Declining reimbursement for their work and the burden of prior authorization are nearly universal concerns of U.S. urologists, an exclusive Urology Times survey has found.

Other pain points for urologists also relate to the non-clinical, business side of practice: increasing overhead/overhead management, increasing government regulations, new payment models (eg, bundled payments), quality metrics/reporting requirements, and smaller/narrow insurance networks.

For the second year in a row, the State of the Specialty survey examined practicing urologists’ attitudes toward value-based health care as well as their knowledge of and participation in the two tracks available to choose from under Medicare’s Quality Payment Program. Among survey respondents, 59% currently participate in the Merit-based Incentive Payment System (MIPS) and 23% in an Alternative Payment Model (APM), percentages similar to those recorded in last year’s survey.

The State of the Specialty survey was rolled out in 2006 and has been conducted by Urology Times annually since then. It quantifies the pressing issues facing urologists, trends in the workforce, and much more.

Top pain points: Drop in revenue, prior auth
Understanding of QPP options remains low

Richard R. Kerr / Content Channel Director

For the full article, please turn to page 24

PROSTATE CANCER
Journal Article of the Month

What do recent studies tell us about finasteride and PCa?

Updated results from the Prostate Cancer Prevention Trial showed that the reduced risk of cancer detection is maintained over the long term in patients taking finasteride (Prosca) (J Natl Cancer Inst 2018; 110:1208-15). But two recent studies reported associations between finasteride use and prostate cancer (JAMA Intern Med 2019; 179:812-9; JAMA Netw Open 2019; 2:e1913612). In his latest “Journal Article of the Month” column, Badar M. Mian, MD, examines these studies’ findings and what they mean for clinicians and patients.

More survey results
Read about urologists’ top concerns, MIPS participation, practice size, and more. See pages 26-27
SUTENT® (sunitinib malate) provided patients with a 14.4-month increase in median DFS benefit vs placebo

**INDICATION**
SUTENT® (sunitinib malate) is indicated for the adjuvant treatment of adult patients at high risk of recurrent RCC following nephrectomy.

**IMPORTANT SAFETY INFORMATION**
- **Boxed Warning/Hepatotoxicity**: Hepatotoxicity has been observed in clinical trials and postmarketing experience. Hepatotoxicity may be severe, and in some cases fatal. Monitor hepatic function and interrupt, reduce, or discontinue dosing as recommended. Fatal liver failure has been observed. Monitor liver function tests before initiation of treatment, during each cycle of treatment, and as clinically indicated. Interrupt SUTENT for Grade 3 or 4 drug-related hepatic adverse reactions and discontinue if there is no resolution. Do not restart SUTENT if patients subsequently experience severe changes in liver function tests or have signs and symptoms of liver failure.
- **Cardiovascular events**, including myocardial ischemia, myocardial infarction, left ventricular ejection fraction declines to below the lower limit of normal, and cardiac failure, including death, have occurred. Monitor patients for signs and symptoms of congestive heart failure. Discontinue SUTENT for clinical manifestations of congestive heart failure. In patients without cardiac risk factors, a baseline evaluation of ejection fraction should be considered. Baseline and periodic evaluations of left ventricular ejection fraction should also be considered while these patients are receiving SUTENT.
- **SUTENT can cause QT prolongation** in a dose-dependent manner, which may lead to an increased risk for ventricular arrhythmias including Torsades de Pointes, which has been seen in <0.1% of patients. Monitor patients who are at higher risk for developing QT interval prolongation, including those with a history of QT interval prolongation, patients who are taking antiarrhythmics, and patients with relevant pre-existing cardiac disease, bradycardia, or electrolyte disturbances. Consider monitoring electrocardiograms and electrolytes. Concomitant treatment with strong CYP3A4 inhibitors may increase sunitinib plasma concentrations and dose reduction of SUTENT should be considered.
- **Hypertension** may occur. Monitor blood pressure and treat as needed with standard antihypertensive therapy. In cases of severe hypertension, temporary suspension of SUTENT is recommended until hypertension is controlled.
- **Hemorrhagic events**, including tumor-related hemorrhage, and viscous perforation (both with fatal events) have occurred. These events may occur suddenly, and in the case of pulmonary tumors may present as severe and life-threatening hemoptysis or pulmonary hemorrhage. Perform serial complete blood counts (CBCs) and physical examinations.
- **Cases of tumor lysis syndrome (TLS)** (some fatal) have been reported. Patients generally at risk of TLS are those with high tumor burden prior to treatment. Monitor these patients closely and treat as clinically indicated.
- **Thrombotic microangiopathy (TMA)**, including thrombotic thrombocytopenic purpura and hemolytic uremic syndrome, sometimes leading to renal failure or a fatal outcome, has been reported in patients who received SUTENT as monotherapy and in combination with bevacizumab. Discontinue SUTENT in patients developing TMA. Reversal of the effects of TMA has been observed after treatment was discontinued.
- **Proteinuria and nephrotic syndrome** have been reported. Some of these cases have resulted in renal failure and fatal outcomes. Monitor patients for the development or worsening of proteinuria. Perform baseline and periodic urinalysis during treatment, with follow-up measurement of 24-hour urine protein as clinically indicated. Interrupt treatment for 24-hour urine protein ≥3 grams. Discontinue for repeat episodes of protein ≥3 grams despite dose reductions or nephrotic syndrome.
- **Dermatologic toxicities**: Severe cutaneous reactions have been reported, including cases of necrotizing fasciitis, erythema multiforme (EM), Stevens-Johnson syndrome (SJS), and toxic epidermal necrolysis (TEN), some of which were fatal. If signs or symptoms of SJS, SJS, or TEN are present, discontinue SUTENT treatment. If a diagnosis of SJS or TEN is suspected, treatment must be stopped.
- **Necrotizing fasciitis**, including fatal cases, has been reported, including the perineum and secondary to fistula formation. Discontinue SUTENT in patients who develop necrotizing fasciitis.
- **Thyroid dysfunction** may occur. Monitor thyroid function in patients with signs or symptoms suggestive of thyroid dysfunction, including hypothyroidism, hyperthyroidism, and thyroiditis, and treat per standard medical practice.
SUTENT® (sunitinib malate) is indicated for the adjuvant treatment of adult patients with clear-cell histology and high risk of recurrence (defined as ≥3 and/or N+ tumors) following nephrectomy.

Patients were required to have clear-cell histology and high risk of recurrence (defined as ≥3 and/or N+ tumors) following nephrectomy. 615 patients were randomized 1:1 to receive either 50-mg SUTENT or placebo once daily on a schedule of 4 weeks on treatment followed by 2 weeks off.

Treatment was initiated 3 to 12 weeks postnephrectomy.

Unscheduled dose interruption and/or dose reduction to a minimum of 37.5 mg of SUTENT was allowed.

Treatment continued for 9 cycles (~1 year) or until disease recurrence, unacceptable toxicity, or withdrawal of consent.

The primary endpoint of DFS was assessed by blinded independent central review (BICR).

Secondary endpoints included OS and safety.

Temporary suspension of SUTENT is recommended; following resolution, treatment may be resumed at the discretion of the treating healthcare provider.

Pancreatic function: Pancreatitis was observed in 5 patients (1%) receiving SUTENT for treatment-naïve RCC compared to 1 patient (<1%) receiving IFN-α, in a trial of patients receiving adjuvant treatment for RCC. 1 patient (<1%) on SUTENT and none on placebo experienced pancreatitis. Pancreatitis was observed in 1 patient (1%) receiving SUTENT for pNET and 1 patient (1%) receiving placebo.

CYP3A4 Inhibitors and Inducers: Dose adjustments are recommended when SUTENT is administered with CYP3A4 inhibitors or inducers. During treatment with SUTENT, patients should not drink grapefruit juice, eat grapefruit, or take St John’s Wort.

Most common ARs & most common grade 3/4 ARs (adjuvant RCC): The most common ARs reported in ≥20% of patients receiving SUTENT for adjuvant treatment of RCC and more commonly than in patients given placebo (all grades, vs placebo) were mucositis/stomatitis (61% vs 15%), diarrhea (57% vs 22%), fatigue/asthenia (57% vs 34%), hand-foot syndrome (50% vs 10%), hypertension (39% vs 14%), altered taste (38% vs 6%), nausea (34% vs 15%), dyspepsia (27% vs 7%), abdominal pain (25% vs 9%), hypothyroidism/TSH increased (24% vs 4%), rash (24% vs 12%), bleeding events, all sites (24% vs 5%), and hair color changes (22% vs 2%).

Most common grade 3/4 lab abnormalities (adjuvant RCC): The most common grade 3/4 lab abnormalities occurring in ≥2% of patients receiving SUTENT included neutropenia (13%), thrombocytopenia (5%), leukopenia (3%), lymphopenia (3%), elevated alanine aminotransferase (2%), elevated aspartate aminotransferase (2%), hyperglycemia (2%), and hyperkalemia (2%).

Please see Brief Summary of full Prescribing Information, including BOXED WARNING, on the following pages.


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U.S. Pharmaceuticals
WARNING: HEPATOTOXICITY

Hepatotoxicity has been observed in clinical trials and postmarketing experience. Hepatotoxicity may be severe in some cases fatal. Monitor hepatic function and interrupt, reduce, or discontinue as recommended.

INDICATION AND USAGE: SUTENT is indicated for the indicated adult treatment of patients at high risk of recurrent renal cell carcinoma (RCC) following nephrectomy.

DOSE AND ADMINISTRATION

Recommended Dose: The recommended dose of SUTENT for the indicated treatment of RCC is 50 mg taken orally once daily, on a schedule of 4 weeks on treatment followed by 2 weeks off (Schedule 4/2), for nine 8-week cycles. SUTENT may be taken with or without food.

Dose Modification for Adverse Reactions

Dose interruption and/or dose modification in 12.5 mg increments or discontinuation is recommended based on individual safety and tolerability. In the adjuvant RCC study, the minimum dose administered was 37.5 mg.

Dose Modification for Co-administration of Strong CYP3A4 Inhibitors or Inducers

A dose reduction for SUTENT as a minimum of 37.5 mg daily should be considered if SUTENT must be co-administered with a strong CYP3A4 inhibitor. A dose increase for SUTENT to a maximum of 87.5 mg daily should be considered if SUTENT must be co-administered with a CYP3A4 inducer. If dose is increased, the patient should be monitored carefully for toxicity.

Dose Modification for End-Stage Renal Disease (ESRD) Patients on Hemodialysis

No starting dose adjustment is required in patients with end-stage renal disease (ESRD) on hemodialysis. However, given the decreased exposure compared to patients with normal renal function, subsequent doses may be increased to ≤2 fold based on safety and tolerability.

CONTRAINDICATIONS: None.

WARNINGS AND PRECAUTIONS

Hepatotoxicity. SUTENT can cause severe hepatotoxicity, resulting in liver failure or death. Liver failure occurs at an incidence of <1% in clinical trials. Liver failure signs include jaundice, elevated transaminases and/or hyperbilirubinemia in conjunction with encephalopathy, coagulopathy, and/or renal failure. Monitor liver function tests (alanine aminotransferase [ALT], aspartate aminotransferase [AST], and bilirubin) before initiation of treatment, during each cycle of treatment, and as clinically indicated. Interrupt SUTENT for Grade 3 or 4 drug-related hepatic adverse reactions and discontinue if there is no resolution. Do not restart SUTENT if patients subsequently experience severe changes in liver function tests or have other signs and symptoms of liver failure.

Safety in patients with ALT or AST >2.5 × upper limit of normal (ULN) or, if due to liver metastases, >5 × ULN has not been established.

Cardiovascular Events. Discontinue SUTENT in the presence of clinical manifestations of congestive heart failure (CHF). Interrupt SUTENT and/or reduce the dose in patients without clinical evidence of CHF who have an ejection fraction of <20% but >50% below baseline or below the lower limit of normal where the reduction is not explained.

In patients without cardiac risk factors, a baseline evaluation of ejection fraction should be considered. Carefully monitor patients for clinical signs and symptoms of CHF while receiving SUTENT. Baseline and periodic evaluations of left ventricular ejection fraction (LVEF) should also be considered while patients are receiving SUTENT.

Cardiovascular events, including heart failure, cardiomyopathy, myocardial ischemia, and myocardial infarction, some of which were fatal, have been reported. In patients treated with SUTENT (N=7627) for GIST, advanced RCC, advanced treatment of RCC and pNET, 3% of patients experienced heart failure; 71% of the patients with heart failure were reported as recovered. Fatal cardiac failure was reported in <1% of patients.

In the adjuvant treatment of RCC study, 11 patients in each arm experienced a decreased ejection fraction of <50% (of SSCE), of whom 26% had left ventricular dysfunction (LVD). Patients in each treatment arm did not return to >30% or baseline by the time of last measurement. No patients who received SUTENT were diagnosed with CHF.

Patients who presented with cardiac events within 12 months prior to SUTENT administration, such as myocardial infarction (including severe/unstable angina), coronary/peripheral artery bypass graft (CABG) or coronary stenting, or left ventricular dysfunction (LVD), should be excluded from SUTENT clinical studies. Patients with prior atrial arrhythmia use or cardiac radiation were also excluded from some studies. It is unknown whether patients with these concomitant conditions may be at a higher risk of developing drug-related left ventricular dysfunction.

QT Interval Prolongation and Torsade de Points

SUTENT can cause QT interval prolongation in a dose-dependent manner, which may lead to an increased risk for ventricular arrhythmias including Torsade de Points. Torsade de Points has been observed in <0.1% of SUTENT-exposed patients. Monitor patients with a history of QT interval prolongation, patients who are taking antiarrhythmics, or patients with a history of hypokalemia or hypomagnesemia. Torsade de Pointes is usually preceded by a history of atrial fibrillation or flutter. In rare cases, Torsade de Pointes has been fatal.

In patients treated with SUTENT (N=7627) for GIST, advanced RCC, advanced treatment of RCC and pNET, 29% of patients experienced proteinuria, 30% of patients experienced hemorrhagic events, and 4.2% of patients experienced heart failure; 71% of the patients with heart failure were reported as recovered. Fatal cardiac failure was reported in <1% of patients.

Hypertension. SUTENT is contraindicated in patients with moderate to severe proteinuria has not been systematically evaluated.

Hypertension. SUTENT is contraindicated in patients who are receiving an angiotensin-converting enzyme (ACE) inhibitor or an angiotensin II receptor blocker (ARB). SUTENT should be used in patients who are taking an ACE inhibitor or an ARB after careful consideration of the benefit versus risk.

Hypertension. SUTENT is contraindicated in patients who are receiving SUTENT and concomitantly taking a medication that may cause blood pressure to increase. These patients are receiving SUTENT.

Renal and Hematologic Diseases

Hemorrhagic Events and Viscus Perforations

Hemorrhagic events reported during postmarketing experience in some of which were fatal, have included GI, respiratory, tumor, urinary tract, and brain hemorrhages. In patients treated with SUTENT (N=7627) for GIST, advanced RCC, advanced treatment of RCC and pNET, 29% of patients experienced hypertension. Grade 3 hypertension was reported in 7% of patients, and Grade 4 hypertension was reported in 0.2% of patients.

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Adverse reactions in the study of SUTENT for the adjuvant treatment of RCC. The safety of SUTENT was evaluated in S-TRAC, a randomized, double-blind, placebo-controlled trial in which patients who had undergone nephrectomy for RCC received SUTENT 50 mg daily (n=306) on Schedule 4/2 or placebo (n=304). The median duration of treatment was 12.4 months (range: 0.13-14.9) for SUTENT and 12.4 months (range: 0.03-13.7) for placebo. Permanently discontinuation due to an adverse reaction occurred in 28% of patients on SUTENT and 6% on placebo. Adverse reactions leading to permanent discontinuation in ≥2% of patients include hand-foot syndrome and fatigue/asthenia. Dosing interruptions or delays occurred in 166 (54%) and 84 (28%) patients on SUTENT and placebo, respectively. One hundred forty patients (45.8%) out of 306 patients in the SUTENT arm and 15 patients (5%) out of 304 patients in the placebo arm had dose reductions. The following table compares the incidence of common (≥10%) treatment-emergent adverse reactions for patients receiving SUTENT versus placebo.

### Adverse Reactions Reported in S-TRAC in ≥10% of Patients With RCC Who Received SUTENT and More Common Than in Patients Given Placebo

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>SUTENT (n=306) All Grades</th>
<th>Placebo (n=304) All Grades</th>
<th>Grade 3-4 All Grades</th>
<th>Grade 3-4 All Grades</th>
</tr>
</thead>
<tbody>
<tr>
<td>Any Adverse Reactions</td>
<td>99 (60)</td>
<td>80 (53)</td>
<td>15 (48)</td>
<td>8 (26)</td>
</tr>
<tr>
<td><strong>Constitutional</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue/asthenia</td>
<td>57 (19)</td>
<td>34 (11)</td>
<td>2 (19)</td>
<td>1 (26)</td>
</tr>
<tr>
<td>Localized edema</td>
<td>18 (&lt;1)</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Pyrexia</td>
<td>12 (&lt;1)</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong>Gastrointestinal</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mucositis/stomatitis</td>
<td>64 (21)</td>
<td>15 (5)</td>
<td>4 (26)</td>
<td>1 (6)</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>57 (20)</td>
<td>22 (&lt;1)</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Nausea</td>
<td>34 (11)</td>
<td>15 (5)</td>
<td>1 (7)</td>
<td>1 (6)</td>
</tr>
<tr>
<td>Vomiting</td>
<td>25 (32)</td>
<td>9 (&lt;1)</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Diarrhea</td>
<td>19 (28)</td>
<td>7 (2)</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong>Cardiac</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypertension</td>
<td>39 (13)</td>
<td>4 (1)</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Edema/Peripheral edema</td>
<td>10 (&lt;1)</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong>Dermatologic</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hand-foot syndrome</td>
<td>50 (16)</td>
<td>10 (3)</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Hair color changes</td>
<td>22 (7)</td>
<td>2 (1)</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Rash</td>
<td>24 (8)</td>
<td>12 (4)</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Skin desquamation/yellow skin</td>
<td>18 (6)</td>
<td>1 (0)</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Hair color changes</td>
<td>14 (4)</td>
<td>6 (2)</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong>Neurologic</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Ataxia</td>
<td>38 (12)</td>
<td>6 (2)</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td>Headache</td>
<td>19 (&lt;1)</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong>Malignant/neoplastic</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pain in extremity</td>
<td>15 (5)</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong>Endocrine</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hypothyroidism/TSH increased</td>
<td>24 (8)</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong>Metabolic/Endocrine</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Anorexia/diabetes hyperglycemia</td>
<td>19 (&lt;1)</td>
<td>5 (2)</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
<tr>
<td><strong>Hematologic</strong></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bleeding events, all sites</td>
<td>24 (8)</td>
<td>&lt;1</td>
<td>&lt;1</td>
<td>&lt;1</td>
</tr>
</tbody>
</table>

*Common Terminology Criteria for Adverse Events (CTCAE), version 3.0. Abbreviations: ARs=adverse reactions; N=number of patients; RCC=renal cell carcinoma.

