



## **Urology Interagency Coordinating Committee Meeting**

### **Enhancing Awareness and Management of Urologic Conditions in the Context of Obesity**

Hybrid Meeting  
June 26, 2023

#### **Meeting Summary**

##### **OPEN SESSION**

##### **Welcome and Introductions**

*Julia Barthold, M.D., Program Director, Division of Kidney, Urologic, and Hematologic Diseases (KUH), National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), National Institutes of Health (NIH)*

Dr. Julia Barthold welcomed attendees to the meeting of the NIDDK Urology Interagency Coordinating Committee (UICC). She explained that the UICC was mandated by Congress to encourage cooperation, communication, and collaboration among all federal agencies involved in urology research, care, and public health activities. The NIDDK recognized the need for better coordination of the federal response to urologic conditions and, through UICC, strives to foster discussion to solicit feedback on plans and ideas for reducing the burden of urologic diseases. Today's meeting focuses on enhancing awareness and management of obesity in the context of urologic conditions. To frame the day's discussions, she posed the following question for consideration: How can current and future clinical and translational studies inform standards of care in these overlapping populations?

Dr. Barthold thanked Dr. Ziya Kirkali, Program Director, KUH, NIDDK, NIH, and Dr. Jenna Norton, Program Director, KUH, NIDDK, NIH, for assisting with organizing the meeting. She invited participants to introduce themselves.

##### **Obesity/Metabolic Phenotypes and Urinary Incontinence (UI) in the National Health and Nutrition Examination Survey (NHANES)**

*Julia Barthold, M.D., Program Director, KUH, NIDDK, NIH*

Dr. Barthold described studies investigating the association between obesity and metabolic phenotypes and UI, as well as sex-specific risk factors for UI. In both sexes, UI is associated with increased age, obesity, metabolic syndrome, and medical comorbidities, including diabetes and chronic kidney disease. Dr. Barthold's group investigated the hypothesis that differentiating between obesity, metabolic syndrome, and diabetes in their associations would provide insight into their relationships with UI. The studies were conducted using combined data from several NHANES cycles (2003–2020). The National Cholesterol Education Program Adult Treatment Panel III definition of metabolic syndrome was used (i.e., three of the following symptoms: waist circumference greater than 40 inches in men or 35 inches in women, blood pressure greater than 130/85 mmHg, fasting triglyceride [TG] level greater than 150 mg/dL, fasting high-density lipoprotein [HDL] cholesterol level less than 40 mg/dL in men or 50 mg/dL in women, and fasting blood sugar greater than 100 mg/dL). To differentiate obesity from metabolic syndrome, obesity was defined as a body mass index (BMI) greater than 30. Diabetes was

defined by self-report or by having a fasting glucose of more than 126 mg/dL or hemoglobin A1c greater than 6.5 percent. In NHANES, UI is defined by self-report and includes stress and urgency UI. The study grouped patients into several categories: metabolically healthy and non-obese, metabolically unhealthy and non-obese (MUNO), metabolically healthy and obese (MHO), metabolically unhealthy and obese (MUO), and overt diabetes. Risk factors for UI were compared among the groups and by sex.

Dr. Barthold shared several variables that were highly significant among the groups. The study confirmed associations between diabetes and UI but also identified independent sex-specific associations. UI was more common in women than in men. While urgency UI was equally distributed between men and women, stress UI was more common in women. The risk of UI in both men and women was higher in any category with metabolic disease or obesity and was highest in the overt diabetes group. One exception was the MUNO phenotype, which was protective against UI, but only in men. The MUO group was associated with urgency UI in men, and the MUNO and MHO groups were associated with stress UI in women. Dr. Barthold noted discussions in the literature positing that UI could be caused by abdominal pressure during obesity. Because of its association with the MUNO group, Dr. Barthold suggested that UI likely is caused by more than just physical stress. These potentially modifiable factors could provide avenues for the prevention and treatment of UI.

