Diagnosis and Treatment of Overactive Bladder (Non-Neurogenic) in Adults: AUA/SUFU Guideline

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Purpose: The purpose of this guideline is to provide a clinical framework for the diagnosis and treatment of non-neurogenic overactive bladder (OAB).

Materials and Methods: The primary source of evidence for this guideline is the systematic review and data extraction conducted as part of the Agency for Healthcare Research and Quality (AHRQ) Evidence Report/Technology Assessment Number 187 titled *Treatment of Overactive Bladder in Women* (2009). That report searched PubMed, MEDLINE®, EMBASE and CINAHL for Englishlanguage studies published from January 1966 to October 2008. The AUA conducted additional literature searches to capture treatments not covered in detail by the AHRQ report and relevant articles published between October 2008 and December 2011. The review yielded an evidence base of 151 treatment articles after application of inclusion/exclusion criteria. When sufficient evidence existed, the body of evidence for a particular treatment was assigned a strength rating of A (high), B (moderate) or C (low). Additional treatment information is provided as Clinical Principles and Expert Opinions when insufficient evidence existed.

Results: The evidence-based guideline statements are provided for diagnosis and overall management of the adult with OAB symptoms as well as for various treatments. The panel identified first through third line treatments as well as non-FDA approved, rarely applicable and treatments that should not be offered. **Conclusions:** The evidence-based statements are provided for diagnosis and overall management of OAB, as well as for the various treatments. Diagnosis and treatment methodologies can be expected to change as the evidence base grows and as new treatment strategies become obtainable.

Key Words: urinary bladder, overactive; urinary bladder; urinary incontinence; nocturia; guideline

SECTION 1: PURPOSE

This guideline's purpose is to direct specialist and non-specialist clinicians and patients regarding how to recognize non-neurogenic overactive bladder, conduct a valid diagnostic process and establish treatment goals that maximize symptom control and patient quality of life

while minimizing adverse events and patient burden. The most effective approach for a particular patient is best determined by the individual clinician and patient. As the science relevant to OAB improves, Guideline amendment will assure the highest contemporary clinical standards.

Abbreviations and Acronyms

AE = adverse event

ER = extended release

FDA = Food and Drug Administration

IR = immediate release

OAB = overactive bladder

$$\begin{split} & \text{PTNS} = \text{peripheral tibial nerve} \\ & \text{stimulation} \end{split}$$

PVR = post-void residual

QoL = quality of life

SNS = sacral neuromodulation

UTI = urinary tract infection

The complete guideline is available at http://www.auanet.org/content/media/0AB_guideline.pdf.

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SECTION 2: METHODOLOGY

The primary evidential source for this guideline was the systematic review and data extraction conducted by the Agency for Healthcare Research and Quality) producing Evidence Report/Technology Assessment Number 187 titled *Treatment of Overactive Bladder in Women.* Studies focusing on males, nocturia and the use of neuromodulation therapies, including sacral neuromodulation, peripheral (or posterior) tibial nerve stimulation and intravesical onabotulinumtoxinA to treat non-neurogenic OAB patients were added to the database. The AUA performed its own qualitative and quantitative analyses of these extracted data.

OAB Diagnosis

The review revealed insufficient evidence-based publications to address diagnosis; the diagnosis portions of the algorithm (see figure) are provided as *Clinical Principles* or as *Expert Opinions*. A *Clinical Principle* is a statement about a component of clinical care that is widely agreed upon by urologists or other expert clinicians for which there may or may not be evidence in the medical literature. *Expert Opinion* refers to a statement achieved by consensus of the Panel that is based on members' clinical training, experience, knowledge and judgment for which there is no evidence.

OAB Treatment

A total of 151 articles met the treatment inclusion criteria, judged a sufficient evidence base to construct the majority of the treatment algorithm. Data on study type, treatment

parameters, patient characteristics, AEs and primary outcomes were extracted.