**Adjuvant treatment for RCC, 1 patient (<1%) on SUTENT and none on placebo experienced pancreatitis. Pancreatitis was observed in 1 patient (1%) receiving SUTENT for pNET and 1 patient (1%) receiving placebo.**

### Postmarketing Experience

The following adverse reactions have been identified during post-approval use of SUTENT. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

**Blood and lymphatic system disorders:** hemoglobinemia associated with thrombocytopenia.*

Suspension of SUTENT is recommended; following resolution, treatment may be resumed at the discretion of the treating healthcare provider.

**Gastrointestinal disorders:** anaphylaxis.

**Hypersensitivity disorders:** cholezystitis, particularly acalculous cholezystitis.

**Immune system disorders:** hypersensitivity reactions, including angioedema.

**Infections and infestations:** serious infection (with or without neutropenia).* The infections most commonly observed with SUTENT treatment include respiratory, urinary tract, skin infections, and sepsis/septic shock.

**Mucosal and connective tissue disorders:** fibula formation, sometimes associated with tumor necrosis and/or regression,* myopathy and/or rhabdomyolysis with or without acute renal failure.* Patients with signs or symptoms of muscle toxicity should be managed as per standard medical advice.

**Renal and urinary disorders:** renal impairment and/or failure.*

**Respiratory disorders:** pulmonary embolism.*

**Skin and subcutaneous tissue disorders:** pyoderma gangrenosum, including positive dechallenges.

**Vascular disorders:** arterial thromboembolic events.* The most frequent events included cerebrovascular accident, transient ischemic attack, and cerebral infarction.*

*Including some fatalities.

### Drug Interactions

**Effects of Other Drugs on SUTENT**

**Strong CYP3A4 Inhibitors:** Co-administration with strong CYP3A4 inhibitors may increase sunitinib plasma concentrations.

Select an alternate concomitant medication with no or minimal enzyme inhibition potential. Consider a dose reduction for SUTENT when it is co-administered with strong CYP3A4 inhibitors [see Dosage and Administration].

**Strong CYP3A4 Inducers:** Co-administration with strong CYP3A4 inducers may decrease sunitinib plasma concentrations.

Select an alternate concomitant medication with no or minimal enzyme induction potential. Consider a dose increase for SUTENT when it must be co-administered with CYP3A4 inducers [see Dosage and Administration].

### Use in Specific Populations

**Pregnancy**

**Risk Summary:** Based on animal reproduction studies and its mechanism of action, SUTENT can cause fetal harm when administered to a pregnant woman. There are no available data in pregnant women to inform a drug-associated risk in animal. In animal developmental and reproductive toxicology studies, oral administration of sunitinib to pregnant rats and rabbits throughout organogenesis resulted in teratogenicity (embryonic, craniofacial and skeletal malformations) at 5.5 and 0.3 times the AUC in patients administered the recommended daily doses (RDD), respectively [see Data]. Advise pregnant women or females of reproductive potential of the potential hazard to a fetus.

The background risk of major birth defects and miscarriage for the indicated populations are unknown. However, the estimated background risk in the United States (U.S.) general population of major birth defects is 2%-4% and of miscarriage is 15%-20% of clinically recognized pregnancies.

**Data**

**Animal Data.** In a female fertility and early embryonic development study, female rats were administered oral sunitinib (0.5, 1.5, 5 mg/kg/day) for 21 days prior to mating and for 7 days after fertilization. Embryolethality was observed at 5 mg/kg/day (approximately 5 times the AUC in patients administered the RDD of 50 mg/day).

In embryo-fetal developmental toxicity studies, oral sunitinib was administered to pregnant rats (0.3, 1.5, 5 mg/kg/day) and rabbits (0.5, 1.5, 5 mg/kg/day) during the period of organogenesis. In rats, embryolethality and skeletal malformations of the ribs and vertebrae were observed at the dose of 5 mg/kg/day (approximately 5.5 times the systemic exposure [combined AUC of sunitinib + primary active metabolite] in patients administered the RDD). No adverse fetal effects were observed in rats at doses ≥3 mg/kg/day (approximately 2 times the AUC in patients administered the RDD). In rabbits, embryolethality was observed at 5 mg/kg/day (approximately 3 times the AUC in patients administered the RDD), and craniofacial malformations (cleft lip and cleft palate) were observed at 1 mg/kg/day (approximately 0.3 times the AUC in patients administered the RDD of 50 mg/day).

Sunitinib (0.3, 1, 3 mg/kg/day) was evaluated in a pre- and postnatal developmental study in pregnant rats. Maternal body weight gains were reduced during gestation and lactation at doses ≥1 mg/kg/day (approximately 0.5 times the AUC in patients administered the RDD). At 3 mg/kg/day (approximately 0.5 times the AUC in patients administered the RDD), reduced neonate body weights were observed at birth and persisted in the offspring of both sexes during the preweaning period and in males during postweaning period. No adverse developmental effects were observed at doses ≤1 mg/kg/day.

**Lactation.** There is no information regarding the presence of sunitinib and its metabolites in human milk. Sunitinib and its metabolites were excreted in rat milk at concentrations up to 12-fold higher than in plasma. Because of the potential for serious adverse reactions in breastfed infants from SUTENT, advise a lactating woman not to breastfeed during treatment with SUTENT and for at least 4 weeks after the last dose.

**Data**

**Animal Data.** In lactating female rats administered 15 mg/kg/day, sunitinib and its metabolites were detected in milk. Because of the potential for serious adverse reactions in breastfed infants from SUTENT, advise a lactating woman not to breastfeed during treatment with SUTENT.

**Pregnancy Testing**

Females of reproductive potential should have a pregnancy test before treatment with SUTENT is started.

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SUTENT in an attempted suicide was reported without adverse reaction. In nonclinical studies, or without adverse reactions. A case of intentional overdose involving the ingestion of 1500 mg of cases were associated with adverse reactions consistent with the known safety profile of SUTENT, and tolerability.

OVERDOSAGE

and severe hepatic impairment. SUTENT was not studied in patients with severe (Child-Pugh Class A or B) hepatic impairment. SUTENT was not studied in patients with severe (Child-Pugh Class C) hepatic impairment.

Renal Impairment. No starting dose adjustment is required in patients with mild or moderate (Child-Pugh Class A or B) hepatic impairment. SUTENT was not studied in patients with severe (Child-Pugh Class C) hepatic impairment.

Renal Impairment. No starting dose adjustment is recommended in patients with mild (CLcr 50 to 80 mL/min), moderate (CLcr 30 to <50 mL/min), or severe (CLcr <30 mL/min) renal impairment who are at risk of overdosage.

OVERDOSAGE

Treatment of overdose with SUTENT should consist of general supportive measures. There is no specific antidote for overdosage with SUTENT. If indicated, elimination of unabsorbed drug should be achieved by emesis or gastric lavage. Cases of accidental overdose have been reported; these cases were associated with adverse reactions consistent with the known safety profile of SUTENT, or without adverse reactions. A case of intentional overdose involving the ingestion of 1500 mg of SUTENT in an attempted suicide was reported without adverse reaction. In nonclinical studies, no adverse effects were observed as few as 5 daily dosing of 1500 mg (3000 mg/m²) in rats. At this dose, signs of toxicity included impaired muscle coordination, head shakes, hypoactivity, ocular discharge, piloerection, and gastrointestinal distress. Mortality and similar signs of toxicity were observed at lower doses when administered for longer durations.

NONCLINICAL TOXICOLOGY

Carcinogenesis, Mutagenesis, Impairment of Fertility. The carcinogenic potential of sunitinib has been evaluated in 2 species: rasH2 transgenic mice and Sprague-Dawley rats. There were similar positive findings in both species. In rasH2 transgenic mice, gastrointestinal carcinomas and/or gastric mucosal hyperplasia, as well as an increased incidence of background hemangiosarcomas were observed at doses of ≥2.5 mg/kg/day following daily dose administration of sunitinib in studies of 1 or 6 months duration. No proliferative changes were observed in rasH2 transgenic mice at 8 mg/kg/day. Similarly, in a 2-year rat carcinogenicity study, administration of sunitinib in 28-day cycles followed by 7-day dose-free periods resulted in findings of duodenal carcinoma at doses as low as 1 mg/kg/day (approximately 6 times the AUC in patients given the RDD of 50 mg/day). At the high dose of 3 mg/kg/day (approximately 8 times the AUC in patients at the RDD of 50 mg/day), the incidence of tumors was increased and was accompanied by findings of gastric mucous cell hyperplasia and by an increased incidence of pheochromocytoma and hyperplasia of the adrenal gland.

Sunitinib did not cause genetic damage when tested in in vitro assays (bacterial mutation [Ames test], human lymphocytes), in vivo chromosomal aberrations, or in vivo rat bone marrow micronucleus tests.

In a female fertility and early embryonic development study, female rats were administered oral sunitinib (0.5, 1.5, 5 mg/kg/day) for 21 days prior to mating and for 7 days after mating.

Preimplantation loss was observed in females administered 5 mg/kg/day (approximately 5 times the AUC in patients administered the RDD of 50 mg/day). No adverse effects on fertility were observed at doses ≤1.5 mg/kg/day (approximately 1 time the clinical AUC at the RDD of 50 mg/day). In addition, effects on the female reproductive system were identified in a 3-month oral repeat-dose mouse study (2, 6, 12 mg/kg/day). Ovarian changes (decreased follicular development) were noted at 12 mg/kg/day (approximately 5 times the AUC in patients administered the RDD), while uterine changes (endometrial atrophy) were noted at ≥2 mg/kg/day (approximately 0.4 times the AUC in patients administered the RDD). With the addition of vaginal atrophy, the uterine and ovarian effects were reproduced at 16 mg/kg/day (approximately 0.8 times the AUC in patients administered the RDD) in a 9-month mouse study (0.3, 1.5, and 6 mg/kg administered daily for 28 days followed by a 14-day respite).

In a male fertility study, no reproductive effects were observed in male rats dosed with 1, 3, or 10 mg/kg/day oral sunitinib for 58 days prior to mating with untreated females. Fertility, copulation, conception indices, and sperm evaluation (morphology, concentration, and motility) were unaffected by sunitinib at doses ≤10 mg/kg/day approximately ≥26 times the AUC in patients administered the RDD.

PATIENT COUNSELING INFORMATION

Advise patients to read the FDA-approved patient labeling (Medication Guide).

Hypersensitivity Informs patients of the signs and symptoms of hypersensitivity. Advise patients to contact their healthcare provider immediately for signs or symptoms of hypersensitivity.

Cardiovascular Events
Advise patients to contact their healthcare provider if they develop symptoms of heart failure.

QT Prolongation and Torsade de Points
Inform patients of the signs and symptoms of QT prolongation. Advise patients to contact their healthcare provider immediately in the event of scheduled dose at its regular time, and cardiac palpitations.

Hypertension
Inform patients of the signs and symptoms of hypertension. Advise patients to undergo routine blood pressure monitoring and to contact their health care provider if blood pressure is elevated or if they experience signs or symptoms of hypertension.

Hemorrhagic Events
Advise patients that SUTENT can cause severe bleeding. Advise patients to immediately contact their healthcare provider for bleeding or symptoms of bleeding.

Gastrointestinal Disorders
Advise patients that gastrointestinal disorders such as diarrhea, nausea, vomiting, and constipation may develop during SUTENT treatment and to seek immediate medical attention if they experience persistent or severe abdominal pain because cases of gastrointestinal perforation and fistula have been reported in patients taking SUTENT.

Dermatologic Effects and Toxicities
Advise patients that depigmentation of the hair or skin may occur during treatment with SUTENT due to the drug color (yellow). Other possible dermatologic effects may include dryness, thickness or cracking of skin, blister or rash on the palms of the hands and soles of the feet. Severe dermatologic toxicities including Stevens-Johnson syndrome, Toxic Epidermal Necrolysis, exanthema multiforme, and necrotizing toxicities have been reported. Advise patients to immediately inform their healthcare provider if severe dermatologic reactions occur.

Thyroid Dysfunction
Advise patients that SUTENT can cause thyroid dysfunction. Advise patient to contact their healthcare provider if symptoms of abnormal thyroid function occur.

Hypoglycemia
Advise patients that SUTENT can cause severe hypoglycemia and may be more severe in patients with diabetes taking antidiabetic medications. Inform patients of the signs, symptoms, and risks associated with hypoglycemia. Advise patients to immediately inform their healthcare provider if severe signs or symptoms of hypoglycemia occur.

Osteonecrosis of the Jaw
Advise patients to consider preventive dentistry prior to treatment with SUTENT. Inform patients being treated with SUTENT, particularly who are receiving bisphosphonates, to avoid invasive dental procedures if possible. If possible, avoid invasive dental procedures while on SUTENT treatment, particularly in patients receiving intravenous bisphosphonate therapy.

Concomitant Medications
Advise patients to inform their healthcare providers of all concomitant medications, including over-the-counter medications and dietary supplements.

Embryo-Fetal Toxicity
Advise females to inform their healthcare provider if they are pregnant or become pregnant. Inform female patients of the risk to a fetus and potential loss of the pregnancy.

Advise females of reproductive potential to use effective contraception during treatment and for 7 weeks after receiving the last dose of SUTENT.

Lactation
Advise lactating women not to breastfeed during treatment with SUTENT and for at least 4 weeks after the last dose.

Infertility
Advise patients that male and female fertility may be compromised by treatment with SUTENT.

Missed Dose
Advise patients that miss a dose of SUTENT by less than 12 hours to take the missed dose right away. Advise patients that miss a dose of SUTENT by more than 12 hours to take the next scheduled dose at its regular time.

This product’s label may have been updated. For full prescribing information, please visit www.pfizer.com.
Table of Contents

1 Cover Feature
Top pain points: Revenue decline, prior auth

SEXUAL DYSFUNCTION
10 Clinical Updates Guideline adherence raises infection risk in diabetic penile prosthesis patients
10 Letter Patients in stem cell study not charged for treatment

OAB/INCONTINENCE
12 Clinical Updates Selective bladder denervation found efficacious in refractory OAB

KIDNEY STONES
13 Clinical Updates Antibiotic prophylaxis varies widely prior to stent removal
14 Protocol cuts opioid prescribing in stone patients
14 Letter Advanced practice provider shares protocol for tracking ureteral stents

BPH
16 Clinical Updates Training era linked to TURP outcomes

BLADDER CANCER
17 Clinical Updates Worse perioperative outcomes seen in bladder Ca patients ≥80 years / Financial toxicity prevalent with bladder Ca patients

PROSTATE CANCER
20 Clinical Updates Imaging agent shows impact on PCa decisions
24 Journal Article of the Month What do recent studies tell us about finasteride and PCa?

COLUMNS/DEPARTMENTS
8 Chairman’s Letter Final rule, State of Specialty mark end of 2019 and what lies ahead
9 From the Board Survey reveals new realities of work-life balance
28 Q&A Patient, tumor factors dictate partial vs. radical nephrectomy
30 Coding and Reimbursement 2020 final rule reveals small gains for urology reimbursement
33 Practice Matters How MIPS Cost category changes will affect urologists
34 Money Matters Inherited retirement accounts: What are your options?
36 Speak Out How have your benefits changed over the past several years?
41 Washington and You Report urges action on physician burnout
42 Malpractice Consult Is clinician at fault for vesicovaginal fistula?
Here at Urology Times, the end of the calendar year is always marked by two key events: the release of the Medicare Physician Fee Schedule final rule, and the publication of our exclusive State of the Specialty survey results.

For the final rule, our Business of Urology columnists offer comprehensive overviews of what’s new for 2020. In Ray Painter, MD, and Mark Painter’s “Coding and Reimbursement” column, you’ll learn about reimbursement updates for 2020 and also about significant CPT changes coming in 2021. In his “Practice Matters” column, Robert A. Dowling, MD, looks at changes to the Quality Payment Program of interest to urologists, including a stone treatment-related episode-based Cost measure (page 33).

Our State of the Specialty report, now in its 14th year, provides an excellent high-level view of urology, examining topics such as value-based health care, trends in the workforce, and your opinion on prior authorization, overhead management, quality metrics and reporting requirements, and more. Content Channel Director Richard R. Kerr summarizes the results of this year’s survey beginning on page 1, and UT Clinical Practice Board member and bloggerHen-ry Rosevear, MD, provides his own insights on the results and what they mean for urologists on page 9.