### ***Discussion***

- In response to a question from Dr. Aruna Sarma about the NHANES categories, Dr. Barthold explained that patients were categorized by such measures as TG levels, HDL levels, hypertension, and waist circumference. Patients were categorized by glucose intolerance (i.e., pre-diabetes) rather than diabetes. The study excluded patients who did not provide fasting blood samples.
- Dr. Barthold confirmed that the NHANES study included patients with both type 1 and type 2 diabetes.
- Dr. Kirkali asked about the lack of association between urgency UI and obesity in women. Dr. Barthold answered that the documentation of UI in the NHANES study is not as thorough as in the Symptoms of Lower Urinary Tract Dysfunction Research Network (LURN) study, which used the Symptom Index-29 (SI-29) questionnaire. Many more patients self-report incontinence than would indicate by their health records, which also poorly document UI.

### **Obesity, Lower Urinary Tract Symptoms (LUTS), and Erectile Dysfunction (ED)**

*Aruna Sarma, M.H.A., Ph.D., Assistant Dean of Research Faculty, Chief, Dow Division of Health Services Research, Research Professor of Urology and Epidemiology, School of Public Health, University of Michigan*

Dr. Sarma provided an overview of the effects of obesity on male health. Sexual function in men is a bio-psychosocial process that involves psychological, endocrine, vascular, and neurological systems. ED is the persistent inability to achieve or maintain an erection for satisfactory sexual performance. Under healthy conditions, the parasympathetic nervous system becomes activated during arousal, leading to a release of nitric oxide that increases the production of cyclic guanosine monophosphate (cGMP) in the penis. Higher levels of cGMP relax the vascular endothelium of the penis and increase blood flow, causing an erection. The primary driver of ED is generally vascular endothelial dysfunction. ED is considered an age-related condition and affects 20 percent of men aged 40 years and older. ED increases across the life span and with comorbidities. Although obesity is not an independent risk factor for ED, incidences of ED are directly proportional to obesity levels. In a 2020 meta-analysis of 45 studies with more than 40,000 participants, ED was experienced by 75 percent of obese men, compared with

35 percent of non-obese men. Men with ED reported significantly higher BMI and waist circumference values than men without ED. Testosterone is a key regulator of nitric oxide synthase in the penis, and obesity leads to leptin secretion by adipocytes, which inhibits the testicular steroidogenic pathway and downregulates gonadotropin-releasing hormone production and secretion, causing low testosterone levels in men. Increases in adipose tissue also are associated with an increase in the enzyme aromatase, which converts testosterone to estradiol, further diminishing testosterone levels. ED in patients with severe obesity is linked to reduced responsiveness to PDE5 inhibitors (i.e., cGMP breakdown inhibitors). Reducing adiposity is a crucial approach in patients with ED affected by obesity. For example, several studies have shown that bariatric surgery reduces ED, but large cohort studies with multivariate regression models are required to determine the exact influence of weight loss on ED.

LUTS are defined as symptoms that result from dysfunction of the bladder, prostate, and/or urethra. LUTS constitute two issues: urine storage issues (e.g., urgency, frequency, nocturia) and urine voiding issues (weak stream, incomplete voiding, post-void dribble). In 2018, LUTS were estimated to affect approximately half of the world's population (or 2.3 billion people). LUTS prevail among men aged 50 and older and have multifactorial causes, which presents a challenge to understanding and managing these chronic conditions. The 2014 Health Professionals Follow-Up Study prospectively assessed the association between obesity and the incidence and progression of LUTS. An increase in the incidence of moderate or severe LUTS—as well as increased LUTS progression—was observed with increasing BMI. The LURN study examined the relationship between metabolic factors and LUTS and found that both general obesity and central obesity (i.e., excess fat in the abdominal area) were associated with increased odds of UI and urge UI. General obesity was associated with increased odds of UI and urgency UI. Several biological mechanisms for the connection between obesity and LUTS have been proposed. Obese men have larger prostates that might increase obstructive LUTS. The aromatization of testosterone to estrogen in adipose tissue might increase prostate tissue hyperplasia. Leptin from adipose tissue has been shown to stimulate nervous system activity and increase smooth muscle contraction in the prostate, leading to increased irritative LUTS. A meta-analysis of seven studies showed that patients experienced improvements in their LUTS after bariatric surgery. Further analysis of these associations will require longitudinal studies to understand the effects of the life course of obesity on ED and LUTS; studies with comprehensive and validated measurements of obesity, ED, and LUTS; and an understanding of the effects of obesity on these complications inside and outside the context of diabetes.

