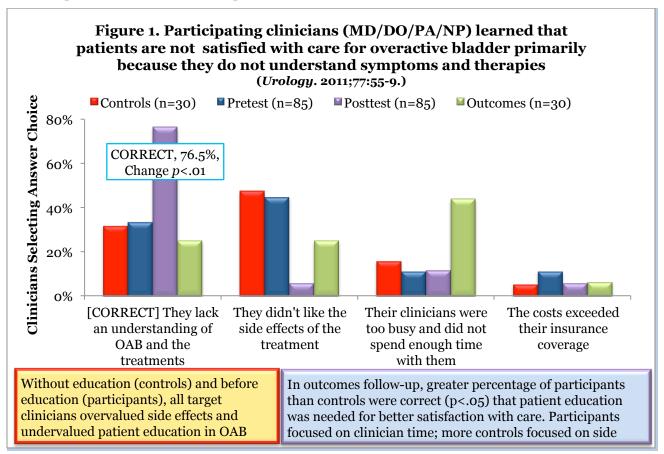
Clinicians increased rates of individualizing therapy and counseling on overcoming barriers to adherence to improve QoL and increased competence in choosing a beta-3-adrenergic agonist when antimuscarinics failed.

A women's focus group showed that, patient-centered care is the best approach to managing the chronicity of overactive bladder (OAB) symptoms that affect patients' lives.¹ With a 75% super-majority of patients with an OAB diagnosis going untreated,² patients who actually do receive treatment need education on the benefits of adherence for improving quality of life (QoL) and on managing side effects when they begin therapy,³ to help them persist with treatment: Research shows that 43% – 83% had discontinued pharmacotherapy at 30 days,⁴ and guidelines cite evidence that "the majority of patients discontinue anti-muscarinic therapy after a few weeks or months," with side effects "commonly cited as the [patient's] reason for discontinuation." This CME Outfitters educational initiative on adherence and personalized therapy in OAB helps clinicians adhere to the guidelines' Expert Opinion that "the clinician should offer follow up with the patient to assess compliance, efficacy, side effects and possible alternative treatments."³

Clinicians can encourage patients to adhere to OAB therapy as a means of improving QoL, so to meet guidelines-level recommendations, they must consider various therapeutic options to help patients manage possible side effects of therapy. Discussing ways to overcome barriers to medication adherence can help patients control wetness and manage both medication side effects and OAB triggers. Showing improvement from pretest data (yellow) in Figure 1, clinicians were educated on the evidence that patients' satisfaction with care depended more on patient education than on issues with side effects, increasing knowledge by 43.1 points (129.4%, p < .01). Outcomes data show that more participants (green) than controls (red) remembered the greater importance of patient education (p < .05) and lesser importance of side effects to patient satisfaction with care.



Performance-Level Findings

Strong performance change was associated with participation in this initiative. Presurvey data gathered for participants in the live meeting and enduring Module 1 showed that 30.0% of responding clinicians had believed that less than half of their patients were adhering to medication for OAB. Despite this belief, performance in counseling on adherence was low: just 23.5% had been counseling at least half of their patients on the role of adherence for improved QoL, and just 36.9% had been discussing specific ways to overcome patients' barriers to adherence.

CME Outfitters significantly changed participants' practice patterns for both of these counseling performance measures, by nearly 100% to nearly 250%, as shown in Figure 2 (data and calculations) and Table 1 (statistical summaries, additional data, and comments). Participation in the activity also raised participants' poor pre-activity performance rates on "individualizing treatment plans by evaluating the efficacy and safety data of all available OAB treatment options" to the point where participants had exceeded rates of controls. We interpret participants' performance improvement thus: because performance rates on individualizing treatment plans and helping patients overcome barriers to adherence were no longer statistically different between groups but participants had started with lower rates than controls, participants were aware of their needs and challenges, and sought education to assist them in improving practice. Even more dramatically, participants significantly increased their suboptimal rates of counseling on adherence for better QoL to a point where they had significantly higher rates than controls had.

