Burnout: How can it be prevented?

Are you burned out? If not, you may know someone who is; 40% of respondents to the 2016 AUA Annual Census reported burnout. In this interview, Raj S. Pruthi, MD, discusses the factors behind burnout and steps that can be taken to address and prevent it.

Dr. Pruthi is Rhodes Distinguished Professor and chair of urology at the University of North Carolina, Chapel Hill. Dr. Pruthi was interviewed by Urology Times Editorial Consultant Stephen Y. Nakada, MD, the Uehling Professor and founding chairman of urology at the University of Wisconsin, Madison.

Q: Please describe the problem of physician burnout.

A: Burnout in medicine is a national, complex, and systemic issue whose effects go far beyond physicians themselves, impacting our patients and even having far-reaching societal implications. Sadly, across the world, I believe that physician burnout is becoming the norm within our career path.

The term “burnout” was first used in 1974 to describe stress related to one’s occupation. It can

For the full article, please turn to page 34

Urologists adhere poorly to value-based pathway

‘More powerful incentives than data feedback are needed,’ study author says

Cheryl Guttman Krader
UT CONTRIBUTING EDITOR

Urologists’ adherence to value-based care pathways (VBCP) for BPH surgery is extremely low and only modestly improved when they are given individualized feedback on patient outcomes, costs, and practice patterns relative to peers, according to a study presented by University of California Los Angeles (UCLA) researchers at the AUA annual meeting in Boston.

“Since passage of the Affordable Care Act, there has been a lot of talk about the need to transition from fee-for-service to value-based care. The results of our study show that we still have a long way to go before we reach that goal,” said first author Alan L. Kaplan, MD, fellow in health care strategy and leadership and clinical instructor of urology at UCLA.

“Furthermore, our research indicates that merely showing surgeons how they are performing compared to their colleagues, a strategy that might drive change through competition, is not enough to meaningfully move behavior toward a VBCP for BPH surgery. Clearly, more powerful incentives than data feedback are needed,” Dr. Kaplan added.

Please see VALUE, on page 37
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There was no evidence of altered fertility.

at doses of 2, 10, and 50 mg/kg (12, 60, and 300 mg/m²) from day 15 of pregnancy and up to 20 days post partum.

of lidocaine on post-natal development was examined in rats by treating pregnant female rats daily subcutaneously

toxicity and evidence of delayed fetal development, including a non-significant decrease in fetal weight (7%) and an

was no indication of any mutagenic effect in these studies.

The safety and effectiveness of lidocaine depend on proper dosage, correct technique, adequate precautions, and

General

PRECAUTIONS

EXCESSIVE DOSAGE, OR SHORT INTERVALS BETWEEN DOSES, CAN RESULT IN HIGH PLASMA LEVELS AND SERIOUS

ADVERSE REACTIONS

The lowest dosage that results in effective anesthesia should be used to avoid high plasma levels and serious adverse effects. Repeated doses of lidocaine may cause significant increases in blood levels with each repeated dose because of slow accumulation of the drug or its metabolites. Tolerance to elevated blood levels varies with the status of the patient. Debilitated, elderly patients, acutely ill patients, and children should be given reduced doses commensurate with their age and physical status. Lidocaine should also be used with caution in patients with severe shock or heart block.

Lidocaine should be used with caution in patients with known drug sensitivities. Patients allergic to para-aminobenzoic acid derivatives (procaine, tetracaine, benzocaine, etc.) have not shown cross sensitivity to lidocaine.

Many drugs used during the conduct of anesthesia are considered potential triggering agents for familial malignant hyperthermia. Since it is not known whether amide-type local anesthetics may trigger this reaction and since the need for supplemental general anesthesia cannot be predicted in advance, it is suggested that a standard protocol for management should be available. Early unexplained signs of tachycardia, tachypnea, tachyphylaxis, lability blood pressure, and metabolic acidosis may precede the onset of malignant hyperthermia. Successful outcome is dependent on early diagnosis, prompt discontinuance of the suspect triggering agent(s) and institution of treatment, including oxygen therapy, indicated supportive measures and dantrolene (consult dantrolene sodium intravenous package insert before using).

Information for Patients

When topical anesthetics are used in the mouth, the patient should be aware that the production of topical anesthesia may impair swallowing and thus enhance the danger of aspiration. For this reason, food should not be ingested for 60 minutes following use of local anesthetic preparations in the mouth or throat area. This is particularly important in children because of their frequency of eating.

Numbness of the tongue or buccal mucosa may enhance the danger of unintentional biting trauma. Food and chewing gum should not be taken while the mouth or throat area is anesthetized.

Carcinogenesis—Long-term studies in animals have not been performed to evaluate the carcinogenic potential of lidocaine.

Mutagenesis—The mutagenic potential of lidocaine has been tested in the Ames Salmonella reverse mutation assay, in an in vitro chromosome aberrations assay in human lymphocytes and in an in vivo mouse micronucleus assay. There was no indication of any mutagenic effect in these studies.

Impairment of Fertility: The effect of lidocaine on fertility was examined in the rat model.

Administration of 30 mg/kg, i.e., (180 mg/m²) to the mating pair did not produce alterations in fertility or general reproductive performance of rats. There are no studies that examine the effect of lidocaine on sperm parameters.

There was no evidence of altered fertility.

Use in Pregnancy

Teratogenic Effects: Pregnancy Category B

Reproduction studies for lidocaine have been performed in both rats and rabbits. There was no evidence of harm to the fetus at subcutaneous doses of up to 50 mg/kg lidocaine (300 mg/m² on a body surface area basis) in the rat model. In the rabbit model, there was no evidence of harm to the fetus at a dose of 5 mg/kg, i.e., (30 mg/m² on a body surface area basis). Treatment of rabbits with 25 mg/kg (300 mg/m³) produced evidence of maternal toxicity and evidence of delayed fetal development, including a non-significant decrease in fetal weight (7%) and an increase in minor skeletal anomalies (skull and skeletal deformity, reduced ossification of the phalanges). The effect of lidocaine on post-natal development was examined in rats by treating pregnant female rats daily subcutaneously at doses of 2, 10, and 50 mg/kg (12, 60, and 300 mg/m³) from day 15 of pregnancy and up to 20 days post partum. No signs of adverse effects were seen even in doses in the rats up to and including the dose of 10 mg/kg (60 mg/m³); however, the number of surviving pups was reduced at 50 mg/kg (300 mg/m³), both at birth and the duration of lactation period, the effect most likely being secondary to maternal toxicity. No other effects on litter size, litter weight, abnormalities in the pups and physical developments of the pups were seen in this study.

A second study examined the effects of lidocaine on post-natal development in the rat that included assessment of the pups from weaning to sexual maturity.

Rats were treated for 8 months with 10 or 30 mg/kg, i.e., lidocaine (60 mg/m² and 180 mg/m² on a body surface area basis, respectively). This time period encompassed 3 mating periods. There was no evidence of altered post-natal development in any offspring, however, both doses of lidocaine significantly reduced the average number of pups per litter surviving until weaning of offspring from the first 2 mating periods.

There are, however, no adequate and well-controlled studies in pregnant women. Because animal reproduction studies are not always predictive of human response, this drug should be used during pregnancy only if clearly needed.

Labor and Delivery

Lidocaine is not contraindicated in labor and delivery. Should LIDO be used concomitantly with other products containing lidocaine, the total dose contributed by all formulations must be kept in mind.

Nursing Mothers

Lidocaine is secreted in human milk. The clinical significance of this observation is unknown. Caution should be exercised when lidocaine is administered to a nursing woman.

Pediatric Use

Although, the safety and effectiveness of LIDO in pediatric patients have not been established, a study of 19 premature neonates (gestational age <33 weeks) found no correlation between the plasma concentration of lidocaine or monoocthydroxy-lidocaine and infant body weight when moderate amounts of lidocaine (i.e. 0.3 ml/kg of lidocaine gel 20 mg/m³) were used for lubricating both intranasal and endotracheal tubes. No neonate had plasma levels of lidocaine above 750 mg/m³. Doses in children should be reduced, commensurate with age, body weight, and physical condition. (See DOSAGE AND ADMINISTRATION.)

ADVERSE REACTIONS

Adverse experiences following the administration of lidocaine are similar in nature to those observed with other amide local anesthetic agents. These adverse experiences are, in general, dose-related and may result from high plasma levels caused by excessive dosage or rapid absorption, or may result from a hypersensitivity, idiosyncrasy, or diminished tolerance on the part of the patient. Serious adverse experiences are generally systemic in nature. The following types are those most commonly reported:

There have been rare reports of endotracheal tube occlusion associated with the presence of dried jelly residue in the inner lumen of the tube. (See also WARNINGS and DOSAGE AND ADMINISTRATION.)

Central Nervous System

CNV manifestations are excoriatory and/or depressed and may be characterized by light-headedness, nervousness, apprehension, dizziness, drowsiness, tremor, blurring or double vision, vomiting, sensations of heat, cold or numbness, twitching, tremors, convulsions, unconsciousness, respiratory depression, and arrest. The excoriatory manifestations may be very brief or may not occur at all, in which case the first manifestation of toxicity may be drowsiness merging into unconsciousness and respiratory arrest.

Drowsiness following the administration of lidocaine is usually an early sign of a high blood level of the drug and may occur as a consequence of rapid absorption.

Cardiovascular System

Cardiovascular manifestations are usually depressant and are characterized by bradycardia, hypotension, and cardiovascular collapse, which may lead to cardiac arrest.

Allergic

Allergic reactions are characterized by cutaneous lesions, urticaria, edema, or anaphylactoid reactions. Allergic reactions may occur as a result of sensitivity either to the local anesthetic agent or to other components in the formulation. Allergic reactions as a result of sensitivity to lidocaine are extremely rare and, if they occur, should be managed by conventional means. The detection of sensitivity by skin testing is of doubtful value.

OVERDOSAGE

Acute emergencies from local anesthetics are generally related to high plasma levels encountered during therapeutic use of local anesthetics. (See ADVERSE REACTIONS, WARNINGS, and PRECAUTIONS.)

Management of Local Anesthetic Emergencies

The first consideration is prevention, best accomplished by careful and constant monitoring of cardiovascular and respiratory vital signs and the patient’s state of consciousness after each local anesthetic administration. At the first sign of change, oxygen should be administered.

The first step in the management of convulsions consists of immediate attention to the maintenance of a patent airway and assisted or controlled ventilation with oxygen and a delivery system capable of permitting immediate positive airway pressure by mask. Immediately after the institution of these ventilatory measures, the adequacy of the circulation should be evaluated, keeping in mind that drugs used to treat convulsions sometimes depress the circulation when administered intravenously. Should convulsions persist despite adequate respiratory support, and if the status of the circulation permits, small increments of an ultra-short acting barbiturate (such as thiopental or thiamyl) or a benzodiazepine (such as diazepam) may be administered intravenously. The clinician should be familiar, prior to use of local anesthetics, with these anticonvulsant drugs. Supportive treatment of circulatory depression may require administration of intravenous fluids and, when appropriate, as a vasopressor as directed by the clinical situation (e.g., ephedrine).

If not treated immediately, both convulsions and cardiovascular depression can result in hypoxia, acidosis, bradycardia, arrhythmias, and cardiac arrest. If cardiac arrest should occur, standard cardiopulmonary resuscitative measures can be instituted.

Dialysis is of negligible value in the treatment of acute overdose with lidocaine.

The oral LD₅₀ of lidocaine HCl in non-fasted female rats is 459 (246 to 773) mg/kg (as the salt) and 214 (159 to 234) mg/kg (as the salt) in fasted female rats.

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Data feedback is not enough to change care

T
he work of Kaplan and associates from UCLA, highlighted in this issue (page 1), provides a sobering reminder of the difficulties in changing physician practice. Briefly, the authors found that data feedback, in this case adherence to AHP management protocols, was insufficient—as the sole strategy—to improve care more than modestly.

Data feedback has assumed a prominent role in quality improvement efforts in health care, with varying success. Data dashboards are frequently used by clinical and operational leaders to inform decisions about quality improvement targets. This feedback is an integral part of the “Plan-Do-Check-Adjust” cycle of quality improvement.

Data feedback directly to physicians and other providers, however, is often less effective. We have seen all monitors or posters displaying time since the last accident at work, monthly adherence to hand-washing, rate of re-admission within 30 days for this or that diagnosis, or similar metrics. There is no doubt that in some cases—where the barriers to quality improvement are minimal and the physician motivation to change practice exceeds the reasons not to do so—these simple data feedbacks can induce impressive improvements. In other settings, including that of Kaplan and associates, data feedback alone is not adequate.

A more effective method to use data feedback in quality improvement is to use it as only the first step in a more comprehensive program. What is most impactful is collaborative provider engagement and intervention that is based on the data. After identifying gaps in physician performance (which is where data feedback to individual physicians stops), a highly functioning quality collaborative then goes on to devise and implement strategies to improve performance by using factors associated with high performance to create care pathways or other clinical interventions. Interventions are then implemented with particular attention to helping low performers overcome their personal and systemic barriers. Such a system is used in successful quality collaboratives such as the Michigan Urologic Surgery Improvement Collaborative (MUSIC), and is being started in the AUA Quality (AQUA) Registry (see “First national urology-wide registry gathers steam,” May 2017, page 1).
**BLOG**

**Burnout, biopsy, BPH, and more: Dr. Rosevear’s post-AUA review**

This year’s AUA annual meeting provided some great teaching points. For Henry Rosevear, MD, those included: Burnout is real, and exercise is one way to prevent it. MRI-ultrasound fusion technology for prostate biopsy is impressive, but cost is a major hurdle. And PD-1 inhibitors for bladder cancer are similarly impressive—and similarly costly.

