depersonalization, and reduced personal accomplishment—acknowledging a number of other symptoms including physical exhaustion and feelings of inefficacy.

In the general population, the incidence of occupational burnout is 28%. In physicians, the incidence is almost twofold higher at 54% and appears to be rising (Arch Intern Med 2012; 172:1377-85). According to a recent Medscape
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report, the overall physician burnout rate is 44%, with urologists having the highest rate at 54% (Medscape National Physician Burnout, Depression & Suicide Report 2019, bit.ly/burnoutreport).

It is time to recognize that the term “burnout” may not capture the components of the injurious process itself. By focusing on existing symptoms of physicians and not underlying causes, the term “burnout” may overlook real potential solutions. The term may not help point to real solutions within our profession and the health care system in general. Burnout suggests that the fundamental problem lies with health care providers themselves.

Accordingly, health care systems and programs focus on physician resilience and wellness, including creating forums to discuss the problems and symptoms providers face and elective or urgent support programs (eg, “Code Lavender” and “Taking Care of Our Own”), which strive to ease provider stress and improve physician resilience. Hiring wellness officers and creating wellness programs are important steps to alleviate these symptoms of distress and burnout and provide support for the burned-out provider. However, they don’t address the underlying causes and thereby are inherently limited.

In addition, focusing on the symptoms of burnout alone may be shortsighted or a Band-Aid for a deeper injury. To this point, according to Robert McLean, MD, president of the American College of Physicians, “You can’t yoga yourself out of burnout” (“The real reason docs burn out,” Medical Economics Jan. 25, 2019, page 14).

Burnout vs. moral injury
A more accurate term for what is occurring to health care providers may be “moral injury.” The term “moral injury” was first used by Shay et al to describe some symptoms experienced by war veterans (Shay, J; Munroe, J. Group and milieu therapy for veterans with complex posttraumatic stress disorder. Posttraumatic stress disorder: A comprehensive text. Boston: Allyn & Bacon, 1998. 391-413). According to Shay, moral injury had three components: 1) It is present when there has been a betrayal of what is morally right, 2) by someone who holds legitimate authority, and 3) is in a high-stakes situation. Since this original definition, other definitions have subsequently developed. The concept has been most commonly applied to the mental health of military veterans who have witnessed or perpetrated an act in combat that transgressed their deeply held moral beliefs.


Moral injury can only be alleviated when the conflicting obligations beyond the Hippocratic oath-directed patient obligations are reduced, eliminated, or made not to be in conflict.

In the context of health care, Wendy Dean, MD, and colleagues have recently used the term to explain the challenges facing physicians beyond burnout alone (“Physicians aren’t burning out. They’re suffering from moral injury,” STAT, bit.ly/moralinjuryindoctors). According to Dean, the moral injury felt by physicians results from their obligations of electronic health records, their own student loans, hospital requirements for patient load and number of procedures performed, and government- or payer-related bureaucratic burdens—all while working toward the goal of trying to provide the best care possible to patients.

“How do you answer to all those masters and do what you pledged under the Hippocratic oath, which is always to work in the best interests of the patient?” Dean asks (“The real reason docs burn out,” Medical Economics Jan. 25, 2019, page 14). “With every patient encounter you’re in a bind and not able to do what you were trained to do. When this seeming betrayal happens every day it becomes a ‘death by a thousand cuts.’”

Moral injury can only be alleviated when the conflicting obligations beyond the Hippocratic oath-directed patient obligations are reduced, eliminated, or made not to be in conflict. This points to fundamental systemic changes in our health care delivery systems.

There are a number of solutions that may affect diagnoses, coding, and documentation in the U.S. health care system still uses ICD-10, so it’s unclear how this decision would affect diagnoses, coding, and documentation in the U.S.

According to the WHO, physicians can issue a diagnosis of burnout if a patient exhibits three symptoms: feeling depleted of energy or exhausted, feeling mentally distanced from or cynical about one’s job, and problems getting one’s job done successfully.

To read the full article on this topic, published by (Urology Times sister brand Medical Economics, go to bit.ly/burnoutdx.

BURNOUT ADDED TO ICD-11
Physicians can now diagnose a patient with “burnout,” according to a decision made by the World Health Organization (WHO).

The decision adds burnout to the International Classification of Diseases, 11th Edition (ICD-11). Right now, the U.S. health care system still uses ICD-10, so it’s unclear how this decision would affect diagnoses, coding, and documentation in the U.S.

According to the WHO, physicians can issue a diagnosis of burnout if a patient exhibits three symptoms: feeling depleted of energy or exhausted, feeling mentally distanced from or cynical about one’s job, and problems getting one’s job done successfully.
After the landmark first laparoscopic nephrectomy in 1991, urologists charted a minimally invasive surgical quest to limit morbidity without sacrificing success during complex operations. Proficient laparoscopy required years to develop with expertise limited to fewer surgeons, especially with such challenging procedures as radical prostatectomy, partial nephrectomy, and pyeloplasty.

Robotic surgery seemingly leveled the playing field, coordinating precision suturing, six degrees of surgical freedom, camera motion, and retraction, all with 3-D vision.

Naturally, there has been a push to reduce the footprint of robotic surgery, including the number of incisions, size of incisions, and the financial and physical impact of the surgical system. However, as with most new technology, the objective merits of robotic miniaturization are still under study.

In this article, we describe current and future surgical platforms and instrumentation designed to meet the goal of minimizing the robotic surgery footprint.

### Fewer incisions

With significantly improved patient convalescence and satisfaction transitioning from open to laparoscopic and robotic surgery, it was a reasonable assumption that fewer incisions would improve patient outcomes. Laparoendoscopic single-site surgery (LESS) was a challenge that many accepted, but few conquered. Robotic-LESS (R-LESS) promised to ease the challenge, and the initial series by Kaouk et al demonstrated improved suturing and ease of dissection with the help of the robot (BJU Int 2009; 103:366-9). However, a cross-armed technique was still required.

Perhaps the greatest concern with early LESS and R-LESS series was whether or not the technique improved surgical outcomes. Early comparative series were small, retrospective, and non-randomized, and demonstrated non-significant clinical benefit in most outcomes, including pain (Eur Urol 2011; 59:26-45). The obvious potential benefit of improved cosmesis was most notable in younger patients undergoing surgery for benign disease (Eur Urol 2011; 60:1097-104). Ultimately, the challenge of the operation along with questionable clinical benefit led to most minimally invasive surgeons abandoning the technique.

It could be argued that the full potential of R-LESS was not realized due to technical challenges; a purpose-built single-site surgical robot could broaden approval. Intuitive Surgical developed the da Vinci SP, a dedicated single-port robot with four double-waisted arms that recreate triangulation after passing through a 25-mm port (figure 1). The first case series using the da Vinci SP demonstrated the feasibility to perform radical prostatectomy, partial nephrectomy, and nephrectomy (Eur Urol 2014; 66:1083-8). This ultimately led to FDA approval in May 2018 for the above-listed procedures, with more recent small case reports of cystectomy (Eur Urol 2019; 75:684-91) and ureteral reconstruction (J Endourol Case Rep March 8, 2019 [Epub ahead of print]).

After accessing the abdomen with a Hasson technique, the 25-mm port can be placed directly into the abdomen or through a product such as GelPOINT (Applied Medical) that allows placement of additional assistant ports through the same incision. Optimal working distance is a minimum of 10 cm from the target anatomy to allow for triangulation of the arms, with a maximal reach of 25 cm. Because da Vinci SP works on a single boom, there is 360-degree access to the abdomen, making multi-quadrant surgery feasible through a single incision. Such surgical freedom was not possible with prior R-LESS technology.

In addition, the single port allows the potential to access more confined surgical approaches: retroperitoneal, extraperitoneal, and areas with significant surrounding adhesions. More natural handling, especially given the familiarity with other da Vinci robots, likely implies wider utilization and a better understanding of the device’s potential in the coming years.

### Smaller incisions

When Clayman and colleagues reported the first laparoscopic nephrectomy, they utilized three 11-mm and two 5-mm trocars (J Urol 1991; 146:278-82). Many minimally invasive surgeons still use similar-sized laparoscopic ports today, even though 2- to 3-mm laparoscopic instrumentation exists. Most current da Vinci instrumentation works through 8-mm ports, although 5-mm instrumentation is available in limited selection.

The pinnacle of minimally invasive surgery is the incisionless procedure, although the feasibility has been questioned. Natural Orifice Transluminal Endoscopic Surgery (NOTES) achieved that goal, but adoption was limited to experimental animal studies due to technical difficulty. Perhaps magnetic surgical instruments are a more realistic alternative.

The Levita Magnetic Surgical System works as an intra-abdominal retractor.
FIGURE 2A / The Levita Magnetic Surgical System works as an intra-abdominal retractor anchored via an extracorporeal magnet.

FIGURE 2B / Using the Levita magnet, the surgeon controls where retraction needs to be while the bedside assistant places the magnet at the corresponding extracorporeal location. (Photos courtesy of Levita Magnetics)

MINIATURIZATION
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anchored via an extracorporeal magnet (figure 2a). The magnet can be placed on the abdomen or manipulated via an arm secured to the operating table side-rail. After grasping the desired tissue to retract, the bedside assistant separates the clamp from the introducer. The surgeon then controls where the retraction needs to be while the bedside assistant places the magnet at the corresponding extracorporeal location (figure 2b).

This device has FDA approval for robotic prostatectomy, and has demonstrated feasibility to manipulate and retract the colon, peritoneum, seminal vesicles, and prostatic capsule during neurovascular bundle dissection, and bladder during lymphadenectomy (Urology 2019; 126:237). While current technology is limited to retraction, the potential for a magnetic device to control a camera or a surgical arm might prove to be the epiphene of incisionless surgery.

Endoscopic robots

Although endoscopic robots currently trail laparoscopic robot innovation, there is certainly optimism for the near future. Some might question the need for endoscopic robots given most procedures are naturally incisionless. However, optimizing ergonomics and improving instrumentation and functionality of endoscopes will not only improve the surgeon experience, but also expand the types of surgeries performed.

