I. GENERAL INFORMATION

Definition of Urge Incontinence/Overactive Bladder
Overactive bladder (OAB) is a syndrome of urinary urge, frequency, nocturia (getting up at night to void) and urge incontinence. You only need one of these symptoms to have OAB. Many patients start out with urge and then progress to frequency and eventually incontinence. When the bladder is healthy, we are in control and can decide when and where to urinate. When the urge to urinate is actually strong enough, we need to stop what we are doing and walk to the bathroom and empty our bladders voluntarily. OAB can occur in as many as 10% of people and increase with age. OAB is not a life-threatening condition but can significantly decrease quality of life.

Definition of Refractory Overactive Bladder
Refractory Overactive Bladder, also known as ROAB, is a condition that is seen commonly in Urology, Female Pelvic Medicine and Urogynecology practices. If the overactive bladder is related to a neurologic condition it is often referred to as NOAB. If it is of an unknown cause (idiopathic) it is commonly referred to as IOAB. ROAB may be due to either neurogenic cause or idiopathic causes. Patients are considered refractory when they have failed at least two medications for overactive bladder and/or simpler measures, such as self-care, or pelvic floor therapy.

Management of Refractory Overactive Bladder can be challenging but fortunately in 2014 and beyond, we have multiple medications to treat OAB. We have Botox therapy, Percutaneous Tibial nerve stimulation (PTNS) and sacral nerve Stimulation (SNS). In the past, as recent as 1998 the only treatment that was considered after failure of one single overactive bladder drug (Ditropan also known as generic Oxybutynin) was Bladder Augmentation. Bladder Augmentation is a large surgical procedure that is only indicated in the most refractory of cases as this procedure is effective in enlarging the bladder but has significant complications and can sometimes lead to chronic urinary tract infections or the need for intermittent catheterization.

What are the symptoms of overactive bladder?
These symptoms include urinary urgency frequency, urgency incontinence, and nocturia. Patients with ROAB have tried simple measures such as self-care, reducing fluids, avoiding caffeine, alcohol and other bladder irritants. In addition the patient has tried at least two medications for Overactive Bladder know as antimuscarinics, anti-cholinergics or OAB meds. Patients have failed the therapy in that their symptoms did not resolve or they were unable to tolerate the side effects of the overactive bladder medications. These symptoms are now significant and patients are considered refractory hence urology/ urogynecologic involvement is often necessary at this point.

Causes and Diagnosis:
The cause of OAB is unclear in most cases (85%). In some cases it is related to a neurologic condition such as Multiple sclerosis (MS), SCI (spinal cord injury), Parkinson’s disease and spina bifida. OAB is a diagnosis of exclusion that is conditions such as UTI, bladder cancer and BPH (men only, enlarged prostate) should be ruled out first. Work-up may include history, physical, bladder log, questionnaires, pad test, urine analysis, cystoscopy, ultrasound and urodynamics. In most instances OAB can be treated empirically following non-invasive tests. For ROAB cases more advanced testing is usually necessary.

II. TREATMENT OPTIONS FOR OAB

• Self-care
• Behavioral therapy, physical therapy, biofeedback
• Pharmacologic therapy, medications

Self Care: Diet/Fluid Intake/Weight Loss/Smoking Cessation/Hygiene:
• Avoid food and drink that are known bladder irritants and/or diuretics such as coffee, tea, soda pop, alcohol (beer, wine, liquor).
• Drink 48-64 oz (1500-2000ml) of fluid/day that is 6 or 8, 8 oz glasses. This based on a 175lb man. This may require slight increase or decrease in hot or cold weather or on your body weight. Another option is drink only if you are thirsty or if your urine looks or swells “concentrated.” Any more fluid than 2000 ml has no proven health benefit. If your are thirsty due to dry Colorado Climate or medication than chew gum, suck on hardy candy or use artificial saliva. “What comes in must come out. If you drink 4000ml of fluid/day you will urinate 3500-4000 ml/day. If your bladder holds 250 ml then you will have to void 16/24 hours.”
• Belly fat sits on your bladder and causes urgency. Also make your cloths tight so your belt squeezes the bladder. Weight loss will allow better mobility and reaction time for prompt toileting.
• Tobacco and cannabis can irritate the bladder lining and can cause OAB and eventually lead to bladder cancer
• Avoid tight fitting pants or shirts as they can squeeze the bladder and cause urge
• If you have incontinence change your pad and bath frequently to prevent skin breakdown, rashes and infections (vaginal and bladder)