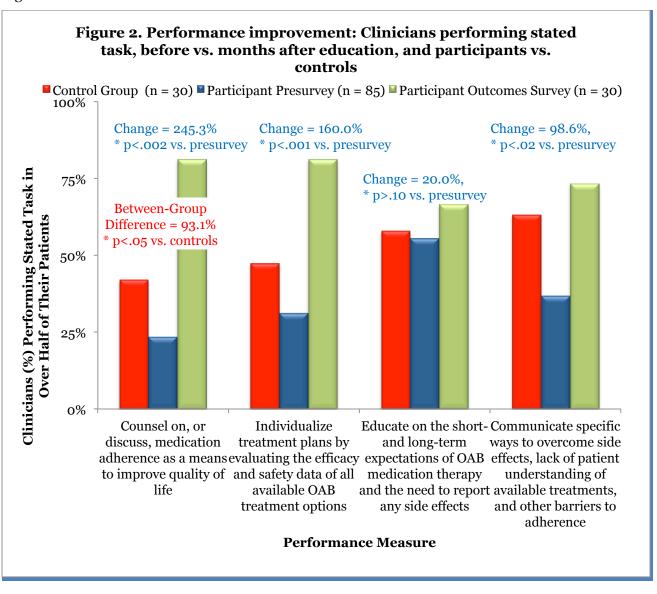


Table 1. Statistical Analyses and Outcomes Comments on Performance Data Is Difference Significant¹? **Performance Expectation Change Due to** Difference (Clinical task **Participation** Between **Comment or Additional Data** performed with (Presurvey vs. **Groups** 51% - 100% of Outcomes) (Outcomes vs. patients) Controls) Counsel on, or **Yes** (p < 0.01)**Yes** (p < 0.05)· Education was needed and effective. discuss, medication • Participants reported moderate levels of adherence as a means ongoing, educational need, as well as high to improve quality of levels of patient-related barriers in the life outcomes survey. For controls, mean was lowest among the four performance expectations. Individualize **Yes** (p < 0.02)Participants raised performance to exceed that **No** (p > 0.05)treatment plans by of controls, indicating that participants selfevaluating the selected education, having identified a gap vs. efficacy and safety data of all available Participants reported high levels of ongoing, OAB treatment educational need, as well as low levels of options confidence. **No** (p > 0.10)High participant baseline meant less room for **No** (p > 0.10)Educate on the shortimprovement. and long-term • Participants reported some need for additional expectations of OAB education or improved confidence, but medication therapy practice- and patient-related barriers had

greater influence on performance.

• Among live-meeting respondents to the

less need for education.

measure with zero patients.

(20.0% were counseling).

peers.

Outcomes showed *all* participants

High control-group performance rates suggest

presurvey, 30.0% had been performing the

• Webcast participants had *better* self-reported

rates at baseline (44.4% counseling more than

half of patients) than live-meeting participants

communicating with at least some patients on

Participants raised performance to exceed that of controls, indicating that participants self-selected education, having identified a gap vs.

overcoming barriers (change vs. presurvey).

No (p > 0.10)

Outcomes Data on Competence in Selecting OAB Therapy

Yes (p < 0.01)

and the need to

report any side effects

Communicate with

and counseling on

specific ways to

overcome OAB

patient

treatment-related

side effects, lack of

understanding of

available treatments,

and other barriers to

medication adherence

Presurvey data gathered via live ARS at the symposium also revealed that nearly one quarter (23.5%) of participants would choose only behavioral therapy for OAB, even for those patients with major OAB impacts on quality of life (illustrated with a video case vignette of "Mrs. Thompson"); 14.7% selected a beta 3-adrenergic agonist; 61.8% an antimuscarinic agent (n = 34). The subset of clinicians who would choose behavioral therapy alone is following practice patterns that are not consistent with the evidence that behavioral therapy is most effective when combined with pharmacotherapy.⁶ Another live ARS question showed that 82.6% of live participants knew this evidence at the time (presurvey n = 23; posttest data showed gap closure, with 100.0% correct, posttest n = 51).

¹ Statistical significance determined via Fisher's exact test of 2x2 contingency table (chi square).

A case scenario outcomes survey highlights differences between participants and controls, in addition to participants' changing their preferences for medication-switching when a patient experienced side effects and incomplete symptom control with antimuscarinic therapy (see Table 2A and 2B).

Participants cited far lower educational needs and higher confidence with carrying out specific performance tasks, suggesting that their changed treatment strategies in switching OAB therapies improved their perceptions of their educational needs and self-efficacy. Margaret is a 47-year-old administrative assistant who has developed symptoms of overactive bladder with urge and increasing incontinence over the last two years. She was first prescribed an antimuscarinic agent that did not completely control the symptoms. A different antimuscarinic was tried that led to increased side effects and incomplete symptom control. She states that she does not have time for behavioral therapy. Please RANK the clinical options that you might choose next for Margaret, from inappropriate or worst to best.