Most urologists would attest that ureteroscopy is often not ergonomically ideal. A robotic platform would certainly improve this. To date, the only functional ureteroscopic robot is the Avicenna Roboflex (ELMED), a robotic manipulator that adapts universally to any ureteroscope to remotely control deflection, rotation, insertion, and even irrigation and laser. From a procedural standpoint, the device is as miniaturized as current ureteroscope technology (7.5F-9.9F), although the current surgeon cart and robotic arm take a sizable footprint. Future applications would hopefully miniaturize this space, as well as the cost, which might be prohibitive for certain health systems.

While no true robotic ureteroscope currently exists, robotic endoscopes in other fields give promise to a future ureteroscope. Developed by Intuitive Surgical, Ion is a 3.5-mm robotic catheter that recently received FDA approval for bronchoscopy and peripheral lung biopsy (CHEST 2017; 152(suppl):A858). It has 180 degrees of flexion and a 2-mm working channel. Visualization is obtained intermittently via a separate probe that fills the working channel. Auris Health Inc. is also developing a robotic endoscope known as Monarch, likely with similar functionality.

For this technology to accommodate ureteroscopy, simultaneous vision and a capable working channel is necessary. In addition, reducing the outer sheath size to be more in line with current endoscopes would facilitate adoption for retrograde intrarenal surgery.

Although transurethral resection of the prostate is the gold-standard treatment for symptomatic BPH, enucleation procedures (ie, simple prostatectomy and holmium laser enucleation of the prostate [HoLEP]) have consistently demonstrated superior outcomes. For HoLEP specifically, the learning curve is steep and performing the procedure through an endoscope sacrifices dexterity and fine positioning.

Virtuoso Surgical developed a miniature two-arm robot that fits through the 5F working channel of a standard endoscope (figure 3). Initial experimental testing was promising, showing coordinated manipulation of the arms to allow for improved retraction and fine targeting of the laser fiber (J Endourol 2016; 30:692–6). The ability to perform complex movements allows for accurate endoscopic dissection in a more intuitive platform, which could broaden adoption of HoLEP and potentially even expand to bladder tumor resection as well as bladder and distal ureter reconstruction.

Conclusion

Continued development of the aforementioned surgical platforms will undoubtedly lead urologists to further minimize the surgical footprint. As more companies and collaboratives innovate and enter this market, we expect significant growth and continued miniaturization. Further, market competition might improve access to surgical robotic technology, which is often limited to more prominent health systems. While exciting, it is imperative that we objectively test this technology to truly understand the role in patient recovery and outcomes.
Increase reimbursement, reduce take-backs with these 4 steps

A few extra minutes spent on documentation yields several benefits

In general, urologists are doing quite well financially. The laws of supply and demand have finally caught up with the profession, as we had predicted years ago. However, you could do better. How can urologists increase their income? In this article, we share with you steps you can take to increase your income, and, at the same time, significantly decrease the chances of take-backs.

In previous articles and seminars, we have discussed the “Wheel of Fortune,” a graphic that depicts the 20 steps performed between the time a patient makes an appointment and the final money is deposited in the bank. If all steps are performed accurately, you are paid the maximum amount you need to provide a clear picture of the patient’s condition, the circumstances for the visit, and service/procedures provided. Your documentation should support the clinical reasons for the efforts required.

If more than one service was provided or more than one problem was addressed, the note should support the clinical reasons for the efforts required.

Documentation. Document clearly what services were provided and why. Update the patient record with each visit. The documentation should clearly and accurately help to ensure accurate initial coding, supports appeals and medical record requests, and protects from medicolegal issues. It is the foundation of the clinical practice and the revenue cycle management Wheel of Fortune.

Identification of all services provided. Identification should be made by checking each procedure on a short list or favorites list depending on your systems, which may include selecting a code-specific template or marking a superbill that you have prepared ahead of time. This task should take less than 15 seconds. Using a sample of 400 plus urologists, 80% of urology revenue is represented by 47 CPT codes and 40 ICD-10 codes. Your short list and your understanding of your high-volume/high-dollar services and procedures and common ICD-10 codes will allow you to make quick work of this.

The short list should be prepared as follows:

- Ask the billing staff to retrieve the 50 to 60 most common services performed and your top 40 ICD-10 codes by place of service. This list can then be shortened for each location (hospital, hospital #2, ambulatory surgery center, office, etc.)
- Plan a 1-hour (more or less) meeting with your billing staff initially and at the beginning of each year to review that list of services.
- Confirm that the codes being billed represent the services you have provided. (You may be shocked at some of the things you have billed.)
- Refine, review, and learn the codes on the lists and every effort has been made to ensure its accuracy at the time it was written. However, readers are encouraged to check with their individual carrier or private payers for updates and to confirm that this information conforms to their specific rules.

The final list should contain about 80% of all services you will provide. Do not sweat the small stuff or one-offs for this list. All you have to do is

Source: Ray Painter, MD, and Mark Painter

FIGURE / Revenue cycle ‘Wheel of Fortune’

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Twelve Part D urology meds top $100 million in spending

Prostate cancer, overactive bladder drugs at head of list

Robert A. Dowling, MD
Dr. Dowling is the president of Dowling Medical Director Services, a private health care consulting firm specializing in quality improvement, clinical informatics, and health care policy affecting specialty care. He is the former medical director of a large, metropolitan single-specialty urology group in Ft. Worth, TX.

As providers whose patient populations generally contain a significant percentage of Medicare beneficiaries, it is in urologists’ best interest to be aware of trends in drug costs and spending for both Medicare’s Part B program (generally injectable medications purchased by providers and administered in a clinical setting) and Part D program (generally prescribed oral and patient-administered medications).

In my previous column (“CMS data reveal trends in Part B drug spending,” May 2019, page 26), I discussed the most common Part B drugs used by urologists in the office setting, where “drug costs” also represent gross revenue to the practice in a “buy-and-bill” model. In this article, I will discuss Part D drug spending that may be of interest to the practicing urologist: those drugs prescribed, and in some cases, dispensed in the urology practice. (For more on this, see bit.ly/PartDdashboard.)

The Centers for Medicare & Medicaid Services (CMS) recently released detailed drug spending data for the years 2013-2017. “Spending” in this context includes the estimated total costs—including deductible, coinsurance, and Medicare spending. Total spending in 2017 for the Part D program was $151.6 billion, up 4.05% from 2016. (This compares to about $30 billion and a 6% increase in the Part B program.) Spending on any single drug may increase because of increased price, increased utilization, or both.

See PART D MEDS, page 22

4 STEPS

check off the services provided at each encounter.

Don’t reinvent the wheel; use the short list to identify your services each time you perform a surgery. For those few procedures that are not on the list, plan to seek assistance.

Determination of the circumstances/reason all the procedures performed. Even though the reason for most of your procedures and services is routine medical practice, you need to document what services you provided and why you provided that service that day.

It’s sort of like taking your car to a mechanic. The car has multiple problems and is still under warranty. The mechanic’s job is to determine what’s covered by warranty and what can be charged extra.

Consider multiple procedures reported on the same date, for example. When you are paid for providing the primary procedure, the “global” payment for that procedure includes all related procedures and services for that date. The computer has been programmed not to pay you for any related procedure or service. If the secondary procedure was performed to facilitate or is a necessary part of the primary procedure, you should not ask to be paid.

However, if the procedure was unrelated, performed at a different encounter, performed on another organ, etc., then it should be paid and, in most cases, can’t be paid if the appropriate modifier is not attached. The problem lies in the fact that sometimes the secondary procedure is related to the primary procedure and other times it was performed for a different reason. At times, the appropriate modifier should be applied and additional payment requested; other times it should not.

Herein lies the problem. If you do not convey the reason the procedure was performed to your staff, they may misinterpret. A biller’s job is to collect money for the services that are billed. A good biller will determine if special reporting, such as a modifier, is required. The tools available and the time available to the biller are limited. If the biller cannot support a modifier or is not required to review documentation, you risk billing fraudulently or the biller will be required to contact you for clarification. Medicare is obsessed with not overpaying you for any service performed.

Once you understand these concepts, you will be able to improve your communication, documentation, and your income. It will also cut down on time spent answering questions and improve the efficiency of the billing staff, allowing them to focus on the hard stuff.

Accurate communication to your billing staff in a timely manner. Using the short list as described above, you have identified services provided and should be able to quickly provide the information to your billing support team.

Delay in communication is another problem for most practices. Dumping charges or waiting weeks or months to submit charges increases errors, slows your revenue stream, and sidetracks your billing staff. Communicating with a short list on your high-volume routine work is easy and should be completed within 48 hours of providing a service.

Next, you need to develop communication with your staff as to how you convey the circumstances for those services outside the norm. You could use emojis, shorthand, or different letters to convey different things. Or, if you’re knowledgeable, you could add the appropriate modifier when required. You can learn this by adding to your knowledge in increments and some additional time. You did not become a urologist overnight; build your knowledge by investing time in increments.

Remember, your part in the Wheel of Fortune is the foundation of the wheel, but it is not the only part of the process required. Billing is a team sport. Lean on your team. Ask for feedback. And get help where and when you need it.

In summary, you do not have to be a certified coder, take the time to look up specific codes, or become an expert on modifiers to provide the functions you need to provide as a member of the team. However, if you do your job and appropriately document, identify the services provided using the recommended shortcuts, determine the circumstances for each procedure, and communicate accurately to your billing staff, you will save yourself time, improve your take-home pay without working any harder, and significantly lower your risk of take-backs.
KIDNEY PRESERVATION IN UTUC: ARE WE DOING ALL WE CAN?

The case for prioritizing kidney-sparing approaches in low-grade UTUC treatment

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 associated with endoscopic procedures, 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,” said Brian Hu, assistant professor of urologic oncology at Loma Linda University in Loma Linda, CA. “At times, removing a kidney for low-grade UTUC can be overkill.”