Behavioral Therapy/Physical Therapy/Biofeedback
• Bladder Retraining: Timed voiding or bladder retraining drills are very helpful and usually the first line of therapy for Overactive Bladder. This excellent treatment is free, completely safe and effective in curing or improving symptoms in two thirds of women suffering from this very common disorder. In timed voiding you may fill out a chart of voiding and leaking such as the voiding diary mentioned in the last paragraph. From the patterns that appear in the voiding chart, you can plan to empty before you would otherwise leak. The intervals that you urinate at can gradually be lengthened by 15 minutes each week while you are awake. In this way, you may stretch or increase the intervals at which you void. Another similar approach to bladder drills is to begin voiding every hour on the hour, except while in bed, whether the urge is felt or not. This pattern is continued for two weeks. Then, you move up to voiding every hour and a half. Every two weeks, you increase the interval between voids by 30 minutes, until you have retrained yourself up to voiding at a comfortable interval of, for example every three to four hours. This biofeedback technique known as bladder training can alter or change the bladder schedule for storing or emptying urine. These techniques are effective for overactive bladder.
• Kegel Exercises: Pelvic muscle exercises (Kegel) are used to strengthen or retrain the muscles of the pelvic floor. Regular daily exercising of the pelvic muscles can improve and even prevent urinary incontinence. This is helpful for younger woman. The Kegel exercises should be performed 30-80 times daily for eight weeks before you may notice any difference. Most Kegel exercises do not require equipment.
• Pelvic Floor Stimulation: Other biofeedback techniques such as pelvic floor electrical stimulation also improve urge incontinence. This technique will help women identify their pelvic muscles. It works with a little bit of effort on your part. The electrical stimulation exercises the pelvic muscle for you. A small instrument is inserted into the vagina to deliver a tiny electrical pulse that causes the pelvic muscles to contract for you. It feels like a hum and a pull in your pelvic muscle and is not uncomfortable. This technique may reduce urgency, frequency symptoms, overactive bladder and especially urgency incontinence.

Pharmacologic Therapy/Medications:
Some medications prevent contractions of an overactive bladder. Your physician to improve your urgency, frequency and urge incontinence symptoms may utilize several prescription medications. Estrogen or HRT (Hormone Replacement Therapy) is believed to cause the muscles and nerves in urination to function normally. Estrogen must be used with progesterone, if you have not had a hysterectomy, because estrogen therapy alone has been associated with an increased risk of cancer of the uterus. Talk to your doctor about the risks and benefits of long-term use of hormone replacement therapy.
HRT may improve the way your muscles and nerves of the pelvic floor and bladder function and may reduce incontinence. HRT is available in pill form, patch, vaginal form pill, cream, or ring and used under the direction of your doctor.

If you fail the usual OAB medications, which are, all anti-muscarinics (ditropan, detrol, vesicare, sanctura, oxytrol, enablex, gelnique) a consideration would be a new class of drugs called Beta-3 agonist like Myrbetriq (Mirabegron). This drug works well especially in those that have had side effects from the 1st or 2nd tier OAB medications as is it a Beta-3 agonist which do not cause the usual ant-muscarinics side effects including dry mouth, dry eyes, constipation and cognitive impairment. The down side of the medication is that is extremely expensive. It is not always covered by insurance. The side effect could be that it could raise your blood pressure by as much as ten points but this is usually not clinically significant. Another option for pharmacologic therapy would be dose escalation beyond what is the recommended dose. It is not uncommon that we double or sometimes even triple the recommended dose. This is effective but does lead to more side effects and more cost as insurance companies and prescription plans commonly do not cover dose escalation.