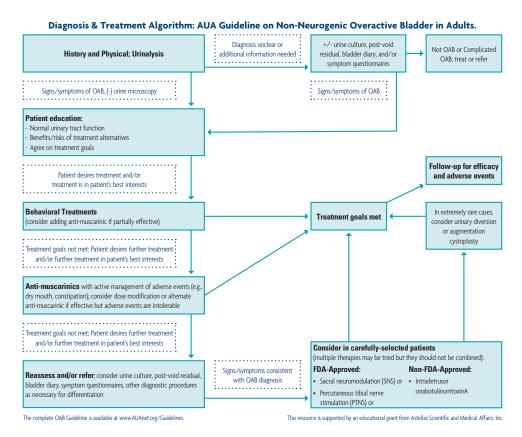
Limitations of the Literature

There are significant limitations to the OAB literature. For example, despite the relatively large number of randomized controlled trials with placebo control groups and randomized designs with active controls that assessed pharmacologic OAB treatments, the overwhelming majority of trials followed patients for only 12 weeks. This presents a severe limitation of the literature as OAB is a condition requiring long-term treatment.

For a complete discussion of the methodology and evidence grading, please refer to the full-length version of this guideline available at http://www.auanet.org/content/media/OAB_guideline.pdf.

SECTION 3: BACKGROUND

OAB is a clinical diagnosis defined by the International Continence Society as the presence of "urinary urgency, usually accompanied by frequency and nocturia, with or without urgency urinary incontinence, in the absence of a urinary tract infection (UTI) or other obvious pathology." Methodological differences across studies challenge any interpretation of the OAB literature related to epidemiology and treatment. Most studies of OAB, including this guideline, exclude individuals with symptoms related to neurologic conditions.



Diagnosis and treatment algorithm



Urgency is the "complaint of a sudden, compelling desire to pass urine which is difficult to defer." Urgency is the hallmark symptom of OAB, but it has proven difficult to precisely define or to characterize for research or clinical purposes. Therefore, many studies of OAB treatment response have relied upon other measures (eg, number of voids, number of incontinence episodes).

Urinary frequency can be reliably measured with a voiding diary. Traditionally, up to seven micturition episodes during waking hours has been considered normal,³ but this number is highly variable based upon hours of sleep, fluid intake, comorbid medical conditions and other factors.

Nocturia is the interruption of sleep one or more times because of the need to void² and is a multifactorial symptom often due to factors unrelated to OAB, including excessive nighttime urine production and sleep apnea.

Urgency urinary incontinence is the involuntary leakage of urine associated with a sudden compelling desire to void. Incontinence episodes can be measured reliably with a diary. However, in patients with mixed urinary incontinence (both stress and urgency incontinence), it can be difficult to distinguish between incontinence subtypes.

SECTION 4: PATIENT PRESENTATION

Symptoms

When urinary frequency (both daytime and night) and urgency, with or without urgency incontinence, in the absence of UTI or other obvious pathology are self-reported as bothersome, the patient may be diagnosed with OAB.⁴

Differentiation

The differential of nocturia includes nocturnal polyuria, low nocturnal bladder capacity or both. In nocturnal polyuria, nocturnal voids are frequently normal or large volume as opposed to the small volume voids commonly observed in nocturia associated with OAB. Sleep disturbances, vascular and/or cardiac disease and other medical conditions are often associated with nocturnal polyuria.

Frequency that is the result of polydipsia and resulting polyuria may mimic OAB; the two are distinguished with the use of frequency-volume charts. Polydipsia-related frequency is physiologically self-induced and should be managed with education and consideration of fluid management.

While the clinical presentation of interstitial cystitis/ bladder pain syndrome shares the symptoms of OAB, bladder and/or pelvic pain, including dyspareunia, is a crucial component of its presentation in contradistinction to OAB.

SECTION 5: DIAGNOSIS

The Diagnostic Approach

The section titled *Diagnosis* is based on Clinical Principles or Expert Opinions with consensus achieved using a modified Delphi technique when differences of opinion emerged. This section is intended to provide clinicians and patients with a framework for determining whether a diagnosis of OAB is appropriate; it is not intended to replace the judgment and experience of the individual clinician faced with a particular patient.