Preservation of renal function is essential to an elderly population

UTUC typically presents in patients between 70 and 90 years, and in this aging population, kidney function is already likely to be compromised.2–4 A 2017 retrospective chart analysis of 731 patients undergoing radical nephroureterectomy (RNU) for UTUC at 8 academic medical centers found that 50% of patients had preoperative chronic kidney disease (CKD) stage 3.3

Not surprisingly, RNU only accelerates declining kidney function and progression to CKD.4,5

Additionally, many UTUC patients suffer from comorbid conditions such as cardiac disease, hypertension, diabetes, or hyperlipidemia.3,6

“UTUC typically presents later in life with many more competing risks for patients, including baseline renal dysfunction,” said David Morris, MD, FACS, of Urology Associates PC in Nashville, TN. “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.”

Accurate risk stratification is paramount to identifying candidates for kidney-sparing treatment

Guidelines from the European Association of Urology (EAU) assert that “it is useful to ‘risk stratify’ UTUC between low- and high-risk tumours to identify those who are more suitable for kidney-sparing treatment.”2

But, as Hu points out, “Understanding [patients’] baseline renal function and risk for further deterioration are also important when selecting the appropriate treatment.”2

The EAU recommends offering kidney-sparing treatment in all low-risk cases, regardless of the health of the contralateral kidney. It further recommends a kidney-sparing approach for high-risk tumors in patients with a solitary kidney and/or impaired renal function, as well as high-risk tumors of the distal ureter.2

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Let’s take a closer look at some individual drugs that urologists typically prescribe in their practice. Note: It is not possible using this data to determine what fraction of spending is “ordered” by urologists, or the indication for any individual drug.

Abi tops list of urology-related drugs
Among 12 drugs commonly prescribed by urologists with spending over $100 million in 2017, the drug with the largest 2017 total spend was the prostate cancer agent abiraterone acetate (ZYTIGA) ($877 million). In 2017, utilization for abiraterone decreased 3.5%, spending per dose increased 10.5%, and total spending increased 6.6% compared to 2016. Spending on this expensive drug (over $50,000 per patient per year in 2017) has increased 9.76% per year over the last 5 years.

Total spending in 2017 on enzalutamide (XTANDI), another oral oncolytic drug prescribed for similar indications, was $855 million—down 5.8% compared to 2016. Utilization was down 15.6% for the same time period, and annual growth in average spending is 7% over the last 5 years. Both of these drugs are also commonly dispensed in large urology practices or practice-owned retail pharmacies (table).

Among six drugs prescribed to more than 1 million unique beneficiaries in 2017 and commonly prescribed by urologists were four common antibiotics (ciprofloxacin, cephalexin, levofloxacin, and nitrofurantoin Monohyd/M-Cryst), tamsulosin, and finasteride. All of these “generic” drugs have multiple manufacturers and decreased cost/unit in 2017 compared to 2016. Almost all have negative annual growth rates in spending per dose over the last 5 years and are a good example of how multiple manufacturers can drive competition and lower costs for the Medicare program.

In the overactive bladder market, 15 drugs accounted for over $2 billion in Medicare Part D spending in 2017. Total spending on mirabegron (Myrbetriq) ($787 million) increased almost 52% in 2017, and spending on this drug has increased 10% per year for the last 5 years. The inverse relationship between annual growth rates and numbers of manufacturers in this market is particularly striking.

Sildenafil is another drug often prescribed by urologists and dispensed in urology offices or pharmacies. Generic sildenafil spending per dosage unit decreased 3.1% in 2017 despite increased utilization (9%) and has seen almost 20% annual decline in spending per dose over the last 5 years. (The cost numbers in this category may not reflect actual utilization, as many Medicare beneficiaries buy sildenafil without filing insurance and/or from Canadian or online pharmacies.)

Bottom line: Drug costs to the Medicare Part D program as a whole continue to increase each year, and the most important determinant of a drug’s price is the number of manufacturers competing in the market. Expensive oral drugs used to treat cancer are under close scrutiny, and urologists prescribe—and in some cases dispense—these drugs. Urologists should be familiar with the costs under their direct or indirect control, and understand the availability and costs of generic alternatives when clinically appropriate.

### TABLE UROLOGY-RELATED DRUGS WITH $100+ MILLION IN TOTAL 2017 SPENDING

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<thead>
<tr>
<th>Brand name</th>
<th>Generic name</th>
<th># Manufacturers</th>
<th>Total spending, 2017</th>
<th>Total units, 2017</th>
<th>Total beneficiaries, 17</th>
<th>Avg. spending per dosage unit, 17</th>
<th>Avg. spending per beneficiary, 17</th>
<th>Change in total spending, 2016-'17</th>
<th>Change in total dosage unit, 2016-'17</th>
<th>Change in avg. spending per dosage unit, 2013-'17</th>
<th>Annual growth rate in avg. spending per dosage unit, 2013-'17</th>
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</table>

Source: Adapted from Centers for Medicare & Medicaid Services data by Robert A. Dowling, MD
How to assemble your financial professional network

Resources include CPA, estate planning attorney, mortgage broker, among others

Q: What financial professionals should be included in my financial network?
A: Creating a network of financial professionals is important if you want to stay on track and reach your financial goals as efficiently as possible. Physicians often attempt to manage their own financial lives but quickly realize their demanding schedules prevent them from devoting the necessary time to effectively grow and sustain their wealth. Whether due to exhaustion, burnout, or just procrastination, important tasks fall by the wayside.

Over time, physicians fall behind in their financial goals and have difficulty catching up later in their careers. Building a network of financial professionals can ensure that all tasks are handled in an efficient manner to keep you on track.

Everyone’s needs are different, but here is a list of financial professionals you may find useful:

- **Certified public accountant (CPA).** A CPA can assist with many areas of your financial life. These services may include business and individual tax preparation, tax mitigation, financial reporting, and charitable gifting.

- **Financial adviser.** This title can mean many different things. Many financial advisers hold different licenses that allow them to provide different services. For example, a stock broker can facilitate the purchase or sale of stocks for a commission, and a certified financial planner can manage a much wider range of financial services. These services may include investment management, wealth preservation, tax mitigation, cash flow management, insurance, education savings, asset protection, and estate planning. Make sure you understand the various licenses and the difference between advisers.

- **Estate planning attorney.** This attorney should help you prepare a last will and testament, draft health care and durable powers of attorney, draft living trusts, develop a plan to mitigate or avoid estate taxes, and safeguard your life's savings and assets from creditors.

- **Insurance agent.** Like the financial planner, it is important to know which products an insurance agent is licensed to sell. Some agents may only specialize in disability, life insurance, long-term care, and annuities. Others may only focus on car, homeowners, health, renters, flood, and umbrella policies. It is likely you will need two insurance professionals in your network.

- **Banker.** You should develop a relationship with a banker at the bank where you have a checking and/or savings account. Additionally, they may be able to assist you if you need short-term savings instruments such as certificates of deposit.

- **Mortgage broker.** Many banks offer mortgages, but it is not always their core area of competence. It is typically better to find a mortgage broker who specializes in only mortgages.

The professionals listed here could all play a role in your financial life. It is important you find individuals you trust who have the expertise to assist you. If you are just developing your financial network, we recommend interviewing multiple professionals. Ask them questions about their experience, how they approach their craft, and how their services may be able to assist you. Then, choose the person you feel most comfortable working with. These are relationships you may keep for the rest of your life, so it is important to take your time and get it right.

If you are looking to expand your network and aren’t sure where to start, speak with your existing financial professionals. Many will know excellent options in each category and may assist you in interviewing candidates. Another good place to start is family and friends; just use extra caution as these suggestions can be hit or miss.

If you can develop a network of professionals that work hand in hand, where everyone is working toward your goals, you have a much greater chance of being financially successful throughout your lifetime.

Q: As a young physician, are there any estate planning items I should take care of early in my career?
A: If you own a home or assets of significant value, have children, and/or are married, then you may want to consider putting a last will and testament in place. These are relationships you may keep for the rest of your life, so it is important to take your time and get it right.

If you are not in any of the above situations, then at least getting a durable and health care power of attorney (POA) in place is important. A health care POA will identify who will make decisions for you in the event you are incapacitated. A durable POA will identify who will make financial decisions for you (pay your rent/mortgage, utilities, insurance, debts, etc.).
Cybersecurity: What you need to know to protect your practice

Threats are growing in sophistication; here’s what you can do to stop them

Every practice is a target
One of the biggest mistakes a practice can make is to assume it won’t be a target because it is too small or has nothing of value.

“Hackers are not going after you specifically, they are going after everybody,” said Johnson. “They target large numbers of victims, because it doesn’t take much more effort to send out millions of attacks versus a hundred, because it is all automated.”

One of the biggest mistakes a practice can make is to assume it won’t be a target because it is too small or has nothing of value.

The idea that a hacker is someone living in their mom’s basement is almost always wrong. In fact, most cyberattacks are coming from complex organizations.

“A lot of these groups would be considered mid-sized businesses,” said Elliott. “They have full-time staff, their own R&D teams, and in some ways are on par with many tech companies.”

Broad attacks are the most common, but practices can still be singled out by hackers. Elliott says that there are huge markets for stolen information, including specific markets with established prices for health care records. Because cybercriminals know the potential return, they can calculate whether targeting a specific practice is a good investment, either through the number of health records they might obtain or through ransomware.

“They may see a smaller organization as a more tempting target,” said Bruce Snell, director, emerging threats and disruptive technologies, for Tokyo-based NTT Security. “The thought process is that a smaller practice may not have good backups or a security plan or tools in place, so it might be worth their time to spend eight hours putting together a phishing attack that might get them $15,000-$30,000 out of them through ransomware.”

Threat types
Practices need to defend against several threat types as part of a comprehensive cybersecurity plan, but ransomware is still the leading one.

“Ransomware in particular works from a cybercrime perspective because it’s straightforward and uses malware to infect the system,” said Snell, who adds that medical organizations are particularly vulnerable because of their immediate need for access to patient information.

Because some health care organizations pay the ransoms, it leads to more ransomware attacks across the industry, because cybercriminals see they can profit from it. But paying a ransom doesn’t always work, says Snell. The ransomware code is sometimes poorly written, so even when the victim pays the ransom, they still are not able to recover their data using the key.

Phishing attacks, where a cybercriminal uses an email pretending to come from someone the recipient knows, are also common, says Elliott. The sophistication of attacks has evolved well beyond the old ruse of the Nigerian prince who requires a little money upfront to secure a much bigger payout later.