Clinically speaking, this issue contains our usual robust coverage of benign and malignant urologic disease. In the area of sexual dysfunction, we report on a study regarding an association between guideline adherence and increased infection risk in diabetic patients undergoing penile prosthesis implantation (page 10). Our overactive bladder/incontinence coverage includes a report on the use of selective bladder denervation for refractory OAB (page 12), while in the area of stone disease, look for articles regarding antibiotic prophylaxis prior to stent removal as well as a protocol for reducing opioid prescriptions in stone patients (pages 13-14).

Moving on to BPH, we report on research suggesting that the era in which a urologist is trained is associated with transurethral resec-tion of the prostate outcomes (page 16).

This month’s bladder cancer content features coverage from the recent American College of Surgeons Clinical Congress in San Francisco, with articles highlighting research on perioperative outcomes in patients >80 years of age as well as observed financial toxicity in patients with bladder cancer (page 17). In the area of prostate cancer, look for a report on fluorine-18-labeled fluciclovine (18F-fluociclovine [Axumin]) position emission tomography/computed tomogra-phy imaging (page 24), as well as a compelling “Journal Article of the Month” column from Badar M. Mian, MD, evaluating recent research on finasteride (Proscar) use and prostate cancer (page 24). Finally, in the area of kidney cancer, UT Editorial Consultant J. Brantley Thrasher, MD, sits down with Chandra P. Sundaram, MD, of the Indiana University Medical Center, Indianapolis, for a discussion regarding important patient and tumor characteristics to consider when deciding between partial and radical nephrectomy.

Moving beyond clinical topics, Jeff Vize, CFP, examines inherited retirement accounts in his latest “Money Matters” column (page 34), while three urologists discuss how their employment benefits have changed over the years in this month’s “Speak Out” (page 36). For “Malpractice Consult,” Acacia Brush Perko, Esq., explains the case of a patient who underwent a total abdominal hysterectomy and eventually developed a vesicovaginal fistula (page 42).

This issue of Urology Times marks the final “Washington and You” column from long-time correspondent Bob Gatty (page 44). All of us at UT salute Bob for his years of dedicated reporting on legislative and policy news, and wish him all the best.

Finally, we thank you, the reader, for accompanying UT through another year of covering your special-ty. From all of us to all of you, Happy Holidays!
Survey reveals new realities of work-life balance

HENRY ROSEVEAR, MD
Dr. Rosevear, a member of the Urology Times Clinical Practice Board, is a urologist in community practice in Colorado Springs, CO.

In my very first blog post 6 years ago, I shared some financial advice from an old friend who said that my wife can buy anything she wanted; she just can’t buy everything she wants. The same can be said about any other activity. A person can do just about anything they want (with some exceptions) if they are willing to make it a priority and sacrifice. When I reviewed the results of this year’s Urology Times State of the Specialty survey, I see my fellow urologists trying to balance the medical and business side of medicine with mixed results.

Urology is an incredible field in which we directly improve our patients’ quality of life. Yet 28% of urologists wouldn’t choose medicine as a career if they could choose again, the survey showed. Why? Probably because 53% of us feel burned out, and the three biggest reasons for burnout cited in the survey—use of electronic records, increasing workload, and falling professional revenue—are likely only going to get worse.

What are we doing about it? Over half of those surveyed have made some sort of plans to retire in 5-10 years! Think about that. Urology is one of the most in-demand specialties (over half of us are concerned about hiring another urologist) and has one of the highest mean ages (both according to last year’s AUA Survey—use of electron-ic records, increasing workload, and falling professional revenue—are likely only going to get worse.

The federal government is not helping. Almost 50% of us admit to not understanding very well at all how MIPS (Merit-based Incentive Payment System) or APMs (Alternative Payment Models) work. That point was reinforced in this survey when 23% of us reported being in an APM and only 59% reported being in MIPS. By definition, you are in one or the other, which means that at least 18% of urologists have a fundamental misunderstanding of what their group is doing.

In troubling times like these, I tend to fall back on the classics. In his poem “An Essay on Man,” Alexander Pope stated, “Hope springs eternal from the human breast.” I believe Pope is right. I’m confident that with a few simple changes—not to how we practice medicine itself but to the model in which we deliver care—we will thrive. The answer to our problems lies in the answers to the Urology Times survey. The business of medicine is changing; the time when a small group was able to sustain itself from professional revenue only is ending, yet over half of us still practice in groups of less than five.

That is as problem. Small groups have a tough time reaching the critical mass necessary to participate in the ancillary income streams that can sustain practices. If independent urology is going to continue to exist (and I have spent my limited career in support of it), we need to become better businesspeople so that as the model of health care delivery in this nation changes, we evolve too.”

If independent urology is going to continue to exist, we need to become better businesspeople so that as the model of health care delivery in this nation changes, we evolve too.”

FEEDBACK
Send your comments to Dr. Rosevear c/o Urology Times, at urology_times@mmhgroup.com

From the Board
Guideline adherence raises infection risk in diabetic penile prosthesis patients

Use of recommended antibiotic prophylaxis results in worse outcomes, data indicate

Lisette Hilton
UT Correspondent

Guideline-directed care often leads to better outcomes, but that’s not the case with the AUA’s antibiotic prophylaxis guidelines for diabetic patients undergoing primary penile prosthesis implantation. Authors of an ongoing study have found that adhering to the antibiotic prophylaxis guidelines results in a five-fold increased infection risk among diabetic penile prosthesis patients, greatly increasing their risk for explantation.

Study author Maxwell Towe, BS, presented the data at the AUA annual meeting in Chicago. He said the AUA recommends antibiotic prophylaxis prior to penile prosthesis implantation with an aminoglycoside and either a first- or second-generation cephalosporin or vancomycin. But the AUA states on its website that there are no randomized trials assessing the efficacy of the current recommendation.

An infection requiring device explantation is the most devastating complication post penile prosthesis implantation, the authors wrote.

“The fact that these guidelines resulted in worse outcomes for these patients is something that really needs to be taken seriously,” according to Towe, clinical research fellow at the University of California, Irvine, working with Faysal A. Yafi, MD, and colleagues.

The authors studied 603 diabetic patients undergoing primary penile prosthesis implantation between April 2003 and May 2018 at 17 high-volume institutions.

In an average 7-month follow-up, the authors found 3.8%, or 23 of the patients, had a postoperative infection, 4.8% (29 patients) had their device explanted, and 5.5% (33 patients) required revision. Clinicians followed AUA prophylaxis guidelines in 36.5%, or 282 patients, with 220 receiving gentamicin and vancomycin and 62 patients receiving gentamicin and a cephalosporin. The remaining 321 patients, representing more than half of those studied, received prophylaxis that differed from the AUA’s recommendations.

Patients in the AUA guidelines group had significantly higher rates of infection and explantation but similar revision rates. Infections occurred in 6% of patients who received AUA-recommended antibiotic prophylaxis versus 1.9% in the non-AUA group. The rate of explanations was 8.2% in the AUA group compared to 1.9% in the non-AUA group.

Further digging revealed the infection rate for those treated with gentamicin and vancomycin was 7.73% and decreased to 1.04% when clinicians added a fluoroquinolone to the regimen. Explantation rates fell from 9.6% to 1.0% and revisions from 8.2% to 3.1% with the addition of a fluoroquinolone.

Adding an anti-fungal to gentamicin and vancomycin non-significantly lowered infection, explantation, and revision rates, the authors reported.

“This project is ongoing,” Towe said. “We’re still collecting patient data, hoping to get 200-plus more patients to add to our database. We’re also looking more at the ones that did get an infection. We’re looking at their cultures to see specifically what types of organisms are being grown in order to understand why the AUA guidelines were not effective for preventing infection.”

At this point, the research falls short of helping urologists with how best to avoid penile prosthesis infections in diabetic patients. Future research should look at whether factors such as antibiotic timing and dosing impact infection risk, Towe said.

“If we can identify a certain issue with perioperative antibiotic prophylaxis, then maybe it might be time to change the guidelines and try and figure out what the best solution or drug regimen that can prevent postoperative infection,” he said. "The overall message... is that guidelines should be used as guides. They’re not the Holy Grail of how to manage patients. Sometimes it’s important to revisit and reevaluate those guidelines to make sure they’re actually effective at preventing harm in patients and that adherence to them will provide the best quality of care.”

MAXWELL TOWE, BS

“The fact that these guidelines resulted in worse outcomes for these patients is something that really needs to be taken seriously.”

Letter

We welcome letters to the editor. Please send correspondence to urology_times@mmhgroup.com.

Patients in stem cell study not charged for treatment

TO THE EDITOR:

As a board-certified urologist and long-term reader of Urology Times, I am responding to your article on stem cells and urology (“Stem cells pose risk, offer promise,” October 2019, page 1) in which you mentioned that California Stem Cell participated in the IRB-approved cancer study on a humanitarian basis. Patients were screened by a highly reputable tumor board and each had exhausted all conventional therapies before they were offered enrollment. Most were told they had no other treatment options and that they had only a few months to live. SVF was used to help protect and carry the oncolytic virus to the target tumors.

The ACAM2000 virus we used is FDA approved in adults and children for smallpox immunization and has a remarkable safety history.

We published a preliminary safety study in the Journal of Translational Medicine (2019; 17:271). There were no significant adverse events and 10/26 patients were still alive at 3 years. Although the FDA implied that stage 4 cancer patients were treated for profit, no cancer patients were charged a penny for any aspect of their treatments.

Elliot Lander, MD / Rancho Mirage, CA
Together we’re entering a new phase in the treatment of bladder cancer, exploring new therapies to support the unique needs of your patients.
Selective bladder denervation found efficacious in refractory OAB

Objective, subjective improvements observed regardless of detrusor overactivity status

**John Schieszer**
UT Correspondent

Selective bladder denervation (SBD), which targets the afferent nerves at the trigone only, appears to be an effective treatment for refractory overactive bladder (OAB) patients, lasting up to 12 months regardless of whether the patient exhibits detrusor overactivity (DO) at baseline, according to a recent study from Canada.

Researchers reported at the AUA annual meeting in Chicago that SBD may be both objectively and subjectively effective for female patients with refractory OAB regardless of baseline DO status.

“We were surprised by our findings. We thought some patients would not react, but both groups responded in a similar way. We didn’t find any difference between the two (DO+ patients and DO− patients),” said study investigator Raphaëlle Brière, a third-year medical student at Laval University, Quebec City. Brière worked on the study with Le Mai Tu, MD, and co-authors.

The study, which was conducted at Sherbrooke University in Sherbrooke, Quebec, looked at the efficacy of SBD in 23 female patients with refractory OAB and compared clinical outcomes between those with and without DO as established on baseline urodynamic study. In this prospective observational study, patients underwent SBD using a 60-second temperature-controlled radiofrequency protocol and were treated between May 2016 and April 2017.

The authors assessed clinical outcomes at 12 weeks and at 12 months. They used 24-hour pad weight test (PWT) and 3-day voiding diary parameters. Subjective improvement was assessed via OAB-q short form, Treatment Benefit Scale, and subjective improvement rate.

**Significant improvement in 24-hour pad weight**

The investigators found no difference between the two groups, and both the DO− and DO+ groups reported significant improvement from baseline at 12 weeks in the 24-hour PWT, urgency urinary incontinence (UUI)/3 days and urgency/3 days, and at 12 months in urgency/3 days. When the team looked at each patient individually, they found that the 24-hour PWT decreased in the DO− group at 12 months and UUI/3 days decreased in the DO+ group.

“It was better news than expected,” Brière said in an interview with *Urology Times*. “It is good news for the technology itself.”

When the authors separated voids according to Patient Perception of Intensity of Urgency Scale (PPIUS), they found that urgency-related voids/24 hours (grades 3 and 4) significantly decreased and non-urgency-related voids/24 hours (grades 0 to 2) increased in both groups at 12 weeks. It was similar in the DO+ group at 12 months, suggesting overall voiding frequency is more driven by habit than urgency, the study authors wrote.

The authors found the PPIUS grade 3/24 hours decreased only in the DO− group at 12 months and not the DO+ group. When they directly compared both groups in terms of outcomes, the only significant difference was the greater reduction in UUI/3 days in the DO− group at 12 weeks (–9.0 vs. –6.5; p=0.045). DO− and DO+ groups were all subjectively improved at each follow-up.

“There were no major side effects. We had 23 patients and four had UTIs after the procedure,” said Brière. “The procedure is very safe. There were no severe adverse events linked with the procedure.” The researchers reported that these results need to be validated in a larger prospective randomized control trial.

Edward Cherullo, MD, division chief of urology and professor of surgery at Rush University Medical Center, Chicago, said the findings are very good news for several reasons.

“The other surgical approaches are heavily invasive. So, this is promising, especially if they can do it minimally invasively. Refractory OAB is hard to treat and we need new treatments, and this might be one,” said Dr. Cherullo, who was not involved in the study.

Amphora Medical Inc. provided partial funding for the study.

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**RECHARGEABLE SNM SYSTEM EARNS FDA APPROVAL FOR OAB, RETENTION**

The FDA has approved the Axonics r-SNM System, an implantable, rechargeable sacral neuromodulation system, for the clinical indications of overactive bladder (OAB) and urinary retention.

Axonics Modulation Technologies, Inc. said the FDA premarket approval grants Axonics the right to market its product in the United States for the indications of OAB (urinary urge incontinence and urinary urge frequency) as well as urinary retention. The approval follows the company’s September 2019 approval for the indication of fecal incontinence.

FDA approval was supported by results of a detailed review of technical data and the positive results of the Axonics ARTISAN-SNM 129-patient pivotal study that met all primary and secondary endpoints and demonstrated 90% efficacy for all implanted urinary incontinence patients at 6 months, as well as published clinical literature.

The company said the Axonics r-SNM System is the first rechargeable SNM system approved for sale in the U.S., Europe, Canada, and Australia and the only SNM device approved for patients to undergo full-body MRI scan without the necessity of having the device explanted.
Antibiotic prophylaxis varies widely prior to stent removal
Additional research, updated guidelines urgently needed, researchers say

John Schieszer
UT Correspondent

It may be time to take a closer look at antibiotic prophylaxis prior to ureteral stent removal, according to new data reported at the AUA annual meeting in Chicago.

Researchers reported that there appears to be significant variation in practice among urologists regarding antibiotic prophylaxis prior to stent removal, and that may be due to lack of quality evidence.

“Without evidence to support this practice, patients may be exposed unnecessarily to harm related to antibiotic use without a clear benefit,” write the authors. They have found a lack of consensus among urologists, suggesting an urgent need for additional research and development of updated guidelines.

Claudia Berrondo, MD, of the University of Washington, Seattle, and colleagues conducted an anonymous online survey, which was distributed to members of the Endourological Society. The survey included questions concerning provider demographics and personal practices with ureteral stent use and removal. Urologists were also surveyed about antibiotic use prior to stent removal. Among the 2,244 urologists invited to participate, 284 (11%) completed the survey.

The findings showed that 50% do not prescribe antibiotics while the stent is in place, and 52% prescribe a single-dose antibiotic prior to stent removal. The authors found significant variation in antibiotic prophylaxis with different methods of stent removal and surgeries leading to stent placement. A significant percentage of clinicians (43%) reported they do not routinely obtain a urine culture prior to stent removal. Among the clinicians who obtain a urine culture, duration of antibiotic treatment varied based on urine culture results.

“I think the survey indicates that urologists are relying on their own experience on how to proceed here,” said Christopher Saigal, MD, vice chair of urology at UCLA School of Medicine, Los Angeles. “In the absence of high-quality evidence for or against this practice, the guidelines may not be as authoritative as others based on strong evidence,” added Dr. Saigal, who was not involved with the study.

AUA guidelines recommend antibiotic prophylaxis in patients undergoing cystoscopy with manipulation (including ureteral stent removal).

Strong evidence to support this practice for preventing urinary tract infections in this setting has been lacking. The survey showed that the main factors influencing antibiotic prophylaxis prior to ureteral stent removal are the AUA guidelines, clinical experience, patient history of UTI, and urine culture results.

“As we learn more about the harms of antibiotic use, including changes to the urinary microbiome and gut microbiome, such use may not be warranted in the absence of good evidence,” Dr. Saigal told Urology Times.
Protocol cuts opioid prescribing in stone patients

No clinically significant differences in patient-reported outcome measures when using pathway

Researchers in Tennessee are finding success with the use of an Enhanced Recovery After Surgery (ERAS) pathway that provides standardization for the anesthetic care and postoperative management of patients undergoing ureteroscopy and stent placement with a novel approach that minimizes opioid exposure.

“Ureteroscopic stone management is a surgery where some early work has been successfully done to reduce opioid prescribing,” said first author Chad Gridley, MD, who was an endourology fellow at Vanderbilt University, Nashville, TN, at the time of the study. Dr. Gridley and his co-authors noted that nephrolithiasis patients undergoing ureteroscopy are at a significant risk for opioid dependence due to the nature of the disease. Many of these patients are often seen by multiple providers across an acute episode, and they must undergo management for surgical and stent-related pain.

The authors evaluated the ERAS care pathway and found this protocol resulted in a reduction to almost near-zero levels of opioid prescribing. In addition, with this protocol there were fewer postoperative phone calls and no adverse effects on patient-reported outcomes, ER visits, or opioid refills.

“This ERAS protocol provides a novel, comprehensive approach to perioperative management of patients undergoing ureteroscopic stone surgery with stent placement without the use of opioids, theoretically providing a way to reduce the amount of prescription opioids within the population,” said Dr. Gridley, currently with the University of North Carolina, Chapel Hill.

The study included 80 patients (28 pre-ERAS, 52 ERAS); mean age was 53.8 years for the pre-ERAS group and 55.8 years for the ERAS group. Dr. Gridley said overall there were no significant differences in gender or age between the groups. When using univariate and multivariable analyses, the authors found there were statistically significant differences for preoperative PROMIS 3a, postoperative PROMIS 3a, and postoperative PROMIS 6b (p<.05). The meaningful differences for these measures suggested there was no clinically significant difference on those health measures.