Table 2A. Clinical Approaches for Case Patient "Margaret"

	Participants' Ranking Choices (n = 30 participants)						Controls' Ranking Choices (n = 30)
	Not Appropriate	1 (Worst, but Appropriate)	2	3	4 (Best)	Sum: Range 3 – 4 (Best)	Sum: Range 3 – 4 (Best)
Switch to an antimuscarinic agent with a lower side- effect profile	0.0%	13.3%	30.0%	26.7%	30.0%	56.7%	53.4%
[BEST ANSWER] Switch to a beta-3- adrenergic agonist	6.7%	13.3%	13.3%	30.0%	36.7%	66.7% (over half, or 54.5%, of these at Rank "4 (Best)")	56.7% (but only 25% rank as "4 (Best))
Try to convince her that behavioral therapy is important	13.3%	6.7%	40.0%	13.3%	26.7%	40.0%	36.7%
Recommend electrical stimulation of the sacral nerve	13.3%	50.0%	6.7%	30.0%	0.0%	30.0%	36.7%

Table 2B. Comments on Findings on Treatment-Selection

Clinical	Comments on Participants' Treatment	Comments on Controls' Treatment
Approach	Selection for Margaret	Selection for Margaret
Switch to an antimuscarinic agent with a lower side-effect profile	15% more participants chose prescribing a beta-3-adrenergic agent over prescribing a 3 rd antimuscarinic agonist to Margaret as the "best" or second-best clinical approach.	26.7% of controls find prescribing a 3 rd antimuscarinic agonist to Margaret after two treatment failures as the "best" option, and another 26.7% find it second-best. More controls than participants find such treatment selection the "best" next step.

[BEST ANSWER] Switch to a beta- 3-adrenergic agonist	66.7%, or 15% more participants than controls, ranked switching to a beta-3-adrenergic agonist as "4 (best)" or "3" (second-best). Furthermore, of the 66.7% who ranked this as as top-two approach, more than half made it the top rank. Also, 50.0% more participants than controls choose it as "best" among four clinical approaches for a patient who had failed antimuscarinic therapy twice.	While over half of controls ranked switching to a beta-3-adrenergic agonist as "4 (best)" or "3" (second-best), only one third, or 36.7%, of these at Rank "4 (Best)." We attribute controls' higher preference for antimuscarinic agonists to their lower knowledge of these agents' side effects and high discontinuation rates; 50.0% - 56.7% of controls also cited "Educational Need" as the TOP reason for which they had neither "individualized treatment plans by evaluating the efficacy and safety data of all available OAB treatment options" nor "educated [their] patients on the short- and long-term expectations of OAB medication therapy and the need to report any side effects."
Try to convince her that behavioral therapy is important	60.0% of participants ranked behavioral therapy a poor or inappropriate option, and 40.0% ranked it as a top-two choice. Of the remaining 40.0% who ranked it a top-two choice, two thirds chose it as the best next step when Margaret's antimuscarinic therapy failed twice. Participants prefer behavioral therapy to electrical stimulation, perhaps because they learned evidence that behavioral therapy works best when combined with pharmacotherapy, which they support more than controls do.	63.3% of controls ranked behavioral therapy a poor or inappropriate option. Of the remaining 36.7% who ranked it a top-two choice, nearly three quarters (71.4%) chose it as the best next step when Margaret's antimuscarinic therapy failed twice. This indicates that control-group clinicians have an even greater ongoing need to gain or reinforce knowledge of the evidence for multimodal treatment.
Recommend electrical stimulation of the sacral nerve	Participants divided into 2 camps on electrical stimulation of the sacral nerve: 30.0% ranked this option as "3" (good; none ranked it "best"), and most (91.9%) of the remaining 71% as ranked electrical stimulation an "inappropriate" or "1 (worst)" option. Interestingly, the same percentage of participants ranked stimulation therapy and use of a third antimuscarinic for Margaret as a "3" (or "good"). Still, but no participants chose stimulation therapy as their first "best" clinical option, which is consistent with their earlier posttest scores where more thought "bladder retraining" was better than "neuromodulation," which itself was a misunderstanding.	Controls did not divide into camps, with rankings falling into a bell curve that leaned toward "worst." A higher percentage (36.7%) of controls than participants ranked electrical stimulation "3" or "4 (best)," but in stark contrast to participants' rankings,, 42.9% of this 36.8% chose it as their top choice (0% of participants did). This indicates that participants have greater preference than controls for pharmacotherapeutic options, and greater preference for OAB behavioral therapies than for electrical stimulation of the sacral nerve.

Educational Activity Impact

Clinicians' knowledge changed regarding patients' preferences for care (that they needed to understand the treatments) and managing pharmacotherapeutic efficacy with fewer side effects, and these translated to better competence with treatment-selection, and better performance in individualizing therapy and initiating a dialogue with all patients about adherence to recommended treatments for OAB.

After clinicians learned that behavioral therapy is most efficacious when combined with medication therapy for OAB, they significantly narrowed pre-activity patient-counseling gaps related to medication adherence as a means of improving quality of life and overcoming barriers to adherence. They also significantly improved their rates of individualizing treatment plans by considering the efficacy and

safety data of all available agents. These improvements show that clinicians kept their post-activity commitments to improve their practices, and because their baseline performance was lower than that of controls, we believe that they chose to participate because of perceived gaps in OAB care.