“Attackers are realizing they need to put in more effort to create a realistic scenario,” he said. “It’s much more common now for malicious emails to look legit and be relevant to the victim.”

Emails targeting medical practices are now more likely to contain names of doctors or accounts payable staffs, with requests for modest money transfers or patient records.

When cybercriminals want to attack a specific organization, they’ll do the research required to get as many details as possible.

“They are looking up identities on social media like LinkedIn and Facebook,” said Elliott. “They are using these sources to target people not traditionally targeted five or 10 years ago.”

A rising threat to practice cybersecurity is through devices connected to the Internet, collectively known as the “Internet of things” (IoT). This can include everything from medical equipment to thermostats. As medical
technology advanced, many of these devices began collecting and storing patient data like a computer, says David Finn, MA, executive vice president, strategic innovation for SynergisTek, an Austin, TX-based cybersecurity consulting firm. These devices are often connected to a practice’s network and offer a gateway for hackers to get in.

While computers might get changed out every 3 to 4 years, medical devices are typically kept for a decade or longer, meaning many older devices weren’t designed with security features to deal with today’s hacking threats, says Finn.

“There are literally millions of devices deployed across the country in hospitals and practices, and nothing can be done in terms of protecting the device,” he added.

More troubling is that some hackers have attacked devices not to steal or ransom data, but simply to be malicious and shut them down—including one example from Russia last year where hackers shut down all of the operating-room equipment during a 13-year-old’s brain surgery.

For example, a practice sending lots of emails or receiving files from outside sources needs to invest in making sure those systems are secure and that it is taking extra precautions when accepting files or getting requests for information, such as some sort of secure email delivery service, says Elliott.

Basic security hygiene is also important.

“Make sure your passwords are different for your work email and personal email,” said Elliott. “Make sure your desktops and laptops are secured at the system level, and ensure you have anti-virus or endpoint detection of threats.”

Snell says that every log-in for every computer and device should have a different password and should not be common words. If it’s too complicated to manage, he suggests using a password tool such as LastPass or 1Password.

Johnson recommends working with the practice’s IT expert or vendor to reduce the number of ways an attacker can potentially gain access to the network or its data.

“Too many organizations buy computers that are way more powerful than they need that run lots of applications,” said Johnson. “Evaluate using something like a Chromebook.”

Because of the device’s simplicity, there are fewer ways for hackers to exploit them. He compares using Chromebooks, which are stripped down computers, to removing half the windows and the back door to the garage on a house—fewer points for an intruder to get in.

Similarly, using as many cloud-based services as possible can help a small practice with security because the application provider—with its superior resources—will be responsible for securing its platform, says Snell.

An often overlooked security measure is training staff members to recognize potential risky links and to not click on them.

“Users have to understand they are the first line of defense,” said Johnson. “They have to think through what they are doing and ask themselves if it makes any sense.”

Snell says education can be one of the most effective defensive tactics a practice can use.

“Make sure everyone in the organization is part of the overall security program,” he said. “Make sure everyone is aware of the risks they may see on a daily basis.”

For example, Johnson says, an office manager received what looked like a request from a supervisor for all the employee W-2 forms. The office manager was a little suspicious and so encrypted the data and sent it with a message that the encryption key was texted to his phone.

The attacker, still posing as the supervisor, emailed back that he lost his phone and requested the key by email—and the office manager complied, thus giving the attacker the data and the key because of a compromised email account.

“People think computers are different,” says Johnson. “If you got a letter in the mail asking for everyone’s sensitive data, would you comply? They need to think about what they are doing.”

When purchasing new medical devices with Internet connections, always ask about the security standards on the device, says Finn.

“Ask if it can be upgraded if a vulnerability is found and if it can run some sort of anti-virus program on its system,” he said.

One other caution with connected medical devices is to know whether they store patient data, and if so, to make sure the data is purged on a regular basis, says Finn.

“When you scan a document, some of what you are putting in is stored and retained by the device and most people don’t even think about that,” he said.

If cost is an issue to securing a practice’s data, Tennant says to look at free resources first, then bringing in outside help to deal with the unresolved vulnerabilities. He recommends starting with the Office of the National Coordinator for Health IT website (www.healthit.gov), which has guidance on how to do a security analysis and other tools. Another option is to team up with other practices and share the cost of a security consultant.

Attacks, with the exception of ransomware, are rarely obvious. Experts say a practice most likely wouldn’t even know if its systems are compromised, because there are few tell-tale signs from today’s hackers. Only a security expert examining a practice’s systems will be able to tell if a breach has occurred, and if it has, can take steps to remove the intruder. The best approach is to be proactive and assume an attack is coming, if it hasn’t already happened.

“Security 101 is making sure you have all your data backed up,” said Snell. “Cloud-based backup is inexpensive, and it will give you secure and remote backups so you can recover quickly.”

Tennant says not investing in a backup system to protect the integrity of patient data is irresponsible, and puts the viability of the practice at risk. “It is not a question of if a practice will be attacked, it’s a matter of when,” he said. “You have to assume you are going to be hit with something eventually. If it happens, what is your solution to that?”
Domestic violence: How to minimize risk to your practice

Training, frequent discussion of workplace risk among steps to take

STEVEN S. WILDER, CHSP
Mr. Wilder is president and COO of Sorensen, Wilder & Associates, a health care safety and security consulting group based in Bradley, IL. This article was originally published by Urology Times sister brand Physicians Practice.

Domestic violence is defined as any form of maltreatment that takes place in a romantic relationship between adults or adolescents. One in every four women will be the victim of domestic violence at least once in their life, as will one in every seven men, according to the CDC. And friends, family, and co-workers often have no clue what happens behind closed doors.

Most people will say that what goes on in a person’s home is nobody else’s business. But do employers have a need to know when an employee is in an abusive relationship? Do employers have a right to know?

At most practices I’ve worked with, it is common for an employee’s spouse or significant other to drop by the office unannounced and make themselves at home. Access is easy, and nobody is surprised or threatened by his/her presence. Unfortunately, to the unknowing office staff, this visit may be for a different reason.

Documentation on cases where violence started in the home and escalated into the workplace with catastrophic outcomes is not difficult to find.

I think of the nursing home in North Carolina, where the husband of an employee came into the facility heavily armed with the intent of shooting his soon-to-be-ex-wife. When he realized he couldn’t get to her in the locked memory care unit, he turned his rage on the residents and employees. He killed seven and injured three others.

I think about the beauty salon in Wisconsin. The owner’s husband walked in, killed his wife and two others, and wounded four others before taking his own life.

I think about the manufacturing facility in Indiana. A husband learned that his wife, an employee at the facility, was having an extremartial affair with a co-worker. The husband walked into the plant, shot and killed his wife and her lover, then turned the gun on himself.

There are unfortunately so many more stories, but the point remains the same: The workplace is not the haven of safety we would like to think it is despite how well we think we know our staff.

Thankfully, employers are not helpless. Here are three ways you can promote awareness, gather information, and proactively take steps to minimize the risk of domestic violence at the workplace.

Managers and supervisors should be trained in how to recognize and respond to signs of domestic violence among employees. Early recognition is often key to averting an event.

Develop a written workplace domestic violence plan

There are several federal laws and/or agencies that address workplace violence and domestic violence, including the Equal Employment Opportunity Commission, the Americans with Disabilities Act, and Occupational Safety and Health Administration (OSHA).

In fact, OSHA Guideline 3148, Guideline for the Prevention of Violence for Healthcare and Social Service Workers, requires you to have a written workplace violence prevention plan in place. The plan should encourage workers to come forward and advise management of their situations.

However, from the workers’ perspective, this can be a very private and often embarrassing topic to discuss. They may think that coming forward may be the hardest thing to do, assuming they recognize they are the victim of domestic abuse. It is imperative they know that what they share will be treated as a confidential manner. Employers must also realize that there are laws that protect employees, and employees must be assured they will not be penalized for seeking assistance in the workplace.

You would be well advised to seek legal advice on developing or amending your plan. The final written plan must then be shared with all practice employees.

Provide training

Information on domestic violence is readily available. Most social agencies have programs on the topic, and many of them will gladly send a guest speaker to present at a staff meeting, often at no cost.

Managers and supervisors should be trained in how to recognize and respond to signs of domestic violence among employees. Early recognition is often key to averting an event.

Domestic violence should be frequently mentioned at office staff meetings. Employees should also be encouraged to confidentially report any incidents of domestic violence in the home as well as any change in their relationship status if they feel it may put them or others at risk.

Employee Assistance Program (EAP) providers are well qualified to assist. Many practices have an EAP available to their employees as a workplace benefit, so that EAP provider will be an excellent resource in developing your program and providing training.

Keep domestic violence top of mind

Employers who are committed to safety realize that domestic violence is always a potential risk. When employees are the victim of abuse in the home, it is highly unlikely that they are thinking about safety in the workplace. Their focus will likely be on safety and survival at home.

That’s why it’s even more important to remind employees that they could be putting their co-workers and patients at risk. A study about handwashing found that people often won’t do something for themselves, but they will take action to protect others. Help protect all your employees by frequently discussing the workplace risk of domestic violence.

Domestic violence, like any form of workplace violence, is something we hope we never have to deal with. Yet, like all forms of tragedy, it can happen anywhere, anytime, and to anyone. Employers must recognize the risk and take proactive steps to minimize the likelihood of occurrence.
Do reimbursement trends signal another Dr. Lupron moment?

All societies have myths—stories that are passed down from one generation to another, that at some point become so incredible when viewed through a modern eye that the younger generation hardly believes them. In urology, one such myth is Dr. Lupron. Dr. Lupron was a great doctor. His specialty was metastatic prostate cancer, and he was a game changer. He was also very well reimbursed, and the joke went, “Why don’t urologists work on Fridays? Because Dr. Lupron does.” At one point though, the big bad wolf came around and changed the reimbursement for Dr. Lupron and a lot of urology practices who had become too dependent on him fell into financial disrepair.

I am starting to wonder if urology is about to experience another Dr. Lupron moment.