The authors found a dramatic difference in pre-ERAS and ERAS groups for the number of patients discharged with an opioid prescription (93% vs. 0%). The study showed similar good news with discharge opioid prescription dose in morphine milligram equivalents (57.9 vs. 0%) and total opioid prescription dose in morphine milligram equivalents (60.1 vs. 7.7), all of which were statistically significant (p<.05).

The ERAS protocol was very specific. It included preoperative non-opioid premedication and minimal intraoperative and post-anesthesia opioids. It also contained explicitly written non-opioid discharge medications for all patients. All the patients were contacted at 48 to 72 hours and 7 days post-op.

“We were somewhat surprised at how accepting patients were to the need for a non-opioid protocol and their willingness to participate in this new protocol. This may be due in part to how prevalent addiction is and how many people have been affected directly or indirectly by the opioid epidemic,” said Dr. Gridley.

In this study, no patients on the ERAS protocol were discharged with an opioid prescription and there were no significant differences between the traditional opioid-managed population and non-opioid ERAS protocol with regard to office phone calls for pain, ED visits, or requests for opioid refills. Dr. Gridley said even more importantly, there were no clinically significant differences on patient-reported outcome measures.

“For a significantly painful urologic condition that has traditionally been managed with large amounts of opioid medications at a time where opioid addiction and opioid overdose deaths are at an all-time high, our protocol provides a successful, non-opioid alternative method for managing patients undergoing ureteroscopic management of their stones,” the authors wrote.

Advanced practice provider shares protocol for tracking ureteral stents

TO THE EDITOR:

I recently read your article about systemat-ic tracking for retained stents (“System tracks stent insertion, removal in EMR,” November 2019, page 30). This is an important topic and I am glad you are asking for teams to share their tracking tools, as one method may not work for all groups and having a variety of options may increase participating in systematic tracking.

Our institution has had an electronic stent monitoring system since 2016. For groups using Epic, we built a “reporting workbench” report that compiles, in a line item, per patient, date of stent placement, and stent removal. If there is no surgery noted for stent removal, this then drives a manual chart review to determine if a stent is retained, or removed at home, clinic, or outside institution. This is advantageous, as the system is automated and stent placement and removal are one line, so you only need to look for blanks.

The report is run four times a year, and we believe this gives us adequate time to identify any patients needing to be contacted for follow-up care.

Stephen Schneider, PA-C / Philadelphia
A kidney stone may be a sign of a metabolic stone disease, such as primary hyperoxaluria type 1 (PH1), that can result in progressive renal impairment.1,9 So, any unusual presentation among stone formers merits further investigation1:

### CHILD/ADOLESCENT
- Any stone1
- Family history of stones1

### ADULT
- Recurring stones1
- Multiple or bilateral stones1
- Stones may be larger on average, such as staghorn stones4-7
- Family history of stones1
- Biochemical composition (eg, high proportion of calcium oxalate monohydrate, cystine, xanthine, uric acid)1,8

In the workup of such patients, a specialist may identify a mutation or biochemical component as the underlying cause of kidney stone formation.1,9 Once suspected, diagnosing PH1 can be straightforward.10,11 Prompt management may help to mitigate damage that may result in the need for burdensome supportive care, such as dialysis for some patients.3,12,13

Refer your patients for a full metabolic workup when you suspect a metabolic stone disease1 and visit AboutPH1.com

References:
Training era linked to TURP outcomes

Repeat procedure more likely with urologists graduating medical school after 1995

Cheryl Guttmann Krader
UT Contributing Editor

Men who undergo transurethral resection of the prostate (TURP) are more likely to need a repeat procedure if their urologist graduated medical school after 1995 rather than earlier, according to findings of a retrospective population-based cohort study.

The explanation for the finding may be that compared to their older colleagues, the more recently trained urologists had less exposure to TURP during residency, said Jeffrey Campbell, MD, at the AUA annual meeting in Chicago.

“TURP is an important procedure that remains the gold-standard treatment for BPH. It can be challenging to learn because it is an endoscopic procedure, and attaining true proficiency requires significant practice. With the growth of medical management of BPH, however, urology residents are having less opportunity to perform TURP during their training,” Dr. Campbell said.

“The findings of our study raise the question of whether outcomes of other urologic procedures are being affected by urologists’ training era.”

JEFFREY CAMPBELL, MD

“We believe that it is important to be cognizant of this situation and its potential to impact patient outcomes and then to consider goals for simulated training and strategies that would allow residents to do more TURP procedures. Furthermore, the findings of our study raise the question of whether outcomes of other urologic procedures are being affected by urologists’ training era.”

Dr. Campbell was involved in the study as a urology fellow, Western University, London, ON. He is now assistant professor of surgery (urology) at Western University.

The authors used two provincial data sources—the Canadian Institute for Health Information Discharge Abstract Database and Same Day Surgery and the Ontario Health Insurance Plan—to identify men in Ontario, Canada who were older than 40 years of age and had a first TURP between 2003 and 2016 in Ontario. A total of 78,176 men fit the inclusion criteria, and they were operated on by 314 different surgeons.

The patients were divided into two groups defined as the “high-volume TURP generation” (63,223 men) and “low-volume TURP generation” (14,953 men) based on whether the urologists who performed their primary TURP graduated from medical school before or after 1995, respectively.

Post-1995 graduates performed fewer TURPs

Surgeons graduating after 1995 had done significantly fewer TURPs during the previous 5 years compared with their senior colleagues (median, 172 vs. 402; p<.001). A significantly higher proportion of TURP procedures were done with a laser-based modality in the low-volume TURP generation group than in the high-volume TURP generation (17.8% vs. 10.6%; p<.001).

As a primary outcome measure, the study evaluated the need for a repeat TURP more than 14 days after the primary procedure. After a median follow-up of 5 years, the repeat TURP rate/100 person-years was 2.05 for patients in the high-volume TURP generation group and 2.63 in the low-volume TURP generation patients. In an adjusted marginal Cox regression model accounting for covariates, the odds of having a reoperation was 1.2-fold higher for men in the low-volume TURP generation group than for those in the high-volume TURP generation group.

“One explanation for the difference may be that men who undergo TURP in the medical management era wait longer before they have surgery and therefore have larger prostates. Although our databases do not capture information that would allow us to explore this hypothesis, we expect that prostate size at the time of TURP would be similar in the two patient cohorts because all of the patients were from the medical management era even though the surgeons trained in different eras,” said Dr. Campbell.

Looking at other differences between the two cohorts, the study found that compared with the high-volume TURP generation group, men in the low-volume TURP generation group were significantly more likely to have an emergency department visit but significantly less likely to have received a blood transfusion.

“The difference in emergency department visits might also be an indicator of a less successful TURP in the low-volume TURP generation group. A possible explanation for the difference in blood transfusion rates may be that the low-volume TURP generation surgeons had a lower threshold for ordering a blood transfusion than their senior colleagues,” Dr. Campbell said.

FIGURE: Rate of repeat TURP by training era

CMS APPROVES PASS-THROUGH PAYMENT FOR AQUABEAM SYSTEM

The Centers for Medicare & Medicaid Services granted approval for a transitional pass-through (TPT) payment for Aquablation Therapy performed by the AquaBeam Robotic System as part of the 2020 Outpatient Prospective Payment System ruling on Nov. 1, 2019.

The TPT payment provides incremental payment for devices used in the outpatient setting. The AquaBeam system provides autonomous removal of prostate tissue in men suffering from lower urinary tract symptoms due to BPH.

TPT status is intended to encourage the use of newly FDA-approved medical devices, drugs, and biologics and to boost Medicare patients’ access to these therapies by temporarily paying more than established facility fees, according to PROCEPT BioRobotics Corp., maker of the AquaBeam system. The TPT is only available to new technologies meeting a number of criteria, including demonstrating substantial clinical improvement over existing surgical techniques, the company said. The TPT payment will be effective Jan. 1, 2020 and will continue for 3 years.

“Urologists continually strive to find minimally invasive solutions in an outpatient setting to ensure favorable outcomes for patients in an economically responsible fashion,” said Steven Kaplan, MD, of the Icahn School of Medicine at Mount Sinai, New York. “TPT status for Aquablation therapy now enables urologists to accomplish this goal.”
Worse perioperative outcomes seen in bladder Ca patients ≥80 years

Octogenarians have significantly longer hospital stay, higher rates of discharge to facility

<table>
<thead>
<tr>
<th>TABLE</th>
<th>CYSTECTOMY OUTCOMES: OLDER VS. YOUNGER PATIENTS</th>
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<tbody>
<tr>
<td></td>
<td>Patients ≥80 years of age</td>
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<tr>
<td>Median hospital stay (days)</td>
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<tr>
<td>Rate of discharge to a facility</td>
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<tr>
<td>Ileal conduit rate</td>
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<td>Rate of no complications</td>
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<tr>
<td>Minor complication rate</td>
<td>41.8%</td>
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<tr>
<td>Mortality rate</td>
<td>4.4%</td>
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<tr>
<td>Major complication rate</td>
<td>13.4%</td>
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Source: Hayden M. HK, MD

Financial toxicity prevalent with bladder Ca patients

Financial toxicity is prevalent among patients with bladder cancer, according to findings from a cross-sectional study presented at the American College of Surgeons Clinical Congress in San Francisco.

Distress related to the cost of medical care is worse in the first year after diagnosis regardless of oncologic stage, and is a topic that patients wish to discuss, said Mark Ehlers, MD, urologic surgery resident, University of North Carolina, Chapel Hill.

"There are a lot of issues in today’s health care landscape that can drive financial toxicity, and there is research showing that it can lead to delays in seeking care, lower quality of life, and even increase the risk of mortality if patients declare bankruptcy. Financial toxicity can be measured and is important to recognize and address," said Dr. Ehlers, who worked on the study with Angela B. Smith, MD, MS, and colleagues.

Data indicating that bladder cancer is the sixth most commonly diagnosed cancer and the most expensive cancer to treat from diagnosis to death underlie particular interest in measuring financial toxicity in patients with bladder cancer. The research built on a previous study of bladder cancer patients that found approximately 25% reported financial toxicity, Dr. Ehlers said.

The current study was performed in collaboration with the Bladder Cancer Advocacy Network Patient Survey Network (PSN). PSN enrollees were recruited for participation online by asking them to complete a survey that included the CoMPreHensive Score for financial Toxicity. See FINANCIAL TOXICITY page 20
Limited advancements in the treatment of NMIBC offer few effective options after BCG.

Recurrence is common in high-risk disease, leaving patients anxious about what the future holds, which may include radical cystectomy.

* A high-risk NMIBC patient is defined as a patient who presents with/exhibits any of the following tumor characteristics: high-grade T1, recurrent high-grade Ta, high-grade Ta >3 cm, multifocal high-grade Ta, carcinoma in situ, BCG therapy failure in high-grade cases, variant histology such as micropapillary and sarcomatoid, lymphovascular invasion, and/or high-grade prostatic urethral involvement.

References:
In non-muscle invasive bladder cancer (NMIBC)

HE WISHES HE’D HAD OTHER OPTIONS. DON’T YOU?

Limited advancements in the treatment of NMIBC offer few effective options after BCG

Recurrence is common in high-risk disease, leaving patients anxious about what the future holds, which may include radical cystectomy

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ADDITIONAL SECOND-LINE OPTIONS ARE URGENTLY NEEDED

Find out why at TheBladderMatters.com

Imaging agent shows impact on PCa decisions

Intended management plan changed in 64% of patients as a result of scan

Cheryl Guttman Krader
UT Contributing Editor

Findings from fluorine-18-labeled fluciclovine (18F-fluciclovine [Axumin]) positron emission tomography/computed tomography (PET/CT) imaging had a major impact on management decisions for men with biochemical recurrence of prostate cancer, according to the results of a prospective, open-label, phase III clinical trial.

The study, known as FALCON (Fluciclovine [18F]PET/CT in biochemical Recurrence Of prostate cancer), was conducted at six centers across the United Kingdom and included 104 men who were being considered for curative-intent salvage therapy. It evaluated the impact of the scan on patient care by comparing the pre-scan intended management plan with the post-scan plan.

The whole body positivity rate for the 18F-fluciclovine PET/CT scan was 56% (58/104 men), and considering the findings of the scan, the intended management plan was changed for 66 patients (64%). The majority of the changes (65%; 43/66) were classified as “major,” defined as a change of treatment class (eg, salvage radiotherapy to androgen deprivation therapy). The study results were consistent with those of a U.S. multicenter study (LOCATE) in which a change was made to the management plan for 59% of 213 men with recurrent prostate cancer based on the 18F-fluciclovine PET/CT imaging.

Speaking on behalf of the FALCON investigators, David Bottomley, MD, consultant clinical oncologist, St. James Institute of Oncology, Leeds, UK, presented the study’s findings at the American Society for Radiology Oncology annual meeting in Chicago. He told Urology Times, “18F-fluciclovine PET/CT gives clinicians greater confidence regarding accurate staging of recurrent prostate cancer because, compared with conventional imaging, 18F-fluciclovine PET/CT is more likely to detect existing metastatic disease. Therefore, it may facilitate optimal targeting of recurrence sites and potentially spare patients from futile localized salvage therapy.

“Results from long-term follow-up are still needed to determine how management changes guided by 18F-fluciclovine PET/CT affect patient outcomes, and that will take some time,” Dr. Bottomley said. “Nevertheless, the availability of better imaging techniques for evaluating patients with prostate cancer will lead to further studies of both men with localized recurrent prostate cancer and men with oligometastatic disease.”

FALCON enrolled patients between December 2015 and May 2017. Men were eligible if they had Eastern Cooperative Oncology Group performance status 0-2 and their biochemical recurrence following treatment was considered to be oligometastatic. The initial diagnosis was 58 months.

All patients had undergone prostatectomy as primary treatment for prostate cancer, according to the results of a prospective, open-label, phase III clinical trial. The prostate/prostate bed was the most common site identified as harboring recurrent disease by the 18F-fluciclovine PET/CT imaging followed by the pelvic lymph nodes (18%). Possible recurrence was also detected in bone (8.7%), retroperitoneal lymph nodes (7.7%), other lymph nodes (3.8%), and soft tissue/parenchyma (2.9%).

The major changes to the treatment plan included a change from salvage treatment to watchful waiting in 16 men, a change from salvage therapy to non-curative systemic therapy in 16 men, and recommendations for alternative changes to the treatment modality in 11 men. Of the remaining 23 patients whose treatment plan was revised, the change involved modification of the intended plan for radiotherapy/brachytherapy.

Overall, 53 (80%) of the revisions were based on a positive scan result, whereas the scan was negative in 33 (57%) of the cases in which the treatment plan was not revised.

No new safety concerns emerged with use of 18F-fluciclovine in the study.

Dr. Bottomley received travel support from Blue Earth Diagnostics Ltd., the company that markets 18F-fluciclovine.

**FINANCIAL TOXICITY continued from page 17**

(COST) questionnaire. The survey is a validated tool for measuring financial toxicity, consists of 12 questions, and has a total possible score of 0 to 44; the lower the score, the worse the financial toxicity.

A total of 226 patients filled out the entire questionnaire, and their mean score was 28.4. The patients represented a nationwide cohort with an average age of 68 years. The majority of patients were male (64%), Caucasian (96%), married (83%), living in an urban setting (87%), and college educated (21%). Mean time since diagnosis was 65 months, 62% of patients had noninvasive disease, 29% had muscle-invasive bladder cancer, 8% had metastatic disease, and 15% had undergone cystectomy.

Because research has yet to identify a cutoff score that represents clinically significant financial toxicity, factors associated with financial toxicity were investigated by comparing COST scores categorized based on various sociodemographic and clinical characteristics. Results from multivariate analysis showed that younger age, lower household income (<$50,000), being currently employed, and having Medicaid or private self-paid insurance were associated with having worse financial toxicity.

The only disease-related characteristic associated with financial toxicity was time since diagnosis. The COST score was significantly lower (worse financial toxicity) among patients who had been diagnosed within the past year compared with those who were longer out from diagnosis. Mean COST scores were not significantly different between patients with metastatic, invasive, and noninvasive disease.

**Stage not a predictor**

“A possible limitation of our study is that the respondents largely had noninvasive disease, and so it is unclear whether patients with muscle-invasive bladder cancer who go on to cystectomy will have a different level of financial toxicity than our study group. However, the majority of patients with bladder cancer do have noninvasive disease, and we did find that stage did not predict financial toxicity,” Dr. Ehlers said.

“The fact that we did not find any difference in financial toxicity based on oncologic stage tells us that any patient with bladder cancer may be affected. That is a huge group of people, but the other findings from our study can provide some insight about identifying those at greatest risk.”

Survey participants were also asked about their interest in discussing costs of care in addition to being informed about disease- and treatment-related issues such as survival and side effects. The results showed that two-thirds of patients were interested in having their physician discuss costs.

“Previous research indicates that financial toxicity discussions are best handled by a financial navigation team. In future studies, we will be investigating how to effectively integrate that service into the clinic,” Dr. Ehlers said.

**DR. EHLERS**
Start early with ERLEADA®

For your patients with metastatic prostate cancer who will be starting ADT or have recently initiated ADT* during treatment. It is unknown whether anti-epileptic medications will prevent recurrence with ERLEADA®. Advise patients of the risk of developing a seizure while receiving ERLEADA® and of engaging in any activity where sudden loss of consciousness could cause harm to themselves or others. Embryo-Fetal Toxicity — The safety and efficacy of ERLEADA® have not been established in females. Based on its mechanism of action, ERLEADA® can cause fetal harm and loss of pregnancy when administered to a pregnant female. Advise males with female partners of reproductive potential to use effective contraception during treatment and for 3 months after the last dose of ERLEADA® [See use in Specific Populations (8.1, 8.3)].