READ MORE OF DR. ROSEVEAR'S POST-AUA MUSINGS AT: urologytimes.com/rosevear

**AACU LEGISLATIVE UPDATE**

**Drug importation: Shortsighted and ineffective**

In the face of mounting pressure to keep prescription drug costs down, an increasing number of legislators are addressing drug costs in a variety of ways. One method gaining traction in Washington is drug importation. As alluring as it may seem at first glance, importation is as dangerous as it is ineffective, writes the AACU’s Ally Lopshire.

urologytimes.com/AACU

**BLOG**

**A chief urology resident’s 7 lessons in leadership**

With her residency coming to a close, *Urology Times* blogger and chief resident Amy Pearlman, MD, says developing as a leader has proven difficult to master. “I have come to realize that my sense of what being an effective leader entailed could not have been further from the truth,” she writes. Dr. Pearlman outlines seven lessons of “her new truth.”

urologytimes.com/leadership-lessons

**UT FOLLOWER OF THE MONTH**

**@HAUROFPFR**

Himanshu Aggarwal, MD, urologist in Montgomery, AL, is the *Urology Times* Twitter follower of the month! To be featured in this section, engage with us.

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**MAY’S QUESTION OF THE MONTH**

Does telemedicine have a future in urology?

- Yes: 51%
- No: 33%
- Not sure: 16%

**QUESTION FOR JUNE**

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Hospital ratings correlate with Ca surgery outcomes
Information could guide hospital choice for major urologic cancer surgery

Wayne Kuznar
UT CORRESPONDENT

Boston—Medicare beneficiaries who undergo major urologic cancer surgery at hospitals with higher Hospital Compare Star Ratings introduced by the Centers for Medicare & Medicaid Services (CMS) in 2016 have short-term outcomes that are superior to those of patients operated on at hospitals with a lower Hospital Compare rating, according to data presented at the AUA annual meeting in Boston.

The finding suggests a potential role for these ratings in guiding choice of hospital for major cancer surgery, said lead investigator Deborah Kaye, MD.

“We were really surprised by these findings. We set out to say basically that these rankings mean nothing but then we had this finding, and we did multiple sensitivity analyses across everything we could possibly think of, and the results still came up that they correlated,” said Dr. Kaye, a urologic oncology fellow at the University of Michigan, Ann Arbor, working with David C. Miller, MD, MPH, and colleagues.

The best way for patients to determine where to obtain hospital-based care remains a topic of debate in the lay press and the scientific literature. The stated goal for CMS’s Hospital Compare Star Rating System is to help patients make more informed health care decisions.

The program assigns hospitals a star rating ranging from 1 (lowest score) to 5 (highest score). The star rating system is a composite measure comprised of 64 possible measures based on seven health areas (general information, survey of patients’ experiences, timely and effective care, complications, readmissions and deaths, use of medical imaging, and payment and value of care). The summary score is a weighted average of each category.

To receive a star rating, a hospital has to report a minimum of three measures in at least three categories, including one of the outcomes categories. CMS calculates a hospital star rating in only the measures on which the hospitals choose to report.

The ratings are publicly available on the Hospital Compare website (www.medicare.gov/hospitalcompare/).

“How the star ratings have the benefit of being publicly available, they have also been criticized as being inaccurate, and there’s little data to validate whether the star ratings reflect patient outcomes,” Dr. Kaye said.

“We identified similar relationships [between outcome and star rating] across individual procedures.”

DEBORAH KAYE, MD

Her group evaluated whether CMS’s Hospital Compare Star Rating is associated with short-term outcomes after major cancer surgery. They used national Medicare claims data from the American Hospital Association annual survey and CMS Hospital Compare data. Patients 66 to 99 years of age who underwent major prostate, bladder, or kidney cancer surgery from Jan. 1, 2011 through Nov. 30, 2013 were identified. The four surgical outcomes examined were the occurrence of 30-day rate of complications, 30-day mortality, rate of 30-day readmissions, and prolonged length of stay.

Some 122,321 patients undergoing urologic surgery at 2,147 hospitals with a 1- to 5-star rating were identified. Star ratings were as follows: 1 star: 5%, 2 stars: 24%, 3 stars: 44%, 4 stars: 25%, and 5 stars: 3%.

These ratings corresponded roughly with patients’ ratings. A greater share of patients at 5-star hospitals was Caucasian, and patients managed at 5-star hospitals tended to have fewer comorbidities. Five-star hospitals were less likely to be located in the Northeast, were larger, were more likely nonprofit, and less likely to be a teaching hospital.

Outcomes differ between 1-, 5-star hospitals

In unadjusted analyses, a significant inverse association was observed between CMS star ranking and the occurrence of all four adverse outcomes. In adjusted analyses, the differences in all outcomes between 1- and 5-star hospitals were significant, except for 30-day complication rates.

The 30-day complication rate for 1-star hospitals was 34% compared with 28% for 5-star hospitals (p=0.074), the 30-day readmission rate was 11% vs. 8% (p<0.001), the 30-day mortality rate was 1.7% vs. 0.6% (p<0.001), and prolonged length of stay was experienced by 6% vs. 3% (p<0.001), respectively.

The relationship between outcome and star rating was fairly small, said Dr. Kaye, but could serve as a guide for patients who have no other information on which to base a choice.

“We identified similar relationships across individual procedures,” she said. “Additional research is required to determine whether the star ratings accurately reflect other star measures of quality of urologic cancer care.”

Clinical Updates

Prostate Cancer page 7
Infertility page 10
BPH page 12

For up-to-date news, visit urologytimes.com/InBrief

Web information linked to PCa treatment regret

Men who use the Internet as their primary source for prostate cancer treatment decision-making are more likely to regret those decisions a year after treatment than those whose primary sources of information are radiation oncologists or urologists.

That finding is based on a new study of men with favorable-risk prostate cancer who were treated with radiation therapy. The results were presented at the Genitourinary Cancers Symposium in Orlando, FL. For more, go to www.urologytimes.com/PCa-regret.
The genomic Decipher test, which predicts metastasis risk after radical prostatectomy, influences providers’ decision-making for post-surgery adjuvant and salvage treatment, according to research presented at the AUA annual meeting in Boston.

“The Decipher test is unique in that it applies a genomic signature to the prediction of clinical metastases at 5 years post-prostatectomy,” said presenting author John L. Gore, MD, MSHS, associate professor of urology at the University of Washington School of Medicine and affiliate investigator at the Fred Hutchinson Cancer Research Center, Seattle. “It is not the first genomic test, but most of the available tests are being applied in the pre-treatment space, to either reassure patients about active surveillance or support decisions to undergo definitive treatment. This test, in our study, is being applied to the clinical situations where patients and their providers are trying to navigate complex decisions regarding adjuvant and salvage therapy after prostatectomy.”

“From our results, the Decipher test helps reassure low-risk patients that observation may be warranted or confirm that high-risk patients need additional treatment.”

JOHN L. GORE, MD, MSHS

Dr. Gore and colleagues studied 150 patients considering adjuvant radiation therapy and 115 patients considering salvage radiation therapy. Providers caring for these patients submitted their recommendations for management before processing the Decipher test and again after receiving the test’s results. The patients submitted validated surveys on prostate cancer-specific quality of life, decision quality, and prostate cancer-related anxiety, according to the study’s abstract.

Researchers found that the test influences providers’ management recommendations. Low-risk patients, based on the Decipher test, are more likely to receive observation recommendations. High-risk patients are more likely to receive recommendations to undergo adjuvant or salvage treatments, usually with radiation therapy, according to Dr. Gore.

More specifically, prior to the Decipher test, providers recommended observation for 89% of adjuvant patients and 58% of salvage patients. Post Decipher, 18% of treatment recommendations changed in the adjuvant group, including 31% of high-risk Decipher patients, and 32% of providers’ recommendations changed in the salvage group, including 56% of high-risk Decipher patients, the study found.

Higher perceived decision quality observed

Researchers also found that the inclusion of the Decipher test in clinical care was associated with higher perceived decision quality among patients and providers.

“In other words, patients who see their Decipher score, and providers who see their patients’ Decipher scores, have less uncertainty about their treatment recommendations,” Dr. Gore told Urology Times.

Administering the test, according to Dr. Gore, is not time consuming. It is a send-out test, however, so it might require an additional communication with the patient to review implications of the test results, he said.

“The main indication discussed in our study is to help guide men considering adjuvant radiation therapy, when they have high-risk features at the time of radical prostatectomy, [such as] nonorgan-confined prostate cancer or positive margins, [as well as] when their PSA is rising after prostatectomy. From our results, the Decipher test helps reassure low-risk patients that observation may be warranted or confirm that high-risk patients need additional treatment,” Dr. Gore said.
Adding RRP to castration linked to survival improvement
Gains in cancer-specific, overall survival observed at 10 and 20 years

Cheryl Guttman Krader
UT CONTRIBUTING EDITOR

Analyses of outcomes after long-term follow-up of men with pathologic node-positive prostate cancer (pN+ PCa) show the addition of radical retropubic prostatectomy (RRP) to surgical castration and pelvic lymphadenectomy is associated with improved cancer-specific and overall survival, according to findings of a retrospective matched-cohort study presented at the AUA annual meeting in Boston.

“Because there is unmeasured selection bias and confounding that we cannot account for in an observational study, our findings would need to be confirmed with a randomized clinical trial in order to confidently recommend radical prostatectomy as the standard of care for men with node-positive prostate cancer,” said Bimal Bhindi, MD, a Society of Urologic Oncology fellow at Mayo Clinic, Rochester, MN.

“Considering the data and our study’s strengths and while awaiting a definitive clinical trial, however, we believe that aggressive loco-regional resection may be worth considering in well-selected patients as a part of a multimodal approach in the management of men with node-positive prostate cancer,” added Dr. Bhindi, working with R. Jeffrey Karnes, MD, and colleagues.

Men included in the study had a minimum potential follow-up of 20 years. They were identified from among those diagnosed between 1967 and 1995 with pN+ PCa on pelvic lymphadenectomy who underwent early bilateral orchietomy alone (382 men) or with RRP (79 men). The latter 79 men were matched 1:1 with men having orchietomy alone based on age, year of surgery, clinical grade, clinical stage, number of positive nodes, and preoperative PSA (available for 34 men in each group; median value, 51.4 ng/mL).

Of the 158 men included in the study, 146 (92%) were followed until death. Among men undergoing orchietomy only, 76 men died, including 60 from prostate cancer. In the RRP plus orchietomy group, 70 men died during follow-up, including 28 from prostate cancer.

Survival significantly higher with combination
In Kaplan-Meier analysis, cancer-specific survival was significantly higher in the RRP plus orchietomy cohort compared to the orchietomy alone group at both 10 years (79% vs. 35%) and 20 years (59% vs. 18%). Overall survival was also significantly better in the RRP plus orchietomy group compared with the orchietomy alone group at both 10 years (66% vs. 27%) and 20 years (22% vs. 9%).

In Cox regression analyses, men who underwent RRP plus orchietomy had a 72% lower risk of prostate cancer-specific death and 52% lower risk of death from any cause compared with the cohort that had orchietomy only. Kaplan-Meier and Cox regression analyses that included only men with preoperative PSA data available generated results that were similar to those obtained for the entire study group.

The research, which is in press in the Journal of Urology, represents an update to an analysis of the same cohort that was published in 1999 (J Urol 1999; 161:1223-7). The earlier study found overall and cancer-specific survival advantages at 10 years in the RRP plus orchietomy group. Adding RRP to orchietomy did not significantly improve survival at 5 years in the subgroup of men with preoperative PSA available.

“There were fewer events in the earlier study due to the shorter duration of follow-up, and so it may have lacked sufficient power to detect statistically significant differences between groups in the subset of patients with PSA available,” Dr. Bhindi told Urology Times. “In this updated analysis, added RRP was significantly associated with improved cancer-specific and overall survival outcomes even among the subset with PSA available.

“Adds Hristo Stamenov, MD, PhD, who presented the results, ‘there is the need for further clinical trials to confirm the results of this study. However, it would be unethical to perform such trials without adding RRP to orchietomy.”

The authors also noted that although medical androgen deprivation therapy is now used more commonly than surgical castration, they believe their findings can be generalized to the current era because there is no strong evidence suggesting efficacy differences between surgical and medical castration.

UT STAT
Post Decipher, 18% of treatment recommendations changed in the adjuvant group, including 31% of high-risk Decipher patients.

PCa TEST

continued from page 7

Dr. Gore and colleagues are completing their analysis of the data from follow-up visits to evaluate the treatments that were actually received among study patients and their follow-up decision quality. They also will assess the impact of prostate cancer-specific quality of life on the treatment decisions and decision quality outcomes that they observed, he said.

But while the test appears to improve provider and patient confidence, it has yet to prove it leads to better outcomes.

“We have not yet proven that the decisions made on the basis of these genomic tests are the ‘correct’ decisions. That is, when we make a decision to observe a rising PSA, is that associated with better health outcomes? And when we make a decision to treat someone with adverse features at the time of radical prostatectomy, is that associated with better health outcomes?” Dr. Gore said. “That requires a comparison of patients who view their Decipher test results with those whose adjuvant and salvage therapy decisions are informed by clinical and pathological variables alone.”

GenomeDx Biosciences provided funding for the study. Several of Dr. Gore’s co-authors are employees, consultants/advisers, investigators, board members/officers/trustees, and/or have an investment interest in GenomeDx Biosciences.
Hypothermia during RARP: No significant benefit seen
Single-surgeon study success not replicated in randomized controlled trial

Cheryl Guttman Krader
UT CONTRIBUTING EDITOR

Although theory and preliminary clinical data indicated that intraoperative regional hypothermia could improve the return to potency and continence after robot-assisted radical prostatectomy (RARP), the intervention did not have any significant benefits when put to the more rigorous test of a randomized controlled trial.

Results of the latter investigation, however, did underscore the critical role of surgeon skill in the post-RARP course of recovery, reported researchers from the University of California, Irvine (UCI), at the European Association of Urology annual congress in London.