Recognizing the limitations of behavioral therapy alone and side effects seen with anti-muscarinic therapy, the guidelines include the Standard (Evidence Strength Grade B) that "clinicians should offer oral anti-muscarinics or oral beta 3-adrenoceptor agonists as second-line therapy" and the "Clinical Principle" that "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 or a beta 3-adrenoceptor agonist may be tried."

Voice of the Patient

Individualizing therapy to improve medication adherence improves OAB symptoms for better quality of life, and helps patients who are troubled by wetness, urgency, frequency, side effects of pharmacotherapy, and clinicians' advice on toileting behavior. For example, this writer recalls a coworker's frustration (in 2001) with both pharmacotherapy and her doctor's advice to "wait a little while and try again before leaving the restroom," which caused stress because the advice seemed inconsistent with her need to return quickly to job duties. Since that time, new clinical evidence and a better understanding of patient-centered care for OAB have emerged. This education helped participating clinicians improve their existing misconceptions and patient miscommunication highlighted by Smith, et al., and learn that patients will be more satisfied with their care if they understand OAB. Because side effects are less important than understanding to patients, clinicians have a great opportunity to handle side effects by considering other therapies, as per AUA guidelines, and then return immediately to educating their patients about pathophysiology and OAB therapies to support adherence for better quality of life. With 16% – 45% of adults having OAB symptoms and an aging population, the needs for improving patients' daily productivity and quality of life are high.

Future Educational Needs

A 2012 Cochrane Review studied the selection of anticholinergic agents for the treatment of OAB.⁷ The mere existence of this review and the preceding one in 2005 indicate both the pace of medical advances and clinician's needs for additional education on making appropriate choices for individual patients from the OAB treatment armamentarium. With an understanding of medication side effects and new therapeutic options to consider, clinicians are more likely to select therapy that suits their patients' needs and improves quality of life with overactive bladder.

Yet greater needs are reinforcement and education with broader reach on patients' needs for education on OAB and its treatments, which go hand-in-hand with the performance expectations of counseling on 1) medication adherence as a means to improve QoL and 2) specific ways to overcome OAB treatment-related side effects, lack of patient understanding of available treatments, and other barriers to medication adherence. The opportunities for additional narrowing of gaps is indicated by participants' significantly better than controls' performance on counseling adherence for better QoL and significantly greater than controls' knowledge that dissatisfaction with OAB treatment-related side effects was not patients' greatest reason for dissatisfaction with care.

Box. Educational Design and Outcomes Methods Highlights.

Format

CME Outfitters Medical Meeting at the American Urological Association 2013 Annual Meeting, with on-demand, enduring material Webcasts (3): <u>Module 1</u>: Prevalence and Impact on QoL; <u>Module 2</u>: Treatment; <u>Module 3</u>: Medication Adherence.

Practice Patterns (Outcomes Measures)

- Regularly discuss medication adherence as a means to improve quality of life with 20% more patients with OAB in the next 3 months, with incremental increases thereafter.
- Communicate specific ways to overcome barriers to adherence to treatment plans with 20% more patients

with OAB in the next 3 months, with incremental increases thereafter.

Demographic Inclusion Criteria

Degrees: Physicians, physician assistants, nurse practitioners

Specialties: Urology, obstetrics/gynecology, primary care

Participation Dates: Credit requests through 10/15/13 for the live session and through 4/30/14 for one or more

enduring webcasts

Patients with OAB: Range 1 - 50 seen monthly

Pre- and post-testing and surveying

Live Symposium via ARS/PollsEverywhere technology: <u>Pre-activity</u> knowledge, practice, and reflection data gathered from participants via an audience-response (ARS). <u>In-content</u> ARS post-test participant question. <u>Post-activity</u> test and practice commitment survey (with credit request).

Archive (3 Modules): Pre-activity knowledge and practice data gathered via online registration process. Post-activity knowledge test and practice commitment survey for each of 3 modules.

Outcomes testing, surveying, and analysis

Case vignette, reflection, and practice survey with staggered timing after live/enduring participation.

Outcomes survey range two months to one year after participation.

Control group surveyed simultaneously with participant outcomes survey.

Statistical comparisons of knowledge and self-assessment performance data via Fisher's exact test of 2x2 contingency tables (chi square, alpha set at .05): 1) participant presurvey vs. posttest or outcomes, as appropriate; 2) participant outcomes vs. control clinicians. Software: GraphPad QuickCalcs at http://graphpad.com/quickcalcs/contingency1/.

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