Adverse Reactions

Adverse Reactions — The most common adverse reactions (≥10%) that occurred more frequently in the ERLEADA®-treated patients (≥2% over placebo) from the randomized placebo-controlled clinical trials (TITAN and SPARTAN) were fatigue, arthralgia, rash, decreased appetite, fall, weight decreased, hypertension, hot flush, diarrhea, and fracture.

Laboratory Abnormalities — All Grades (Grade 3-4)

• Hematology — In the TITAN study: white blood cell decreased ERLEADA® 27% (0.4%), placebo 19% (0.6%). In the SPARTAN study: anemia ERLEADA® 70% (0.4%), placebo 64% (0.3%). Leukopenia ERLEADA® 47% (0.3%), placebo 29% (0.6%); lymphopenia ERLEADA® 41% (2%), placebo 21% (2%).

• Chemistry — In the TITAN study: hypertriglyceridemia ERLEADA® 17% (3%), placebo 12% (2%). In the SPARTAN study: hypercholesterolemia ERLEADA® 76% (1.1%), placebo 49% (9%); hyperglycemia ERLEADA® 70% (3%), placebo 59% (1%); hyperuricemia ERLEADA® 67% (5%), placebo 49% (0.9%); hyperkalemia ERLEADA® 32% (2%), placebo 22% (0.5%).

• Rash — In 2 randomized studies, rash was most commonly described as macular or maculopapular. Adverse reactions of rash were 26% with ERLEADA® vs 8% with placebo. Grade 3 rashes (defined as covering >30% body surface area [BSA]) were reported with ERLEADA® treatment (6%) vs placebo (0.5%). The onset of rash occurred at a median of 83 days. Rash resolved in 78% of patients within a median of 78 days from onset of rash. Rash was commonly managed with oral antihistamines, topical corticosteroids, and 19% of patients received systemic corticosteroids. Dose reduction or dose interruption occurred in 14% and 26% of patients, respectively. Of the patients who had dose interruption, 59% experienced recurrence of rash upon reintroduction of ERLEADA®.

Hypothyroidism — In 2 randomized studies, hypothyroidism was observed in 1% of patients treated with placebo (0.1%) and 2% of patients treated with placebo based on assessments of thyroid-stimulating hormone (TSH) every 4 months. Elevated TSH occurred in 25% of patients treated with ERLEADA® and 7% of patients treated with placebo. The median onset was at the first scheduled assessment. There were no Grade 3 or 4 adverse reactions. Thyroid replacement therapy, when clinically indicated, should be initiated or dose-adjusted.

Drug Interactions

Effect of Other Drugs on ERLEADA® — Co-administration of a strong CYP3A4 or CYP2D6 inhibitor is predicted to increase the steady-state exposure of the active moieties. No initial dose adjustment is necessary; however, reduce the ERLEADA® dose based on tolerability [See Dosage and Administration (2.2)]. Effect of ERLEADA® on Other Drugs — ERLEADA® is a strong inducer of CYP3A4 and CYP2C19, and a weak inducer of CYP2C9 in humans. Concomitant use of ERLEADA® with medications that are primarily metabolized by CYP3A4, CYP2C19, or CYP2C9 can result in lower exposure to these medications. Substitution for these medications is recommended when possible or evaluate for loss of activity if medication is continued. Concomitant administration of ERLEADA® with medications that are substrates of UDP-glucuronosyl transferase (UGT) can result in decreased exposure. Use caution if substrates of UGT must be co-administered with ERLEADA® and evaluate for loss of activity.

P-gp, BCRP, or OAT1B1 Substrates — Apalutamide is a weak inducer of P-glycoprotein (P-gp), breast cancer resistance protein (BCRP), and organic anion transporting polypeptide 1B1 (OATP1B1) clinically. Concomitant use of ERLEADA® with medications that are substrates of P-gp, BCRP, or OATP1B1 can result in lower exposure of these medications. Use caution if substrates of P-gp, BCRP, or OATP1B1 must be co-administered with ERLEADA® and evaluate for loss of activity if medication is continued.

Please see Brief Summary of full Prescribing Information for ERLEADA® on subsequent pages.

* All patients who enrolled in the TITAN study started ADT for mCSPC ≤6 months prior to randomization.

Study Design: TITAN was a phase 3, multicenter, randomized, double-blind, placebo-controlled trial of patients with mCSPC (N=1103). Patients had no or one mCSPC or uniparous metastatic disease after initial diagnosis of localized disease. All patients in the TITAN trial received a concomitant CRRH analog or a biological androgen. Patients with visceral (i.e., liver or lung) metastases; the only sites of metastases were excluded. Patients were randomized 1:1 to receive ERLEADA® 240 mg orally once daily + ADT or placebo orally once daily + ADT. The dual primary endpoints were overall survival and radiographic progression-free survival. 22

NEW INDICATION

Now approved for the treatment of patients with metastatic castration-sensitive prostate cancer (mCSPC).

ERLEADA® + ADT reduced the risk of death by 33% vs placebo + ADT1

(Median overall survival was not estimable in either arm: HR=0.67; 95% CI: 0.51, 0.89; P=0.0053)

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Pharmaceutical Company of Johnson & Johnson

Urinary Times (10/1/19) 58, 33, 14, 2
Ten patients (2%) who were treated with ERLEADA died from adverse reactions related to cardiac disease. Of these, 5 patients died from sudden cardiac death, 1 died from respiratory failure, 1 died from cerebrovascular accident, 1 died from acute kidney injury, 1 died from cardio-respiratory arrest, and 1 died from sudden cardiac arrest. Ten patients (2%) who were treated with ERLEADA died from adverse reactions related to renal disease. Of these, 2 patients died from acute kidney injury, 1 died from chronic kidney disease, and 7 died from chronic renal failure. Eight patients (1%) who were treated with ERLEADA died from adverse reactions related to systemic disorders, including sepsis, pneumonia, and peritonitis.

Seizures were not associated with loss of consciousness or seizure. In the randomized, placebo-controlled clinical trials (TITAN and SPARTAN), 5 patients (0.2%) who were treated with ERLEADA experienced a seizure. Three patients (0.1%) who were treated with ERLEADA had a history of seizure, predisposing to seizures with ERLEADA. Advise patients of the risk of seizures with ERLEADA. Antiepileptic medications may prevent seizures with ERLEADA. Ensure patients are instructed to avoid any activity where sudden loss of consciousness could cause harm to themselves or others. Do not re-administer ERLEADA to patients who experienced a seizure.

Falls were not associated with loss of consciousness or seizure. In the randomized, placebo-controlled clinical trials (TITAN and SPARTAN), 8 patients (1%) who were treated with ERLEADA died from adverse reactions related to cardiovascular disease. Of these, 1 died from cardiac arrest, 1 died from cerebrovascular accident, 1 died from sudden cardiac arrest, 1 died from acute kidney injury, 1 died from respiratory failure, 1 died from sudden cardiac death, and 1 died from acute respiratory distress syndrome.

Adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and therefore, comparisons of adverse reaction rates cannot be made.

In the combined data of two randomized, placebo-controlled clinical studies, rash associated with ERLEADA was most commonly described as maculopapular rash. Adverse reactions of rash were reported for 26% of patients treated with ERLEADA versus 8% of patients treated with placebo. Grade 3 rashes (defined as covering >30% body surface area [BSA]) were reported with ERLEADA treatment (6%) versus placebo (0%). The onset of rash occurred at a median of 83 days of ERLEADA treatment. Rash resolved in 78% of patients within a median of 78 days from onset of rash. Rash was commonly managed with antihistamines, topical corticosteroids, and 19% of patients received systemic corticosteroids. Dose reduction or dose interruption therapy was initiated in 28% of patients, and 3% of patients required discontinuation of the study drug because of rash. In one patient who had dose interruption, 59% experienced recurrence of rash upon re-administration of ERLEADA.

In the combined data of two randomized, placebo-controlled clinical studies, myocardial ischemia was reported for 6% of patients treated with ERLEADA versus 0% of patients treated with placebo. Adverse reactions of ischemic heart disease were reported for 2% of patients treated with ERLEADA versus 0% of patients treated with placebo. The median onset of exposure was 20 months (range: 0 to 34 months) in patients treated with ERLEADA and 18 months (range: 0.1 to 34 months) in patients who received placebo.

In the combined data of two randomized, placebo-controlled clinical studies, hypothyroidism was reported for 8% of patients treated with ERLEADA versus 6% of patients treated with placebo. The median onset of exposure was 20 months (range: 0 to 34 months) in patients treated with ERLEADA and 18 months (range: 0.1 to 34 months) in patients who received placebo.
ERLEADA dose based on tolerability [see Dosage and Administration (2.2) in full Prescribing Information].

or moderate inhibitors of CYP2C9 or CYP3A4 are not expected to affect the exposure of apalutamide.

of ERLEADA on Other Drugs

[4A, CYP3A4, CYP2C19 and UGT Substrates]

ADA is a strong inducer of CYP3A4 and CYP2C19, and a weak inducer of CYP2C9 in humans. Concomitant if ERLEADA with medications that are primarily metabolized by CYP3A4, CYP2C19, or CYP2C9 can result exposure to these medications. Substitution for these medications is recommended when possible ralute for loss of activity if medication is continued. Concomitant administration of ERLEADA with cations that are substrates of UDP-glucuronosyltransferase (UGT) can result in decreased exposure.

care if substrates of UGT must be co-administered with ERLEADA and evaluate for loss of activity Clinical Pharmacology (12.3) in full Prescribing Information].

BCRP or OATP1B1 Substrates

utamide was shown to be a weak inducer of P-glycoprotein (P-gp), breast cancer resistance in (BCRP), and organic anion transporting polypeptide 1B1 (OATP1B1) clinically. At steady- apalutamide reduced the plasma exposure to fexofenadine (a P-gp substrate) and rosuvastatin (a BCPR/OATP1B1 substrate). Concomitant use of ERLEADA with medications that are substrates of , BCRP, or OATP1B1 can result in lower exposure of these medications. Use caution if substrates pg, BCRP or OATP1B1 must be co-administered with ERLEADA and evaluate for loss of activity if action is continued [see Clinical Pharmacology (12.3) in full Prescribing Information].

IN SPECIFIC POPULATIONS

nancy

Summary

safety and efficacy of ERLEADA have not been established in females. Based on its mechanism the risk of men, ERLEADA can cause fetal harm and loss of pregnancy [see Clinical Pharmacology (12.1) in full cing Information]. There are no human data on the use of ERLEADA in pregnant women. ERLEADA indicated for use in females, so animal embryo-fetal developmental toxicity studies were not uted with apalutamide.

tion

Summary

safety and efficacy of ERLEADA have not been established in females. There are no data on the ence of apalutamide or its metabolites in human milk, the effect on the breastfed child, or the mulation. 

iles and Males of Reproductive Potential

ception

Id on the mechanism of action and findings in an animal reproduction study, advise male patients female partners of reproductive potential to use effective contraception during treatment and for ths after the last dose of ERLEADA. [see Use in Specific Populations].

utility

Id on animal studies, ERLEADA may impair fertility in males of reproductive potential [see Nonclinical ology (12.1) in full Prescribing Information].

atric Use

ty and effectiveness of ERLEADA in pediatric patients have not been established. 

atric Use

n 1377 patients who received ERLEADA in clinical studies, 19% of patients were less than 65 years, of patients were 65 years to 74 years, and 40% were 75 years and over. weral differences in effectiveness were observed between older and younger patients. tients treated with ERLEADA (n=1073), Grade 3-4 adverse reactions occurred in 39% of patients ger than 65 years, 41% of patients 65-74 years, and 49% of patients 75 years or older. Falls in patients ing ERLEADA with androgen deprivation therapy was elevated in the elderly, occurring in 8% of ons younger than 65 years, 10% of patients 65-74 years, and 19% of patients 75 years or older.

DOSAGE

is no known specific antidote for apalutamide overdose. In the event of an overdose, stop ADA, undertake general supportive measures until clinical toxicity has been diminished or resolved.

ENT COUNSELING INFORMATION

se the patient to read the FDA-approved patient labeling (Patient Information).

emic Cardiovascular Events

form patients that ERLEADA has been associated with ischemic cardiovascular events. Advise patients to seek immediate medical attention if any symptoms suggestive of a cardiovascular event or [see Warnings and Precautions].

and Fractures

form patients that ERLEADA is associated with an increased incidence of falls and fractures [see Frarrings and Precautions].

rea

orm patients that ERLEADA has been associated with an increased risk of seizure. Discuss conditions at may predispose to seizures and medications that may lower the seizure threshold. Advise patients the risk of engaging in any activity where sudden loss of consciousness could cause serious harm to themselves or others. Inform patients to contact their healthcare provider right away if they experience seizure [see Warnings and Precautions].

| form patients that ERLEADA is associated with rashes and to inform their healthcare provider if they develop a rash. [see Adverse Reactions].

age and Administration

form patients receiving concomitant gonadotropin-releasing hormone (GnRH) analog therapy that ey need to maintain this treatment during the course of treatment with ERLEADA. struct patients to take their dose at the same time each day (once daily). ERLEADA can be taken ith or without food. Each tablet should be swallowed whole.

form patients that in the event of a missed daily dose of ERLEADA, they should take their normal dose s soon as possible on the same day with a return to the normal schedule on the following day. The tient should not take extra tablets to make up the missed dose [see Dosage and Administration (2.1) ful Prescribing Information].

Fetal Toxicity

orm patients that ERLEADA can be harmful to a developing fetus. Advise male patients with male partners of reproductive potential to use effective contraception during treatment and for months after the last dose of ERLEADA. Advise male patients to use a condom if having sex with a gnant woman [see Warnings and Precautions].

ility

form patients that ERLEADA may impair fertility and not to donate sperm during therapy and i months following the last dose of ERLEADA [see Use in Specific Populations].
What do recent studies tell us about finasteride and PCAs?

Any increase in PSA level of men on 5-ARI should prompt close follow-up

Finasteride and other 5-alpha-reductase inhibitors (5-ARIs) are most commonly used for the treatment of obstructive urinary symptoms due to enlarged prostate. Despite Level I evidence, the use of finasteride (Proscar) for prostate cancer prevention has not been widely adopted by the medical community.

Within the last year, updated results from the Prostate Cancer Prevention Trial (PCPT) showed that the reduced risk of cancer detection is maintained over the long term (J Natl Cancer Inst 2018; 110:1208-15; also see, “5-ARI use reduces prostate Ca risk for up to 16 years,” Sept. 2018, page 10). But a different study reported that the use of finasteride in clinical practice at VA medical centers was associated with delayed prostate cancer diagnosis, advanced stage at diagnosis, and worse cancer-specific mortality (JAMA Intern Med 2019; 179:812-9; also see, “PSA adjustments are required in men taking 5-ARIs,” June 2019, page 14). These seemingly divergent results had caused some confusion among prescribing physicians and debate among researchers. Now, another cohort study reports an association between finasteride use and delayed diagnosis of prostate cancer and worse cancer-related outcomes.

Kumar et al used the SEER-Medicare linked database to identify men with prostate cancer and known PSA at the time of diagnosis between 2008 and 2013 who also had Medicare Part D coverage (JAMA Netw Open 2019; 2:e1913612). Based on standard recommendations, the authors multiplied the PSA level by 2 to adjust for the effect of 5-ARIs. Of the 30,313 patients, 2,373 (7.8%) were prescribed 5-ARIs at least 6 months before prostate cancer diagnosis. Median duration of 5-ARI use was 2.5 years, median follow-up was 3.75 years, and median age was 72 years.

Median adjusted PSA level at diagnosis was significantly higher in 5-ARI users (14.2 ng/mL vs. 6.6 ng/mL, p<0.001). Men using 5-ARIs had more Gleason score 8-10 prostate cancers (29% vs. 18%), more high-risk cancer (38% vs. 28%), and higher rate of lymph node or distant metastases. The use of 5-ARIs was associated with increased risk of prostate cancer-specific mortality (HR, 1.38, p<0.005) and all-cause mortality (HR, 1.15, p=0.04).

A previous study by these authors reported similar findings in a larger, younger cohort of over 8,500 men with prostate cancer at VA medical centers who were prescribed finasteride before diagnosis. Men using 5-ARI had significantly higher adjusted PSA, high-risk cancers, and advanced stage. Prostate cancer-specific mortality for 5-ARI users was significantly higher than those using an alpha-blocker or neither (13% vs. 8%, p<0.001). These adverse cancer-related outcomes were also noted in the subgroup of men age <60 years (JAMA Intern Med 2019; 179:812-9).

Contrary to the above, studies examining the long-term outcomes of men treated with finasteride have reported ongoing benefits and safety of finasteride. Unger et al analyzed the risk of prostate cancer diagnosis in over 14,000 PCPT participants with an average time between randomization to the end of the study of about 16 years. Analyzing the risk of prostate cancer diagnosis, they reported that the reduction in prostate cancer diagnosis continued even after the finasteride use had ended at 7 years. There was a 21.1% decrease in hazard ratio during the follow-up period between 7.5 to 16 years. Further, there was no evidence that stopping finasteride at the end of the trial resulted in more or worse cancer diagnoses (J Natl Cancer Inst 2018; 110:1208-15).

Differences in study populations

These studies bring to the fore several clinically relevant questions. Is the long-term use of finasteride safe and beneficial (as per PCPT follow-up) or does it result in worse cancer-related outcomes (as per current and previous study)? An understanding of the differences in the study populations would suggest that the outcomes reported by these studies are not mutually exclusive.