“Most single-surgeon studies report that advancing age is an independent factor for delaying return of continence and reducing overall continence rates following RARP, and it is believed that inflammation is the key mediator for these outcomes, with the presumption being that older men do not recover from the inflammation induced by surgical trauma as well as younger patients. The idea for regional hypothermia is to provide a local anti-inflammatory effect, and we found it had benefit in a single-surgeon study,” said Linda Huynh, BS, assistant research specialist in urology at UCI.

“With further evaluation, however, in a multinational randomized controlled trial involving five high-volume surgeons recruited from outside of our institution, any potential benefit of hypothermia was overwhelmed by the consequences of significant individual surgeon outcome. These results are hypothesis-generating. They suggest that surgeon skill dwarfs the impact of anti-inflammatory action from regional hypothermia and that minimizing surgical trauma is much more effective than accepting the trauma and trying to preemptively prevent the inflammatory process with hypothermia,” Huynh added.

The technology used for regional hypothermia during RARP was developed and patented by researchers in the UCI department of urology in 2009. It consists of an endorectal cooling balloon that circulates 4°C saline in the rectum to reduce the local tissue temperature to about 20°C during RARP.

Thomas Ahlering, MD, professor and vice chairman of urology at UCI, performed all of the procedures in the single-surgeon study. Young Hwii Ko, MD, a visiting research professor from Korea, was lead author of the study that included 930 non-high risk men who underwent nerve-sparing RARP. The population was comprised of two sequentially operated series, the first including 464 men who had a standard, normal thermic procedure and the next 466 who received regional hypothermia. All men had a minimum follow-up of 12 months post-RARP.

Postoperative potency was defined by data from the 5-item International Index of Erectile Function (IIEF-5) questionnaire and required a score >17. Return of continence was defined as being pad-free. Outcomes were analyzed with men divided into two groups defined based on age and preoperative IIEF-5 scores. Group 1 included men aged <66 years with an IIEF score of 22-25. Group 2 was comprised of men who were aged ≥66 years or who were younger but had an IIEF-5 score of 17-21.

IEF-5 score improvement observed
Linear regression analysis showed that in both groups, regional hypothermia significantly improved IIEF-5 scores at all postoperative time intervals, and it was also associated with significantly earlier time to pad-free continence.

“The positive results in the single-surgeon study prompted us to conduct a randomized controlled trial,” said Huynh. “In all randomized controlled trials investigating the value of surgical devices, however, individual surgeon skill exists as an unknown confounding variable.”

In the adjusted analysis of data from the randomized controlled trial, regional hypothermia improved potency and continence outcomes only for the subgroup of patients operated on by one of the five surgeons.

Dr. Ahlering told Urology Times, “For the single-surgeon study, Dr. Ko performed a superlative statistical analysis of our database. The results confirmed our previous finding and validated our concept about regional hypothermia, which helped us intellectually. In the randomized controlled trial, however, the benefit did not apply to most surgeons.

“We believe the explanation is that the anti-inflammatory benefit of regional hypothermia manifests if the surgery is technically well done. If the surgeon is too rough and causes too much iatrogenic trauma, regional hypothermia provides no measurable benefit, not even a trend.”

Infertility
Cost-per-pregnancy lower with banking vs. microTESE/ART

Cryopreservation is a far more cost-effective fertility preservation strategy than post-treatment surgical sperm extraction and assisted reproductive technology (ART) for men with testis cancer undergoing chemotherapy or radiation therapy, according to an analysis conducted by urologists at Emory University, Atlanta.

“Too often, men with testis cancer are deciding not to cryopreserve sperm because they are being misinformed about the cost of cryopreservation, the recovery of spermatogenic function after cancer therapy, or the success rates for ART. They are being told that sperm cryopreservation is expensive, and microdissection testicular sperm extraction (microTESE) combined with ART is a reliable option if they have no sperm in the ejaculate after completing cancer therapy,” said senior author Akanksha Mehta, MD, MS, senior associate and health services scholar in urology at Emory.

Banking confers psychological benefit
“Our research shows that sperm is not always found at the time of microTESE among testis cancer survivors, and even if it is, banking sperm upfront has a far lower cost-per-pregnancy than microTESE combined with ART, even when sperm is banked for several years. Therefore, we encourage physicians to consistently counsel patients to bank sperm. It is not only more cost-effective, but men will benefit psychologically knowing they have sperm in the bank before beginning gonadotoxic treatment.”

The analysis, presented at the AUA annual meeting in Boston, was performed using a decision tree constructed with the TreePlan add-in for Microsoft Excel. Cost-effectiveness
IT TAKES INSIGHT TO SEE THAT NO TWO STONE PATIENTS ARE ALIKE.

THAT’S THE DIFFERENCE BETWEEN MAKING DEVICES AND MAKING PROGRESS.

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Jeffrey Leow, MBBS, MPH

The use of robot-assisted simple prostatectomy (RASP) is increasing for the management of BPH in the United States. Patients were nearly seven times more likely to undergo RASP in 2011-2015 compared to 2003-2006, after adjusting for confounders.

“The robotic approach has gained steady traction across the years, from 1.5% in 2003 to over 10% in 2015, overtaking pure laparoscopy as the main [minimally invasive surgical] method of performing simple prostatectomy in the United States in 2010,” said Jeffrey Leow, MBBS, MPH, at the AUA annual meeting in Boston.

The analysis found that “there was also a decreasing trend in number and proportion of open simple prostatectomies” said Dr. Leow, urology resident at Tan Tock Seng Hospital, Singapore, and research fellow at the Center for Surgery and Public Health, Brigham and Women’s Hospital, Boston, working with Jesse Sammon, DO, and co-authors.

The growing popularity of holmium laser enucleation of the prostate (HoLEP) probably explains the stable rate of total simple prostatectomies over the study period. Guidelines from the AUA in 2014 and the European Association of Urology in 2017 for men with symptomatic BPH recommend simple prostatectomy or HoLEP, especially for prostate volumes >80 grams.

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Vibration therapy promising for treating stone fragments

51% stone-free rate observed by week 5 of prospective, randomized, controlled trial

External physical vibration lithecbole (EPVL) may be the ideal adjunct to retrograde ureteroscopic treatment of renal stones in trying to render patients free of stone fragments. This is based on a prospective, randomized, controlled trial performed at eight different centers in China that demonstrated a 51% increase in the stone-free rate by week 5. The findings were published in the Journal of Urology (2017; 197:1289-95).

Several hundred thousand extracorporeal shock wave lithotripsy (ESWL) and ureteroscopic stone extraction procedures are performed each year in the United States. Depending upon the size, location, and composition of the original stone, residual fragments may be noted in as many as 50% of the patients and are a major risk factor for stone recurrence and stone growth. Residual stone fragments cause infection, pain, renal dysfunction, ER visits, and secondary procedures. Clearly, the removal of residual fragments is a major challenge in kidney stone management.

In this study, Wu et al randomized 173 patients (128 men, 45 women) with residual stone fragments <4 mm in size, 1 week after ureteroscopy, including 87 patients who underwent EPVL and 86 patients who served as controls. Both groups were advised to increase their hydration and activity level, and to use inversion therapy in case of lower pole fragments.

The EPVL apparatus includes a table with a built-in oscillator (with adjustable frequency and magnitude of the vibration) that can be tilted. The second component is a handheld oscillator

**In addition to the accelerated stone passage, the ongoing hematuria and urinary leukocytosis were lower in the EPVL group at week 3 and 5, presumably because there were fewer fragments left to cause these symptoms.**

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The EPVL apparatus includes a table with a built-in oscillator (with adjustable frequency and magnitude of the vibration) that can be tilted. The second component is a handheld oscillator that can deliver multi-directional vibration of variable amplitude, frequency, and power. With the patients in supine or prone or lateral position, the fragment is repositioned with the help of multidirectional vibrations and is monitored real time with an ultrasound as it passes the ureter into the bladder. The entire procedure took about 20 minutes, and 41 patients (47%) required a second EPVL procedure if there were still some stones fragments noted by week 2.

**Significant increase in stone-free rate seen**

There was a significant and sustained increase in the stone-free rates at weeks 2, 3, and 5 (based on KUB or US or computed tomography scan) between controls and the EPVL group at week 2: 31% versus 53%; week 3: 51% versus 71%; week 5: 59% versus 90%. Most of the benefit was noted in patients with lower pole, renal pelvis, or with multiple fragments. There was no difference in stone-free rates for patients with upper or middle calyceal fragments, but the fragments were expelled earlier in the EPVL group.

In addition to the accelerated stone passage, the ongoing hematuria and urinary leukocytosis were lower in the EPVL group at week 3 and 5, presumably because there were fewer fragments left to cause these symptoms. The procedure requires no anesthesia as it is totally noninvasive and appears to be well tolerated as no side effects related to EPVL were reported. Other studies have reported variable degree of success while using interventions such as inversion, activity, percussion, medications, and hydration. The current study appears to combine several of these measures into one and more importantly, EPVL appears to be an active intervention that monitors the propulsion of the fragments into the ureter/bladder during the procedure. These authors had previously reported similarly improved outcomes with use of EPVL after ESWL (J Urol 2015; 195:965).

While some questions remain about the use of imaging modality (KUB, US), the length of follow-up beyond 5 weeks, and any complications in the control group, this approach (once validated and externally reproducible) has the potential to significantly reduce the morbidity associated with upper tract stone management.
Verbal anesthesia: How it’s used in urologic procedures

‘Conversational distraction’ offers clinical, efficiency benefits to patients and physicians

Steven N. Gange, MD ▪ Neil Baum, MD

A number of favorable patient and physician factors have led urologists to consider performing procedures in an office setting. The success of procedures conducted in this venue requires that patients have a safe and comfortable experience without impacting the quality of their outcome. Once established in this treatment pattern, the physician stands to gain efficiency, possible revenue enhancement, and overall satisfaction.

This article will discuss the adjunctive role of verbal anesthesia in easing the urology patient’s in-office procedure experience.

Many diagnostic and therapeutic urologic procedures can be performed easily and safely in the office, with limited anesthesia administration. In-office procedures offer many benefits to patients and also to physicians. While adult diagnostic flexible cystoscopy, vasectomy, and transrectal ultrasound-guided biopsy are almost uniformly performed in urology offices, other procedures such as neuromodulation, endoscopic injections, transurethral resection of bladder tumor, minimally invasive surgical therapy for BPH, are increasingly performed in the office setting, often under strict local anesthesia. Despite potential advantages, some urologists are hesitant to expand their in-office procedural offerings.

Patients appreciate some unique benefits of in-office procedures. The average patient is already comfortable in the office and with the office staff, and may perceive a surgical facility as intimidating. Typically, for procedures performed in the office, there is no required fasting period, no needle sticks for labs or IV placement, and less paperwork. From a financial standpoint, patient co-pays and out-of-pocket costs are typically lower for in-office procedures. Also, since many urologic procedures can be done under strict local anesthesia (without sedation), this allows patients with significant comorbidities to complete an in-office procedure with much lower risk. Finally, as opposed to strict post-anesthetic surgical facility requirements, many patients also enjoy the freedom of driving themselves home without an escort following a straightforward office procedure.

From the urologist’s standpoint, being away from the office to conduct surgical cases seriously impairs one’s efficiency. Even when a day of OR cases begins and flows as scheduled, turnover time in the hospital or ambulatory surgery center results in excessive downtime, time spent away from tasks accumulating on the office EMR, and potential lost revenue (Am J Surg 2012; 204:23-7).

What is verbal anesthesia (aka ‘vocal local’)?

Verbal anesthesia (VA) is the art of conversational distraction associated with measures to ensure a calming environment. It is commonly but haphazardly used by in-office surgeons of many disciplines, and is poorly described in the literature (Urology 2011; 77:12-6). Generally speaking, well-focused VA draws a patient’s attention away from negative stimuli, thereby reducing pain, anxiety, and stress. In so doing, VA encourages a procedural environment that helps to maintain relaxation, well-being, and comfort, enhancing and expanding the urologist’s in-office procedural armamentarium.

Good VA begins with clear preoperative communication. It is important to set patient expectations at the time of scheduling. On the procedure day, an assistant is assigned the role of “verbal anesthetist” for the case and begins to set the tone with calming conversation while rooming the patient. Furthermore, care is taken to ensure that the room temperature is made

Since many urologic procedures can be done under strict local anesthesia (without sedation), this allows patients with significant comorbidities to complete an in-office procedure with much lower risk.

Once the patient has disrobed, been properly positioned, prepped, draped (preferably with warm soap), and anesthetized as required, the procedure is undertaken. For many urologic procedures, a surgical blinding screen is advantageous, minimizing anxiety resulting from a patient seeing our large and unfamiliar instruments.

As the physician begins to work, the conversation between the verbal anesthetist and the patient is deliberately guided to something entirely unrelated to the procedure (eg, weather, family, hobbies, etc.). Along the way, specific coaching comments from the urologist will occasionally be needed. When such encouragement is offered, very selective phrases are used, such as “You will feel some cold water,” “Breathe slowly and easily,” “Try to wiggle your fingers and toes,” “Here come those noises I told you about,” and “let me know when your bladder feels full.” Stress-inducing phrases are avoided, such as “I’m going to insert the scope now,” “This is going to hurt a little,” “I’m going to fire the gun/device,” or “Hold your breath,” and use of the word “pain,” as it seems intuitive that certain words and phrases actually increase a patient’s anxiety.

Meanwhile, the more the verbal anesthetist can personalize the conversation, the more likely the patient can be effectively distracted throughout the procedure and the need for physician coaching comments reduced. Everyone in the treatment room strives to maintain a calm and peaceful environment. The aim of this standardized approach is to reduce the likelihood of surprises to the patient during the procedure. It is our experience that a well-informed and artfully distracted patient tolerates outpatient procedures better, with less anxiety and discomfort.