The next strategy for pharmacologic therapy would be using an antimuscarinic and a beta-3 agonist in combination such as using Vesicare with Myrbetriq. This is an effective therapy but does lead to poly-pharmacy and increased cost.

III. TREATMENT OPTIONS FOR ROAB

In these cases we recommend the patient continue standard treatments for OAB as outlined above (self-care, medications, etc.) in addition to one of the following therapies

- Botox therapy
- Neuromodulation (PTNS and SNS)
- Bladder enlargement (augmentation)

**Botox™ (onabotulinumtoxinA) Therapy**

Botox™ (produced by Allergan) is an office-based treatment and considered 2nd tier therapy for those who do not respond to simpler measures as mentioned in the OAB discussion. Botox bladder injection is a novel treatment that we have offered at the University of Colorado for many years. University of Colorado has a rich history of Botox therapy and was developed in part by Dr. Rick Schmidt. We have been using Botox therapy in Urology since 2004 well before FDA approval. In fact we have been fortunate enough to be involved in late Phase III and post market trials on Botox therapy. Botox is placed through a needle that is directed by a cystoscope. We can inject anywhere from 50 to as much as 300 units. The dose is adjusted based on the patient's needs. If the patient is voiding normally and does not wish to perform intermittent catheterization typically we inject 50 - 100 units. If the patient is catheterization dependent we more commonly inject 200 - 300 units. The therapy is effective for urinary urgency incontinence especially. The down side is the drug does need to be re-injected every 6-12 months the cost is sometimes prohibitive and there is inconvenience of having to have an office procedure to have the drug injected.
Percutaneous Tibia Nerve Stimulation (PTNS),™ “Ankle Stimulation”

PTNS (Urgent PC™ by Uroplasty) is an office-based treatment and considered 2nd tier therapy for those who do not respond to simpler measures as mentioned in the OAB discussion. This treatment requires a 30-minute/week-office treatment for 12 consecutive weeks. A needle is place percutaneously (through the skin to the tibial nerve that lies next to the ankle), therefore the therapy is commonly referred to as “ankle stimulation.” The electrode stimulates the tibial nerve and acts as a surrogate for the sacral nerve (the dominant nerve to the bladder) similar to acupuncture. Once the nerve is properly stimulated after about 3 to 4 treatments the patient will see noticeable improvement in their bladder over activity and an improvement in incontinence, frequency, urgency and urgency incontinence. After the 12-week treatment is complete the patient will then go on maintenance therapy that will require once a month treatment. In the future we hope that home therapy with a patient directed unit will be available but this is not available currently. Downside is PTNS is less effective then Botox or SNS.

Sacral Nerve Stimulation (SNS) also known as Interstim™

Interstim™ (made by Medtronic®) is an electronic device that has been FDA approved since 1998. This procedure is considered 3rd tier therapy for OAB. It is more invasive than Botox of PTNS, but is a great option for people who do not want to have frequent office visits for Botox of PTNS. This therapy is indicated for people with urinary urgency, frequency, urgency incontinence, and bladder incomplete emptying and even idiopathic retention in younger women. The therapy works by placing a temporary electrode through the lower back to the sacral foramen (S3) to stimulate the S3 nerve. This is tested in the office under local anesthesia (PNE, percutaneous nerve stimulation). The patient is tested for approximately three to seven days and if they have a positive response (meaning more that 50% improvement in their bladder symptoms) then they would be candidate for permanent implantation.

Permanent implantation would require a surgical procedure done in the operating room done under sedation. It consists of a battery-powered stimulator (the size of a stop watch) connected to a lead, which is placed near the root of the S3 nerves in the back. It is meant to 'down regulate' the bladder muscle s sensitivity and thereby decrease bladder contractions and the resulting urgency, frequency and urge incontinence.
This device is placed under the skin and therapy will last approximately 5-7 years depending on how much voltage is used from the battery. Currently the battery cannot be recharged and requires replacement (surgery) once the battery is discharged. Other issues with the device, is the lead can migrate or the patient can develop an open or short circuit, which also leads to surgical revision. The device is easily damaged if the patient falls or gets into a car accident. This often leads to short circuiting or open circuits. The device can be a fairly temperamental device and often requires need to be re-programming. Fortunately the device can be reprogrammed with a magnet and does not require open surgical revision. The patient will be set up with at least 4 programs and the patient will have a controller and may be able to turn the device on and off, increase or decrease the amplitude and change programs.