Urology is still a great field, and I truly consider myself blessed to be a member. It is an aging field, though, with over half of all urologists over 55, according to the AUA Census, which means there will always be a job for us younger urologists. Further, the population is only getting older and we all know that our average patient is on the older end of the spectrum.

That being said, in the short to medium term, many urology practices are facing a tidal wave of increasing costs and decreasing revenue, which unless appropriate steps are taken, could cause significant financial problems in the future.

The cost side of the equation

Let’s start with the cost side. In 2015, when the government passed the Medicare Access and CHIP Reauthorization Act of 2015 (better known as MACRA) and put all medical practices on the path toward the Merit-based Incentive Payment System (also known as MIPS), many people I spoke with expected the government to treat this no differently than the old sustainable growth rate equation for Medicare and simply pass a “doctor fix” each year to prevent significant pay cuts from hitting doctors. That hasn’t happened, and while I’m certainly not walking the halls of Congress on a regular basis, I’ve heard no rumors about such a fix in the future either.

Don’t forget, the only alternative to MIPS is to join an alternative payment model (APM), of which there are precisely zero in urology. And when you realize that MIPS is curved and revenue neutral, meaning that even if your group scores a 98 out of 100, if everyone else gets a 99, you lose. And they win. This year the cut to Medicare reimbursement is 5% and by 2022 it will be 9%. Ask yourself, can your business survive a 9% cut to all Medicare-related reimbursements?

On the revenue side, it’s no secret that over the last 20 years the pay that urologists receive for doing their job (the professional component of the bill) has not seen any increase. As a result, most groups aggressively pursued ancillary income streams such as dispensing advanced prostate cancer medications, intensity-modulated radiation therapy (IMRT), and extracorporeal shock wave Lithotripsy (ESWL) to name a but a few.

ESWL, IMRT concerns

It only made sense that ESWL can and should be controlled by the doctor specifically trained to treat stones. The technology behind IMRT for prostate cancer has improved dramatically over the last few decades, and as the complications decreased and patients started asking about this option, the specialist specifically trained to treat prostate cancer should be able to discuss it. The same is true for dispensing advanced prostate cancer medications. I’ve heard some consultants say that up to one-third of all of our business is related to prostate cancer, so being able to provide these lifesaving drugs to our patients is not only vital, but simply good medicine. The fact that doing so was also good business was simply good luck.

But the times are changing. Let’s start with ESWL. CMS recently made a seemingly minor change in how ESWL is paid and as an unintended consequence, it’s possible that starting this year we will see a 22% reduction in payment for ESWL. I ask, is your ESWL practice profitable after a 22% reduction in reimbursement?

The IMRT situation is equally troubling. It is no secret that since the early 2000s, the number of urology groups that own and operate their own IMRT has increased dramatically (Medicine [Baltimore] 2017; 9625: e6929). More recently, however, reimbursement for IMRT has been declining. Just as important, the recommended number of fractions is decreasing when reimbursement is on a per fraction basis and not a per patient basis. In the most recent NCCN guidelines on prostate cancer, table 1 of the Principles of Radiation Therapy shows that 60 Gy at 3 Gy per fraction could be considered equivalent to 80 Gy at 2 Gy per fraction. That is a reduction from 40 to 20 fractions. I ask, is your IMRT practice profitable at half the average daily number of patients?

And how about those advanced prostate cancer drugs? Very appropriately, many urology groups started dispensing these lifesaving drugs and were well compensated for doing it. Compensation from dispensing drugs comes in two forms: the reimbursement for the actual drug and any rebate the drug company provides. There is legislative action to reduce the reimbursement on both fronts. A CMS report explains in great detail that, while the rebates have gone up over the last few years, those savings are not being passed on to CMS, according to a Policy & Medicine article.

Further, just look at the recent Senate hearing on drug pricing and ask yourself if these costs are sustainable. I’m not in a position to predict how reimbursement will change over the next few years, but I find it unlikely that reimbursement will go up.

There will always be a need for urologists. Of that I have no doubt. I simply fear that unless some smart businessperson can find a new source of revenue or a new business model for independent urologists, we are facing our generation’s Dr. Lupron moment.
‘Mesh morass’ leaves future in question

Mesh banned for prolapse, but midurethral slings remain crucial treatment option for SUI

The use of surgical mesh in urology has long been the subject of debate and scrutiny, with particular concern raised about its safety in the treatment of pelvic organ prolapse. On April 16, after years of escalating actions, the FDA ordered an immediate halt to the sale and distribution of surgical mesh kit products indicated for the transvaginal pelvic organ prolapse repair. The announcement generated widespread reaction and coverage in the lay press, including The New York Times and USA Today. In this interview, Eric S. Rovner, MD, discusses the FDA’s announcement, the status of midurethral slings for the treatment of stress urinary incontinence, and how he expects his treatment of prolapse to change in the wake of the FDA’s announcement.

Q: Please discuss the recent FDA announcement regarding surgical mesh products.
A: The FDA’s April 16 statement was limited to pelvic organ prolapse mesh, specifically for the indication of anterior vaginal wall reconstruction through a transvaginal approach. This statement did not pertain to posterior vaginal wall mesh or apical vaginal mesh used for abdominal sacral colpopexy. Posterior mesh products have not been available in the United States since 2016. In fact, at the time of the FDA statement, the only remaining products that were being commercially marketed for vaginal pelvic organ prolapse repair were for anterior vaginal wall reconstruction. In essence, the FDA gave a cease-and-desist order to the remaining two manufacturers of pelvic organ prolapse mesh—Boston Scientific and Coloplast—directing them to discontinue all sales and distribution and have a plan to do so within 10 days.

This FDA directive also did not apply to currently available transobturator and retropubic midurethral slings. Those slings currently on the market are unaffected by this FDA directive. In addition, currently used transabdominal mesh products such as those used for abdominal sacrocolpopexy, either through an open approach or through a robotic or laparoscopic approach, are not affected by this statement.

Q: To reiterate, it is still permissible to use mesh for slings if providers are trained to do so?
A: That is essentially correct. The mesh used for laparoscopic, robotic, and open abdominal sacrocolpopexy was not specifically mentioned in the FDA statement. In addition, the mesh specifically used for midurethral slings such as transobturator slings and retropubic slings was not mentioned by the FDA in this particular statement.

Q: Was the FDA’s April 16 announcement premature, given that the agency’s request for 522 postmarket surveillance data had a due date of December 2019?
A: The results of the FDA-mandated 522 studies have not been published in journal or abstract form to my knowledge. It is conceivable therefore that the FDA made this decision prior to the final results of these studies. The data upon which the FDA made this decision is unclear. Furthermore, whether the FDA decision is final or potentially reversible when the 522 studies are completed is speculative.

Q: Very few urologists are board certified in female pelvic health, but sling surgery is still part of urology training. Do you feel urologists need further training in this procedure?
A: Whenever we ask, “Is somebody able to do a given procedure?” there are many factors that play into the answer. There is no single learning curve that applies to all surgeons. I don’t believe that any surgery we do in urology is necessarily “easy.” Some surgeons need only a few cases for proficiency, others need many. Having said that, in my personal opinion there is adequate training in many, but not all programs to do female incontinence surgery, of which stress incontinence surgery using midurethral slings is a central component.

I don’t feel that sub-specialization in Female Pelvic Medicine and Reconstructive Urology is a prerequisite for doing these midurethral sling procedures, and I believe that the American Board of Urology would agree with that statement. If a given practitioner is adequately trained in the diagnosis of the condition, is adequately trained in the relevant pelvic anatomy and surgical techniques, and is competent to perform the procedure and take care of the patient postoperatively, then there is no reason that they shouldn’t be able to perform the procedure in practice and do so safely and effectively.

Q: What do clinical guidelines say regarding this topic?
A: The joint AUA/Society of Urodynamicists, Female Pelvic Medicine & Urogynecological Reconstruction (SUFU) guideline for surgical treatment of female stress urinary incontinence supports the use of midurethral slings as an option for the treatment of stress urinary incontinence. In fact, the AUA, SUFU, American Urogynecological Society, and a variety of other organizations have reiterated their prior position statements regarding the use of midurethral slings as an important, effective, and safe procedure for the treatment of stress urinary incontinence in females.
Q: How do urologists who are currently in practice obtain further training? Is there another path other than a formal fellowship?

A: That’s a very good question. Currently, I don’t know of a formal training program for practitioners who wish to learn to do these types of procedures but were not trained adequately during residency or fellowship. For an inexperienced surgeon who is not familiar with the diagnosis and management of female stress urinary incontinence, or the surgical technique, or the management of the complications that can result from the surgery, a weekend course is, in my estimation, insufficient. Additional training for such an individual is necessary.

Q: You’ve published a great deal in this field. What have you learned about complications from slings?

A: Over the past 20 or so years, dating back to the approval of midurethral slings, the number of cases of stress urinary incontinence surgery has gone way up. It is likely that there were surgeons performing these procedures who were not adequately trained, and certainly there were adverse outcomes in certain patients. For a physician who is adequately trained in the performance of these procedures, the diagnosis and treatment of the condition, and the management of the complications, I’m reasonably sure that midurethral slings are among the best procedures we’ve ever had to treat stress urinary incontinence safely and effectively.

Like any other surgery that is done poorly, or is performed in a poorly selected patient, or for the wrong indication, or in a patient who wasn’t adequately counseled regarding the potential adverse effects, the potential outcome can be devastating. But that is not unique to mesh or vaginal surgery; that applies across all surgeries. Perhaps the number of midurethral slings that are done magnify the problem somewhat, but I don’t think it’s intrinsic at all to the procedure itself nor the material used for the procedure.

Q: Being in the field and knowing that the percentage of complications with slings is so low, I was surprised to see in a recent JAMA commentary a statement that a lifetime of follow-up is needed before the procedure is considered safe (JAMA 2019; 321:1338-40).

A: Perhaps part of the perceived problem is that midurethral slings are so commonly performed and so well studied that the blemishes, if you will, are out of proportion to the positive outcomes that we see with this procedure. If you look at data from well-done trials, the complication rate for midurethral slings is less than or equivalent to all of the other procedures that we’ve historically done for this condition with the only unique complication being that related to foreign body mesh exposure or mesh erosion into the urinary tract.