While VA is poorly defined and not well studied in the literature, it has become an essential adjunct in achieving patient tolerability among dentists and oral surgeons, dermatologists performing Mohs surgery, and gynecologists conducting hysteroscopy and uterine ablations. Most proceduralists, including urologists, have begun to adopt VA to some limited degree with widespread, albeit anecdotal, success.

Conclusion
VA is a simple technique of saying the right thing at the right time while avoiding words and phrases that evoke anxiety, thus creating a relaxed procedural environment by focusing a patient’s attention away from anxiety-producing stimuli and onto something more familiar. By employing VA for in-office procedures, almost any office procedure can be accomplished without adding safety concerns associated with adjunctive medications (Patient Prefer Adherence 2016; 10:147-52); “Step by step guide to verbal-anesthesia,” LondonVision Clinic 2009 [bit.ly/VAguide]. In the end, we believe that VA can be a helpful addition to the overall experience for patients undergoing local anesthetic urologic procedures.
How your practice can avoid medical necessity denials

Documentation, working knowledge of AUA guidelines among recommendations

Medical necessity denials are encountered for many reasons—a cloak of many colors. Generally, medical necessity is used to describe care that is reasonable, necessary, and/or appropriate, based on evidence-based clinical standards of care. Payer policies and legal challenges for coverage of services are based on slight variations of this general definition and of course are subject to interpretation. Payers, in earlier years, would not have dared to deny a service provided by physician as “not medically necessary.” That has gradually changed, with the changes coming exponentially in the last few years.

The practical application of medical necessity has taken many forms, and in this increasingly complex world of health care, understanding these applications has become a critical component of your business. We will explore a few of these areas in this article and outline some solutions that can be implemented in your business process.

Medical Necessity a factor in value-based pay
Although payment under fee-for-service systems is the primary focus of most medical necessity policies, value-based payment systems also rely on medical necessity for both payment comparison and as a measure of the care provided. In short, medical necessity is not going away as we move to value-based payment systems.

Some of the best-known medical necessity-based payment policies fall under published coverage policies. Medicare policies include National Coverage Decisions (NCD), Local Coverage Decisions (LCD), and non-coverage decisions included in the fee schedule. Private payers and other government payers will have published policies as well. These policies will include:
- ICD-10 restrictions indicating that services will be considered medically necessary and payable only with listed Dx codes
- ICD-10 restrictions indicating that services will not be paid for certain diagnosis codes
- Frequency restrictions indicating how often a service may be reported and paid
- Treatment restrictions indicating treatments that have been provided and failed prior to considering a service or drug as medically necessary and payable
- Time-based restrictions indicating when a service may be reported for a patient and considered medically necessary and payable in relation to other services or procedures provided
- Coverage in total indicating that a service is considered either not yet proven to be medically necessary or has proven not to be medically necessary and therefore not payable or covered as medically unnecessary (ie, new technology or drugs)
- Statutory/policy coverage exclusion indicating a service is not considered medically necessary because the service is not a part of the plan or service package as dictated by statute or by plan type (ie, cosmetic surgery and some preventive services).

Services provided that do not meet these published rules will be denied for medical necessity. Not all of these published guidelines make sense, and we have often received documents and calls pointing to the fact these guidelines do not conform to the true definition of “medically necessary.”

More recently, we have seen an increase in medical necessity denials that are not based on published policy but instead appear to be arbitrary denials that portend to be based on specialty society guidelines, standard of practice, or practice patterns. We add downcoding of services to this group of medical necessity denials. Many of these types of denials, although labeled as medical necessity denials, are actually a thinly disguised request to review medical records or hassle the physician group to avoid payment.

In any particular case, the rules may make sense or may not make sense. But as we’ve said before, “it is the way it is” and we have to learn to live with it. Yes, “cookbook medicine,” with exceptions, is here to stay.

The problem is much greater than a denied claim and lost revenue. A payer that determines that services were medically unnecessary after payment was made will ask for a refund, and if this “mistake” has been made over a number of years, they may extrapolate the mistakes discovered in the reviewed charts and factor this into a request for payment for that same percent of mistakes over many years, plus interest.

If Medicare determines that you know that you were being paid for medically unnecessary services, according to the rules, you can be prosecuted for fraud and fined up to $10,000 for each service plus three times the amount you were overpaid.

Please see NECESSITY, page 27
Indication

TECENTRIQ (atezolizumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who:

- Are not eligible for cisplatin-containing chemotherapy, or
- Have disease progression during or following any platinum-containing chemotherapy, or within 12 months of neoadjuvant or adjuvant chemotherapy

This indication is approved under accelerated approval based on tumor response rate and durability of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in confirmatory trials.

Important Safety Information

Serious Adverse Reactions

Please refer to the full Prescribing Information for important dose management information specific to adverse reactions.

Immune-Related Pneumonitis

- Immune-mediated pneumonitis or interstitial lung disease, including 2 fatal cases, occurred with TECENTRIQ treatment
- Across clinical trials, 2.6% of patients developed pneumonitis
- Monitor patients for signs with radiographic imaging and symptoms of pneumonitis. Administer steroids for ≥Grade 2 pneumonitis.
- Withhold TECENTRIQ until resolution of Grade 2 pneumonitis. Permanently discontinue for Grade 3 or 4 pneumonitis

Immune-Related Hepatitis

- Immune-mediated hepatitis, including a fatal case, and liver test abnormalities have occurred with TECENTRIQ treatment
- Across clinical trials, Grade 3 or 4 elevation occurred in ALT (2.5%), AST (2.3%), and total bilirubin (1.6%). In patients with urothelial carcinoma (UC), immune-mediated hepatitis occurred in 1.3% of patients
- Monitor patients for signs and symptoms of hepatitis. Monitor AST, ALT, and bilirubin prior to and periodically during treatment
- Administer corticosteroids for ≥Grade 2 transaminase elevations, with or without concomitant elevation in total bilirubin.
- Withhold TECENTRIQ for Grade 2 and permanently discontinue for Grade 3 or 4 immune-mediated hepatitis

PD-L1=programmed death-ligand 1.
For locally advanced or metastatic urothelial carcinoma

TECENTRIQ®: FIRST-LINE AND SECOND-LINE+ TREATMENT FOR ELIGIBLE PATIENTS

<table>
<thead>
<tr>
<th>Urothelial carcinoma patients who are eligible for TECENTRIQ</th>
<th>Locally advanced or metastatic setting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Locally advanced or metastatic setting</td>
<td>First line</td>
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<tr>
<td>Neoadjuvant or adjuvant platinum</td>
<td>TECENTRIQ</td>
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<tr>
<td>Progression ≤12 months</td>
<td>TECENTRIQ</td>
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**Important Safety Information (cont’d)**

**Immune-Related Colitis**
- Immune-mediated colitis or diarrhea, including a fatal case of diarrhea-associated renal failure, have occurred with TECENTRIQ treatment.
- Across clinical trials, colitis or diarrhea occurred in 19.7% of patients. In UC, immune-mediated colitis or diarrhea occurred in 0.8% of patients.
- Monitor patients for signs and symptoms of diarrhea or colitis. Withhold TECENTRIQ for Grade 2 or Grade 3 diarrhea or colitis. Permanently discontinue for Grade 4 diarrhea or colitis.

**Immune-Related Endocrinopathies**
- Immune-related thyroid disorders, adrenal insufficiency, hypophysitis, and type 1 diabetes mellitus, including diabetic ketoacidosis, have occurred in patients receiving TECENTRIQ. Monitor patients for clinical signs and symptoms of endocrinopathies.
- Across clinical trials, hypothyroidism occurred in 3.9% and 1.0% of patients, respectively. For symptomatic hypothyroidism, withhold TECENTRIQ and initiate hormone replacement as needed. Manage isolated hypothyroidism with replacement therapy and without corticosteroids. For symptomatic hypothyroidism, withhold TECENTRIQ and initiate an anti-thyroid drug as needed.
- Across clinical trials, adrenal insufficiency occurred in 0.4% of patients. For symptomatic adrenal insufficiency, withhold TECENTRIQ and administer corticosteroids.
- Hypophysitis occurred in 0.2% of patients with UC. Administer corticosteroids and hormone replacement as clinically indicated. Withhold for Grade 2 or Grade 3, and permanently discontinue for Grade 4 hypophysitis.
- New onset diabetes with ketoacidosis occurred in patients. Diabetes mellitus without an alternative etiology occurred in 0.2% of patients with urothelial carcinoma. Initiate treatment with insulin for type 1 diabetes mellitus. For ≥Grade 3 hyperglycemia (fasting glucose >250-500 mg/dL), withhold TECENTRIQ.

**Other Immune-Related Adverse Reactions**
- Other immune-related adverse reactions, including meningoencephalitis, myasthenic syndrome/myasthenia gravis, Guillain-Barré syndrome, ocular inflammatory toxicity, and pancreatitis, including increases in serum amylase and lipase levels, have occurred in ≤1.0% of patients treated with TECENTRIQ.
- Monitor patients for clinical signs and symptoms of meningitis or encephalitis, as well as symptoms of motor and sensory neuropathy. Permanently discontinue TECENTRIQ for any grade of meningitis or encephalitis or any grade of myasthenic syndrome/myasthenia gravis or Guillain-Barré syndrome.
- Monitor patients for signs and symptoms of acute pancreatitis. Withhold TECENTRIQ for ≥Grade 3 serum amylase or lipase levels (>2.0 ULN), or Grade 2 or 3 pancreatitis. Permanently discontinue for Grade 4 or any grade of recurrent pancreatitis.

**PD-L1 testing is not required to prescribe TECENTRIQ**
Durable responses achieved in first-line and second-line+ patients (median follow-up: 14.4 months)¹

<table>
<thead>
<tr>
<th>First-line, cisplatin-ineligible patients</th>
<th>Platinum-treated patients</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>23.5% ORR</strong></td>
<td><strong>14.8% ORR</strong></td>
</tr>
<tr>
<td>6.7% CR</td>
<td>5.5% CR</td>
</tr>
<tr>
<td>16.8% PR</td>
<td>9.4% PR</td>
</tr>
</tbody>
</table>

(n=28/119*; 95% CI, 16.2, 32.2)  
(n=46/310*; 95% CI, 11.1, 19.3)

MEDIAN DoR NOT REACHED  
(range: 3.7, 16.4+)  
(range: 2.1+, 13.8+)

* denotes censored value.
*Number of IRF-assessed confirmed responders.

**Most common adverse events (≥20%)**¹

- **Cisplatin-ineligible patients**: fatigue (52%), decreased appetite (24%), diarrhea (24%), and nausea (22%)
- **Platinum-treated patients**: fatigue (52%), decreased appetite (26%), nausea (25%), urinary tract infection (22%), pyrexia (21%), and constipation (21%)

IMvigor210 was a pivotal Phase II, multicenter, open-label, 2-cohort trial in locally advanced or metastatic urothelial carcinoma. Cohort 1: 119 patients who were ineligible for cisplatin-containing chemotherapy and were previously untreated or had disease progression >12 months after neoadjuvant or adjuvant chemotherapy. Cohort 2: 310 patients who had disease progression during or following a platinum-containing regimen, or ≤12 months of treatment with a platinum-containing neoadjuvant or adjuvant regimen. Patients were treated with TECENTRIQ 1200 mg IV q3w.

Major efficacy endpoints included ORR as assessed by IRF using RECIST v1.1 and DoR.¹,²

CI=confidence interval; CR=complete response; DoR=duration of response; IRF=independent review facility; IV=intravenous; ORR=objective response rate; PR=partial response; q3w=every 3 weeks; RECIST=Response Evaluation Criteria In Solid Tumors.

**Important Safety Information (cont’d)**

**Infection**

- Severe infections, including sepsis, herpes encephalitis, and mycobacterial infection leading to retroperitoneal hemorrhage occurred in patients receiving TECENTRIQ
- Across clinical trials, infections occurred in 38.4% of patients
- In urothelial carcinoma, infection occurred in 37.7% of patients. Grade 3 or 4 infection occurred in 11.5% of patients, while 3 patients died due to infections. Urinary tract infections were the most common cause of Grade 3 or higher infection, occurring in 7.1% of patients
- Monitor patients for signs and symptoms of infection and treat with antibiotics for suspected or confirmed bacterial infections. Withhold TECENTRIQ for ≥Grade 3 infection

**Infusion-Related Reactions**

- Severe infusion reactions have occurred in patients in clinical trials of TECENTRIQ. Infusion-related reactions occurred in 1.7% in UC
- Interrupt or slow the rate of infusion in patients with mild or moderate infusion reactions. Permanently discontinue TECENTRIQ in patients with Grade 3 or 4 infusion reactions

**Embryo-Fetal Toxicity**

- Based on its mechanism of action, TECENTRIQ can cause fetal harm when administered to a pregnant woman. Advise pregnant women or women planning to become pregnant of the potential risk to the fetus
- Females of reproductive potential to use effective contraception during treatment with TECENTRIQ and for at least 5 months after the last dose of TECENTRIQ

**Nursing Mothers**

- Because of the potential for serious adverse reactions in breastfed infants from TECENTRIQ, advise female patients not to breastfeed while taking TECENTRIQ and for at least 5 months after the last dose

**Most Common Adverse Reactions**

The most common adverse reactions in cisplatin-ineligible UC (rate ≥20%) were fatigue (52%), decreased appetite (24%), diarrhea (24%), and nausea (22%).

The most common adverse reactions (rate ≥20%) in previously treated UC were fatigue (52%), decreased appetite (26%), nausea (25%), urinary tract infection (22%), pyrexia (21%), and constipation (21%).

You may report side effects to the FDA at 1-800-FDA-1088 or www.fda.gov/medwatch. You may also report side effects to Genentech at 1-888-835-2555.

