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RE: Comments on Key Questions on Diagnosis and Comparative Effectiveness of Treatments for Urinary Incontinence in Adult Women

To Whom It May Concern:

On behalf of the 74,000 members of the American Physical Therapy Association (APTA), I would like to thank the Agency for Healthcare Research and Quality (AHRQ) for the opportunity to comment on key questions related to the diagnosis and treatment of urinary incontinence in adult women. APTA is a professional association representing physical therapists, physical therapist assistants, and students of physical therapy. Physical therapists are health care professionals who diagnose and manage individuals of all ages who have musculoskeletal problems or other health-related conditions that limit their abilities to move and perform functional activities in their daily lives. Physical therapists examine each individual and develop a plan of care using treatment techniques to promote the ability to move, reduce pain, restore function, and prevent disability.

Role of Physical Therapists in the Diagnosis and Treatment of Urinary Incontinence

Stress urinary incontinence is the involuntary loss of bladder control. It often occurs during physical activity or when sneezing or coughing. Urge incontinence occurs when individuals are unable to hold urine in response to a sudden compelling need to urinate. It is a common misconception that urinary incontinence only occurs in older patients. In fact, the condition affects men and women alike, young and old. According to the National Association for Continence, more than 25 million Americans have urinary incontinence, and the experience can leave them feeling ashamed, socially isolated, and depressed. Urinary incontinence can also lead to falls due to the patient rushing to the bathroom. And according to a study in the *New England Journal of Medicine*, urinary incontinence can lead to an overall reduction in quality of life.¹ The estimated cost associated with urinary incontinence is \$10 billion a year with nursing homes spending approximately 10% of their budgets on UI treatment, or \$2 billion.² Perhaps due to the social stigma associated with urinary incontinence, it is estimated that only 25% of women impacted by the condition seek medical treatment³ which means that the actual cost of treating urinary incontinence could be much higher. One study estimated that expenses related to urinary incontinence not covered by insurance, such as pads and

¹ Roger, RG. Urinary stress incontinence in women. *N Eng J Med*. 2008; 10: 1029-1036.

² Yamanishi, T, Yasuda K. Electrical Stimulation for Stress Incontinence. *International Urogynecology Journal*. 1998; 9: 281-290.

³ Bo K, Talseth T, Holme I. Single blind, randomized controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. *BMJ* 1999; 318:487-493.

laundering soiled clothes, could be as high as \$900 a year.⁴ Many patients believe that because of their age or medical history, urinary incontinence is something they can do nothing about or must live with. However, interventions provided by physical therapists can improve a patient's quality of life and resolve incontinence.

Physical therapists are crucial in the evaluation and treatment of urinary incontinence because of their clinical knowledge and skills in both assessing and treating musculoskeletal conditions. With the interventions physical therapists provide individuals have options beyond diapers, medication, or surgery. Physical therapists use a variety of methods to help individuals correct pelvic floor dysfunction. The initial patient evaluation requires determining the type of incontinence (stress, urge, or both), the extent of incontinence, assessing the strength, motor control and endurance of pelvic floor muscles, and screening for any other musculoskeletal issues, then developing an individualized plan of care, and making sure individuals understand their role and the importance of adherence in the treatment program for optimal outcomes.

Studies have found that many women perform pelvic floor muscle exercises incorrectly and as a result require the specialized instruction of a healthcare provider such as a physical therapist.⁵ Hay-Smith and Dumoulin also found that Kegel exercise programs are more effective if steps are taken to ensure that patients are exercising the correct muscles and are given support in continuing with their exercise program.⁶ This further indicates the need for a trained healthcare professional, such as a physical therapists, to provide interventions designed to educate the patient and improve their functional capacity.

Diagnosis of Urinary Incontinence

It is important to note that a comprehensive history and combination of assessment tools are necessary in order to evaluate the different aspects of pelvic floor muscle function that are important to continence.⁷

Clinical Exam

Manual muscle testing and perineometry are two tools a physical therapist might use as part of a clinical exam to determine pelvic floor muscle function. National standards for the practice of physical therapy require comprehensive screening and the performance of specific tests and measures of neuromusculoskeletal function leading to a diagnosis,

⁴ Subak LL, Brown JS, Kraus SR, et al. The "costs" of urinary incontinence for women. *Obstet Gynecol.* 2006;107(4):908-916.