**Bladder Enlargement (Augmentation)**

Bladder augmentation, also known as augmentation cystoplasty, is a large surgical procedure used in men and women to physically enlarge the bladder in patients with small bladder capacity, impaired compliance high pressure or spasticity leading to incontinence that is refractory to simpler measure. There is 4th tier therapy and reserved for the most severe cases. Most patients have NOAB from a fixed neurologic lesion such as SCI or spina bifida but we may offer this in rare instance to those with IOAB. See handout on NGB, NOAB and Bladder augmentation for more detail.

**IV: SUMMARY**

In summary refractory overactive bladder is a difficult problem to have. It does significantly affect quality of life. It does lead to significant economic impact due to the cost of sanitary pads and clothing. It does often lead to patient isolation and embarrassment. Fortunately, we have exciting treatments that are effective and rapidly evolving to become less invasive and more patient centered.

We offer a step-wise approach that is individualized to the patient. We often guide the patient in which therapy to choose based on the predominance of a certain symptom or based on the etiology of their overactive bladder. Neurogenic patients are good candidates for Botox and PTNS they’re not good candidates for SNS. Idiopathic overactive bladder patients are candidates for all three therapies. All patients are candidates for drug therapy.

All of these therapies do require insurance authorization. Oftentimes insurance is not cooperative in providing these therapies, as they can be very expensive especially long term. We hope this handout is helpful and informative and we look forward to speaking to you in more detail about these therapies.

**IV: ADDITIONAL INFORMATION AND REFERENCES**

**Glossary of terms:**
- OAB: overactive bladder
- ROAB: refractory overactive bladder
- NOAB: neurogenic overactive bladder
- MS: Multiple sclerosis
- IOAB: idiopathic overactive bladder
- UUI: urinary urge incontinence
- Botox: onabotulinumtoxinA
- PTNS: percutaneous nerve stimulation
- SNS: sacral nerve stimulation

For more information regarding the treatment of urinary incontinence, please check the following links:

**Websites:**
Women:
American Urogynecology Society: www.augs.org

Men and Women:
National Multiple Sclerosis Society: www.nationalmssociety.org
National Association for Continence: www.nafc.org
American Urological Association: www.auanet.org
Society of Urodynamics, Female Pelvic Medicine & Urogenital Reconstruction: www.sufu.com
Wikipedia: www.en.wikipedia.org
Emedicine: www.emedicine.medscape.com
Botox: www.allergan.com
PTNS (Urgent PC): www.uroplasty.com
SNS (Interstim): www.medtronic.com

V. CONTACT INFORMATION

UCH numbers: Main Hospital number Phone 720-848-0000, Admissions 720-848-4251, Medical records 720-848-1031

Julie Porcelli Surgery Coordinator: Call Julie to schedule surgery, preop and postop appointments, Insurance related Q’s, etc..Phone 720-848-1802, Fax: 720-848-4276, Email: Julie.Porcelli@UCH.edu

Urology Nurse Triage Line: Call the nurse line for Q’s about postop complaints bathing, wound care, activity, diet, catheter care, uncontrolled pain, prescriptions, etc…Phone 720-848-1800 option 2. M-F 830-430. Leave a message and someone will get back with you as soon as possible.

Urology Resident on Call: For urgent matters only. Routine Q’s please wait until ordinary clinic hours. Phone 720-848-0000, after hours, weekends, Holidays. Ask to speak to the Urology resident on 2nd call. The operator will then page the resident and if available they will call back and speak with you at that time.

Call 911: For emergencies such as chest pain, shortness of breath, passing out, etc…..

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