**References:**
TECENTRIQ® (atezolizumab)

Initial U.S. Approval: 2016

This is not a therapeutic summary of information about TECENTRIQ. Before prescribing, please see full Prescribing Information.

1 INDICATIONS AND USAGE

1.1 Locally Advanced or Metastatic Urothelial Carcinoma

TECENTRIQ® (atezolizumab) is indicated for the treatment of patients with locally advanced or metastatic urothelial carcinoma who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR mutation or ALK rearrangement should have these aberrations prior to receiving TECENTRIQ. [see Clinical Studies (14.2)].

1.2 Metastatic Non-Small Cell Lung Cancer

TECENTRIQ® is indicated for the treatment of patients with metastatic non-small cell lung cancer (NSCLC) who have disease progression during or following platinum-containing chemotherapy. Patients with EGFR mutation or ALK rearrangement should have these aberrations prior to receiving TECENTRIQ. [see Clinical Studies (14.2)].

2 CONTRAINDICATIONS

None.

5 WARNINGS AND PRECAUTIONS

5.1 Immune-Related Pneumonitis

Immune-mediated pneumonitis, interstitial lung disease, defined as requiring the use of corticosteroids ≥ 1 month. Resume treatment with TECENTRIQ if the event improves to Grade 0 or 1 within 12 weeks and Grade 3 diarrhea or colitis, when symptoms improve to Grade 0 or Grade 1, taper steroids over ≥ 1 month. Do not taper steroids or recurrent immune-mediated colitis or diarrhea with a median time to onset of 1.7 months (range: 1.1 to 3.1 months). Start steroid taper when symptoms improve to ≤ Grade 1 and taper steroids over ≥ 1 month. For symptomatic adrenal insufficiency, withhold TECENTRIQ and administer methylprednisolone 1–2 mg/kg per day IV followed by oral prednisone 1–2 mg/kg per day equivalent or once equivalent amounts improve to ≤ Grade 1. Taper oral prednisone to a total of 1–2 mg/kg prednisone equivalents for Grade 2 or greater immune-mediated colitis or diarrhea with a median time to onset of 1.4 months (range: 1.2 to 2.4 months). Monitor patients for symptoms of endocrinopathies.

Hyperthyroidism occurred in 1.1% (11/1027) of patients with NSCLC. Eight patients had Grade 2 and three patients had Grade 1 hyperthyroidism. The median time to onset was 3.2 months (range: 1.4 to 6.8 months). TSH was decreased and below the patient’s baseline in 17.6% (184/1027) of patients with follow-up measurements.

Necrotizing sarcoid-like vasculitis occurred in 1.4% (43/3053) of patients across clinical trials, including two patients with cutaneous sarcoidosis (2/324), one patient with hypesthesia (1/324), and one patient with pustular eruption (1/324). For symptomatic sarcoidosis, withhold TECENTRIQ and administer prednisone 1–2 mg/kg per day IV followed by oral prednisone 1–2 mg/kg per day equivalent or once equivalent amounts improve to ≤ Grade 1. Taper oral prednisone to a total of 1–2 mg/kg prednisone equivalents for Grade 2 or greater immune-mediated colitis or diarrhea with a median time to onset of 1.4 months (range: 1.2 to 2.4 months). Monitor patients for symptoms of endocrinopathies.

Hyperthyroidism occurred in 1.1% (11/1027) of patients with NSCLC. Eight patients had Grade 2 and three patients had Grade 1 hyperthyroidism. The median time to onset was 3.2 months (range: 1.4 to 6.8 months). TSH was decreased and below the patient’s baseline in 17.6% (184/1027) of patients with follow-up measurements.
6. ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the label:

- Immune-Related Pneumonitis (see Warnings and Precautions (5.6))
- Immune-Related Hepatitis (see Warnings and Precautions (5.2))
- Immune-Related Colitis (see Warnings and Precautions (5.3))
- Immune-Related Endocrinopathies (see Warnings and Precautions (5.4))
- Other Immune-Related Adverse Reactions (see Warnings and Precautions (5.5))
- Infusion (see Warnings and Precautions (5.8))
- Infusion-Related Reactions (see Warnings and Precautions (5.7))

6.1 Clinical Trials Experience

Because clinical trials are conducted under widely varying conditions, 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 may not reflect the rates observed in practice.

Urothelial Carcinoma

Cisplatin-Ineligible Patients with Locally Advanced or Metastatic Urothelial Carcinoma

The safety of TECENTRIQ was evaluated in Study 4, a multicenter, open-label, single-arm trial that included 119 patients with locally advanced or metastatic urothelial carcinoma who were ineligible for cisplatin-containing chemotherapy and were either previously untreated or had disease progression at least 12 months after nephrectomy or adjuvant chemotherapy (see Clinical Studies (14.3)). Patients received 1200 mg of TECENTRIQ intravenously every 3 weeks until unacceptable toxicity or death due to disease progression. The median duration of exposure was 15.0 weeks (range, 0.1, 52 weeks).

The most common adverse reactions (≥ 20%) were fatigue (52%), diarrhea (24%), dyspnea (22%), abdominal pain (21%), nausea (20%), and anemia (18%). The most common Grade 3–4 adverse reactions (≥ 2%) were pulmonary toxicity, urinary tract infection, anemia, diarrhea, hypertension, and metastatic disease.

Eighteen patients (15%) received an oral prednisone dose equivalent to ≥40 mg daily for an immune-mediated corticosteroid therapy and 2.6% (8/310) patients who required only hormone replacement therapy. Of these patients, the most common (≥ 1%) were intestinal obstruction, fatigue, diarrhea, urinary tract infection, anemia, acute kidney injury, and renal failure.

Immune-related adverse reactions requiring systemic corticosteroids or hormone replacement therapy occurred in 10.3% (32/310) patients, 12.6% (39/310) patients who required systemic corticosteroids, and 8.7% (27/310) patients who required only hormone replacement therapy. Six patients (0.6%) received an oral prednisone dose equivalent to >40 mg daily for an immune-mediated adverse reaction (see Warnings and Precautions (5)).

Table 1 summarizes the adverse reactions that occurred in ≥ 10% of patients treated with TECENTRIQ in Study 4.

Table 1: All Grade Adverse Reactions in ≥ 10% of Patients with Urothelial Carcinoma in Study 4

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>TECENTRIQ N = 119</th>
<th>All Grades (%)</th>
<th>Grades 3–4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>52</td>
<td>8</td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>24</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>22</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>16</td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td>15</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>15</td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>Metabolism and Nutrition Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>24</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal and Connective Tissue Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Back/Neck pain</td>
<td>18</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Arthritis</td>
<td>13</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Skin and Subcutaneous Tissue Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pruritus</td>
<td>19</td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td>17</td>
<td>0.8</td>
<td></td>
</tr>
<tr>
<td>Infections</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>17</td>
<td>5</td>
<td></td>
</tr>
<tr>
<td>Respiratory, Thoracic, and Mediastinal Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>14</td>
<td>0</td>
<td></td>
</tr>
<tr>
<td>Dyspnea</td>
<td>12</td>
<td>0</td>
<td></td>
</tr>
</tbody>
</table>

1 Includes fatigue, asthenia, lethargy, and malaise
2 Includes edema periphera, scrub edema, lymphedema, and edema
3 Includes diarrhea colitis, frequent bowel movements, abdominal colitis
4 Includes abdominal pain, upper abdominal pain, lower abdominal pain, and flank pain
5 Includes decreased appetite and early satiety
6 Includes rash, dermatitis, dermatitis acniform, rash maculo-papular, rash erythematosus, rash pruritic, rash macular, and rash papular
7 Includes urinary tract infection, urinary tract infection bacterial, cystitis, and ureasepsis
8 Includes cough and productive cough
9 Includes dyspnea and exertional dyspnea

Previous Treated Patients with Locally Advanced or Metastatic Urothelial Carcinoma

The safety of TECENTRIQ was evaluated in Study 1, a multicenter, open-label, single-arm trial that included 310 patients in a single-arm trial with locally advanced or metastatic urothelial carcinoma who had disease progression during or following at least one platinum-containing chemotherapy regimen or who had disease progression within 12 months of treatment with a platinum-containing neoadjuvant or adjuvant chemotherapy regimen (see Clinical Studies (14.4)). Patients received 1200 mg of TECENTRIQ intravenously every 3 weeks until unacceptable toxicity or death due to disease progression. The median duration of exposure was 12.3 weeks (range: 0.1, 46 weeks).

The most common adverse reactions (≥ 20%) were fatigue (52%), diarrhea (25%), urinary tract infection (22%), pruritus (21%), and constipation (21%). The most common Grade 3–4 adverse reactions (≥ 2%) were urinary tract infection, anemia, fatigue, dehydration, intestinal obstruction, urination dysfunction, hematuria, dyspareunia, acute kidney injury, abdominal pain, venous thromboembolism, sepsis, and pneumonia.

Three patients (1%) who were treated with TECENTRIQ experienced one of the following events which led to death: sepsis, cardiac arrest, myocardial infarction, respiratory failure, or respiratory distress.

Table 2: Grade 3–4 Laboratory Abnormalities in Patients with Urothelial Carcinoma in Study 4 in 1% or More of Patients

<table>
<thead>
<tr>
<th>Laboratory Test</th>
<th>Grades 3–4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphopenia</td>
<td>10</td>
</tr>
<tr>
<td>Hypoalbuminemia</td>
<td>10</td>
</tr>
<tr>
<td>Anemia</td>
<td>8</td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>7</td>
</tr>
<tr>
<td>Hyponatremia</td>
<td>6</td>
</tr>
<tr>
<td>Increased ALT</td>
<td>5</td>
</tr>
<tr>
<td>Increased AST</td>
<td>4</td>
</tr>
<tr>
<td>Increased AKP</td>
<td>3</td>
</tr>
<tr>
<td>Increased Creatine</td>
<td>2</td>
</tr>
<tr>
<td>Increased ALT</td>
<td>2</td>
</tr>
<tr>
<td>Hypomagnesemia</td>
<td>1</td>
</tr>
</tbody>
</table>

Table 3: All Grade Adverse Reactions in ≥ 10% of Patients with Urothelial Carcinoma in Study 1

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>TECENTRIQ N = 310</th>
<th>All Grades (%)</th>
<th>Grades 3–4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Gastrointestinal Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Nausea</td>
<td>25</td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Constipation</td>
<td>21</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Diarrhea</td>
<td>18</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Abdominal pain</td>
<td>17</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Vomiting</td>
<td>17</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>General Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Fatigue</td>
<td>52</td>
<td>6</td>
<td></td>
</tr>
<tr>
<td>Pyrexia</td>
<td>21</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Peripheral edema</td>
<td>18</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Infections</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Urinary tract infection</td>
<td>22</td>
<td>9</td>
<td></td>
</tr>
<tr>
<td>Musculoskeletal and Connective Tissue Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>26</td>
<td>1</td>
<td></td>
</tr>
<tr>
<td>Respiratory, Thoracic, and Mediastinal Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyspnea</td>
<td>16</td>
<td>4</td>
<td></td>
</tr>
<tr>
<td>Cough</td>
<td>14</td>
<td>0.3</td>
<td></td>
</tr>
<tr>
<td>Renal and urinary disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Hematuria</td>
<td>14</td>
<td>3</td>
<td></td>
</tr>
<tr>
<td>Skin and Subcutaneous Tissue Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Rash</td>
<td>15</td>
<td>0.3</td>
<td></td>
</tr>
</tbody>
</table>

Table 4: Grade 3–4 Laboratory Abnormalities in Patients with Urothelial Carcinoma in Study 1 in 1% or More of Patients

<table>
<thead>
<tr>
<th>Laboratory Test</th>
<th>Grades 3–4 (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Lymphopenia</td>
<td>10</td>
</tr>
<tr>
<td>Hypoalbuminemia</td>
<td>10</td>
</tr>
<tr>
<td>Anemia</td>
<td>8</td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>7</td>
</tr>
<tr>
<td>Hyponatremia</td>
<td>6</td>
</tr>
<tr>
<td>Increased ALT</td>
<td>5</td>
</tr>
<tr>
<td>Increased AKP</td>
<td>4</td>
</tr>
<tr>
<td>Increased Creatine</td>
<td>3</td>
</tr>
<tr>
<td>Increased ALT</td>
<td>2</td>
</tr>
<tr>
<td>Increased AST</td>
<td>2</td>
</tr>
<tr>
<td>Hypomagnesemia</td>
<td>1</td>
</tr>
</tbody>
</table>
NSCLC

The safety of TECENTRIQ was evaluated in Study 3, a multicenter, international, randomized, open-label trial in patients with metastatic NSCLC who progressed during or following a platinum-containing regimen, regardless of PD-L1 expression [see Clinical Studies (14.2)]. Patients received 1200 mg of TECENTRIQ (n=142) administered intravenously every 3 weeks until unacceptable toxicity or other radiographic or clinical progression or docetaxel (n=133) administered intravenously at 75 mg/m² for every 3 weeks until unacceptable toxicity, or disease progression. The median duration of exposure was 3.7 months (range: 0.9–18 months) in TECENTRIQ-treated patients and 2.1 months (range: 0.7–17 months) in docetaxel-treated patients.

The most common adverse reactions (≥20%) in patients receiving TECENTRIQ were fatigue (40%), decreased appetite (36%), dyspnea (30%), cough (30%), nausea (29%), musculoskeletal pain (22%), and constipation (20%). The most common Grade 3–4 adverse reactions (≥2%) were dyspnea, pneumonia, hypoxemia, fatigue, anemia, musculoskeletal pain, AST increase, dysphagia, and arthralgia.