The PCPT included men with normal PSA using finasteride to prevent prostate cancer detection, whereas in clinical practice, 5-ARIs are used to treat voiding symptoms in men with an enlarged prostate and often an elevated PSA. The PCPT trial design had built-in mechanisms for adjusting the lab-reported PSA level (multiplied by at least 2). Apparently, this adjustment in PSA level has not been taking place in routine clinical practice as evident from the two cohort studies showing significantly high PSA levels at time of biopsy in men using 5-ARIs. Further, in the PCPT, compliance with the indications and timing of prostate biopsy was enforced through trial design, while in clinical practice, these would be at the discretion of the individual practitioners.

With regard to prostate cancer and finasteride, the long-term safety (and benefits) of finasteride, when used in controlled setting (such as PCPT), have been fairly well established. Yet, new two cohort studies reported an association between 5-ARI use and a delay in prostate biopsy, resulting in worse pathologic outcomes and worse prostate cancer-specific mortality in men using 5-ARIs.

These findings should be a cause for concern. The message to prescribers should be very clear and simple. Proper adjustment of PSA level (by a factor of at least 2) is required and any increase in the PSA level of men on finasteride should prompt close follow-up and discussion about prostate biopsy. The relevant professional associations in the field of medicine and/or urology must do their part to inform and educate their members about the appropriate use of finasteride and PSA to eliminate avoidable morbidity and mortality from prostate cancer.
Catherine & Joseph Aresty  
Department of Urology

**USC Urology** is part of Keck Medicine of USC, the University of Southern California’s medical enterprise. In 2019, *U.S. News & World Report* ranked **USC Urology #4 in the nation overall, and #1 in Southern California**. An analysis of the USN&WR data revealed that during the past decade (2009-2019), **USC Urology** was the fastest-growing program in the nation in all the 3 major categories: USN&WR rankings (81% increase); Surgical volumes (91% increase); Reputation score (78% increase). The **USC Urology** team is humbled by this national recognition.

**QR code**
We recently published the first “dynamic paper” in the field of Urology that uses a QR code to provide readers with an innovative, immersive, high-quality and user-friendly experience (Cacciamani, et al: World J. Urol, 2019: 1-14). There are 4 QR codes in this communication. How to use the QR code? For iOS users: Use the Camera app on your device and hover over the QR code. For Android users: download a QRcode scanner app and follow instructions.

**Lancet Oncology**

*Cancer Awareness Crusades – Pink Ribbons and Growing Moustaches*


Our analysis of web-traffic showed that between the pink ribbons and mustaches, both these campaigns have very visual elements that can reinforce their online visibility. However, a successful health awareness campaign will need to go beyond reach and virality to ensure that the public understands the call to action.

**New England Journal of Medicine**

*Colovesical Fistula*


A 72-year-old woman had new-onset UTIs and pneumaturia following acute sigmoid diverticulitis. Cystoscopy revealed bladder mucosal edema with a central orifice that extruded gas and feculent material upon abdominal straining, confirming the diagnosis of colovesical fistula. Robotic fistula repair with sigmoid colectomy was performed successfully. The patient was symptom-free at two months follow-up. Side note: Our team has amongst the world’s largest experiences with successful robotic surgery for complex and recurrent genitourinary fistulae.

**JAMA Surgery**

*Automated Performance Metrics and Machine Learning Algorithms Anticipate Clinical Outcomes in Robotic Surgery*


Surgical performance in the operating room has direct consequences for the patient. However, sizing up a surgeon's performance is not so straightforward. Our team has developed and validated Automated Performance Metrics which objectively capture in real-time a surgeon's Machine Learning algorithms to process these automated metrics to anticipate a patient's outcomes. Without any patient information, our models can predict with 87.2% accuracy whether the hospital stay of a patient undergoing robotic radical prostatectomy will be 2 or fewer versus more than 2 days.
and retirement, workload, and practice type and size, among other topics. The majority of respondents are in the age 45-59 (50%) or 60-65 age group (22%). Most are in private practices of seven or fewer physicians (36%) or employed by a hospital or health system (25%).

Given a list of potential issues of concern, almost all urologists say they were either very concerned or concerned about declining reimbursement and prior authorization requirements (98% and 97%, respectively). This was followed by increasing overhead/overhead management (92%), escalating government regulations (90%), new payment models (86%), quality metrics and reporting requirements (85%), smaller/narrow insurance networks (80%), and the growing number of patients with high-deductible insurance (79%).

Asked to characterize their opinion of value-based care, most respondents (64%) chose the option, “It’s a good idea in theory, but much harder to execute in practice.” Eighteen percent said value-based care is a bad idea that will not succeed, 14% need to do more research before forming an opinion, and 2% said it’s good for both the health care system and patients.

“IT’s ridiculous; no one wants to take care of the difficult or non-compliant patient population,” one respondent wrote in a fill-in option. “We need good doctors, not more regulation.”

When asked how well they understand the choices regarding MIPS and APMs, nearly half of urologists (49%) report that they don’t understand them very well at all. Forty percent understand these options somewhat and 11% understand them very well. Forty percent currently participate in the AUA Quality Registry (AQUA Registry) or another Qualified Clinical Data Registry (QCDR), the survey found.

Among those participating in MIPS, 47% say they report MIPS data directly to the Centers for Medicare & Medicaid Services via their electronic health record, 15% report data using the AQUA Registry or other QCDR, and 6% use a third-party vendor. About 10% of urologists say their practice has had to appeal its MIPS score at least once, and of those, 3% were successful, 4% were not, and 38% were not sure yet of the outcome of their appeal.

As the New Year approaches, the most frequently cited initiative for 2020 was to hire a new urologist (21%). Other plans include retirement from the practice of urology (10%), reduction in workload/partial retirement (8%), seeking a medical job in a non-clinical setting (6%), doing locum tenens work (6%), merging with another urology group/groups (6%), and becoming a hospital-employed urologist (4%).

Burnout was reported by 53% of survey respondents, a sharp increase over the 33% reported in the 2018 State of the Specialty survey. Factors listed as “very much” contributing to burnout were use of EHRs (66%), falling revenue and/or rising overhead (60%), prior authorizations (48%), and unappreciative patients/unreasonable patient expectations (43%). With a high rate of burnout, it may come as little surprise that only 41% of urologists would choose medicine as their career if they were starting out today, although 78% would choose urology.

Despite the growth of large groups and practice mergers in urology, 20% of urologists report being in solo practice and 31% are in groups of two to four physicians, according to the survey. One-fifth are now in groups of 20 or more.
STATE OF THE SPECIALTY SURVEY / Cover Feature

Is your practice currently participating in MIPS?

- Yes: 59%
- No: 36%
- I am exempt from MIPS: 5%

What are your primary concerns?

- Declining reimbursement: 98%
- Prior authorization requirements: 97%
- Increasing overhead/overhead management: 92%
- Increasing government regulations: 90%
- New payment models: 86%
- Quality metrics/reporting requirements: 85%
- Smaller/narrow insurance networks: 80%

Would you choose medicine as your career again?

- Yes: 41%
- No: 30%
- Not sure: 29%

Would you still choose to work in the field of urology?

- Yes: 78%
- No: 19%
- Not sure: 3%

What method does your practice use for MIPS reporting?

- Report directly to CMS via EHR software: 47%
- AUA Quality Registry or other QCDR: 15%
- Third-party vendor: 6%

UROLOGISTS’ LEVEL OF AGREEMENT WITH THESE STATEMENTS:

<table>
<thead>
<tr>
<th>I used to enjoy being a physician more, but it is less financially lucrative/more stressful now</th>
<th>Board certification/recertification are necessary to preserve the integrity of our specialty</th>
<th>Telemedicine has a viable future in urology</th>
<th>I would favor a single-payer health insurance system</th>
</tr>
</thead>
<tbody>
<tr>
<td>STRONGLY AGREE</td>
<td>AGREE</td>
<td>NEUTRAL</td>
<td>DISAGREE</td>
</tr>
<tr>
<td>7%</td>
<td>11%</td>
<td>16%</td>
<td>27%</td>
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<tr>
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<td>12%</td>
<td>34%</td>
<td>38%</td>
</tr>
<tr>
<td>1%</td>
<td>9%</td>
<td>15%</td>
<td>20%</td>
</tr>
</tbody>
</table>

Source: All graphics based on Urology Times State of the Specialty survey results
Q&A

Patient, tumor factors dictate partial vs. radical nephrectomy

In patients with localized kidney cancer, treatment has evolved with the utilization of minimally invasive surgery. In this interview, Chandru P. Sundaram, MD, explains the important patient and tumor characteristics to consider in deciding between partial and radical nephrectomy. Dr. Sundaram also discusses surgical planning, complications of both approaches, and pathologic examination.

Q: Please start by explaining patient selection for partial versus radical nephrectomy and why you might choose one over the other.
A: It’s all about individualizing treatment to the patient and to the tumor as well. You have to put together tumor characteristics and patient characteristics and then decide whether partial or radical is better for that individual patient. There are several aspects of both the tumor and the patient that need to be looked at.

Q: Do you feel that doing a biopsy makes a difference in that surgical plan?
A: There is a huge range of practice with regard to biopsies in an individual patient. In my practice, the question I ask myself with each patient is, will biopsy make a difference to my management? If it does, then I do it. With that principle in mind, I would say about one-fourth of my patients end up getting a biopsy.

Q: Other factors are important in the surgical planning?
A: Let’s talk about the patient first—the patient’s renal function, comorbidities, age, body habits, and past surgeries. The individual surgeon’s training and experience also need to be considered. All these would make a difference in what surgery you do and what approach you take.

Q: Let’s consider a patient with a tumor that’s not hilar, and it’s exophytic. Would you generally choose partial over radical nephrectomy most of the time, and why?
A: For a T1a tumor, my default surgical approach, assuming the patient is a surgical candidate, would be a partial nephrectomy. Then I would ask, are there any factors in this patient or this tumor that would prevent me from doing a partial safely? If the answer is yes, then I would explore other options: Would radical nephrectomy be better? Would percutaneous cryoablation be better? Or, most importantly, would active surveillance or watchful waiting be better? All these questions have to be taken into consideration in every patient.

I would definitely do a partial versus radical nephrectomy in a patient whose expected glomerular filtration rate after radical nephrectomy is expected to be less than 45; a patient with a solitary kidney; a patient with multiple risk factors such as hypertension and diabetes; or a patient with other anomalies that would result in high risk for chronic kidney disease in the future.

Q: Which patients would you exclude from partial nephrectomy?
A: I would exclude patients in whom I think doing a partial would really not result in significant nephron sparing—for instance, those with a small kidney and a large tumor. In a patient with a normal contralateral kidney with multiple comorbidities, I have to get this patient off the table as soon as I can. The risk of increased complications may be much higher with the partial nephrectomy when there is a high nephrometry score.

Again, patient characteristics and tumor characteristics are important, and a third component to this treatment decision-making is the surgeon’s experience and capabilities. Those are very important and need to be addressed based on the surgeon’s past experience. It’s important that you look back at your patient outcomes after partial nephrectomy.

Q: Is there a particular position on the kidney that would make surgery a little more difficult laparoscopically or robotically?
A: Yes. It all depends on which approach you use. If you’re doing a transperitoneal approach, an upper pole posterior tumor would be difficult, especially in a morbidly obese man with sticky fat around the kidney. Those are all risk factors that would make it technically challenging.

Q: In which cases are the risk of post-op complications higher?
A: For large tumors with high nephrometry score, there clearly is an increased risk of urologic complications. However, with the utilization of robotics, that difference has decreased considerably.

Q: What are the major complications associated with partial nephrectomy that you generally would not see with a radical?
A: Bleeding and urine leak are the two most important urologic complications where it makes a difference between partial and radical. However, with the robotic approach by an experienced surgeon, the risk of urologic complications should be less than 5%.

Q: Do you drain all of these?
A: No. I drain about 25% of them—usually with complex partial nephrectomies and when a formal two-layer renorrhaphy was not used.

Q: If you’ve gotten into the collecting system, are you going to drain?
A: Actually, no. It’s all a matter of how you progress in practice. When I started doing partial nephrectomies, half of these surgeries were actually open. As time went by, I became more and more comfortable with the robotic approach, and now virtually all of my partials are robotic. I probably do one or two open partial nephrectomies a year; like patients with two previous partial nephrectomies when there is a recurrence. Those are the kind of patients you may consider for an open approach, but the robotic approach is the go-to procedure right now in my armamentarium.

As far as a drain is concerned, I used to drain all my patients, just like we would drain all robotic prostatectomies when we started doing them. We no longer drain robotic prostatectomies. Similarly with robotic partial nephrectomies, with an about 1% incidence of a urine leak in my practice, drains are not required in most patients.
Q: Is there a tumor size maximum that will prevent you from doing a partial, or is it based on position?
A: It depends on position. In fact, the largest partial I've done was 10 cm, but it was hanging off the lower pole and was very exophytic. The rest of the kidney was completely normal. As it turned out, this was a low-grade tumor, and I'm glad we did a partial nephrectomy on that patient.

Q: In terms of outcomes for partial versus radical, are cancer-specific survival and overall survival better in one than the other?
A: The only randomized trial showed equivalence with both approaches. There was a recent, large observational report from Mayo Clinic that suggested there was no difference in overall survival between the two groups after adjusting for a wide range of co-variates. But certainly there is an increase in chronic kidney disease after a radical versus a partial.

Q: In the case of partial nephrectomy, do you always send yours down at the time of the operation for frozen section to look at the margin?
A: Frozen section pathology during robotic partial nephrectomy is rarely required. However, ensuring a grossly negative margin is critical and usually possible with the magnification of robotic surgery, especially with a bloodless field due to renal vascular control.

Q: If that frozen section came back positive, would you take another margin?
A: I've done that maybe three or four times—about one in 100 partials. I think the best shot is the first shot at doing this procedure because once you put the kidney back together, reclamping the hilum and taking down the reconstruction is difficult. However, recognizing a positive margin during tumor excision and revising the excision or excising another slice of the tumor bed before staring the renorrhaphy may be required occasionally.

Q: There have been publications in which a laser has been used for a close margin or a possible focal margin. Have you used a laser in a case like that?
A: I would exclude patients in whom I think doing a partial would really not result in significant nephron sparing—for instance, those with a small kidney and a large tumor.

CHANDRU P. SUNDARAM, MD

Which patients would you exclude from partial nephrectomy?
J. BRANTLEY THRASHER, MD

I would exclude patients in whom I think doing a partial would really not result in significant nephron sparing—for instance, those with a small kidney and a large tumor.

Q: What do you use for coagulation? Do you use pledges or a gel foam in the middle of the tumor? Do you generally coagulate the cortical aspects?
A: Again, the technique has evolved. When I started off, I would use bolsters and a hemostatic agent in every patient. Now, I do not use bolsters and occasionally use hemostatic agents. If you do a two-layer renorrhaphy and do a good job of bringing the cortical edges together, argon beam coagulation or hemostatic agents are not required. Having said that, there are certain special circumstances when you need to use these techniques, for example, if you are not doing a two-layer renorrhaphy or with enucleation or multiple renal masses without getting vascular control. Cost has to be considered for every disposable you use, especially when it is of questionable benefit.

Q: What are the differences in chronic renal disease after partial and radical nephrectomy and why might you choose one or the other?
A: There is a distinction between medical chronic renal disease and surgical chronic renal disease. In the old landmark studies, which prompted everyone to go toward partial nephrectomy, there was a significantly higher risk of cardiovascular events in patients with chronic kidney disease. Then, after large studies primarily from Cleveland Clinic, there was a realization that medical chronic renal disease patients fared much worse over the long term than surgical chronic kidney disease patients. That makes sense because they don't all have the comorbidities that medical patients have: no hypertension or diabetes, for example. But a surgical patient could have those as well.

You have to be cognizant that not all chronic kidney diseases are the same, even after partial nephrectomy. These pre-existing comorbidities that can result in medical chronic kidney disease are important. But the bottom line is, there is a difference between medical chronic kidney disease, which continues to progress at a much higher rate than a surgical chronic disease.

Q: A lot of surgeons still do a primary enucleation, especially with some of the small lesions. Would that be your practice, or are you working with scissors almost exclusively?
A: I don’t do enucleation as a standard. I would use enucleation in some cases where every nephron matters and you want to preserve as much renal function as possible. I would also use it in patients with hereditary renal cancer syndromes where there are multiple tumors in the kidneys. Those are the two instances where I would use enucleation.

We also have preliminary data to suggest that renorrhaphy techniques can affect post-op ipsilateral renal volume and function. Techniques to minimize loss of renal function during partial nephrectomy include restricting renal hilar clamping to less than about 20 minutes, enucleation, and excision of minimal normal renal tissue surrounding the tumor. Omitting the second layer of renorrhaphy can be utilized in selected patients. Off-clamp partial nephrectomy has also been described, though a bloodless field with clamping is preferable in most patients.

Q: Let’s talk about the preoperative preparation for partial nephrectomy. You mentioned the situation of a tumor close to the hilum and the likelihood of a large defect growing into the collecting system. Is there anything else you would do for these larger complex tumors in preparation for surgery?
A: For complex surgeries, having blood in the room is important. Putting in a retrograde ureteral catheter can help in an occasional patient with a complex hilar tumor to visualize the renal pelvis and collecting system. Preoperative examination of the CT scan is very important. And in complex patients, including those with a horseshoe kidney, I would obtain a CT angiogram to visualize the secondary arteries close to the tumor. 3-D reconstruction and models are being used for preoperative planning. A recent study suggested that the utilization of detailed 3-D models can improve patient outcomes.

Q: Do you have any other take-home messages about nephrectomy for practicing urologists?
A: The key is doing the correct operation for each particular patient. First decide whether the patient needs a partial or radical based on all the criteria we discussed. Then, based on your own experience, decide whether to do it open or robotically or refer it out to somebody else. I think that’s what’s in the best interest of the patient.
2020 final rule reveals small gains for urology reimbursement

Start familiarizing yourself with 2021 CPT changes now

Urology will make a modest gain overall in the 2020 final rule for the Medicare Physician Fee Schedule, although the truly significant changes won’t be felt until 2021.

