



**Congratulations! To date, there are 12 women enrolled in the MIMOSA Study!**  
**Congratulations! To date, there are 22 women enrolled in the ValUE Study!**

## New UITN Study

*By Linda Brubaker, MD at Loyola University*

The UITN has just started a new study designed to help women with urinary incontinence. The MIMOSA study – Mixed Urinary Incontinence: Medical or Surgical Approach – is open to women who have significant bother from the two most common forms of urinary incontinence – urge incontinence (also called overactive bladder) and stress incontinence. Women with both of these forms of urinary incontinence suffer decreases in the quality of their life from symptoms that cause them to leak urine at the wrong time and place.

The symptom of urge incontinence typically results in urine loss when a woman recognizes a strong, often sudden, need to urinate – but she is unable to get to the toilet in time. This form of incontinence is usually treated with medical (behavioral and/or medication) treatment. The symptom of stress incontinence typically results in momentary urine leakage due to a physical event, such as a cough, sneeze or physical activity like running or jumping. This form of incontinence is often treated with surgery. These two forms of urinary incontinence together are commonly called “mixed urinary incontinence”.

Patients and their doctors face a challenge when planning treatment for mixed urinary incontinence because each individual form of incontinence responds to a different type of treatment – so which treatment to do first? The MIMOSA study will help patients and their doctors determine whether more women are helped by initial medical or initial surgical approaches to treat their urinary incontinence. Based on our clinical experiences treating women with incontinence, we expect that many women in the study may require more than one treatment approach. We hope to find out the best initial treatment for our patients with mixed urinary incontinence. For more information on the MIMOSA study, talk to your UITN team.

This study is part of the continuing effort of the UITN Network to improve the health and well-being of women with urinary incontinence. We greatly appreciate your continued support of this important women’s health research and we look forward to sharing the results as soon as they become available.

## TOMUS Update

*By Holly Richter, MD at University of Alabama*

With the start of a new year, it is time to reflect on our experiences and accomplishments of the past year. Many of you are participating in the **TOMUS** trial, a study comparing the

outcomes of two types of minimally invasive sling procedures, for the treatment of stress urinary incontinence. As you know, we are interested not only in the important treatment efficacy outcomes of these procedures (or how well they treated your urinary incontinence), but also in their effect on your quality of life and sexual function as well as any complications related to the surgery or the sling material itself.

Recently an FDA health notification (<http://www.fda.gov/cdrh/safety/102008-surgicalmesh.html>) was released to healthcare practitioners addressing potential serious complications associated with the mesh material used in these sling procedures and also for the treatment of pelvic organ prolapse. This notification outlined the types of complications that have been reported to the FDA, and included the FDA’s recommendations to reduce the occurrence of these types of complications associated with the use of a foreign body (the mesh) in the vagina.

Synthetic mesh materials have been used to help strengthen surgical repairs for over 50 years, especially in the general and cardiac surgery areas. Their use in the treatment of urinary incontinence and pelvic floor disorders is more recent, starting in the mid 1990’s. The use of these types of materials does confer, in general, an increased risk of infection, bleeding and scarring. Complications do not occur frequently but the more common ones include erosion of the mesh through the vaginal skin, infection, pain, urinary problems and recurrence of incontinence and/or prolapse. There are also reports of bowel and bladder injury and increased risk of bleeding. Some patients have reported continued pain and discomfort with intercourse as well. Many of these complications can occur whether or not mesh is used in your surgery. You are being treated by surgeons who have specialized training to perform these types of procedures at some of the most prestigious medical centers in the US. However, if you feel as if you are having any problems related to your sling procedure, you should definitely contact your surgeon.

The TOMUS study was designed so that we could follow you closely for both outcomes of the surgery and for any complications. The next phase of the TOMUS trial called **E-TOMUS** (Extended-TOMUS) is important in this regard. As a part of E-TOMUS, we will continue to keep a close watch on the recurrence of urinary incontinence symptoms and closely monitor you for any mesh related complications that were included in the FDA report. Many of you may have already been approached to participate in E-TOMUS. If you have not yet been asked to enroll, we hope that you will do so. You are very important to us and we take our responsibility to take care of you very seriously. We are proud to have you in our study and we wish you the best for the year ahead!!!