⁵ Thompson J, O'Sullivan PB, Briffa NK, Neumann, P. Assessment of voluntary pelvic floor muscle contraction in continent and incontinent women using transperineal ultrasound, manual muscle testing and vaginal squeeze measurements. *Int Urogynecol J* 2006; 17: 624-630.

⁶ Hay-Smith EJ, Dumoulin C. Pelvic floor muscle training versus no treatment, or inactive control treatments, for urinary incontinence in women. *Cochrane Database of Syst Rev.* 2006; Jan 25;(1):CD0056540.

⁷ Thompson J, O'Sullivan PB, Briffa NK, Neumann, P. Assessment of voluntary pelvic floor muscle contraction in continent and incontinent women using transperineal ultrasound, manual muscle testing and vaginal squeeze measurements. *Int Urogynecol J* 2006; 17: 624-630.

prognosis and plan of care for a health condition. Internal examination of the pelvic floor muscles is within the scope of practice for physical therapists.⁸ Examination of posture, pelvic mobility, trunk strength and flexibility, and sensation are also included in the initial examination. The use of a questionnaire, such as the Three Incontinence Questions (3IQ) Questionnaire, can help to screen for incontinence and can distinguish stress from urge incontinence.⁹ Additional tests include the use of a bladder diary to document the frequency, timing and number of incontinence periods and a 'cough stress test' to rule out stress incontinence. Pad tests can also be used as an objective measure of urinary incontinence.

Ultrasound

According to a study conducted by Judith Thompson et al, ultrasound is useful to determine the direction of pelvic floor movement in the clinical assessment of pelvic floor muscle function in a mixed subject population.¹⁰ Ultrasound is used to determine pelvic floor muscle function, but some studies have shown that it is as effective as other diagnostic methods including manual muscle testing and perineometry.¹¹ When a correct pelvic floor muscle contraction occurs, there is a cranio-ventral shift of the pelvic organs. Ultrasound can provide a visualization of this process as a displacement of the bladder neck¹² or bladder base¹³. A second study assessing the effectiveness of the use of ultrasound to assess the function of the pelvic floor muscles reiterated the importance of visualizing the actual movements inside the pelvis.¹⁴

Higher elevation of the bladder neck indicates stronger pelvic floor muscles. Women with strong pelvic floor muscles typically do not experience urinary incontinence. The study conducted by Thompson demonstrated that the elevation level of the bladder neck was positively correlated to the strength of the pelvic floor muscles as determined through manual muscle testing. Therefore, the study concludes, ultrasound is a clinically useful tool to assess the direction of movement of the bladder neck during voluntary

⁸ APTA Section on Obstetrics and Gynecology, 1993 (revised August 2000 by Section on Women's Health BoD)

⁹ Brown JS, Bradley CS, Suback LL, et al. The sensitivity of a simple test to distinguish between urge and stress urinary incontinence. *Ann Intern Med* 2006; 144:715-723.

¹⁰ Thompson J, O'Sullivan PB, Briffa NK, Neumann, P. Assessment of voluntary pelvic floor muscle contraction in continent and incontinent women using transperineal ultrasound, manual muscle testing and vaginal squeeze measurements. *Int Urogynecol J* 2006; 17: 624-630.

¹¹ Dietz HP, Steensma AB, Vancaillie TG. (2002) The assessment of levator muscle strength: a validation of three ultrasound techniques. *Int Urogynecol J Pelvic Floor Dysfunct*; 14 (1): 24-26.

¹² Dietz HP, Wilson PD, Clarke B (2001) The use of perineal ultrasound to quantify levator activity and teach pelvic floor muscle exercises. *Int Urogynecol J Pelvic Floor Dysfunct* 12 (3):166-169

¹³ Bo K, Sherburn M, Allen T (2003) Transabdominal ultrasound measurement of pelvic floor muscle activity when activated directly or via a transversus abdominis muscle contraction. *Neurourol Urodyn* 22(6):582-588

¹⁴ Bo K, Talseth T, Holme I. Single blind, randomized controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. *BMJ* 1999; 318:487-493.

pelvic floor muscle contraction in order to establish the correct technique of performing an elevating pelvic floor muscle contraction.¹⁵