The conversion factor update, as expected, is minimal for 2020; the conversion factor is set to increase to $36.09, up from $36.06. With changes in some practice expense values to some higher volume procedures, urology is projected to be up 1% overall.

MIPS and value-based programs
Medicare continues to make changes to both the alternative payment model program and Merit-based Incentive Payment System (MIPS) payment structure. Changes for 2020 for the MIPS program, under which the vast majority of urologists are measured, are focused on making the threshold to avoid penalties more difficult, increasing the number of providers who will potentially pay a penalty. Simultaneously, the rule changes the upper end of the program to attempt to decrease the number of physicians who will be awarded payments for high performance, which may increase the dollar amounts awarded to those that qualify. The combination is designed to increase participatory effort with both the carrot and the stick.

A summary of these changes follows:
- minimum score of 45 for performance in 2020 (up from 30 for 2019)
- Quality category adjusted to 40%
- Cost category adjusted to 20%
- minimum score for exceptional performers will be raised to a minimum of 80 points
- maximum penalty for those failing to meet MIPS requirement increases to –9%, up from –7%
- penalties and bonuses will be applied to payments in 2022 based on 2020 reporting.

The rule also finalized a series of changes to go into effect in 2021 that will attempt to connect the four categories in a new “MIPS Value Pathways” proposal, which the AUA attempted to block. Changes to accountable care organizations were made as well but will not be covered in this article. We refer you to Robert Dowling, MD’s article (“How MIPS Cost category changes will affect urologists,” page 33) and qpp.cms.gov for more detailed information on the Quality Payment Program.

RVU winners and losers
The 1% increase in projected payments for urology is based on the conversion factor change, projected changes in volume, and the changes made to relative value units. The list of RVU percent changes in table 1 shows the effect of RVU changes for the facility setting. Note: Only codes that demonstrated a 5% or greater change are included in the table.

Table 2 represents the percent change for those services provided in the office setting. Note that there are far more codes impacted by negative change. Recall that volume is taken into account when projecting the overall impact of the RVUs on the specialty, demonstrating the impact of 31741 and 31798 due to volume. There were no changes to the documentation guidelines requirements or the rules pertaining to the submission of evaluation and management (E/M) codes for 2020.
However, the planned changes to the new and established office/outpatient visits for 2021 were once again finalized but have been changed from last year's final rules. The changes have codified answers to some controversial interpretations contained in the current rules and regulations as laid out by CPT and the documentation guidelines.

‘Time range’ question clarified
First and foremost, the new times for each CPT code in 2021 to be published by CPT and adopted by CMS will be published as a time range. This change in format appears to be in response to interpretation by coders and payers that have insisted that times for each CPT code are minimal times for each code, ignoring the CPT published language in the current manual noting that times included for each code are average face-to-face times representing a range of time.

We applaud the AMA for taking this stance in the face of compliance personnel, consultants, and others who have been incorrectly teaching that the times published were minimum times required for a specific code, while Physician Reimbursement Services defended the CPT definitions.

The major changes are coming in 2021. We will limit our discussion in this article to the highlights of the proposed changes. The details of the changes in E/M documentation and billing will be covered in other articles and venues.

Let us be clear: The changes discussed in the following paragraphs are only related to the new and established E/M documentation and apply to services provided in 2021 and beyond. For the rest of 2019 and 2020, we are stuck with the same guidelines that we’ve been using since 1995/1997.

Medicare proposed coding, payment, and documentation changes to the new and established office/outpatient visits in the CY 2019 proposed rule, which is now finalized in the CY 2019 final rule, published in November 2018. During the past year, a joint CPT/RVS Update Committee work group formed by the AMA established an alternative solution. CMS rescinded its proposal for valuation changes to the codes and finalized most of the recommended changes to the new and established office/outpatient guidelines and times proposed by the work group and finalized by the CPT Editorial Panel. The changes to these codes will go into effect Jan. 1, 2021 and will be published in the 2021 CPT book. The changes are also currently available on the AMA website at bit.ly/2021codechanges.

CMS adopted the majority of the recommended changes in the final rule. An overview of those changes are discussed below. See FINAL RULE page 32.

TABLE 2 PERCENT CHANGE IN RVUs FOR COMMON UROLOGIC CODES, OFFICE SETTING

<table>
<thead>
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<th>Code</th>
<th>Mod.</th>
<th>Description</th>
<th>% change non-facility</th>
<th>Code</th>
<th>Mod.</th>
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<td>TC</td>
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<td>51785</td>
<td>0</td>
<td>Anal/ urinary muscle study</td>
<td>-16%</td>
<td>51101</td>
<td>0</td>
<td>Drain bladder by trocar/ cath</td>
<td>7%</td>
</tr>
<tr>
<td>56420</td>
<td>0</td>
<td>Drainage of gland abscess</td>
<td>-16%</td>
<td>52285</td>
<td>0</td>
<td>Cystoscopy and treatment</td>
<td>7%</td>
</tr>
<tr>
<td>57061</td>
<td>0</td>
<td>Destory vag lesions simple</td>
<td>-15%</td>
<td>56605</td>
<td>0</td>
<td>Biopsy of vulva/ perineum</td>
<td>7%</td>
</tr>
<tr>
<td>57020</td>
<td>0</td>
<td>Drainage of pelvic fluid</td>
<td>-14%</td>
<td>52441</td>
<td>0</td>
<td>Cystourethro w/ implant</td>
<td>7%</td>
</tr>
<tr>
<td>56501</td>
<td>0</td>
<td>Destory vulva lesions sim</td>
<td>-14%</td>
<td>51610</td>
<td>0</td>
<td>Injection of bladder x-ray</td>
<td>7%</td>
</tr>
<tr>
<td>57180</td>
<td>0</td>
<td>Treat vaginal bleeding</td>
<td>-14%</td>
<td>51728</td>
<td>TC</td>
<td>Cystometrogram w vp</td>
<td>-7%</td>
</tr>
<tr>
<td>56405</td>
<td>0</td>
<td>I &amp; d of vulva/perineum</td>
<td>-14%</td>
<td>50387</td>
<td>0</td>
<td>Change nephrourethral cath</td>
<td>7%</td>
</tr>
<tr>
<td>53860</td>
<td>0</td>
<td>Transurethral re treatment</td>
<td>-13%</td>
<td>51729</td>
<td>TC</td>
<td>Cystometrogram w vp &amp; up</td>
<td>-7%</td>
</tr>
<tr>
<td>50389</td>
<td>0</td>
<td>Remove renal tube w/ fluoro</td>
<td>-13%</td>
<td>52287</td>
<td>0</td>
<td>Cystoscopy chemodenervation</td>
<td>-6%</td>
</tr>
<tr>
<td>53621</td>
<td>0</td>
<td>Dilate urethra structure</td>
<td>-12%</td>
<td>51725</td>
<td>0</td>
<td>Simple cystometrogram</td>
<td>-6%</td>
</tr>
<tr>
<td>57150</td>
<td>0</td>
<td>Treat vagina infection</td>
<td>-12%</td>
<td>51100</td>
<td>0</td>
<td>Drain bladder by needle</td>
<td>-6%</td>
</tr>
<tr>
<td>57130</td>
<td>0</td>
<td>Remove vagina lesion</td>
<td>-11%</td>
<td>51726</td>
<td>TC</td>
<td>Complex cystometrogram</td>
<td>-6%</td>
</tr>
<tr>
<td>53620</td>
<td>0</td>
<td>Dilate urethra structure</td>
<td>-11%</td>
<td>50434</td>
<td>0</td>
<td>Convert nephrostomy catheter</td>
<td>-6%</td>
</tr>
<tr>
<td>56430</td>
<td>0</td>
<td>Nix px neurogram &amp; urtrgram</td>
<td>-11%</td>
<td>51600</td>
<td>0</td>
<td>Injection for bladder x-ray</td>
<td>-6%</td>
</tr>
<tr>
<td>52000</td>
<td>0</td>
<td>Cystoscopy</td>
<td>-11%</td>
<td>51727</td>
<td>0</td>
<td>Cystometrogram w vp</td>
<td>-5%</td>
</tr>
<tr>
<td>51725</td>
<td>TC</td>
<td>Simple cystometrogram</td>
<td>-10%</td>
<td>57003</td>
<td>0</td>
<td>Insert bladder cath complex</td>
<td>-5%</td>
</tr>
<tr>
<td>57135</td>
<td>0</td>
<td>Remove vagina lesion</td>
<td>-10%</td>
<td>52315</td>
<td>0</td>
<td>Cystoscopy and treatment</td>
<td>-5%</td>
</tr>
<tr>
<td>51792</td>
<td>TC</td>
<td>Urinary reflex study</td>
<td>-10%</td>
<td>52270</td>
<td>0</td>
<td>Cystoscopy &amp; revise urethra</td>
<td>-5%</td>
</tr>
<tr>
<td>50435</td>
<td>0</td>
<td>Exchange nephrostomy cath</td>
<td>-10%</td>
<td>52001</td>
<td>0</td>
<td>Cystoscopy removal of clots</td>
<td>-5%</td>
</tr>
<tr>
<td>57160</td>
<td>0</td>
<td>Insert pessary/ other device</td>
<td>-9%</td>
<td>56821</td>
<td>0</td>
<td>Exam/ biopsy of vulva w/ scope</td>
<td>-5%</td>
</tr>
<tr>
<td>57170</td>
<td>0</td>
<td>Fitting of diaphragm/ cap</td>
<td>-9%</td>
<td>50433</td>
<td>0</td>
<td>Plnt nephrourethral catheter</td>
<td>-5%</td>
</tr>
<tr>
<td>56441</td>
<td>0</td>
<td>Lysis of labial lesion(s)</td>
<td>-9%</td>
<td>51728</td>
<td>0</td>
<td>Cystometrogram w vp</td>
<td>-5%</td>
</tr>
<tr>
<td>57105</td>
<td>0</td>
<td>Biopsy of vagina</td>
<td>-9%</td>
<td>56820</td>
<td>0</td>
<td>Exam of vulva w/ scope</td>
<td>-5%</td>
</tr>
<tr>
<td>57065</td>
<td>0</td>
<td>Destroy vag lesions complex</td>
<td>-8%</td>
<td>57100</td>
<td>0</td>
<td>Biopsy of vagina</td>
<td>-5%</td>
</tr>
<tr>
<td>56615</td>
<td>0</td>
<td>Destroy vulva lesion/s compl</td>
<td>-8%</td>
<td>51729</td>
<td>0</td>
<td>Cystometrogram w vp &amp; up</td>
<td>-5%</td>
</tr>
<tr>
<td>51715</td>
<td>0</td>
<td>Endoscopic injection/ implant</td>
<td>-8%</td>
<td>50606</td>
<td>0</td>
<td>Endoluminal bx urtr ml plvs</td>
<td>5%</td>
</tr>
<tr>
<td>50684</td>
<td>0</td>
<td>Injection for ureter x-ray</td>
<td>-8%</td>
<td>50705</td>
<td>0</td>
<td>Ureteral embolization/ occl</td>
<td>5%</td>
</tr>
<tr>
<td>50689</td>
<td>0</td>
<td>Injection for ureter x-ray</td>
<td>-8%</td>
<td>51736</td>
<td>TC</td>
<td>Urine flow measurement</td>
<td>6%</td>
</tr>
<tr>
<td>51717</td>
<td>TC</td>
<td>Cystometrogram w vp</td>
<td>-8%</td>
<td>51741</td>
<td>TC</td>
<td>Electro-uroflowmetry first</td>
<td>6%</td>
</tr>
<tr>
<td>50432</td>
<td>0</td>
<td>Plnt nephrostomy catheter</td>
<td>-8%</td>
<td>55874</td>
<td>0</td>
<td>Txnl plnt biodegradable mat</td>
<td>12%</td>
</tr>
<tr>
<td>52310</td>
<td>0</td>
<td>Cystoscopy and treatment</td>
<td>-8%</td>
<td>51798</td>
<td>0</td>
<td>Us urine capacity measure</td>
<td>19%</td>
</tr>
</tbody>
</table>

Source: Adapted from Centers for Medicare & Medicaid Services data by Ray Painter, MD, and Mark Painter

CODING AND REIMBURSEMENT / Business
FINAL RULE
continued from page 31

We will start by making a very bold statement: You’re going to like the new guidelines. Yes, changing your documentation for the new and established office/outpatient E/M services will be a lot of work, requiring changes to all of your templates and the way you collect and document your history and physical exam, as well as learning new criteria for medical decision-making and how you charge by time, etc. However, taking the time to modify, plan, and learn prior to 2021 will be time well spent.

As you know, currently you have the option to charge by components or, under certain circumstances, by time. Both options are changing significantly. Charging by time becomes a viable option for every encounter without the counseling or coordination of care criteria, and the history and physical exam will no longer be used in determining code levels.

In summary, you can choose to document based on time or medical decision-making each encounter, regardless of whether the patient visit is established or new.

Components
History and physical have been eliminated as elements for code selection. A medically appropriate history and/or physical exam is expected for each encounter. However, you determine what is medically appropriate and document what is pertinent. A one-sentence history and physical will not count against you, nor will a two-page history and physical improve your code level.

Code levels will be determined by medical decision-making. The basic construct and the main elements of medical decision-making—problem, data, and risk—will not change. The risk table will still contain three elements. The code level will continue to be determined by the two highest of the three elements. However, there were significant changes to the sub-elements, particularly in defining the level of data. Much of the ambiguous language has been removed or defined, and many of the issues that were left to interpretation have been clarified. We applaud the AMA here as well. The 2021 guidelines make it clear that each CPT code ordered or reviewed counts as data.

We plan to have an updated pocket card and wall chart reflecting the new and established office/outpatient E/M changes for 2021 within the next few months. (For those who are not familiar, these are summarized cheat sheets for E/M documentation coding.)

The 2021 guidelines make it clear that each CPT code ordered or reviewed counts as data.

Time
Time will now be a viable option for every encounter.

There will be a number of changes in the criteria for charging by time. First, time may be used to select the appropriate code level for all encounters. It will no longer be limited to services where over 50% of time spent has to be spent in counseling or coordination of care.

Second, all the time personally spent by the physician or other qualified health care professional evaluating and/or managing the patient on the date of the encounter counts and includes:

- face-to-face and non-face-to-face time
- time spent preparing to see the patient, reviewing chart, lab test, etc.
- counseling and educating the patient/family/caregiver
- obtaining and/or reviewing separately obtained history
- independently interpreting results and communicating the results to the patient/family/caregiver
- care coordination.

Time in activities normally performed by clinical staff is not included.

Third, the new and established office/outpatient E/M codes will now contain a range of total time for each CPT code, allowing you to pick the correct code without having to do the math to determine which code is closest to the time spent.

As you can see, documentation and code selection will get easier—in 2021. PRS Networks plans to have a ceremonial burial of the 1995 and 1997 documentation guidelines, which have been the bane of physicians’ existence for all these years, on Dec. 31, 2020.

Other 2021 changes to look for relate to prolonged service codes. A new CPT prolonged service code for increments of 15 minutes will be adopted in 2021 to be charged only with the level V codes 99215 and 99205. The old prolonged service codes will not be paid by Medicare after this new code is adopted.

Also look for a new add-on code for E/M services in 2021: GPC1X Visit complexity inherent to evaluation and management associated with medical care services that serve as the continuing focal point for all needed health care services and/or with medical care services that are part of ongoing care related to a patient’s single, serious, or complex chronic condition. [Add-on code, list separately in addition to office/outpatient evaluation and management visit, new or established].

This code can only be used by certain specialties that provide significant amount of care management. Fortunately, urology is one of those specialties.

The code will add an additional payment of approximately $18 per visit.

AMA URGES HEALTH ECONOMICS INSTRUCTION IN MED SCHOOLS, RESIDENCY PROGRAMS

The American Medical Association is calling for medical schools and residency programs to incorporate information on health care economics in their programs, according to a news release from the association.

The new policy is built on the AMA’s ongoing work to ensure students and residents are trained to practice within modern health systems. Specifically, it calls for these programs to incorporate information on the organization of health care delivery, modes of practice, practice settings, cost-effective use of diagnostic and treatment services, practice management, risk management, and quality assurance, according to the release.

Also, the new policy calls on medical student and residency programs to ensure their students and residents are given instruction related to the environment and economics of medical practice in fee-for-service, managed care, and other systems.

“Medical students and residents with a deeper understanding of cost, financing, and medical economics will be better equipped to provide more cost-effective care that will have a positive impact for patients and the health care system as a whole,” said Barbara L. McAneny, MD, former AMA president, in the release.

The AMA has worked for several years to incorporate health systems science education into medical school and residency programs. It is also currently working with the National Board of Medical Examiners to develop a standardized test to ensure medical and other health profession students are proficient in health systems science. The test is expected to be available later in 2019, according to the release.
How MIPS Cost category changes will affect urologists

Stone treatment episode-based cost measure to impact specialty practice

**PRACTICE POINTERS**

- The Centers for Medicare & Medicaid Services has kept the weight of the Quality and Cost categories the same for 2020 as 2019: 45% for Quality and 15% for Cost.
- In the revised Total Per Capita Cost Measure, patients will be attributed preferentially to primary care physicians based on claims for primary care services—not evaluation and management CPT codes shared by all specialists. In addition, patients will not be attributed to specialists with a high frequency of non-primary care services, like surgery. Under the revised measure specifications, CMS estimates that no urologists will be attributed patients for this measure beginning in 2020—a significant departure from past years.
- Finally, CMS will now determine risk scores for a beneficiary using diagnosis data (from claims) compared to benchmarks and a “score” is generated for this measure (lower costs=higher score).