1. The clinician should engage in a diagnostic process to document symptoms and signs that characterize OAB and exclude other disorders that could be the cause of the patient's symptoms; the minimum requirements for this process are a careful history, physical exam and urinalysis. Clinical Principle

The clinician should ascertain the patient's bladder symptoms to document duration of symptoms and baseline symptom levels to ensure that symptoms are not related to some other condition and to determine the complexity of the OAB presentation that may require referral. Questions should assess bladder storage symptoms and bladder emptying. If a patient is not significantly bothered by his/her bladder symptoms, then there is a less compelling reason to treat the symptoms.

Patient reports of bladder function are related to amount and type of fluid intake. Excessive fluid intake can produce voiding patterns that mimic OAB symptoms. A fluid diary can be helpful in this regard. Urinary frequency varies across individuals. In community-dwelling healthy adults, normal frequency consists of voiding every three to four hours with a median of approximately six voids a day.^{5,6} Current medications should be reviewed to ensure that symptoms are not related to medications.

Co-morbid conditions such as neurologic diseases and other genitourinary conditions should be considered as they directly impact bladder function. The clinician should consider referring these patients to a specialist for further evaluation and treatment.

Physical examination. A careful, directed physical exam should include an abdominal exam, a rectal/genitourinary exam and an assessment of lower extremities for edema.

Cognitive impairment is related to symptom severity with therapeutic implications regarding goals and options. In the Panel's experience, the ability of the patient to dress independently is informative of sufficient motor skills related to toileting habits.

Urinalysis. A urinalysis to rule out UTI and hematuria should be performed. If evidence of hematuria



not associated with infection is found, then the patient should be referred for urologic evaluation.

2. In some patients, additional procedures and measures may be necessary to validate an OAB diagnosis, exclude other disorders and fully inform the treatment plan. At the clinician's discretion, a urine culture and/or post-void residual assessment may be performed, and information from bladder diaries and/or symptom questionnaires may be obtained. Clinical Principle

Urine culture. A urine culture may be appropriate in certain patients given that a urinalysis may be unreliable.

Post-void residual. Measurement of the PVR is not necessary for patients who are receiving first-line behavioral interventions (see Guideline Statement 6 below) or for uncomplicated patients receiving antimuscarinic medications. PVR should be assessed in patients with obstructive symptoms, history of incontinence or prostatic surgery, neurologic diagnoses and at clinician discretion.

Anti-muscarinics should be used with caution in patients with PVR >250–300 mL. 7

Bladder diaries. Diaries that document intake and voiding behavior may be useful, particularly for patient education and to document baseline symptoms and treatment efficacy.

Symptom questionnaires. Validated symptom questionnaires^{8–10} are useful in the quantification of bladder symptoms and bother changes with OAB treatment.

3. Urodynamics, cystoscopy and diagnostic renal and bladder ultrasound should not be used in the initial workup of the uncomplicated patient. *Clinical Principle*

For complicated or refractory patients, the choice of additional diagnostic tests depends on patient history, QoL and clinician judgment. Neurogenic OAB requires specific evaluation. Urine cytology is not recommended in the routine evaluation of patients with uncomplicated OAB without hematuria who respond to therapy.

SECTION 6: TREATMENT

OAB may compromise QoL but generally does not affect survival. A treatment plan, therefore, should carefully weigh the patient's potential benefit of a particular treatment against that treatment's risk for, severity and reversibility of AEs. These guideline statements are a framework to assist in developing an individualized treatment plan that optimizes QoL.

Treatment failure occurs when the patient with reasonable expectations does not have the anticipated symptom improvement or is unable to tolerate the treatment due to AEs; lack of efficacy and the presence of intolerable AEs reduce compliance.