# UITN Study Updates

*By Judy Gruss, RN at U. Pittsburgh*

The UITN studies are producing a great deal of information that is proving valuable to doctors, other healthcare providers, and their patients. We are learning more about the women that we treat for incontinence, the treatments that we currently have for incontinence, and even about the way that we study incontinence.

This month we have an article of interest from the BE-DRI study that was published recently in the International Urogynecological Journal.

## **Nocturia, Nocturnal Incontinence Prevalence, and Response to Anticholinergic and Behavioral Therapy.**

Nocturia means waking up at night at least once to empty the bladder. Nocturnal incontinence is accidental leakage of urine during the night. Both can be real problems for women. Women may suffer from lack of sleep, or even suffer a fall during the night trying to get to the bathroom (among the other problems that women with incontinence have). Many studies on the current treatments for incontinence did not include information about nighttime symptoms like nocturia. The investigators in the UITN were interested in looking at these nighttime symptoms.

In the BE-DRI study, women who had urge incontinence received either medication alone or medication combined with behavioral training (which consisted of pelvic floor muscle strengthening exercises). We asked all of these women about their symptoms, both before and after treatment. We looked at the bladder diaries that these women completed, noting particularly when they went to bed at night and got up in the morning so that we could look closely at their nighttime symptoms. We counted how many times they got up during the night to empty their bladder, and how many episodes of incontinence these women had during the night.

In general, the study found that the women in the BE-DRI study had only mild symptoms of nocturia. Approximately 30% of women experienced less than 1 nocturia episode on average (meaning that, although they sometimes got up during the night to go to the bathroom, they did not get up every night). About 73% of the women experienced less than 1 nocturia incontinence (involving accidental leaking) episode, on average, per night. The average woman in the study was getting up about once per night to empty her bladder before treatment.



Although there was great improvement in daytime symptoms in these women after treatment, there was less improvement in their nighttime symptoms. Most women were still getting up about once per night after treatment. Also, older women seemed to have more nighttime symptoms than younger women, regardless of their treatment. Adding the behavioral therapy to the medication did not make a difference in these nighttime symptoms.

The investigators think this is important, particularly in terms of treating women with urge incontinence and carefully considering their nighttime symptoms. Neither the medication nor the combination (medication plus behavioral) therapy made much of a reduction in nighttime symptoms. Doctors and nurses need to ask careful questions about symptoms, and ask both about daytime and nighttime symptoms. Doctors also may need to do further studies to look for different causes of nighttime bladder symptoms. These symptoms may very well need to be treated differently than daytime bladder symptoms.

## Certification of UITN Clinical Staff

*By JoAnn Columbo BS, CCRC, at UCSD*

As a participant in a UITN study, perhaps you've wondered why we ask certain interview questions, why we ask some of the same questions more than once, or why we always ask them in exactly the same way each time. What we are doing is following standardized clinical research methods that have been established to provide unbiased, quality data.

I've worked in Clinical Research for over 14 years, primarily in oncology (cancer) research, and because these studies involve life threatening illness and experimental drugs and procedures, I thought it would be helpful to join an educational/professional organization. One of the pre-eminent professional organizations for clinical research is SoCRA (Society of Clinical Research Associates). They hold annual educational conferences, offer certification courses and a certification exam. In preparing for the exam, I learned the importance of strict attention to detail, maintenance of patient confidentiality, adherence to Good Clinical Practices (GCPs) and FDA regulations, as well as a history of how and why these regulations came into being.

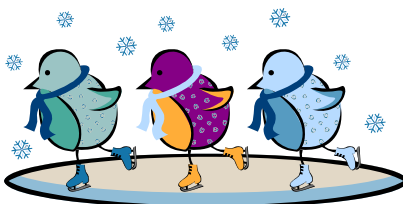
When I joined the UCSD UITN Clinical Trials Team this past March, one of the first things I did as a new UITN Coordinator was attend certification training at New England Research Institutes (NERI) in Boston. This impressed me because although I personally made the choice to become certified through professional organizations in the past, I was never required to become certified by any oncology consortium or study group. Also impressive is the fact that NERI certifies not only Study Coordinators, but all staff involved in the UITN study group, including the Physicians/Surgeons. This

certification process helps to ensure that study procedures are done in a consistent manner at all study sites and contributes to the quality of the information collected.