**CMS will now determine risk scores for a beneficiary using diagnosis data (from claims)**

from the previous 12 months rather than the previous calendar year, which should better represent the current health status of patients.

**Putting it all together: All of the applicable measures within the Cost category contribute equally to the category score, which in turn contributes 15% of the total MIPS score. For example, if a practice had no patients attributed to the TPCC, a score of 0/10 for MSPBC, and a score of 7/10 for episode-based cost measures, their Cost category score would be 0.6 X 15 points=9 points.**

**Bottom line:** The 2020 Quality Payment Program Final Rule is the next step in an attempt to hold providers accountable for costs in the Medicare program, and this year’s changes address some of the concerns raised by earlier versions of the program—including an episode measure that should be broadly applicable to urology and changes to measures that inappropriately assigned accountability to urologists.
Inherited retirement accounts: What are your options?

Avenues for taking distributions vary according to decedent’s age

**Q:** I had a parent recently pass away and I was named the beneficiary on their 401(k). What are my options?

**A:** Losing a loved one is always difficult, and to make things tougher, some important financial decisions often need to be made soon afterwards. If you were named the beneficiary on a retirement account such as a 401(k), 403(b), or IRA, you typically have a couple of options for handling this inheritance. If the decedent was a spouse, there is a wider range of options, but in this case we will focus on non-spouse inherited retirement accounts.

If the decedent was under age 70½, you can keep the money in the existing account but must take distributions in one of two ways. You can choose to distribute the entirety of the account no later than Dec. 31 of the fifth year following the year the account owner died. Alternatively, you can elect to distribute the account in one lump sum. In either case, you will not be charged the 10% early withdrawal penalty if you are under age 59½; however, you must include the distribution in your income and pay income taxes on it.

Depending on the size of the account, the distribution could push you into a higher tax bracket. It’s best to consult with a tax professional to determine the appropriate distribution timeline.

Another option is to transfer the money from the decedent’s retirement account into an inherited IRA. These accounts are specifically designed for retirement accounts inherited by a non-spouse beneficiary and allow you to distribute the money based on your life expectancy instead of the decedent’s. Each year, you are required to distribute a portion of the account based on the previous year-end account value and your IRS life expectancy factor. For example, if the account value was $100,000 on Dec. 31, 2018 and you turn 45 years old during 2019, you would divide $100,000 by your IRS life expectancy factor of 38.8. Your resulting required minimum distribution (RMD) would be $2,578 for this year, and it must be taken by Dec. 31 and included in your taxable income for the year.

Note: Unlike your own IRA, which allows for the IRS factor to be taken from your own IRS life expectancy factor, or you can move the money into an inherited IRA and base the RMDs off your own IRS life expectancy factor. Published tables, inherited IRA factors are generally calculated based on the age the beneficiary will attain the year after the original account owner’s death, then reduced by 1 for each subsequent year.

While you can always take out more than the RMD each year, you must take at least the calculated amount or the penalty for failing to do this is severe. You must pay a 50% tax on any amount that fell short of the RMD. It is important to remember that each year, the RMD must be recalculated since the year-end account value as well as your life expectancy factor will change.

The primary benefit of taking the inherited IRA route is that you can spread the distributions over a longer period of time, leaving the remainder of the account invested to hopefully continue growing tax deferred.

If the decedent was over age 70½, you also have two options for distributing the account. Since they were already taking RMDs at the time of death, you can continue withdrawing the RMD based on their IRS life expectancy factor, meaning you are not forced to distribute the full amount in the 5-year window. You can take out more than the RMD but not less or else the 50% tax applies. The other option is to move the money into an inherited IRA and base the RMDs off your own IRS life expectancy factor as described above.

The rules for non-spouse inherited retirement accounts can be complex, so I recommend discussing your options with your financial adviser or tax professional.

**Q:** What are my options if a non-spouse inherited account was a Roth account?

**A:** If you inherit a non-spouse Roth retirement account, special rules apply. Roth accounts don’t grow tax-deferred (they grow tax-free), and they don’t normally have RMDs. However, if you are a non-spouse and inherited the account after their death, you will be required to make distributions. You must distribute the funds either within the 5-year window, based on the owner’s IRS life expectancy factor, or you can move the money into an inherited IRA and distribute based upon your IRS life expectancy factor.

These are valid options regardless of the decedent’s age. As long as the money has been in the Roth account for more than 5 years, no taxes will be owed when the money is distributed. FT

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**FINANCIAL TIPS**

- If the decedent was under age 70½, you as the non-spouse beneficiary can keep the money in the existing account but must distribute the entirety of the account no later than Dec. 31 of the fifth year following the year the account owner died or distribute the account in one lump sum.

- If the decedent was over age 70½, you can continue withdrawing the required minimum distribution (RMD) based on their IRS life expectancy factor or move the money into an inherited IRA and base the RMDs off your own IRS life expectancy factor.

---

**JEFF WITZ, CFP**

Mr. Witz is education and program director at MEDIQUS Asset Advisors, Inc. in Chicago. He welcomes readers’ questions and can be reached at 800-883-8555 or witz@mediqus.com.
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How have your benefits changed over the past several years?

We’ve had changes in the past year, basically because we were a smaller, single-specialty group, and we joined a larger, multispecialty group last January. As a small group, we had little leverage for negotiating things like health care for the five physicians in our group and staff of 30.

Becoming a member of the larger group has given us more bargaining power in the health care marketplace, so we’ve been able to get better health care, not only for us but for our staff. It’s given us better 401(k)s for retirement and better vacation because we have more support. We don’t come back to work just to have to work harder to pay for the overhead that continued to accumulate while we were gone. Instead of paying for continuing medical education out of my own pocket, it now comes out of the group’s budget.

I was in the single-specialty group for 12 years, and it’s not that we couldn’t adjust things to increase benefits, but we were doing it from a very small pool. Now we’re working with a bigger pool.

That was a huge part of the benefit of joining a large, multispecialty group.

Meredith Baker, MD / Bend, OR

“ I’m in a large single-specialty group with 28 urologists. We’ve been able to maintain our benefits, but the cost of doing things has also gone up. It’s probably what we’ve had to work hardest to manage.

In terms of 401(k)s, we’ve been able to maintain those but have had to shop around to find savings in administrative fees for those plans. We’ve made some adjustments, changing providers. In terms of providing vacation, we still do those at the same level we’ve always done, but we realize that, because overhead keeps going up, the cost of doing those things has also gone up. We have to work more hours to get the same amount of vacation.

The way CME works, since we’re basically our own bosses, every doctor has a different approach of how to spend on CME, so at the end of the year, CME comes out of each individual’s account balance.

Everything’s done in house. So we do have to keep looking for different health insurance companies or different benefits providers—not actually us—but our administrators have to, as overhead costs continue to rise.

There’s always the temptation to go with a hospital; not that we ever had any concrete plans, but we’ve seen other specialists do it. There are benefits to not having to deal with the headaches of keeping up with costs. In exchange, however, you give up your independence. For us that’s pretty important, so we haven’t really looked at it seriously.

We’re not expanding benefits, just trying to maintain what we’ve always had, and we’ve chosen to accept the bill for those because they’re important to us.”

Gerald Park, MD / North Kansas City, MO

“I’m hospital based, and we haven’t seen any change in our benefits over the years. Our retirement plans are the same. They’ve become more vigilant about CME expenses, with more travel policies and more hoops to jump through. They’re always watching when you’re spending money.

The vacation issue doesn’t apply to me because I was grandfathered in, but doctors receiving offers today are getting less vacation than they would have before. There’s a one-policy-fits-all approach where I work, so they don’t offer any more vacation to recruit a new physician just because there is a shortage of urologists.

The benefits have not gotten more generous, that’s for sure, but all the standard benefits have stayed pretty much the same over the years, including our health insurance.

We were a private group for most of my career and became hospital based in 2013. It was becoming more and more difficult to exist in private practice. Expenses were up and reimbursements had plummeted.

The big difference is that salaries are generally higher. There’s more of a move toward reimbursing call, being employed compared to being in private practice. In working for a hospital, we don’t have to deal with managing human resources or things like insurance and retirement; we don’t have those headaches.

They’re a corporation and they’re always looking for ways to save a bit of money. So, we don’t get better benefits, but that’s kind of offset by the fact that our salaries are a bit higher if you’re hospital employed than if you’re in private practice nowadays.”

John Lyne, MD / Grove City, PA
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Recruitment

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Williamsport, PA is located in the scenic Susquehanna Valley of northcentral Pennsylvania. This small, thriving city offers big city amenities such as vibrant downtown with arts, shopping and entertainment, as well as nationally recognized public & private schools, attractive & affordable housing options all among a beautiful landscape that is perfect for hiking & biking. Quick and easy access to NYC, Philadelphia & Baltimore allows for the “city fix” when you want it!

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Champlain Valley Physicians Hospital, Plattsburgh, NY

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.
East Region Director Of Men’s Health
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Hartford HealthCare, the largest integrated health care system in CT, and the Tallwood Urology and Kidney Institute is seeking a urologist with fellowship training in andrology and/or a demonstrated interest in men’s health for a leadership role in our Eastern CT region. Join this well-established east region urology practice with 7 surgeons and 4 advanced practitioners located near the beautiful CT shoreline - and operate at Backus Hospital, a 250 bed community hospital and one of the top performing hospitals in the state.

The Tallwood Urology and Kidney Institute is comprised of world-class urologists and nephrologists who are leaders in their fields. Our physicians are backed by a full team of interdisciplinary medical and surgical specialists, many of whom have advanced sub-speciality training. The East Region Director of Men’s Health will establish and lead a multidisciplinary team near the CT shore with support and guidance from our clinical council and Tallwood’s System Director of Men’s Health. This is an exciting opportunity to blend clinical care, leadership and program development.

We have it all so you can too: Enjoy the support and resources of a successful hospital system AND the autonomy of a close-knit community practice
• Join one of the largest urology groups in New England with 30 urologists, many of whom pioneered treatments that have become the gold standard of care nationwide
• Participate in robust research opportunities available with Institute resources and support
• Maintain balance in your life with a satisfying 1 in 6 call coverage schedule
• Operate out of a single hospital and enjoy the support of a urology trained advanced practitioner to assist you in the office and in the hospital
• Receive generous benefits and compensation including loan repayment and so much more

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Interested candidates please email HHC Physician Recruiter: Jonathan.Nye@hhchealth.org.

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A new report by the National Academy of Medicine urges action by government, educational institutions, and health care organizations to address the causes of physician burnout, which is experienced by up to one-half of clinicians in the U.S. and threatens patient care.

A combination of cumbersome and sometimes seemingly unnecessary rules and payment procedures, plus staff shortages and pressure to enter the age of electronic medical records, is causing emotional exhaustion, detachment, and a low sense of personal accomplishment, the report says.

“Studies estimate that between 35% and 54% of U.S. nurses and physicians have substantial symptoms of burnout, and the range for medical students and residents is between 45% and 60%. There are indications that burnout is a problem among all clinical disciplines and across care settings,” the report states.

“The high rates of burnout reported among U.S. clinicians and learners is a strong signal that the nation’s health care system is failing to achieve its aims for system-wide improvement,” the report states.

“Burnout is real,” said AUA President John H. Lynch, MD. “It impacts the entire health care system, and exacerbates already-existing work force shortages in many specialties, including urology.”

**Report reflects AUA Census findings**

Dr. Lynch said the report reflects the findings of the AUA Census, which reported burnout rates for urologists as being high, with more than one-third experiencing symptoms.

“Addressing causes of burnout is a priority for the AUA,” said Dr. Lynch. The AUA endorses the six goals outlined in the report:

**Creating positive work environments.** Health care executives should commit to, and be accountable for, creating a work environment that promotes high-quality care, job satisfaction, and social support, the report says. It recommends that health care organizations create and maintain an executive leadership role dedicated to clinician well-being.

**Addressing burnout in training and at early career stages.** Schools of health professions (including medical schools, nursing schools, schools of pharmacy, and others) should alleviate major sources of stress by monitoring workload (including preparation for licensure examinations and required training activities), implementing pass-fail grading, improving access to scholarships and affordable loans, and building new loan repayment systems.

**Reducing tasks that do not improve patient care.** Federal agencies, state legislatures, and other standard-setting entities should identify and address the sources of clinician burnout related to laws, regulations, and policies, eliminating those that contribute little or no value to patient care. They should specifically evaluate regulations and standards related to payment, health information technology, quality measurement and reporting, and professional and legal requirements for licensure.

**Improving usability and relevance of health information technology.** Health information technology (IT), including electronic health records, should be as user-friendly and easy to operate as possible to reduce burnout. Health IT vendors and health care organizations should deploy technologies to reduce documentation demands and automate non-essential tasks. In addition, federal policymakers and private sector health IT companies should collaborate to develop the infrastructure and processes that enable shared decision-making between clinicians and patients.

**Reducing stigma and improving recovery services.** Many clinicians do not report burnout because they fear the potential consequences, including loss of licensure. In order to eliminate the stigma of getting help and to promote recovery and well-being, state legislative bodies should facilitate access to employee assistance programs, peer support programs, and mental health providers without the information being admissible in malpractice litigation.

**Creating a national research agenda on clinician well-being.** By the end of 2020, federal agencies—including the Agency for Healthcare Research and Quality, the National Institute for Occupational Safety and Health, the Health Resources and Services Administration, and the U.S. Department of Veterans Affairs—should develop a coordinated research agenda on clinician burnout, according to the report.

The report points out that mounting system pressures have contributed to an imbalance in which the demands of the clinician’s job are greater than the resources available to complete the job effectively.

All of that is intensified by the increasing push for performance improvement, technology that hinders rather than supports patient care, changing professional and societal expectations, and policies that are insufficiently aligned with professional values or the goal of better patient care, the report concludes.

Overwhelming job demands and insufficient job resources cause physical, psychological, and emotional stress, including burnout—a workplace syndrome that is characterized by high emotional exhaustion, high depersonalization (ie, cynicism), and a low sense of personal accomplishment from work, the report observes.

**Work system affects well-being**

“The work system—including the physical environment, the technologies in use, and how care team members interact with each other—deeply influences clinicians’ professional well-being,” said Pascale Carayon, PhD, co-chair of the committee that wrote the report and professor and director of the Wisconsin Institute for Healthcare Systems Engineering at the University of Wisconsin, Madison. “To provide the best patient care possible, health care organizations must create a work environment that fosters clinicians’ safety, health, and sense of fulfillment.”

“For many clinicians, developing real relationships with patients is what attracted us to health care in the first place, but administrative tasks often take us away from patient care,” said Christine Cassel, MD, senior adviser on strategy and policy and professor of medicine at the University of California, San Francisco and committee co-chair. “With this report, we have a real opportunity to change the culture of health care delivery and help restore clinicians’ well-being and joy in medicine.”

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**“Burnout impacts the entire health care system, and exacerbates already-existing workforce shortages in many specialties, including urology.”**

**JOHN H. LYNCH, MD**
AUA PRESIDENT
Is clinician at fault for vesicovaginal fistula?

Case highlights problem with using ‘hindsight bias’

The patient filed a malpractice lawsuit against the OB/GYN. The plaintiff alleged that the OB/GYN failed to fully advise the plaintiff of her surgical options, including undergoing a subtotal hysterectomy, which would have posed virtually no risk of inadvertent injury to the bladder and would have shortened the time of surgery.

The plaintiff also argued that a urologic consult would have determined that there was suture material in the bladder that could have been removed by a urologist using a cystoscope before a fistula developed. According to the plaintiff and her experts, it was below the standard of care for the OB/GYN to continue to believe that the blood in the urine was due to the anticoagulation therapy.

In his defense, the OB/GYN contended that in light of the plaintiff’s significant uterine disease, which existed before his involvement with the patient’s care, performing an operation of less than a total hysterectomy would have been below the standard of care. The OB/GYN and his experts argued that the standard of care did not require any discussion of the option of a subtotal hysterectomy unless the patient requested such information.

The OB/GYN did not dispute the bladder injury during surgery, but maintained that such an injury is a known and accepted risk of a total hysterectomy and can occur in the absence of negligence. The OB/GYN and his experts also argued that it was reasonable to conclude that the blood in the urine was due to the “normal” trauma to the bladder incurred during such a surgery together with the plaintiff’s anticoagulation.

Additionally, on the second postoperative day, the plaintiff’s Foley catheter was inadvertently pulled out, which the defense claimed was a traumatic event that caused bleeding in the bladder and urethra. Any bleeding after this “Foley event” was explained by that trauma plus the anticoagulation. Thus, the defense contended there was no need for a urologic consultation while the plaintiff was in the hospital.

The case proceeded to a jury trial, where the jury returned a 12-0 defense verdict, finding the OB/GYN met the standard of care.

LEGAL PERSPECTIVE: Whenever something does not go as planned, we have the habit of reviewing events in the rear-view mirror. The hindsight bias manifests in the tendency to exaggerate the extent to which a past event could have been predicted beforehand. It is easy to judge someone’s actions when the end result is known. Most people do not wish for their actions to be judged in hindsight; rather, if we are going to be judged, we want to be judged based on what we knew at the time. Thankfully, our civil justice system sees it that way too.

In a medical malpractice action, the standard of care, or the test of reasonableness, requires the jury to consider the defendant-doctor’s conduct in light of all the facts before him under the same or similar circumstances. In this case, it could have been easy to start with the vesicovaginal fistula and work backwards to criticize the OB/GYN. Yet that would be reviewing the defendant-doctor’s conduct in the rearview mirror. When reviewing the facts as presented to him, this jury correctly concluded that the OB/GYN’s actions were reasonable and within the standard of care.
I am a urologist.
I am a patient.

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Peter J. Walter, M.D., F.A.C.S.* Western New York Urology Associates and
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*Dr. Walter is UroLift faculty and a paid consultant for NeoTract|Teleflex
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