4. OAB is not a disease; it is a symptom complex that generally is not a life-threatening condition. After assessment has been performed to exclude conditions requiring treatment and counseling, no treatment is an acceptable choice made by some patients and caregivers. *Expert Opinion*

Initiating treatment for OAB presumes that the patient can perceive an improvement in his or her QoL. Patients who cannot perceive symptom improvements may not need any treatment beyond toileting and/or diapering, as treatment may be potentially unsafe and/or futile (eg, in the very elderly or demented patient). It is important for clinicians who treat this problem to recognize this issue and set feasible therapeutic goals with the patient and/or caregiver.

5. Clinicians should provide education to patients regarding normal lower urinary tract function, what is known about OAB, the benefits vs. risks/burdens of the available treatment alternatives and the fact that acceptable symptom control may require trials of multiple therapeutic options before it is achieved. *Clinical Principle*

Successful OAB treatment requires a willing participant who is informed and engaged in the treatment process, understands that OAB has a variable and chronic course likely requiring multiple management strategies over time with no single ideal treatment and understands that treatments vary in invasiveness, risk of AEs and reversibility. Most OAB treatments improve patient symptoms but are unlikely to eliminate all symptoms. Explaining what is normal can help the patient understand their condition and give a comparator for establishing mutually-identified and realistic goals for treatment. Education empowers the patient to participate in their treatment, an essential factor when interventions rely on behavior change.

6. Clinicians should offer behavioral therapies (eg, bladder training, bladder control strategies, pelvic floor muscle training, fluid management) as first-line therapy to all patients with OAB. Standard (Evidence strength: Grade B)

Behavioral treatments are a group of risk-free tailorable therapies, which improve individual symptoms by changing patient behavior or the patient's environment. They are first-line treatments because they are as effective in reducing symptom levels as are antimuscarinic medications. There are two fundamental



approaches to behavioral treatment. One modifies bladder symptoms by changing voiding habits, as with bladder training and delayed voiding. The other focuses on pelvic floor muscle training to improve control and techniques for urge suppression. Both require the active participation of the patient and/or the patient's caregiver.

While most patients do not experience complete symptom relief, most patients experience significant reductions in symptoms and improvements in QoL. The literature provides clear support for the effectiveness of both bladder and behavioral training. ^{11,12}

The literature supports the positive effects of weight loss on incontinence specifically. A relatively minor weight loss of 8% in obese woman reduced overall incontinence episodes per week and urgency urinary incontinence episodes by 47 and 42% vs. 28 and 26% in controls. ¹³

Fluid management with a 25% reduction in fluid intake reduced frequency and urgency. ¹⁴ A bladder training study reducing caffeine intake also resulted in reductions in voiding frequency. ¹⁵

The literature review of comparative effectiveness randomized trials indicates that behavioral treatments are generally either equivalent to $^{16-18}$ or superior to 12,19,20 medications in terms of reducing incontinence episodes, improving frequency $^{21-23}$ and nocturia 24 and improving QoL.

7. Behavioral therapies may be combined with anti-muscarinic therapies. Recommendation (Evidence strength: Grade C)

A limited literature indicates that initiating behavioral and drug therapy simultaneously may improve outcomes. 19,21,25–27

Second-Line Treatments: Anti-Muscarinics

8. Clinicians should offer oral anti-muscarinics, including darifenacin, fesoterodine, oxybutynin, solifenacin, tolterodine or trospium (listed in alphabetical order; no hierarchy is implied) as second-line therapy. Standard (Evidence strength: Grade B)

Oral anti-muscarinics are second-line therapy, reducing symptoms but commonly associated with non-life-threatening side effects (eg, dry mouth, constipation, dry eyes, blurred vision, dyspepsia, UTI, urinary retention, impaired cognitive function). An extensive review of the randomized trials evaluating pharmacologic therapies for OAB reveal no compelling evidence for differential efficacy across medications

Patients with more severe symptoms, on average, experienced greater symptom reductions. Only patients with relatively low baseline symptom levels are likely to experience complete symptom relief.

As similar efficacy was observed for all oral antimuscarinic medications, the choice of medication is patient dependent; however, AE profiles for dry mouth and constipation vary with medications. For an extensive discussion of side effects, please refer to the complete guideline on the AUA website at http://www.auanet.org/content/media/OAB_guideline.pdf.