Nine patients (6.3%) who were treated with TECENTRIQ experienced either pulmonary embolism (2), deep vein thrombosis (2), pneumothorax, ulcer hemorrhage, cataract secondary to dysphagia, myocardial infarction, or large intestinal perforation which led to death. TECENTRIQ was discontinued due to adverse reactions in 44% (64/142) of patients. Adverse reactions leading to interruption of TECENTRIQ occurred in 24% of patients; the most common (≥5%) were pneumonia, fever, liver function test abnormality, upper respiratory tract infection, pneumolysis, acute kidney injury, hypoxia, hypothyroidism, dyspnea, anemia, and fatigue. Serious adverse reactions occurred in 37% of patients. The most frequent serious adverse reactions (≥2%) were pneumonia, dyspnea, pleural effusion, pyrexia, and venous thromboembolism.

Table 5 summarizes adverse reactions that occurred in at least 10% of TECENTRIQ-treated patients and at a higher incidence than in the docetaxel arm. Table 6 summarizes laboratory abnormalities worsening from baseline that occurred in ≥10% of TECENTRIQ-treated patients and at a higher incidence than in the docetaxel arm.

Table 5: Adverse Reactions Occurring in ≥10% of TECENTRIQ-Treated Patients with NSCLC and at a Higher Incidence than in the Docetaxel Arm (Between Arm Difference of ≥5% [All Grades] or ≥2% [Grades 3–4]) (Study 3)

<table>
<thead>
<tr>
<th>Adverse Reaction</th>
<th>TECENTRIQ (n=142)</th>
<th>Docetaxel (n=133)</th>
<th>Percentage (%) of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>General Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pyrexia</td>
<td>18</td>
<td>0</td>
<td>13%</td>
</tr>
<tr>
<td>Infections</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Pneumonia</td>
<td>18</td>
<td>0</td>
<td>13%</td>
</tr>
<tr>
<td>Metabolism and nutrition disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Decreased appetite</td>
<td>35</td>
<td>1</td>
<td>22%</td>
</tr>
<tr>
<td>Musculoskeletal and connective tissue disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Arthralgia</td>
<td>16</td>
<td>2</td>
<td>9%</td>
</tr>
<tr>
<td>Back pain</td>
<td>14</td>
<td>0</td>
<td>9%</td>
</tr>
<tr>
<td>Psychiatric Disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insomnia</td>
<td>14</td>
<td>0</td>
<td>8%</td>
</tr>
<tr>
<td>Respiratory, thoracic and mediastinal disorders</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dyspnea</td>
<td>32</td>
<td>7</td>
<td>24%</td>
</tr>
<tr>
<td>Cough</td>
<td>30</td>
<td>0</td>
<td>25%</td>
</tr>
</tbody>
</table>

Table 6: Selected Laboratory Abnormalities Worsening from Baseline Occurring in ≥10% of TECENTRIQ-Treated Patients with NSCLC and at a Higher Incidence than in the Docetaxel Arm (Between Arm Difference of ≥5% [All Grades] or ≥2% [Grades 3–4]) (Study 3)

<table>
<thead>
<tr>
<th>Test</th>
<th>TECENTRIQ (n=142)</th>
<th>Docetaxel (n=133)</th>
<th>Percentage (%) of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>All grades</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aspartate aminotransferase</td>
<td>48</td>
<td>13</td>
<td>28%</td>
</tr>
<tr>
<td>Hypoalbuminemia</td>
<td>48</td>
<td>5</td>
<td>49%</td>
</tr>
<tr>
<td>Alkaline Phosphatase increased</td>
<td>42</td>
<td>2</td>
<td>24%</td>
</tr>
<tr>
<td>Aspartate amino transferase</td>
<td>33</td>
<td>2</td>
<td>15%</td>
</tr>
<tr>
<td>Alanine transferase increased</td>
<td>31</td>
<td>1</td>
<td>14%</td>
</tr>
<tr>
<td>Creatinine increased</td>
<td>19</td>
<td>1</td>
<td>10%</td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>16</td>
<td>2</td>
<td>11%</td>
</tr>
<tr>
<td>Hyperkalemia</td>
<td>13</td>
<td>0</td>
<td>5%</td>
</tr>
</tbody>
</table>

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. Among 375 patients in Study 1, 114 patients (31%) tested positive for treatment-emergent antibodies (TEAs) at one or more post-dose time points. Among 135 patients in Study 3, 73 patients (54.1%) tested positive for treatment-emergent ATAs at one or more post-dose time points. In Study 1, Study 3, and Study 4, the presence of ATAs did not appear to have a clinically significant impact on pharmacokinetics, safety or efficacy. Among 111 patients in Study 4, 53 patients (47.7%) tested positive for treatment-emergent ATAs at one or more post-dose time points. In Study 1, Study 3, and Study 4, the presence of ATAs did not appear to have a clinically significant impact on pharmacokinetics, safety or efficacy.

USE IN SPECIFIC POPULATIONS

6.1 Pregnancy

Risk Summary

Based on its mechanism of action, TECENTRIQ can cause fetal harm when administered to a pregnant woman [see Warnings and Precautions (5.1)]. Advise females of reproductive potential to use effective contraception during treatment with TECENTRIQ and for at least 5 months following the last dose.

Table 6: Selected Laboratory Abnormalities Worsening from Baseline Occurring in ≥10% of TECENTRIQ-Treated Patients with NSCLC and at a Higher Incidence than in the Docetaxel Arm (Between Arm Difference of ≥5% [All Grades] or ≥2% [Grades 3–4]) (Study 3)

<table>
<thead>
<tr>
<th>Test</th>
<th>TECENTRIQ (n=142)</th>
<th>Docetaxel (n=133)</th>
<th>Percentage (%) of Patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>All grades</td>
<td></td>
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</tr>
<tr>
<td>Aspartate aminotransferase</td>
<td>48</td>
<td>13</td>
<td>28%</td>
</tr>
<tr>
<td>Hypoalbuminemia</td>
<td>48</td>
<td>5</td>
<td>49%</td>
</tr>
<tr>
<td>Alkaline Phosphatase increased</td>
<td>42</td>
<td>2</td>
<td>24%</td>
</tr>
<tr>
<td>Aspartate amino transferase</td>
<td>33</td>
<td>2</td>
<td>15%</td>
</tr>
<tr>
<td>Alanine transferase increased</td>
<td>31</td>
<td>1</td>
<td>14%</td>
</tr>
<tr>
<td>Creatinine increased</td>
<td>19</td>
<td>1</td>
<td>10%</td>
</tr>
<tr>
<td>Hypokalemia</td>
<td>16</td>
<td>2</td>
<td>11%</td>
</tr>
<tr>
<td>Hyperkalemia</td>
<td>13</td>
<td>0</td>
<td>5%</td>
</tr>
</tbody>
</table>

6.2 Immunogenicity

As with all therapeutic proteins, there is a potential for immunogenicity. Among 375 patients in Study 1, 114 patients (31%) tested positive for treatment-emergent antibodies (TEAs) at one or more post-dose time points. Among 135 patients in Study 3, 73 patients (54.1%) tested positive for treatment-emergent ATAs at one or more post-dose time points. Among 111 patients in Study 4, 53 patients (47.7%) tested positive for treatment-emergent ATAs at one or more post-dose time points. Based on a population pharmacokinetic analysis, no dose adjustment of TECENTRIQ is recommended for patients with hepatic impairment [see Use in Specific Populations (8.7)].

6.3 Females and Males of Reproductive Potential

Contraception

Females

Based on its mechanism of action, TECENTRIQ can cause fetal harm when administered to a pregnant woman (see Warnings and Precautions (5.1)). Advise females of reproductive potential to use effective contraception during treatment with TECENTRIQ and for at least 5 months following the last dose.

Females

Based on animal studies, TECENTRIQ may impair fertility in females of reproductive potential while receiving treatment [see Preclinical/Nonclinical Studies (13.1)].
Measure practice safety, quality with this DIY tool
Survey determines your practice’s areas of strength, improvement opportunities

Physicians in almost all settings are facing extraordinary changes in the way health care is delivered, documented, evaluated, and reimbursed. While the pace of change in medicine is furious, it is not unique to health care and one need not look far for examples of successful and failed management of change in other industries.

A common theme in management books and courses on the subject is that an organization’s culture is a strong determinant of successful adaptation to change (bit.ly/Transformationef-

And you can even be excluded from Medicare.

Of course, you would never do anything intentionally fraudulent. Unfortunately, ignorance is not a defense. You are responsible for knowing all published rules. If CMS or a carrier, through a report, special bulletin, etc. has notified the provider community about a coverage issue, then “you should have known,” according to the law. The larger fraud cases that we have been involved with have revolved around expensive tests or drugs in which the physician profited from the provision of the service that were provided outside of published guidelines.

What can you do?

Develop a better working knowledge of the payment system. “You need to know what you need to know,” but you don’t have to become a certified coder or a billing expert. The billing system is complicated and detailed. The majority of the tasks involved in submitting a clean claim should be delegated to other members of the team. However, there are certain tasks that should not be delegated.

Familiarize yourself with AUA guidelines and standard of practice. Many of the payer “medical necessity” rules are based on guidelines and standards of practice.

Become knowledgeable enough to know whether your team is doing their job.

Document clearly the reason you provide each service. If this service is an exception to the guidelines or common standard of practice, document in detail why it was provided.

Identify all services provided and communicate the reason for the service to your billing team. No one knows better than you what services you provided and why you provided them. This is a task that should not be delegated. To avoid mistakes, this is a task you should perform.

Assign the task of verifying all ICD-10 codes as to accuracy and compliance to published policies (LCDs/NCDs) to those who are trained and have access to these guidelines. However, you will also need to implement policies that do not allow reporting of ICD-10 codes that fit policies but are not supported by the medical record for that visit.

Periodically review the services you typically provide with your billing staff to be sure you are coding and billing correctly, and more importantly, be sure you’re not continuing to bill for services that should not be reported.

Reassess your knowledge and the function of your team. Most physicians feel they have adequate knowledge (but, do you?) and that their team does a good job. Unfortunately, in addition to being good at delegating, physicians can be trusting to a fault. We all believe and trust that our team is doing an excellent job. But, do they? Without reporting metrics and consistent review of processes and results, your office may be losing money or increasing your risk of take backs. What you do not know can cost you.

Rules change; make it mandatory that you have systems in place to keep up.

Appeal. If you have followed the rules and documented well the medically necessary services you have provided to your patients, do not be afraid to challenge the payer’s initial determination. Many medically necessary denials, especially those without clear published coverage restrictions, will be overturned on the first submission. Others may take more steps. Remember that a payer that does not see an appeal for a flimsy medical necessity denial will likely continue to play the same game.

Consider charging the patient. If your office is well educated and well organized, you may be able to charge the patient for services considered to be medically unnecessary. Make sure you understand and are complying with the rules and notify your patients prior to providing the service for these services and/or supplies.

In summary, this system is becoming increasingly complicated. Payers are tightening the criteria for many services for which they will pay. Again, we have to learn to live with it. As we progress toward value-based payment, the skills required to document support for the services you provide, in combination with a clear understanding of evidence-based medicine, should be honed in the fee-for-service environment of today. We anticipate that medical necessity will be a defining factor for those who do well in the value-based world of tomorrow.

In most cases, medical necessity comes back to accurate documentation of the services you provide and clear support for why you have provided them. In our experience in working with lawyers in your defense and auditing thousands of charts, we have concluded that urologist documentation is a weak link. Get educated and get involved.

The Bottom Line

Robert A. Dowling, MD

Dr. Dowling is vice president of medical affairs and policy for IntrinsicQ Specialty Solutions (an AmerisourceBergen Specialty Group company), a board-certified clinical informaticist, and the former medical director of a large metropolitan urology practice. He resides in Ft. Worth, TX.

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SAFETY, QUALITY

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standardized to permit benchmarking (bit.ly/AHRQsurvey).

The survey instrument is available together with a user guide and technical assistance from the AHRQ website (bit.ly/AHRQsurvey). Designed to be self-administered, the survey should be given to all members of a medical practice for the most accurate results—including physicians and owners of the practice, clinical staff, administrative staff, and anyone else who works in the practice. If a practice has multiple locations, the survey should be “location specific” for best results, as the culture can differ between locations.

The survey is about 50 questions and covers topics including availability of charts and results, status of medical equipment, information exchange with other providers, working environment, communication and follow-up, and questions related to governance and support from leadership. It should take no longer than 10-15 minutes to complete.

Results analyzed by group size, specialty

How do you interpret the results? The AHRQ has compiled the responses of over 4,000 survey recipients into a database, which includes 219 in the specialty of urology. In addition to benchmarks on each question, the AHRQ has also created composite benchmarks in 10 different domains for a more comprehensive view of the practice culture. The results can be analyzed by group size, specialty, ownership model, geographic region, type of respondent, and years of tenure in the office.

The basis of comparison is an index called “average percent positive score” in each of the domains, and the premise is that a significant variation below that average in a particular domain could serve as a guide for addressing issues in the practice that contribute to the culture of safety and quality.

The shift to value-based reimbursement and externally imposed measurement of quality is certain to bring practice culture to the forefront.

For example, one of the domains is “Communication about Error.” If a practice had a lower positive response rate (generally five percentage points is recommended as a significant threshold) than peers, it might wish to examine the results of the four contributing survey questions to design an action plan. Benchmarks are included for the entire domain and each contributing question. Those questions include:

• Staff feel like their mistakes are held against them (negatively worded).
• Providers and staff talk openly about office problems.
• In this office, we discuss ways to prevent errors from happening again.
• Staff are willing to report mistakes they observe in this office.

How does urology stack up against the other specialties? Urology ranked second highest (average of all composites positive response rate) among nine specialties listed in the database, with general surgery highest and orthopedics lowest. Within the specialty of urology, the highest composite score was “patient care tracking and follow-up” and the lowest score was in the domain of “work pressure and pace” (see figures).

Bottom line: The AHRQ has provided a do-it-yourself tool for assessing the culture of patient safety and quality in your practice. This is a small step practices of any size can take with minimal effort to determine areas of strength and opportunities for improvement.