But even those two foreign body complications are not unique to midurethral sling incontinence surgery. For many years, surgeons performed Burch procedures with non-absorbable sutures, and the sutures eroded into the bladder. There are case reports of even autologous fascial slings being exposed vaginally. So these are not unique complications. They’re only unique in that mesh is the actual material that is eroding or being exposed to the urinary tract.

How concerned are you that the FDA will extend the ban of mesh to include its use in stress incontinence surgery?

Gopal H. Badlani, MD

As it currently stands, there is no indication that the FDA will act unfavorably toward the existing midurethral sling procedures in the same manner as it has dealt with vagal prolapse mesh.

ERIC S. ROWNER, MD

Q: How is your personal surgery for pelvic organ prolapse going to change without the use of mesh?

A: Like you, I was trained before the era of mesh, so I can do many of these procedures without it, recognizing that the recurrence rate will be somewhat higher, the procedures may take a bit longer, and the recovery and convalescence will also be longer. It is important to recognize that the complication rate with these older procedures is not zero. The historical complication rate, even with native tissue repairs, is certainly not insignificant; I suspect that it just hasn’t been reported accurately as these older procedures were not subjected to the same scrutiny in the literature as the contemporary procedures using mesh. What we have learned in the 25 years or so that I’ve been doing pelvic reconstruction is the importance of the apex of the vagina. Maybe now that we’re better at identifying apical vaginal prolapse problems, when we go back to native tissue repairs or augmented repairs with xenografts or allografts we’ll be better at diagnosing these cases preoperatively and addressing them at the time of surgery. Attention to the apex of the vagina will likely reduce the historically high rate of recurrence with vaginal prolapse procedures.

Q: How concerned are you that the FDA will extend the ban of mesh to include its use in stress incontinence surgery?

A: As it currently stands, there is no indication that the FDA will act unfavorably toward the existing midurethral sling procedures in the same manner as it has dealt with vaginal prolapse mesh. The evidence base for the use of the midurethral sling is strong, and medical societies, as well as the vast majority of practitioners who do pelvic reconstruction, remain very supportive of the procedure.

Q: Is there anything else you would like to add?

A: It’s important to recognize that midurethral slings are an important and even critical part of our armamentarium for the treatment of stress incontinence and, if done well, patients are happy and the procedure is quite durable. That’s what needs to come out of all of this mesh morass once all the litigation is finished and the regulatory problems are over. Hopefully, the procedure will survive because it’s really been a great advance in the care of women.

[LETTER]

ANTERIOR URETHROPEXY OFFERS EXCELLENT, LOW-RISK OPTION TO MESH

To the editor:

As an old retired urologist, I’ve seen and done most of the procedures used for treatment of stress urinary incontinence. With the litigious world of today, I am befuddled why anyone would want to expose themselves to a lawsuit by doing any of the mesh procedures when an excellent, low-risk, highly successful procedure is available.

The anterior urethropexy (Lapides, MMK, Burch) uses absorbable suture (gut) and can be done laparoscopically, robotically, or with a short transverse muscle-splitting incision. Success should be in the 95% range. The procedure can be individualized to suit the skills of the urologist. It basically results in fixing the anterior urethra, bladder neck, and bladder dome anteriorly to the periosteum of pubis and rectus fascia.

Admittedly there are negatives, although not many. Overnight stay may be necessary, and a catheter may need to be left for 1-2 days. But pain is usually mild. Urinary retention is rare, as are long-term complications. Sometimes modifying older procedures is comparable to devising new ones. Practicing medicine is difficult enough these days without doing things to enrich innovation-stifling lawyers. Watch TV some night and note the ads for nonsensical lawsuits. Best of luck.

Jack Francis, MD / Laytonsville, MD
What is your primary concern about the ban of POP mesh?

Kathleen Kobashi, MD  
Society of Urodynamics, Female Pelvic Medicine & Urogynecology Reconstruction

“Speaking on behalf of SUFU, we can’t discount the fact that some patients have had problems with mesh used for prolapse repair. That is an important issue. We await further data, but until then, the FDA has taken its position, and that’s where we are right now. If you ask me what my biggest concern with the issue right now is, it would be the potential for slings to suffer the same fate as mesh for prolapse repair. Frankly, that would be a disservice to women given that the literature on slings supports slings as a safe and efficacious option for treatment of stress incontinence.

SUFU is focusing efforts on making sure that slings don’t get lumped together with the prolapse mesh and end up going down the same path. Slings have been successful with very low risk. The midurethral mesh sling has been studied more than any other anti-incontinence procedure and the literature is very supportive of the sling as a safe and efficacious option.

If someone chooses not to have a sling, that’s fine. We just don’t want women to lose the option to choose something that the literature supports as very viable, with a very good risk-benefit ratio. Prolapse mesh doesn’t have as much literature as the sling, so we wouldn’t want the ban on the use of mesh on prolapse to erroneously be translated to the slings.

I hope sling mesh is not affected, but the possibility is concerning given that it has been banned in other countries. This happened recently in the UK, although they’re calling it a ‘pause’ there, so hopefully it’s only temporary.”

Gary Lemack, MD  
American Urological Association

“The AUA understand the rationale behind the FDA decision. It means we need to focus on using the patient’s own tissues when doing vaginal repairs. The other point is to distinguish that none of this has anything to do with abdominal mesh repairs, so that remains a viable, if not the most viable option for patients with advanced prolapse, particularly when vaginal repairs can’t be done. It’s hard to know with the FDA if this is permanent. They certainly left open the possibility that vaginal mesh repairs would be permitted again. Some ongoing studies [in which] the FDA wants to assess safety and efficacy for vaginal repairs aren’t completed. It’s conceivable that if those come out and show an acceptable rate of adverse events and acceptable outcomes, the FDA will reevaluate.

A relatively select group of patients needs mesh repair vaginally. In that group, it’s more of a challenge to offer vaginal repair that will be effective. For most patients with prolapse, the use of mesh isn’t necessary. Native tissue is perfectly reasonable and successful. It becomes a problem in advanced or recurrent prolapse where mesh may have been a good option but is no longer available.

The most important aspect is getting this procedure into the hands of surgeons who have adequate training and expertise, because if you’re not addressing all aspects of the prolapse, it’s very likely to recur. We understand there were unacceptable adverse effects with mesh, so we have to come up with better options moving forward.”

Geoffrey Cundiff, MD  
American Urogynecologic Society

“I spoke to the FDA OB/GYN device panel and asked questions floating around social media, such as why they didn’t wait for the 3-year data and why they aren’t looking at the use of these devices in high-risk populations. The FDA’s concern about these devices has been gradually escalating since 2008; then came 522 orders that are actually congressionally mandated processes with a specific timeline. The FDA released the recall on these devices because they ran out of time. The companies knew the deadline but didn’t turn the data in on time to support the proposals.

The companies had to show these devices have superior durability at the 3-year mark because that was the outcome recommended to offset the increased risk. But the companies didn’t have that data yet. So the FDA had to stop the sale. The FDA didn’t stop the studies; companies are actually compelled to complete the studies. If they show superiority, manufacturers can get the product back on the market.

My primary concern is that the studies are not completed and there’s a lot of angst that is probably unnecessary.

The companies are in the driver’s seat. If companies want to show that mesh for prolapse is effective in the high-risk population, where most people actually use them, they can do that. But companies haven’t submitted it that way. My hope is that the companies will submit research to support that.”

[EDITORIAL] MESH: EMOTION VS. EVIDENCE

GOPAL H. BADLANI, MD

Fake news rules the world today. It certainly applies to the use of mesh in female pelvic health. The litigation wiped out two of the prominent companies from the market and threatens the availability of product after the recent FDA ban of its use in the vaginal repair of anterior compartment prolapse. Points to ponder:

■ Is the product defective? Obviously not, as it is “safe” to use for slings, in an abdominal approach, and in men for inguinal hernia and abdominal wall repair.

■ Is the ban because complications with use in vaginal surgery are higher? Not according to the literature, where depending on the series, a ballpark exposure rate of 10% is quoted for both abdominal and vaginal approaches for pelvic organ prolapse. In a large cohort study, among 41,604 women who underwent vaginal mesh surgery, the risk of exposure was highest in the anterior vaginal mesh plus sling group (2.72%; 95% CI: 2.31%-3.21%) and lowest in the stress urinary incontinence sling group (1.57%; 95% CI: 1.41%-1.74%) (JAMA Surg 2017; 152:257-63).

■ Is it because litigation is higher against the anterior compartment repair? Once again, two-thirds of the cases are against a sling procedure.

■ Is it because there is no difference in the outcomes of tissue-based repairs and mesh use? Unless you accept the “new” definition of success “as long recurrence does not protrude outside the vagina and the patient is not bothered,” every randomized trial has proven that anatomic success with mesh is superior to tissue-based repair.

■ Are patients demanding that mesh not be used? A plethora of articles suggest patients’ perspective is based on TV news or advertisements for litigation. Despite guidelines and position papers from all leading organizations, which emphasize mesh’s use based on physician training and informed discussion with the patient, many individual health care networks and countries have placed a blanket ban on the mesh use.

In the Q&A with Dr. Eric Rovner (page 28), he has presented an experienced surgeon’s perspective. In all the controversy, what is not emphasized is the operating surgeon’s responsibility. It is well established that the rate of complications relates to the trifecta of host factors, product, and the surgeon. Since it is not polite to blame the surgeon or the patient, it must be the product.

Dr. Badlani, a Urology Times editorial consultant, is professor of urology, Wake Forest Baptist Medical Center, Winston-Salem, NC.
sNDA submitted for new indication for prostate cancer treatment
The Janssen Pharmaceutical Companies of Johnson & Johnson have submitted a supplemental New Drug Application (sNDA) to the FDA seeking approval of a new indication for apalutamide (ERLEADA) for the treatment of patients with metastatic castration-sensitive prostate cancer. The sNDA is based on findings from the phase III TITAN study, whose dual primary endpoints, overall survival and radiographic progression-free survival, were both achieved. The data were presented at the American Society of Clinical Oncology annual meeting in Chicago.