9. If an immediate release (IR) and an extended release (ER) formulation are available, then ER formulations should preferentially be prescribed over IR formulations because of lower rates of dry mouth. Standard (Evidence strength: Grade B)

A meta-analysis indicates that the ER formulations of oxybutynin and tolterodine resulted in statistically significantly fewer patient reports of dry mouth than the IR formulations of either medication.

Optimizing medication tolerability is critical to obtaining patient compliance in the treatment of this chronic condition. ^{28,29} Compliance with a oncedaily dosing is greater than with medications taken more than once a day. ³⁰ In order to minimize patient burden, the decision to prescribe an IR vs. an ER formulation should be made in the context of the patient's prior experience with anti-muscarinics, the availability of medications and payer constraints.

10. Transdermal (TDS) oxybutynin (patch or gel) may be offered. Recommendation (Evidence strength: Grade C)

TDS preparations of oxybutynin may be offered if dry mouth is a concern with oral anti-muscarinics.

11. If a patient experiences inadequate symptom control and/or unacceptable adverse drug events with one anti-muscarinic medication, then a dose modification or a different anti-muscarinic medication may be tried. *Clinical Principle*

Patients who experience inadequate symptom control and/or unacceptable AEs with one anti-muscarinic medication may benefit from a different anti-muscarinic. Dose modification (i.e., reduction and/or combination with behavioral techniques) may achieve a better balance between efficacy and adverse drug events.

12. Clinicians should not use anti-muscarinics in patients with narrow angle glaucoma unless approved by the treating ophthalmologist and should use anti-muscarinics with extreme caution in patients with impaired gastric emptying or a history of urinary retention. Clinical Principle

Prior to initiation of anti-muscarinics, a patient at risk for gastric emptying problems or for urinary retention should receive clearance from a gastroenterologist or urologist, respectively. A PVR may be useful in any patient suspected of a higher risk of



urinary retention. Anti-muscarinics are also contraindicated in patients using solid oral forms of potassium chloride, as the reduced gastric emptying potentially caused by the anti-muscarinics may increase the potassium absorption of these agents. Anti-muscarinic therapy may be used with caution with alternative forms of potassium chloride.

13. Clinicians should manage constipation and dry mouth before abandoning effective anti-muscarinic therapy. Management may include bowel management, fluid management, dose modification or alternative anti-muscarinics. Clinical Principle

Patients should be educated about the possible AEs of these medications on bowel function, the roles of adequate dietary fiber and fluid, psyllium-based fiber supplements, regular exercise and normal bowel habits. Treatment advice regarding possible dry mouth could include oral lubricants, avoiding mouthwashes with alcohol, small sips of water, sucking on sugar-free hard candies and chewing sugar-free gum. In older patients who may metabolize drugs differently, it is advisable to start with a minimal dose and titrate as tolerated.

14. Clinicians must use caution in prescribing anti-muscarinics in patients who are using other medications with anti-cholinergic properties. *Expert Opinion*

Medications with anti-cholinergic properties include tricyclic antidepressants, acetylcholinesterase inhibitors and medications for Parkinsonism, other extra-pyramidal diseases and Alzheimer's disease. Certain anti-nausea medications and those with atropine-like properties may also potentiate AEs. Prescribers should be aware of precautions and contraindications for these medications.

15. Clinicians should use caution in prescribing anti-muscarinics in the frail OAB patient. *Clinical Principle*

OAB medication trials generally are not conducted in the frail elderly, resulting in a lack of efficacy and AE data in this group. Additional AEs are reported in this group, including impaired thermoregulation with dangerous core temperature elevation. Clinicians should begin with the lowest possible dose and titrate slowly while carefully assessing for the balance between symptom control and AEs.