Ultrasound is considered a safe, cost-effective, portable, and clinically accessible method for gathering information about the static characteristics of muscle and muscle behavior during dynamic events. While CT and MRI may provide a higher or better resolution image, these technologies are expensive and may expose the patient to radiation unnecessarily.¹⁶

Physical Therapy Interventions for the Treatment of Urinary Incontinence

Pelvic Floor Muscle Exercises

The pelvic floor muscle group is the only muscle group in the body capable of giving structured support for the pelvic organs including the urethra, vagina, and rectum. Pelvic floor muscles are one component of the stress continence system. A conscious and voluntary contraction of the pelvic floor muscles causes a squeeze and inward lift of this muscle group which results in urethral closure, stabilization, and resistance to downward movement. As a result, the strength of the pelvic floor muscles is a crucial component of maintaining continence. In fact, case control studies have shown a difference in pelvic floor muscle function, strength, and structural support in continent and incontinent women.¹⁷

Pelvic floor muscle exercises (also known as Kegel exercises) involve contracting, holding, and releasing pelvic floor muscles and are recommended as the first-line of treatment.¹⁸ Given the relatively low cost and risk of behavioral and physical therapy, exercises should be the first step in treatment for urinary incontinence.¹⁹ In an article published in *International Urogynecology Journal*, Kari Bo notes that several randomized controlled trials have shown that pelvic floor muscle training is effective in the treatment of female stress and mixed urinary incontinence.²⁰ For instance, it has been demonstrated that if a woman is simply instructed to contract the pelvic floor muscle prior to an activity, such as coughing or sneezing, that causes her to experience leakage that over

¹⁵ Thompson J, O'Sullivan PB, Briffa NK, Neumann, P. Assessment of voluntary pelvic floor muscle contraction in continent and incontinent women using transperineal ultrasound, manual muscle testing and vaginal squeeze measurements. *Int Urogynecol J* 2006; 17: 624-630.

¹⁶ Whittaker J, Teyhen D, Elliott J, Cook K, Langevin H, Dahl H, Stockes M. Rehabilitative Ultrasound Imaging: Understanding the Technology and Its Applications. *Journal of Orthopedic & Sports Physical Therapy* 2007;37: 434-449.

¹⁷ Bo K. Pelvic floor muscle training is effective in treatment of female stress urinary incontinence, but how does it work? *Int Urogynecol J* 2004; 15: 76-84.

¹⁸ Fantl JA, Newman DK, Colling J, DeLancey J, Keeys C, Loughery R, et al (1996) Urinary incontinence in adults: acute and chronic management. 2, update [96-0682], 1-154. U.S. Department of Health and Human Services, Public Health

Service, Agency for Health Care Policy and Research. Clinical Practice Guideline, Rockville, MD

¹⁹ Smith PP, McCrery RJ, Appell RA. Current trends in the evaluation and management of female urinary incontinence. *CMAJ*. 2006;175:1233-40.

²⁰ Bo, K. Pelvic floor muscle training is effective in treatment of female stress urinary incontinence, but how does it work? *Int Urogynecol J* 2004; 15: 76-84.

half of these women will continue to experience episodes of urinary incontinence.²¹ However, within one week of training, women who are taught to contract their pelvic floor muscles before or during a cough can reduce the amount of urine loss by 98%.²² Some experts speculate that if the muscle is weakened, stretched, or in a low position that it may not be able to contract effectively further supporting the need to strengthen this muscle group.²³

The effectiveness of pelvic floor muscle exercises has also been compared to electrical stimulation and vaginal weights in a randomized controlled study. While improvements have been seen with all three treatment interventions, this trial determined that exercises were more effective than electrical stimulation and vaginal weights as demonstrated by a reduction in leakage on a pad test. Additionally, while 14 patients in the exercise group stated they no longer felt as if they had a problem, only three patients in the electrical stimulation group and two patients in the vaginal weight group expressed a similar opinion.²⁴ Of note, the women in the three distinct treatment groups were of similar age, body mass index, duration of symptoms, pelvic floor muscle strength, urodynamic assessment, and degree of leakage. But the compliance rates were somewhat different with a 93% compliance rate for women in the pelvic floor muscle exercise group, 75% compliance in the electrical stimulation group, and 78% compliance among those using vaginal weights during the trial period.