The ability to compare your results to those of other practices may be helpful as you evaluate the culture of your practice and your readiness to navigate change. UT
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*Additional eligibility criteria apply.

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  3. Pembrolizumab + Enzalutamide

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*Additional eligibility criteria apply.

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How often should beneficiaries be reviewed?

**Failing to name a beneficiary can create confusion, anger, delays in settling estate**

Q **My dad apparently never updated his beneficiary designations, and it caused substantial problems after he passed away because one of the beneficiaries had predeceased him. How often should beneficiaries be reviewed?**

A While there is never a bad time to revisit the beneficiary designations you have made over the years, we generally recommend this activity be completed annually. Unfortunately, once various beneficiary forms are completed, they are often forgotten until the time of death. In many cases, executors find that no beneficiaries have been named at all, creating confusion, anger, and time delays in settling an estate. In other cases, the named beneficiaries may no longer be members of the family due to divorce or death.

One of the main reasons for this oversight is that many of the financial accounts requiring a beneficiary designation are established earlier in life. There may be a life insurance policy that was purchased when you were first married, an IRA that you opened prior to marriage, etc.

Having a sound financial plan dictates that you ensure there are designated beneficiaries for all your retirement plan accounts, life insurance policies, and other assets, and that they are the intended recipients based on your current familial arrangement. It is often not as cut-and-dried as it first seems. Following these guidelines should help you avoid the most common mistakes:

- **Do not leave the beneficiary lines blank.** If you don’t name specific beneficiaries for your accounts, or if you name your estate as the beneficiary, your heirs will likely end up in probate court. This can be both time-consuming and costly. If assets go to your estate, they are subject to the reach of creditors. A better option is to choose individual beneficiaries and list them on the forms.

**Financial Tips**

- Do not leave the beneficiary lines blank on your accounts.
- Consider trusts for beneficiaries who are minors.
- Inform your beneficiaries about your designations and where to find important documents.
- Consider percentages instead of dollar amounts.
- Investors use passive management because it provides broad market diversification and low relative internal expense ratios.

- **Let the people you have designated as beneficiaries know where to find important documents and contact information for your professional advisers.**

  - **Consider trusts for beneficiaries who are minors.** In some states, minors face restrictions until they turn 18 or 21. If you designate a minor as a beneficiary, a court will appoint a guardian to manage the funds until the child reaches the age of majority. Alternatively, you might establish a trust to handle the funds and name the trust as the beneficiary. Thus, you maintain control now and provide asset protection for minors when you are gone.
  
  - **Understand the key rules.** Beneficiary designations on retirement accounts and insurance contracts will override your will. If you want someone other than your spouse to inherit retirement account assets, your spouse must sign a written waiver. Without the waiver, a non-spouse beneficiary designation will be invalid upon your death.
  
  - **Inform your beneficiaries.** Do not keep your beneficiary designations a secret. Also, let the people you have designated as beneficiaries know where to find important documents and contact information for your professional advisers. On the other end, make sure your advisers have the vital contact information.

- **Double-check names and numbers.** Make sure names are spelled correctly and that figures are accurate. This is particularly important when listing Social Security numbers as well as telephone numbers and addresses.

- **Consider percentages instead of dollar amounts.** Suppose your IRA is worth $100,000. If the IRA drops in value to $75,000 or below at your death, your nephew gets the entire amount; any additional beneficiaries receive nothing. An alternative way to meet your objectives is to give your nephew 75% of the overall account value.

  - **Name contingent beneficiaries.** If your primary beneficiary has died and you have not updated your accounts with a new primary, the assets would go to your contingent (or “secondary”) beneficiaries. If a contingent beneficiary was never named, the assets are transferred to your estate (see above). Avoid potential problems by indicating contingent beneficiaries in appropriate places.

  - Finally, don’t stuff all the paperwork in a desk or drawer somewhere and forget about it. Make the proper beneficiary designation adjustments when warranted and review these annually with your adviser to ensure that they remain up to date and make financial sense.

Q **What does the term “passive investing” mean?**

A Passive investment management typically refers to the use of index mutual funds within a diversified portfolio. Investors use passive management because it provides broad market diversification and low relative internal expense ratios. Passive management focuses on a buy-and-hold strategy within the portfolio, which results in relatively low trading costs despite the large number of security positions within an index portfolio. Passive investing through an index fund also provides significant diversification benefits since index portfolios hold all the stocks comprising their specific asset class universe.
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Does burnout affect urologists differently than other physicians?

A: I think it affects all physicians, as we share common internal characteristics: drive and determination, motivation, and perfectionism, which paradoxically can actually contribute to burnout by giving one’s self until there’s nothing left to give. Other elements shared by all physicians are external stressors that have worsened recently: government regulations, bureaucratic burdens of providing health care, electronic health records, and so forth. A group at the Mayo Clinic led by Dr. Tait Shanafelt looked at burnout in 2011 (JAMA 2011; 306:952-60). Despite burnout being described for 40-50 years, it was not until this paper that it was really addressed in a broad way in the physician work force. In a subsequent paper, his group broke down burnout rates by specialty (Mayo Clin Proc 2015; 90:1600-13). The rate in urology was 64% and was the highest of the specialties evaluated, which many of us in the field found rather surprising. It is not what we expected; when we went into urology, we had a perception of it being a specialty of very fulfilled, happy, relaxed surgeons who can make a difference.

Subsequent surveys have suggested different numbers. A 2017 Medscape survey suggested a 52% rate for urologists, which is right in the middle of the specialists surveyed. The AUA Annual Census embedded Maslach Burnout Inventory questions in the survey and showed a rate of about 40%. (Also see, “Burnout rate lower than believed, but still too high,” below.) That might be a more accurate number than the Mayo Clinic number as it had a larger sample size than the 2015 Mayo Clinic study. Still, 40% is a high number. It’s something that deserves attention by our field.
**Q:** Why do you think this is happening, specifically to urologists?  

**A:** There are attributes in all surgical specialties that may contribute to burnout. We have an unwritten code: Come in early, stay late, meet multiple deadlines, keep emotional problems at home, never complain, never show weakness. It begins with our training. We work long hours and don’t have a lot of control over our schedules, and I think this contributes to life imbalance beginning in residency. There are data suggesting that when students enter medical school, the depression and burnout rates are the same or slightly lower than the general population. Sadly, we put them through our educational system and then they come out with burnout rates that are two- or three-fold higher. There is something in our process, obviously, that contributes to that.

We delay gratification in residency. We have the feeling that, well, this is residency and when we get through residency, it’s all going to get better. I think the habits formed in residency persist for many people and they don’t regain their work/life balance and some of their personal pursuits. The thinking becomes: I’ve got to establish my practice or I need to become promoted to associate professor or I need to be on this committee or I need to secure this grant in order to get my funding. It never ends, and after a while it becomes habit-forming to put life on hold, which can be a negative.

When I saw the 64% burnout figure, I thought, why in urology, when studies done by the American College of Surgeons showed that burnout rates for neurosurgery and transplant/vascular were much lower? It made me wonder if in urology, we take the external environment stressors that have come along in medicine—less autonomy, administrative tasks—more severely. Expectations in our field are very high. Our medical students are the best and the brightest, and what they like about urology is the ability to make a big clinical impact. We also look at it as a surgical specialty that provides a little bit of balance; you can have it all. When some of those external burdens are put upon us, it disrupts that balance. Again, maybe we’ve taken the external burdens more severely.

**Q:** What are some solutions to urologist burnout?  

**A:** It’s going to take solutions on a lot of levels. This is a national issue. I don’t want to overuse the word “crisis,” but I think it will become a crisis if it’s not addressed in the near future if for no other reason than the work force problem in medicine. It’s estimated we’ll need 90,000 new physicians in the next 10 years. If our ranks are burnout, not performing to their fullest ability, and leaving the work force early, that is going to have implications.
Governmental regulations interfere with our ability to care for patients, and there are steps the government could take to streamline the process of documentation and regulations and so forth. Those requirements have only been additive or even exponentially grown over the years. There are difficulties in getting paid in terms of coding and billing. I think they are intentionally difficult and a burden to us.

The American Board of Medical Specialties can streamline maintenance of certification. Also, can we use EHRs in a more effective way rather than them being a clerical burden for us? What are the ways we could use them to help our practices? State boards can play a role. Many state boards function in almost a punitive way for physicians, which I think may limit admitting a mental health condition or depression; it needs to be much more private and supportive.

**What do you think the future holds?**

STEPHEN Y. NAKADA, MD

“I am optimistic about the future because there is acknowledgement and discussion of burnout.”

RAJ S. PRUTHI, MD

Our institutions play a very, very important role in this. They have long prioritized patient satisfaction and staff satisfaction—very appropriately—but I think there’s been a blind spot to provider satisfaction. A few institutions have taken leads on it, but just as we use patient satisfaction and staff satisfaction as quality measures for how a hospital performs, I think provider satisfaction should be added to that. People call it the “fourth aim” in medicine. As it becomes a priority for the institution then, accordingly, you can allocate the appropriate resources. If patient satisfaction is low, the institution will dedicate financial and other resources to try to improve that. The same could be done for provider satisfaction as well.

Speaking for my own institution, the health care system leadership has to meet their hospital metrics and they get incentivized to do that. If provider satisfaction was part of that, I think they may have some different views on where resources should go and how that should be carried out. It may not even be on their radar, to be honest. If it’s not measured, it doesn’t exist, and people can’t do something about it.

As more and more of us are becoming part of larger organizations, it goes a long way to have physicians in the trenches involved in participatory management and be a part of the process. Sometimes we feel like there’s a disconnect and that’s a cause of dissatisfaction as well. Ultimately, it falls upon us as physicians to address burnout, discuss it, and develop interventions.

A study illustrated the concept of “20% time” in which companies allow their workers 20% of their time to pursue whatever they want to pursue. Google has adopted this concept, and Gmail actually was discovered in 20% time. It’s very renewing for the workers. In medicine, a group at the Mayo Clinic showed that if you can provide 20% of time to a physician to be engaged in meaningful professional activity, that can alleviate burnout by almost half (Arch Intern Med 2009; 169:990-5). Every individual physician will have a different meaningful activity, whether it be teaching, research, process improvement, or community service, and if each individual can find what that 20% of meaningful professional activity is. If department chairs and other mentors for our faculty can help them find that meaningful activity, that goes a long way.

Also, when we’re thinking of life outside of work, talking about it and not hiding it is important. Often in medicine, we try to hide the personal side and not talk about it because it’s considered a sign of weakness or lack of dedication, but I think it can be very positive to talk about it and admit we do have lives outside of work.

On a more practical point, there are studies that show exercise can be a very important factor. If physicians follow the Department of Health and Human Services recommendations for exercise and get 75 minutes of vigorous exercise each week or 150 minutes of more sedentary exercise, they can improve quality of life and reduce dissatisfaction and burnout.

**Q: What do you think the future holds?**

A: I am optimistic about the future because there is acknowledgement and discussion of burnout. We’re having several discussions on a national stage, including this year’s meeting of the Society of Academic Urologists, an organization of academic urologists, chairs, and program directors who can help to discuss this, open this up, and not treat it as a blind spot—at least on the departmental level. As we become more aware of this in our positions, we can lead from the top down and help our learners and our junior faculty with it. At this year’s AUA annual meeting, there was an international plenary panel on burnout that I participated in to discuss the problem and its international implications. To do this in such a public forum is the first positive step.

I do think institutions are beginning to address this issue. I’d love for our institution to do more operationally and structurally, which will require big financial investments. At least we’re beginning at institutions to have seminars and discussions about the issue. We’re starting to measure burnout at our institution as well.

**What do you think a young aspiring urologist can do to mitigate the risks of burnout?**

STEPHEN Y. NAKADA, MD

“You can recover from burnout, but the best strategy is prevention.”

RAJ S. PRUTHI, MD

Until you measure it, you can’t improve it. We have a long way to go, and there are financial hurdles, but from an institution’s perspective and from a department’s perspective, preventing burnout is financially worthwhile. Faculty turnover is very expensive both for a department and an institution. A dissatisfied worker is less productive and a lot more likely to turn over.

**Q: What do you think a young aspiring urologist can do to mitigate the risks of burnout?**

A: You can recover from burnout, but the best strategy is prevention. Actively nurturing personal interests and well-being can help prevent burnout. It helps if you do it early on and if promotion of wellness is openly supported by leadership within a hospital or department or group practice.

I think a younger individual should try to find what their 20% time is. What is a meaningful activity for them? Younger faculty are so intelligent, driven, motivated, and ready to work hard, and one of my goals in meeting with them is to make sure that they’re finding that 20% time, so that practicing medicine doesn’t become a hamster wheel, where 5 years later they wonder, what have I been doing? Again, they’re very smart, driven people and they deserve to be happy and fulfilled in their lives. People need to be aware early on of life outside of work and prioritize that with time with family, with other interests, with exercise.

Maybe some of this could end up being generational too, although some data suggest that younger workers tend to have more burnout. But, we showed some information indicating that burnout peaks in the 40s and 50s. Perhaps the younger generation are ahead of us in that they’ve already walked into this with a sense of proper work/life balance, which the previous generation may have looked on negatively.
A VBCP for BPH surgery was introduced at UCLA in April 2014. Designed to include the mix of preoperative testing and surgery that would provide the highest quality care at the lowest cost, it requires PSA testing when indicated, urinalysis, and post-void residual measurement preoperatively and use of bipolar transurethral resection or vaporization as the surgical option.

"Cystoscopy and urodynamics are not included in the VBCP as UCLA data, which were presented at this year’s AUA meeting, show these invasive tests fail to improve outcomes but greatly increase cost," Dr. Kaplan said.

Since the BPH surgery VBCP was released, all urologists receive a confidential, quarterly report card by email that contains data on their outcomes, costs, and practice pattern (VBCP adherence) compared to de-identified colleagues.