While newer agents (eg, darifenacin) are reported to be less likely to produce cognitive deficits in elderly patients, the literature is limited; the two-week drug administration period in these studies is not long enough to yield definitive conclusions. Patients may not recognize that memory deterioration has occurred, making it essential for monitoring by the clinician, family members and caregivers. ³²

Polypharmacy is common in frail community-dwelling patients,³³ placing them at higher risk for

AEs, including impaired cognition. In dementia patients, anti-muscarinics may be contraindicated entirely depending on the level of cognitive impairment.

16. Patients who are refractory to behavioral and medical therapy should be evaluated by an appropriate specialist if they desire additional therapy. *Expert Opinion*

As behavioral therapies present no risks to patients and anti-muscarinics present risks that cease when the medication is stopped, the remaining treatments present increasing risk that must be balanced with potential efficacy. Before a patient is exposed to these advanced therapies, the patient's realistic desire for further treatment should be ascertained, and a comprehensive evaluation should be conducted to confirm the diagnosis of OAB and not another disease process.

Third-Line Treatments

Neuromodulation or onabotulinumtoxinA therapy may be offered to the carefully selected patient who has failed behavioral and anti-muscarinic therapy or who is not a candidate for these therapies and continues to have bothersome symptoms after appropriate counseling. Neuromodulation therapies are FDA-approved for OAB treatment; however, the use of onabotulinumtoxinA in non-neurogenic OAB patients is not FDA-approved.

FDA-Approved – Neuromodulation Therapies

17. Clinicians may offer SNS as third-line treatment in a carefully selected patient population characterized by severe refractory OAB symptoms or patients who are not candidates for second-line therapy and are willing to undergo a surgical procedure. Recommendation (Evidence strength: Grade C)

SNS is FDA-approved in the treatment of OAB. Studies report that all measured parameters, including QoL and subjective improvement, show improvement with treatment, but improvement dissipates if treatment ceases.

In carefully selected patients, SNS is an appropriate therapy with durable treatment effects but counterbalanced by frequent and moderately severe AEs, including pain at the stimulator and lead sites, lead migration, infection/irritation, electric shock, the need for additional surgeries (a side effect that occurred in greater than 30% of patients) and periodic battery replacement. Patients must be cognitively capable of optimizing their device settings and compliant with the long-term treatment protocols. Given the negative effects on QoL associated with severe OAB, the benefits of SNS in the appropriate patient appear to outweigh the risks/burdens. There is some evidence that newer surgical procedures may be associated with fewer AEs. ³⁴



18. Clinicians may offer PTNS as third-line treatment in a carefully selected patient population. Option (Evidence strength: Grade C)

The most common protocol reviewed was the application of 30 minutes of stimulation once a week for 12 weeks. Longer follow-up periods of time in two studies indicate that improvements are maintained with on-going treatment. The validity of PTNS treatment responses is supported by a study comparing a PTNS group to a sham-PTNS group wherein only the active treatment group exhibited improvements in OAB symptoms. AEs were relatively uncommon and mild. PTNS can benefit a carefully selected group of patients with moderately severe baseline incontinence and frequency and willingness to comply with the PTNS protocol as well as those having resources allowing for frequent office visits for on-going treatment.

Non-FDA-Approved: Intradetrusor injection of onabotulinumtoxinA

19. Clinicians may offer intradetrusor onabotulinumtoxinA as third-line treatment in the carefully selected and thoroughly counseled patient who has been refractory to firstand second-line OAB treatments. The patient must be able and willing to return for frequent PVR evaluation and able and willing to perform self-catheterization, if necessary. Option (Evidence strength: Grade C)

At the time of this writing, intradetrusor onabotulinumtoxinA is not FDA-approved for treatment of non-neurogenic OAB.

Reductions in frequency, nocturia, pad use and incontinence, improvement in urodynamics parameters and improvement in QoL measures diminish over time requiring repeat injections to restore improvements. Substantial rates of AEs occurred in the active treatment groups and included UTIs, elevated PVR and the need for self-catheterization.