Phase III data: OAB agent reduces daily UII episodes, micturitions
Positive phase III pivotal data demonstrating safety and efficacy of vibegron were presented at the AUA annual meeting in Chicago. Vibegron is an investigational novel, once-daily oral beta-3 adrenergic agonist being evaluated as a treatment for adults with symptoms of overactive bladder. Data from the phase III EMPOWUR trial showed statistical significance over placebo in both reduction in daily urge urinary incontinence episodes \((p<.001)\) and reduction in daily micturitions \((p<.001)\). In addition, vibegron met all seven key secondary endpoints, including a clinically meaningful reduction in daily urgency episodes and volume voided versus placebo, according to Urovant Sciences.

Prostate cancer assay shows superior diagnostic accuracy vs. PSA
Results from a multicenter validation study of IsoPSA, a novel structure-based prostate cancer assay, were recently published in the Journal of Urology (2019; 201:1115-20). The study validated the findings from a preliminary study published earlier in European Urology demonstrating that the noninvasive, blood-based IsoPSA assay has superior diagnostic accuracy over PSA in detecting high-grade prostate cancer. The results of the study show that IsoPSA could reduce unnecessary biopsies by at least 45%, according to Cleveland Diagnostics, Inc.

Priority review granted for androgen receptor antagonist
The FDA has accepted the New Drug Application (NDA) for review and granted priority review for darolutamide for the treatment of non-metastatic castration-resistant prostate cancer (nmCRPC) in the U.S. The NDA and priority review status were based on data from the phase III ARAMIS trial in men with nmCRPC. Darolutamide is an investigational, non-steroidal androgen receptor antagonist with a distinct chemical structure that binds with high affinity to the receptor, inhibiting the growth of prostate cancer cells. Darolutamide is being developed jointly by Orion Corp. and Bayer.

Wearable device detects full bladder in pediatric patients
Researchers have published data evaluating an investigational wearable ultrasonic bladder monitor in children during urodynamics. The device, called the SENS-U Bladder Sensor, detected a full bladder before voiding in 27 out of 30 patients (90%) studied. The results were published in the Journal of Pediatric Urology (2018; 6:569.e1-569.e6). The device has a CE mark but is not approved for use in the United States.
C-arm technology reduces radiation in fluoroscopic imaging procedures

The FDA has granted 510(k) clearance for ControlRad Trace and manufacturer ControlRad has initiated its commercial launch. The ControlRad Trace can be integrated into existing mobile C-arms to reduce radiation in any fluoroscopic imaging procedure, according to the company. With its proprietary semi-transparent filter, tablet, and image processing technology, the ControlRad Trace solution can be retrofitted on existing C-arms, lowering the barrier to adopting the technology in order to reduce unnecessary radiation up to 89% without compromising image quality and overall workflow. The medical staff draws a region of interest on a ControlRad tablet, which in real time optimizes image quality in the region of interest while reducing unnecessary radiation in the periphery.

For more information, visit www.controlrad.com.

New consumer sexually transmitted disease lab tests launched

Quest Diagnostics has launched three new sexually transmitted disease (STD) laboratory test packages that individuals can purchase online for some of the most prevalent STDs in the United States. The new STD test packages are the first to be offered directly by Quest Diagnostics or any other major national laboratory to allow individuals to purchase tests at their discretion. These new packages have been designed to meet the needs of individuals who want accurate basic or comprehensive STD testing. The STD test services are available in 45 states through QuestDirect, an enhanced online consumer-initiated testing service provided by Quest Diagnostics. Test results are available on MyQuest, the company’s secure patient portal accessible on a smartphone, tablet, or desktop, typically within a week, and may be shared with the individual’s own physician.

For more information, visit www.questdiagnostics.com.

Reusable, washable incontinence barrier available for post-RP men

Pacey MedTech Ltd. recently announced the creation of the Pacey Cuff Guard, a reusable and washable incontinence barrier, specifically for men who have undergone prostate cancer treatment and regularly experience urinary incontinence. The Pacey Cuff Guard is made from durable neoprene, which doesn’t irritate the skin, is odorless, and has a slim ergonomic design to ensure a comfortable and discreet fit within form-fitting underwear. The Pacey Cuff Guard’s moisture-absorbent padding catches any excess urinary drops, and is a supplementary device designed to add value to the Pacey Cuff Turbo urethral control device, according to the company.

For more information, visit www.paceycuff.com.

Male continence therapy system given reimbursement code

ProACT Adjustable Continence Therapy for Men has received a reimbursement code from the Centers for Medicare & Medicaid Services and is now commercially available in the United States. The code, C9746, is associated with a national average payment of $16,243 in the hospital outpatient setting and $10,706 in ambulatory surgery centers. The ProACT therapy consists of two small, adjustable silicone balloons connected with tubing to a filling port. The implantation procedure lasts approximately 30 minutes and can be performed in ambulatory surgical centers or in the hospital outpatient setting. The balloons are surgically placed in the area where the prostate was removed or resected and the ports are placed underneath the skin. The fluid-filled balloons provide pressure and support at the bladder neck, which protects against accidental leaking of urine. When there is a need to urinate, passing urine requires only a normal amount of bladder effort. The balloon volume can be adjusted at any time to achieve optimal continence. Data from a pivotal trial of ProACT were published in Neurourology and Urodynamics (2018; 37:2854–9).

For more information, visit www.uromedica-inc.com.

Magnetic surgical system granted indication for use in prostatectomy

The FDA has granted Levita Magnetics an expanded indication to market the first-of-its-kind Levita Magnetic Surgical System for use in prostatectomy procedures. Initially indicated for use in laparoscopic cholecystectomy and bariatric surgical procedures, the shaftless Magnetic Surgical System reduces the number of incisions necessary for minimally invasive procedures, according to the company. The Levita System consists of an external magnet placed on the skin that controls a shaftless detachable grasper that enables surgeons to move the grasper without the constraints of a fixed-position pivot point. The Levita System was designed to address the challenges of laparoscopic procedures by reducing the number of incisions and trocars used and facilitating access and visibility to the surgical site, ultimately enabling safe procedures with better cosmetic outcomes.

For more information, visit www.levita.com.

FDA clearance allows addition of STI tests to cobas 6800/8800 Systems

The FDA recently granted 510(k) clearance for the cobas TV/MG test for use on the cobas 6800/8800 Systems for the detection of Trichomonas vaginalis and/or Mycoplasma genitalium DNA in both symptomatic and asymptomatic patients, Roche reported. Laboratories can now simultaneously process from a single patient sample a combination of Chlamydia trachomatis, Neisseria gonorrhoeae, Trichomonas vaginalis, and Mycoplasma genitalium, which provides clinicians the information they need to screen and diagnose sexually transmitted infections and improve patient care.

For more information, visit www.diagnostics.roche.com.

Generic version of overactive bladder medication introduced

Teva Pharmaceutical Industries Ltd. recently announced the launch of a generic version of VESIcare (solifenacin succinate) tablets, 5 mg and 10 mg, in the U.S. Solifenacin is a muscarinic antagonist indicated for the treatment of overactive bladder with symptoms of urge urinary incontinence, urgency, and urinary frequency.

For more information, visit www.tevapharm.com.
What health care issues should presidential candidates address?

I would love to hear candidates talk about the astronomically ridiculous prices hospitals charge for surgeries, even outpatient surgeries. No governing body controls them. They just seem to be phantom charges to scare patients to death.

Patients bring in bills—$60,000 for an outpatient kidney stone case—it just doesn’t make sense. Insurance doesn’t pay that, and if patients can’t afford insurance, they sure won’t have the money to pay that. I don’t know why all these phantom charges are there. They seem to be even more out of control lately.

Another issue nobody discusses is the ‘certificate of need’ [CON]. In some states, physicians can get together and open an ambulatory surgical center, or buy a CT or MRI—without applying for a CON. But North Carolina is a CON state.

It’s not right that only some states have these laws. It’s not an equal playing field. Actually, the state regulatory agency that controls CON laws is always staffed by hospital administrators; they’re never going to vote for competition. If CON laws were banned on a federal level to create a free market situation, it could help lower costs by increasing competition—like gasoline stations: When one lowers the price, competing stations have to lower theirs to compete. Patients could look around and compare prices at ambulatory surgical care centers and hospitals. Typically, out-of-hospital care costs a lot less.

I’d also like to see them talk about access to care for everybody. They’ve been talking about that but I don’t see how they’re going to solve that problem either.

John Kirkland, Jr., MD / Charlotte, NC

I’d like to see candidates come up with ideas to drive down health care costs, and what they think might be the issues, without automatically resorting to Medicare-for-All.

I’d like to see other ideas because then I would know who’s really looking at the issues contributing to health care costs, not just being briefed by staffers or lobbyists.

I’d like to hear their ideas on liability reforms. They can talk about Medicare-for-All, but what about national liability reforms across the board?

If they don’t bring up those issues, like controlling prescription drug prices, they don’t have a clue. Medicare-for-All is their typical response because ‘administrative costs would be so much lower and we’d get rid of the insurance companies.’ I don’t want to hear that same old stale answer. I want to see who’s thinking.

If they took Medicare-for-All off the table, that would tell me how much they understand about what physicians actually deal with in running a practice and what drives health care costs.

All of our costs are driven up because of regulations, medicines, over-documentation, and things like EMR. It’s all gone over the top. How would candidates streamline things? Make liability reform cheaper? Make costs go down?

Are there any independent thinkers out there?

Ernest Bove, MD / Rutland, VT

They must talk about controlling costs of prescription drugs and insurance prices, of course.

The debate also has to be undertaken about coverage for all—again, especially since the current administration is trying to decrease what was already given. That’s difficult to do. But 18% of our GDP is really an unsustainable number—the cost of medicine keeps going up and services restricted. Somehow, there has to be the right of all people to access medical care. Everybody needs to have access to good health care that’s covered at some level, somehow. Whether it’s single-payer or not, it has to be discussed, and ultimately my opinion is that single-payer health care is going to happen. It’s just a matter of how and when.