To study adherence to the BPH surgery VBCP and determine if it was affected by the surgeon-specific feedback, adherence rates for 18 urologists were analyzed at baseline, 6 months, and 12 months after implementation of the quarterly report program.

A similar analysis was performed for adherence to the AUA-recommended pathway for BPH, which is less stringent than the UCLA VBCP because it is silent on both preoperative invasive testing and operation of choice.

Compliance with UCLA pathway 5%

Compliance rates at baseline for the AUA-recommended pathway and the UCLA VBCP were 1.8% and 0%, respectively. Six months later, both rates increased significantly, but adherence was still only 9.2% for the AUA pathway and 5% for the UCLA VBCP.

Although the provision of surgeon-specific feedback had a minimal impact on urologists’ adherence to the BPH surgery VBCP, the quarterly report program has not been abandoned because increasing data transparency is the right thing to do, Dr. Kaplan told Urology Times.

“If we are going to continue the conversation about driving the health care system toward a value-based care model, then data transparency is important, regardless of what our study showed. At the same time, however, we are starting to explore alternative means of incentivizing physicians to modify their practice patterns toward value-based care,” he said.

“Historically, it has been challenging to get physicians to adopt VBCPs, especially in an environment where there is no financial incentive. Giving a financial incentive has not been an option at our institution, and we also think that additional study is needed to understand its effectiveness.”

The authors are also beginning to look at redesigning VBCPs across other clinical service lines, including management for localized prostate cancer, small renal masses, and stone disease.

“Since passage of the Affordable Care Act, there has been a lot of talk about the need to transition from fee-for-service to value-based care. The results of our study show that we still have a long way to go before we reach that goal.”

ALAN L. KAPLAN, MD

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RWJBarnabas Health is seeking a fellowship-trained female urologist or a general urologist, fellowship training preferred but not required, to join a busy, well-established practice that is part of Robert Wood Johnson Physician Enterprise – Somerset Urological Associates. Join a team of three urologists with practice located in Somerville, New Jersey (Central NJ). Clinical case mix would include general urology and female reconstructive cases with access to the da Vinci robotic surgical system. The positions also offer the ability to train urology residents at Robert Wood Johnson University Hospital Somerset and obtain an academic faculty appointment through Robert Wood Johnson University Hospital. This is a unique opportunity that combines the security of being part of the largest integrated healthcare system in New Jersey and the competitive salary and defined partnership path desirable from a private practice setting. Practice also offers a great quality of life – just one hospital, one surgery center and one outpatient office – all within 5 minutes of each other! Location in central New Jersey is also ideal with easy access to New York City, Philadelphia and the Jersey Shore. Successful candidates should be either board-certified or board-eligible.

For more information or to apply please contact
Gary Casino at (908)725-1204 or gary.casino@rwjbh.org
Garden State Urology (GSU), located in Northwest New Jersey, has an outstanding opportunity for a General Urologist with proven and respected leadership skills to join our team of talented physicians. Specialties within GSU include but are not limited to Minimally Invasive Robotic Surgery, Treatment for Stones, Prostate Care, Reconstructive Urology, Female Urology and Men’s Health, and Pediatric Urology. All positions are aligned with the integration of complex clinical care with teaching and research to support the vision of GSU.

Candidates may be Board Eligible or Board Certified. Fellowship trained candidates preferred but not required. New grads strongly encouraged to apply, as we have current and future needs.

**About GSU**

Garden State Urology was formed in 2008, the result of a merger of five of the busiest urology practices in Northwest New Jersey. We joined on the principle that by working cooperatively, we could provide more cost-effective and higher quality care than we did individually. Our mission statement, created at our inception, reflects these beliefs and directs our future growth: To provide comprehensive and compassionate urologic care at the highest possible level.

Candidate and salary will be commensurate with experience. Interested applicants should contact Jessica McCullough at jmccullough3@kumc.edu.

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**New Jersey**

**Seeking Multiple Positions**

- 2018 Graduates
- Urologist, FPMRS, or Urogynecologist
- Hospitalist

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Congress says ‘no’ to Trump NIH budget cuts

Concern remains over possible funding reduction in 2018

The fiscal 2017 appropriations wrap-up package approved by Congress in early May included a $2 billion increase for the National Institutes of Health, despite a Trump administration request for a $1.2 billion reduction for the nation’s primary medical research facility.

That bipartisan action, which funds the federal government through September, came in the face of President Trump’s demand to slash spending for domestic programs to pay for a huge increase in appropriations for defense.

Nevertheless, Republican appropriators in Congress were not swayed by the administration’s demand and thus replicated last year’s $2 billion increase for NIH. Rep. Tom Cole (R-OK), chairman of the House Appropriations subcommittee responsible for NIH, said he was proud of the fact that Congress doubled the NIH budget from 1998 to 2003 and increased it again in the 21st Century Cures Act, passed last year with broad bipartisan support.

Urologist applauds Congress

Congress’ refusal to accede to the White House NIH budget reduction for FY 2017 was applauded by one of the nation’s leaders in urologic research, Neal Shore, MD, current president of LUGPA.

“As a physician, president of LUGPA, secretary-treasurer of the Society of Urologic Oncology Clinical Trials Consortium, and as an educator who has run many advanced prostate cancer programs for the American Urological Association, it would be a huge mistake on the part of the federal government to diminish research funding in both the National Cancer Institute and NIH,” Dr. Shore, who is also medical director of the Carolina Urologic Research Center, told Urology Times.

While he welcomed the congressional action on the 2017 NIH budget, Dr. Shore is concerned about threatened cuts next year. The administration has asked Congress to provide NIH a total of $25.9 billion for FY 2018, which begins Oct. 1—a reduction of $5.8 billion, or 18% from the agency’s 2016 level of $31.7 billion.

“By taking $6 billion from the NIH in 2018 (and funneling that money into the Department of Defense, supposedly to fight ISIS), the Trump administration would set the agency’s budget back 15 years, below its 2003 level,” wrote Michael White, PhD, of Washington University in St. Louis, in an article published by Pacific Standard. “Such a drastic cut would not just reduce the amount of science done by U.S. scientists—it would harm our scientific workforce and infrastructure in ways that would take years, if not decades, to recover from.”

That is a primary concern of Dr. Shore.

“Providing appropriate funding for medical research is really important,” he said. “I feel very passionate about it. If we keep gutting our financial support for the best and brightest minds who have the desire and the DNA to be researchers, what is that going to do to our medical centers, our university research programs, and what will be the impact on everybody in the world who looks to us for a solution?”

In his article, Dr. White cited an analysis by the American Society for Biochemistry and Molecular Biology that estimated Trump’s budget could force NIH to reduce funding for new research grant proposals by “a jaw dropping 88%” in 2018. Currently, he said, NIH awards between 9,000 and 10,000 new proposals each year, but the proposed cut could result in worst-case scenario of funding of just 1,200 new proposals in 2018, which would cause “lasting damage to U.S. science.”

LUGPA announces urology-specific APM

While support for medical research is a major concern for Dr. Shore, he noted that physicians must deal with the reality of how they are paid for their services to Medicare beneficiaries. Thus, in April, LUGPA announced a new urology-specific Alternative Payment Model (APM) for newly diagnosed, localized prostate cancer.

Developed by LUGPA under the Medicare Access and CHIP Reauthorization Act of 2015, which ended the sustainable growth rate formula for Medicare reimbursement, the new APM would make it possible for urologists to be reimbursed based on the value, rather than the quantity, of services provided.

“There is a recognition that historically we have over-treated many patients who may benefit from active surveillance as opposed to active intervention therapy, such as surgery,” Dr. Shore said. “Assuredly, there are many patients who should have active intervention therapy, but we need to do a better job of encouraging the physician in a value-based model so we can get a management fee to provide the right treatment to the right patient at the right time.

“Under our model, there would be better health care provided to patients throughout the country as well as cost savings to the entire health care system. There are provisions to assure high quality is accomplished. There is a monthly fee to help encourage the most appropriate resource utilization of treatment. All advanced alternative payment models are predicated on high-quality patient-physician shared decision-making.”

The new LUGPA APM is to be submitted to the Physician-Focused Payment Model Technical Advisory Committee, which advises the Secretary of Health and Human Services on such proposals. The approval process is complex and could take some time before it is completed, Dr. Shore said.

“But LUGPA believes that this model will optimize outcomes, increase patient satisfaction and reduce utilization of unnecessary services, while simultaneously decreasing health care costs,” he said.
Missed kidney cancer diagnosis leads to death, legal action

Prompt settlement often prudent in malpractice cases involving clear caregiver error

A 59-year-old Ohio man presented to a medical center for a computed tomography scan of his right kidney in 2015. The CT scan was interpreted as normal.

The man was subsequently diagnosed with kidney cancer, and he died about 8 months after the original CT scan was done.

A lawsuit against the medical center was filed by the man’s estate and alleged that those involved with the performance and interpretation of the CT scan failed to diagnose and therefore did not treat the patient’s kidney cancer and caused his death. The case settled for $500,000.

LEGAL PERSPECTIVE: This malpractice case was filed by the man’s wife on behalf of his estate almost a year after the man’s death. The medical center elected not to make a defense argument against the allegations of failing to diagnose the kidney cancer, and no discovery was undertaken. Five days after it was filed, the settlement agreement was reached.

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In malpractice cases where a clear error by the caregivers has occurred and results in the patient suffering an injury, it may be prudent to enter into settlement discussions quickly to come up with a reasonable award of damages. This not only saves the time and money it takes to defend a case through trial, it takes the risk of unpredictable jury awards off the table if a reasonable amount can be agreed upon.

Fistula after prostatectomy

A 67-year-old New York man underwent a prostatectomy performed by his urologist. During the operation, the urologist used a laser to destroy a portion of the prostate. After the procedure, the patient developed a recto-urethral fistula. He died a year later of causes unrelated to the surgery.

The patient’s wife sued the urologist on behalf of the man’s estate and as an individual herself, and alleged that the laser used in the prostatectomy broke down the tissue and that the breakdown caused the development of the fistula. She asserted the urologist should have used another method that would have allowed greater control of the amount of tissue removed.

The urologist maintained that his procedure destroyed a minimal amount of tissue and did not come in contact with the area that developed the fistula, and that any other method attempted would have led to more complications. He argued that the patient’s fistula was a result of the use of radiation in an earlier attempt to eradicate the cancer, not the laser used during his procedure.

The jury returned a defense verdict after deliberating 1 hour at the conclusion of the 4-day trial.

Loss of testicle due to insufficient blood flow

A 10-year-old boy was brought to an Illinois hospital due to pelvic pain. It was determined that the left testicle was undescended and remained in the inguinal canal. An ultrasound was done and interpreted that there was sufficient blood flow to the testicle, and the patient was discharged.

Two days later, he presented to a different hospital where it was determined that the blood flow to the testicle was insufficient and by that time there was irreversible damage and removal was required.

A malpractice case was filed against the physician who interpreted the ultrasound incorrectly and the case was settled for $400,000.

Patient injured during lithotripsy and bladder procedure

A lawsuit was filed after a 44-year-old New York man underwent lithotripsy to break up kidney stones and a procedure to explore his bladder. After the kidney procedure, the patient was moved to another table to perform the bladder exploration. He claimed the OR staff did not use the proper technique while transferring him and he was dropped during the transfer, injuring his back and neck.

The defense asserted that the patient did not fall, but that his weight shifted during the transfer, and the staff correctly decided to lower him to the floor. They claimed that the patient had no proof he had fallen. The jury returned a defense verdict after deliberating for an hour at the conclusion of a 5-day trial.

Burn injuries from transurethral microwave therapy

A 63-year-old man developed incontinence and an enlarged prostate. He consulted his urologist, who suggested transurethral microwave therapy to shrink the prostate.

During the procedure, the urologist placed the device and then left the room. The technician took over and continued the therapy. When the patient experienced excessive pain, an ice pack was placed but the therapy continued. The patient developed a fistula and required a colostomy. He became permanently incontinent and had permanent erectile dysfunction. He was unable to return to his job.

The man sued those involved with the therapy and claimed the rectal thermometer used to monitor the prostate was misplaced and that a hole was burned through the rectum and urethra. He also claimed no one responded to his excessive pain, and that the urologist failed to adequately monitor the procedure.

After an initial defense verdict was reversed on appeal, a second jury found in favor of the patient and awarded $3.9 million.

Know the medicolegal pitfalls of phone triage

“Lawsuits involving telephone triage tend to allege failure in a physician’s duty to treat, abandonment of the patient, or provision of sub-standard care,” writes Brianne Goodwin, JD, RN, in a recent column.

To read the column, go to www.urologytimes.com/malpractice-consult.
Atezolizumab*: an engineered anti-PDL1 antibody under investigation in bladder cancer

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Primary Efficacy Measures:
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• Overall survival

Primary Safety Measure:
• Percentage of participants with adverse events assessed using National Cancer Institute Common Terminology Criteria for Adverse Events v4.0

Secondary Outcome Measures:
• Percentage of participants with best overall response of complete response or partial response assessed by investigator using RECIST v1.1
• Duration of response assessed by investigator using RECIST v1.1

Secondary Outcome Measures (cont’d):
• Percentage of participants alive at 1 year
• Percentage of participants alive and progression free at 1 year using RECIST v1.1
• Median time to deterioration in global health status as measured by the European Organisation for Research and Treatment of Cancer (EORTC) Quality-of-Life Questionnaire Core 30 (QLQ-C30) score
• Median time to deterioration in physical function as measured by the EORTC QLQ-C30 score
• Maximum and minimum atezolizumab serum concentration
• Percentage of participants with anti-therapeutic antibodies
• PFS assessed by investigator using RECIST v1.1 in participants treated with atezolizumab monotherapy compared with placebo arm

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