As an example, the UITN study outcomes (the results to the questions we hope to answer by doing the study) are both objective and subjective. An objective outcome can be measured or determined by uniform methods that can be duplicated regardless of who is measuring. A subjective outcome is specific to that 'subject' providing the response such as 'quality of life' questions which ask your impression of comfort on both a physical and social level. As you might guess, subjective questions leave lots of room for

interpretation. Therefore, in the UITN, we all ask the same questions in exactly the same way. One of the main things stressed during the NERI training was the importance of reading study questions to the subject exactly as written, offering no interpretation that might influence a subjects' response.

At your next visit or phone interview, if our questions sound all too familiar and your Coordinator starts to sound a little bit like a robot, just remember that the information you share cannot be obtained from any other source, and it is invaluable in helping us provide answers to others with urinary incontinence in the future. Our sincere thanks.



## Meet a UITN Team Member

**Name:** Tamara Dickinson, RN, CURN, CCCN, BCIA-PMDB  
**Title:** Senior Research Nurse, Continence and Voiding Dysfunction  
**Institution:** UT Southwestern Medical Center, Dallas TX

**Favorites and why:**

*Holiday?* Not sure. My husband's favorite is definitely Christmas. He is Mr. Christmas. We have 6 Christmas trees INSIDE our 3 bedroom house! I like anytime when it's cold!

*TV Show?* Too many! Comedy is definitely the Big Bang Theory. Brothers and Sisters. The Unit.

*Hobby?* Cooking, decorating, making jewelry.

*Music?* Anything but Country Western and Rap.

*Sport?* Probably football.

*Author?* Louisa May Alcott-I LOVE Little Women. Popular Fiction: Probably Nicholas Sparks.

*Favorite Food?* Lots of ethnic foods, Mexican, Lebanese/Middle Eastern, Indian.



**What can you share about your pre-nurse days?** In high school and nursing school I worked as a sales clerk in a small family owned jewelry store. In high school, I was in the marching band, the choir and took art class. Only went to the football games because I had to be there to march at half time. I grew up in Memphis TN and moved to Dallas/Fort Worth in 1998.

**Interesting fact about you that most people don't know?** I apprenticed with a chef in the early 1990's and thought about leaving nursing but the work was WAY too hard. And when your friends are off work you are working, so I decided to keep it as a hobby.

**Why did you decide to be a Nurse?** When I thought that I might not be able to support myself with a career in Interior Design or Fashion, ☺ I took a Nutrition class and liked it but there was too much chemistry to be a dietician!

**Do you do any volunteer work?** Mostly related to my field in nursing. I have spent the last 6 years on the Board of Directors of SUNA, 2 terms as Treasurer, a year as President Elect and a year as President. I am now serving as the Immediate Past President. I am a member of the ICS School of Urodynamics and the ICS Continence Promotion Committee (CPC). The CPC is gearing up for the first World Continence Week in 2009!

**What is SUNA?** The Society of Urologic Nurses and Associates is a professional subspecialty nursing organization of approximately 3300 members across the US. As part of our mission, we are committed to excellence in clinical practice and research through education of our members, patients, family and community. It is a fantastic organization that provides stellar educational offerings both nationally and at the local level.

**If you had a day to do whatever you wanted to do, what would you do?** Probably spend the whole day cooking a big meal to share with friends!



# Chicken Breast with Spinach Stuffing

Submitted by Jennifer Tabaldo at UCSD Medical Center

## Ingredients:

- 1 (10 ounce) package frozen chopped spinach
- 1/2 cup low fat sour cream
- 1/2 cup shredded (low fat) Pepper Jack cheese
- 4 cloves garlic, minced
- 4 skinless, boneless chicken breast halves - pounded to 1/2 inch thickness
- 1 pinch ground black pepper
- 8 slices turkey bacon

*Prep Time: 15 Min.*

*Cook Time: 45 Min.*

*Ready In: 1 Hour*

## Directions

- Preheat the oven to 350° F.
- Place spinach in a large glass bowl, and heat in the microwave for 3 minutes, stirring every minute or so, or until wilted. Stir in sour cream, pepper-jack cheese, and garlic.
- Lay the chicken breasts out on a clean surface, and spoon some of the spinach mixture onto each one. Roll up chicken to enclose the spinach, and then wrap each chicken breast with two slices of bacon. Secure with toothpicks, and arrange in a shallow baking dish.
- Bake uncovered for 35 minutes in the preheated oven at 350° F, then increase heat to 450° F for an additional 10 – 12 minutes.
- Enjoy!!



**For more information about the UITN studies, please call the office nearest to you.**

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