However, the cure and improvement rates associated with pelvic floor muscle exercises can vary. Arthur Kegel, largely credited with the use of pelvic floor muscle exercises to treat urinary incontinence, reported that 84% of his patients with urinary incontinence were cured after doing pelvic floor muscle exercises.²⁵ In randomized controlled trials, improvement rates for stress and mixed urinary incontinence vary between 56% and 70%.²⁶ In a study conducted by Balmforth it was determined that patients who had undergone 14 weeks of pelvic floor muscle exercises and behavioral modification had significant elevation of the bladder neck position and displacement of the bladder neck on valsalva was reduced. This suggests levator “stiffness.” These changes in anatomy resulted in clinically significant reduction in urinary incontinence and improvement in quality of life.²⁷

²¹ Bump R, Hurt WG, Fantl JA, Wyman JF (1991) Assessment of Kegel exercise performance after brief verbal instruction. *Am J Obstet Gynecol* 165:322–329

²² Miller JM, Ashton-Miller JA, DeLancey JO. A pelvic muscle precontraction can reduce cough-related urine loss in selected women with mild SUI. *J Am Geriatr Soc*. 1998;46:870-874.

²³ Howard D, Miller J, DeLancey J, Ashton-Miller J (2000) Differential effects of cough, valsalva, and continence status on vesical neck movement. *Obstet Gynecol* 95:535–540

²⁴ Bo K, Talseth T, Holme I. Single blind, randomized controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. *BMJ* 1999; 318:487-493.

²⁵ Kegel AH (1952) Stress incontinence and genital relaxation. *Ciba Clin Sympos* 2:35–51

²⁶ Wilson PD, Bø KH-SJ, Nygaard I, Staskin D, Wyman J, Bourchier A (2002) Conservative treatment in women. In: Abrams P, Cardozo L, Khoury S, EinA(eds) *Incontinence*. Plymbridge Ltd, Health Publication Ltd, Plymouth, pp 571–624

²⁷ Balmforth et al 2006

As with many medical conditions, improvement or cure of urinary incontinence is greatly impacted by patient adherence to the treatment regimen.²⁸ In a study that followed up with women five years after initially completing a supervised pelvic floor muscle training program, 70% were still exercising at least once a week and 70% experienced no leakage when coughing.²⁹ These findings were validated by a study conducted by Neumann who also found that patients who remained compliant with an exercise program over a five year period continued to experience positive results.³⁰ A second study found that only 10% of women who had participated in a training program had undergone surgery to address urinary incontinence ten years later.³¹

Electrical Stimulation

Electrical stimulation is used on the pelvic floor muscles with the intent of strengthening these muscles. It is generally chosen because of the need to retrain a specific muscle. A physical therapist would apply stimulation at selected intervals over the motor point of the muscle in order to promote muscle response. In a review of the existing literature, Yamanishi and Yasuda explored the success rates of both short and long-term use of electrical stimulation to treat urinary incontinence. For stress incontinence, the cure rate could be as high as 50% and the improvement rate as high as 90%. The negative consequences or harm associated with short-term electrical stimulation has been shown to be relatively small with only a 14% adverse affect rate while the adverse event rate for long-term electrical stimulation was in the range of 20-30%. The primary complaint is the pain associated with the treatment. Electrical stimulation using external, or non-implantable, electrodes avoids many of the complications of implantable electrodes as they do not require surgery and are relatively simple to apply and use.³²

In the review conducted by Yamanishi and Yasuda, it was found that short-term electrical stimulation produced results relatively quickly, within one to two months.³³ Another study has found that patients with urinary incontinence who receive electrical stimulation report improvements in three of nine domains on the King's Health Questionnaire.³⁴

²⁸ Bo, K. Pelvic floor muscle training is effective in treatment of female stress urinary incontinence, but how does it work? *Int Urogynecol J* 2004; 15: 76-84.

²⁹ Bø K, Talseth T (1996) Long term effect of pelvic floor muscle exercise five years after cessation of organized training. *Obstet Gynecol* 87:261-265

³⁰ Neumann PB, Grimmer KA, Deenadayalan Y. Pelvic floor muscle training and adjunctive therapies for the treatment of stress urinary incontinence in women: a systematic review. *BMC Womens Health*. 2006 Jun 28;6,11.

³¹ Cammu H, Van Nylen M, Amy J (2000) A ten-year follow-up after Kegel pelvic floor muscle exercises for genuine stress incontinence. *BJU Int* 85:655-658

³² Yamanishi, T, Yasuda K. Electrical Stimulation for Stress Incontinence. *International Urogynecology Journal*. 1998; 9: 281-290.