Additional Treatments

20. Indwelling catheters (including transurethral, suprapubic, etc.) are not recommended as a management strategy for OAB because of the adverse risk/benefit balance except as a last resort in selected patients. *Expert Opinion*

Management with diapering and absorbent garments is always preferred to indwelling catheterization because of the high risk of indwelling catheterassociated UTIs, urethral erosion/destruction and urolithiasis. Intermittent catheterization may be an option when concomitant incomplete bladder emptying leads to overflow incontinence; however, this approach generally requires either patient willingness and ability or significant caregiver support. As a last resort, an indwelling catheter might be con-

sidered when urinary incontinence has resulted in progressive decubiti.

21. In rare cases, augmentation cystoplasty or urinary diversion for severe, refractory, complicated OAB patients may be considered. *Expert Opinion*

Surgery is not recommended for OAB patients except in extremely rare cases as there are substantial risks to these procedures, including the likely need for long-term intermittent self-catheterization and the risk of malignancy. The vast majority of case series of augmentation cystoplasty and diversion focus on neurogenic patients. Little is known regarding the impact of these procedures on nonneurogenic OAB patients and, particularly, on their QoL.

Follow-Up

22. The clinician should offer follow-up with the patient to assess compliance, efficacy, side effects and possible alternative treatments. *Expert Opinion*

Follow-up is useful in assessing treatment compliance, questioning patients regarding the balance between symptom improvements and AEs and presenting information about possible alternative treatments for patients with insufficient symptom improvement and/or intolerable AEs. Patients should be encouraged to persist with a particular treatment for four to eight weeks; this time period will identify the majority of responders.⁴⁰

SECTION 7: RESEARCH NEEDS AND FUTURE DIRECTIONS

The panel recognizes that much additional research is needed in OAB including epidemiologic, basic science, translational and clinical research. For a detailed description of research needs and future directions please refer to the full-length version of this guideline available at http://www.auanet.org/content/media/OAB_guideline.pdf.

Conflict of Interest Disclosures

All panel members completed COI disclosures. Relationships that have expired (more than one year old) since the panel's initial meeting, are listed. Those marked with (C) indicate that compensation was received; relationships designated by (U) indicate no compensation was received.

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Disclaimer

This document was written by the Overactive Bladder Guidelines Panel of the American Urological Association Education and Research, Inc., which was created in 2009. The Practice Guidelines Committee of the AUA selected the panel chair. Panel members were selected by the chair. Membership of the panel included urologists and other clinicians with specific expertise on this disorder. The mission of the committee was to develop recommendations that are analysis-based or consensus-based, depending on Panel processes and available data, for optimal clinical practices in the diagnosis and treatment of overactive bladder.

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vic Medicine & Urogenital Reconstruction. Committee members received no remuneration for their work. Each member of the committee provides an ongoing conflict of interest disclosure to the AUA.

While these guidelines do not necessarily establish the standard of care, AUA seeks to recommend and to encourage compliance by practitioners with current best practices related to the condition being treated. As medical knowledge expands and technology advances, the guidelines will change. Today, these evidence-based guideline statements represent not absolute mandates but provisional proposals for treatment under the specific conditions described in each document. For all these reasons, the guidelines do not pre-empt physician judgment in individual cases.

Treating physicians must take into account variations in resources, and patient tolerances, needs, and preferences. Conformance with any clinical guideline does not guarantee a successful outcome. The guideline text may include information or recommendations about certain drug uses ('off label') that are not approved by the FDA, or about medications or substances not subject to the FDA approval process. AUA urges strict compliance with all government regulations and protocols for prescription and use of these substances. The physician is encouraged to carefully follow all available prescribing information about indications, contraindications, precautions and warnings. These guidelines are not intended to provide legal advice about use and misuse of these substances.

Although guidelines are intended to encourage best practices and potentially encompass available technologies with sufficient data as of close of the literature review, they are necessarily time-limited. Guidelines cannot include evaluation of all data on emerging technologies or management, including those that are FDA-approved, which may immediately come to represent accepted clinical practices.

For this reason, the AUA does not regard technologies or management which are too new to be addressed by these guidelines as necessarily experimental or investigational.

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