I certainly hope some valid ideas come from both sides of the aisle; otherwise, what are we doing? We’re talking about almost 20% of this country’s GDP being spent on medicine. We better get some valid ideas going forward; otherwise, we’re going to bankrupt the system. That’s not good for anybody.

The health care that’s generally delivered in the United States is unbelievably fantastic and the opportunities we have are great. But the way it’s done is causing a lot of problems for the country, especially financially. Many people still don’t feel like they are protected and that’s unfortunate. Something like four out of 10 families, if they got a $400 emergency medical bill, could not sustain it. I think it’s overdue that this really comes to the forefront and takes center stage, and I think candidates will make this center stage because they have to.

Daniel Katz, MD / Poughkeepsie, NY

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**Recruitment**

**NEW YORK**

**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

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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

Central Vermont Medical Center

The Division of Urology at the University of Vermont Larner College of Medicine in alliance with the University of Vermont Medical Center, is seeking a Clinical Practice Physician who is a board eligible/board certified Urologist to join the Urology service at our affiliate community medical center, Central Vermont Medical Center (CVMC). This position offers the unique opportunity to work in a community setting while 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. Duties will include general urologic patient care (adult and minor pediatric) with the opportunity to teach medical students and potentially urology residents. Specifically, the Division seeks applications from individuals seeking a community Urology practice opportunity with a collegial and collaborative setting with University support. The central Vermont region, 30 minutes from Burlington, Vermont, offers easy access to numerous outdoor activities with several ski areas just a short drive away.

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

Interested individuals should apply online at http://www.uvmjobs.com/postings/33676 (position number 00023212). Inquiries may be directed to Mark Plante, MD, FRCS(C), FACS, Chief of Urology via Kristin Allard 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.
AUA advocates for GME funding bill

Patient access to care threatened, lawmakers told

In the face of President Trump’s proposed annual budget cuts of $47.9 billion for federal graduate medical education (GME) programs over the next decade, the medical profession is urging Congress to approve legislation to significantly increase federal GME support and help combat looming shortages in both primary and specialty care.

In a May 3 letter to every member of Congress, a long list of organizations, including the AUA, urged lawmakers to co-sponsor “The Resident Physician Shortage Reduction Act of 2019.” That legislation would increase the number of residency positions eligible for Medicare direct graduate medical education and indirect medical education by 15,000 slots over the next 5 years.

In addition, the legislation directs that half of the newly available positions be slotted for training in shortage specialties such as urology; specifies priorities for distributing new slots, such as to states with new medical schools; and provides for studying the needs of the U.S. health care system to allocate residencies accordingly.

In the House of Representatives, the bill, H.R. 1763, was introduced by Reps. Terri Sewell (D-AL) and John Katko (R-NY). The Senate bill, S.348, was introduced by Sens. Robert Menendez (D-NJ), John Boozman (R-AR) and Charles Schumer (D-NY).

Funding formula would slash GME spending

The legislation comes in the face of a proposal contained in the Trump administration’s budget that would replace Medicare and Medicaid GME, as well as Children’s Hospital GME, with a single grant program funded out of the Treasury Department. Growth in funding would be capped at the sum of 2017 payments from the three programs adjusted for inflation, minus one percentage point annually. The new funding formula would slash program spending by $47.9 billion over 10 years.

In their letter to Congress, the medical organizations stressed that while the demand for physicians continues to grow faster than the supply, by 2030 there is expected to be a projected shortfall of between 42,600 and 121,300 physicians, both in primary and specialty care.

“If we do not address this impending problem, patients from pediatrics to geriatrics will find it difficult to access the care they need,” the letter warned. “While this is a serious issue for all of us, it is especially problematic because of our aging population and physician retirement. A person's need for a physician increases with age, and the U.S. population aged 65 and older is predicted to grow 50% by 2030.”

For urology, the situation is especially serious, said AUA Public Policy Chair Christopher M. Gonzalez, MD, MBA.

“We know we have about 12,000 urologists in the country, and really only about 80% of those are actually practicing,” he said during the AUA’s Annual Urology Advocacy Summit in Washington. “So, really the question is where are they practicing and what is the geographic distribution? Digging deeper into the AUA Census, we find we have a maldistribution of doctors and urologists throughout the country.”

FAST FACTS

The Resident Physician Shortage Reduction Act of 2019:

- would increase the number of residency positions eligible for Medicare direct graduate medical education and indirect medical education by 15,000 slots over the next 5 years
- directs that half of newly available positions be slotted for training in shortage specialties such as urology
- is supported by the AUA and other organizations

Thus, the AUA has joined with others in the medical community to urge support for the Resident Physician Shortage Reduction Act.

Census points to work force concerns

According to the 2018 AUA Census, the number of urologists per capita has declined by more than 10% over the past 20 years. The median age of a urologist is 56 years, so many are approaching retirement. Complicating that situation is that training for urologists following medical school graduation is a minimum of 5 years and often longer.

According to the AUA Census, there are 12,660 practicing urologists, but only 10,696 (84.5%) are defined as “active.” As Dr. Gonzalez indicated, geographic distribution is a critical factor, with as many as 1,968 counties—or 62.6%—not having any urologists at all, while another 1,176 have only one urologist.

New Hampshire and New York state have the most urologists per 100,000 population, at 5.21 and 5.00 respectively, compared to a national average of 3.89. Meanwhile, Utah, North Dakota, Idaho, Wyoming, and Nevada have the fewest, all below three urologists per 100,000 population. Nevada is the worst in the nation at 2.40.

Some other key facts from the AUA’s 2018 Census that also indicate the urgency of taking action to increase support for medical education and to attract new physicians into the specialty include:

- The average number of work hours per week increased to 52.9 hours in 2018 from 51.6 hours in 2017.
- The median number of minutes a practicing urologist spends with a patient in a typical office visit is 15.
- Practicing urologists see 75 patients in a typical week, suggesting an estimated 3,600 patient visits/encounters per urologist during the year.
- The top reason urologists plan to retire before age 65 is a lack of time for personal and/or family life.

To increase their ability to serve patients in underserved areas, nearly 12% of practicing urologists in the U.S. participated in a telemedicine program in 2018. A vast majority, 83.3%, who participated in telemedicine expected those services to increase in 3 years.

A recent AUA Workforce and Compensation Survey indicated that up to 20% of currently practicing urologists intend to retire within the next 5 to 10 years, adding to the importance of ensuring a fully trained specialty physician work force for the future.
Did failure to do foreskin exam lead to legal action?

Pathologist, urologists accused of negligence in lawsuit

A 58-year-old male presented to three urologists with a lesion on the glans penis. He reported that the glans penis had been rubbed raw by the foreskin. He was then admitted to the hospital for circumcision and a biopsy of the lesion. The foreskin was also sent for biopsy.

The pathologist subsequently read the pathology slide, diagnosing epithelial dysplasia. The results were sent to the urologists, who did not conduct a further investigation of the results.

Ten months later, the patient was diagnosed with penile squamous cell carcinoma that required surgical removal of the glans penis.

**Pathologist, urologists sued**

The patient sued the pathologist and the three urologists, claiming that the pathologist negligently misread the pathology slide. As against the pathologist, the plaintiff claimed the pathologist was negligent in reading the biopsy as epithelial dysplasia when, in fact, he suffered from carcinoma site II, a non-invasive skin lesion. As against the urologists, the patient claimed the urologists were negligent in relying on the reading from the pathologist and failing to perform a microscopic evaluation of the foreskin. He further claimed the urologists were negligent in failing to advise him of the possibility of a pre-cancerous condition.

The case proceeded to trial. At trial, the patient claimed that the lesion was very treatable with topical creams. The patient also contended that the urologists should have followed him more closely and re-biopsied within 6 weeks.

The patient asserted that he had a second biopsy performed within 6 weeks. The patient's expert dermatologist/oncologist testified that had the patient presented with persistent problems, a second biopsy would have been performed.

The patient's expert psychologist testified that had the patient suffered tremendous psychological trauma due to developing cancer and requiring the removal of the glans penis. The expert psychologist further testified that the patient suffered psychological trauma due to the loss of his marital relationship.

In response, the defendant pathologist testified that he had properly read the biopsy slides as indicating epithelial dysplasia. The defendant pathologist further maintained that it was not proper to perform a microscopic exam of the foreskin unless indicated by a macroscopic exam. The expert testified that epithelial dysplasia was not an unreasonable reading of the slide. The defendant pathologist's second expert agreed that epithelial dysplasia was a reasonable diagnosis.

The three defendant urologists, members of the same medical group who all had some contact with the patient, argued that they had reasonably relied on the report rendered by the defendant pathologist. The defendant urologists further argued that epithelial dysplasia is not a pre-cancerous lesion and is a benign disease.

**Missed follow-up appointment alleged**

The defendant urologists contended that the patient failed to show for a follow-up appointment 6 weeks after biopsy and that they had no reason to believe that a cancerous condition had developed.

The defendant urologists further asserted that the patient failed to follow-up with persistent problems, a second biopsy would have been performed.

The defendant urologists' expert psychologist testified that it was proper to rely on the pathology report. He further testified that epithelial dysplasia is not a pre-cancerous condition. The defendant urologists' additional expert urologist testified that the urologists did not deviate from accepted standards of care. He also opined that epithelial dysplasia is not pre-cancerous. This expert urologist admitted on cross-examination, however, that it was unacceptable practice to fail to microscopically examine the foreskin.

The defendant urologists' expert oncologist testified that epithelial dysplasia is not a pre-cancerous condition and that the urologists acted reasonably in relying on the pathology report.

Following a 2-day deliberation, the jury found in favor of the patient. The defendant pathologist was found 60% negligent, and the defendant urologists were found 40% negligent. Each defendant urologist was found 13.3% negligent. The jury awarded $2 million to the patient and $800,000 to the patient's wife.

**LEGAL PERSPECTIVE:** The failure to perform a microscopic foreskin exam was a failure the urologists were unable to overcome. On cross-examination, their own expert, who testified it was reasonable and within the standard of care to rely on the pathologist's report, conceded that this practice was unacceptable. That testimony, combined with the patient’s experts’ testimony, likely led to the jury’s final determination in this case.
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