³³ Susset J, Galea G, Manbeck K, Susset A. A predictive score index for the outcome associated biofeedback and vaginal electrical stimulation in the treatment of female incontinence. *J Urol* 1995, 153: 1461-1466.

³⁴ Wang AC, Wang YY, Chen MC. Single-blind, randomized trial of pelvic floor muscle training, biofeedback-assisted pelvic floor training, and electrical stimulation in the management of overactive bladder. *Urology*. 2004;63(1):61-66.

Behavioral Therapy

Behavioral therapy addresses lifestyle modifications that the patient has made to compensate for their symptoms. Often these behavioral modifications revolve around eliminating activities or food found to be sources of bladder irritation. Behavioral therapy has been found to be superior to placebo and drug therapy. In a study comparing the three treatments, those receiving behavioral therapy saw a mean reduction in urinary incontinence of nearly 81% while those undergoing drug therapy and placebo saw an improvement of only 69% and 39% respectively.

Vaginal Weights

Vaginal weight training involves holding progressively weighted vaginal cones within the vagina by tightening the vaginal muscles. Caution should be used with patients at risk for hypertonus, so training on muscle release is also important. As noted in our comments for pelvic floor muscle exercise, vaginal weights do help some women dealing with urinary incontinence. Patients treated using vaginal weights have a high compliance rate of 75%. The primary adverse effects of the use of vaginal weights are bleeding and discomfort or pain. Additionally, they have the potential to produce prolonged isometric contractions of the pelvic floor muscles, and in other muscles this may cause injuries as a result of overuse. But vaginal weights have been shown³⁵ to be more effective than no treatment.³⁶

Biofeedback

Biofeedback is an important adjunct to pelvic floor muscle exercise. It may be part of the treatment plan for patients who have difficulty in identifying, controlling and coordinating the function of pelvic floor muscles. Surface electromyography and ultrasound imaging are types of biofeedback that help to facilitate awareness of the state of muscle contraction during exercise. Studies have found that patients treated with biofeedback see a 63% reduction in urinary incontinence.³⁷

Surgery

There are surgical options available to patients with urinary incontinence. While the success rates of these surgical options vary, surgeries for urinary incontinence involve many of the same risks as other surgeries. Surgery requires short-term hospitalization and requires that the patient abstain from normal activity during the recovery period. There have been a limited number of randomized controlled trials that explore the effectiveness of surgery as an intervention for urinary incontinence. Of note, there is little research on the long-term effectiveness and complication rates associated with many of surgeries for urinary incontinence. Additionally, some women who underwent one form of surgery

³⁵ Burgio KL, Goode PS, Locher JL, et al. Behavioral training with and without biofeedback in the treatment of urge incontinence in older women: A randomized controlled trial. *JAMA*. 2002;288(18):2293-2299.

³⁶ Bo K, Talseth T, Holme I. Single blind, randomized controlled trial of pelvic floor exercises, electrical stimulation, vaginal cones, and no treatment in management of genuine stress incontinence in women. *BMJ* 1999; 318:487-493.

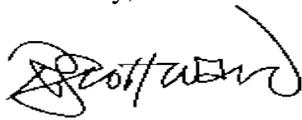
³⁷ Burgio KL, Locher JL, Goode PS. Combined behavioral and drug therapy for urge incontinence in older women. *J Am Ger Soc*. 2000;48(4):370-374.

returned for additionally surgical procedures to address their urinary incontinence at a later date.³⁸

Conclusion

In closing, I would like to thank AHRQ for considering an issue of great significance to many of the patients physical therapists treat. We look forward to partnering with AHRQ on such issues in the future. If you have any questions, please contact Sarah Nicholls, Assistant Director for Payment Policy and Advocacy, at 703-706-3189 or sarahnicholls@apta.org.

Sincerely,

A handwritten signature in black ink, appearing to read "R. Scott Ward". The signature is stylized and cursive.

R. Scott Ward, PT, PhD
President

RSW: sn

³⁸ Ward K, Hilton P. A prospective multicenter randomized trial of tension-free vaginal tape and colposuspension for primary urodynamic stress incontinence: Two-year follow-up. *American Journal of Obstetrics and Gynecology*; 2004, 190: 324-31.