### ***Discussion***

- Dr. A. Roger Wiederhorn asked whether urologic studies on off-label use of GLP-1 agonist drugs for weight loss were being conducted. Dr. Sarma responded that she was not aware of urologic studies but added that cardiovascular and diabetic outcomes of treatment with these drugs are being considered. The participants agreed that urological endpoints should be included in these trials—especially because these endpoints occur early in the context of diabetes and obesity and might be useful indicators of future pathophysiology.

### **Obesity and Urinary Stone Disease**

*Dean Assimos, M.D., Emeritus Professor and Chair, Department of Urology, The University of Alabama at Birmingham School of Medicine*

Dr. Dean Assimos explained that the increase in obesity in the U.S. population during the last 40 years has been paralleled by an increase in the incidence of kidney stones. The geographic prevalences of these conditions overlap. Dr. Assimos noted that increased measures of obesity (e.g., waist circumference, BMI, weight) are associated with an increased risk of kidney stones. Although calcium oxalate stones are most common, uric acid stones increase with obesity. Body weight is inversely correlated with urinary pH; in the presence of lower pH, uric acid—a weak organic acid (pKa of 5.5)—forms stones. This

correlation has been demonstrated in diabetic obese rats, which have higher levels of kidney fat and lower levels of urinary ammonium (an important pH buffer) and pH than healthy rats. The pH of urine and supersaturation of uric acid are more closely related to total body fat and central obesity than lean mass or total body weight. As such, Dr. Assimos pointed out the importance of phenotyping body composition. He added that hepatic steatosis also is associated with low urine pH. In a study of patients stratified by BMI, levels of calcium, oxalate, and uric acid increased with obesity. Urinary oxalate is positively correlated with body weight, body surface area, obesity, and BMI. Among calcium oxalate stone formers, patients with higher BMI had increased urinary oxalate excretion than patients with lower BMI. Urinary oxalate is derived from diet and endogenous synthesis. Endogenous oxalate synthesis is a byproduct of glyoxylate catabolism, but it also can be produced by the nonenzymatic breakdown of vitamin C (i.e., ascorbate). Plasma ascorbate levels are inversely correlated with BMI, and endogenous oxalate synthesis levels correlate with body weight and lean body mass.

Non-alcoholic fatty liver disease (NAFLD) is associated with both obesity and kidney stones. Decreased levels of alanine-glyoxylate aminotransferase (an enzyme that breaks down glyoxylate into glycine, which does not feed into the oxalate pathway) and increased levels of lactate dehydrogenase A (which converts cytosolic glyoxylate to oxalate) have been observed in leptin-deficient mice. With some exceptions, similar responses have been observed in other mouse models of obesity (e.g., Western-type diet) and primary hepatocytes from human NAFLD donors. A recent study found that oxalate secretion was positively correlated with the degree of steatosis in children and adolescents with NAFLD. In the majority of mouse models of steatosis, the activities of several liver enzymes in the pathway (e.g., alanine-glyoxylate aminotransferase) are decreased and urinary oxalate excretion is elevated.

Obesity and kidney stones are both complex, multifactorial conditions and are interlinked. Dr. Assimos emphasized that careful definitions of phenotypes, sociodemographic factors, and genetic and epigenetic factors will be necessary to further explore this connection.

### ***Discussion***

- In response to a question from Dr. Sarma about the difficulty in measuring oxalate in urine, Dr. Assimos explained that the assay can be performed by commercial laboratories, and his research team routinely performs this assay. He added that acidifying urine to below pH 1.0 was important for accurate urine oxalate measurements and, at this time, quantifying 24-hour urine oxalate excretion is preferred, as spot urinary oxalate measurements have limitations.
- Dr. Sarma asked about the connections between ED, LUTS, urinary tract infections, and NAFLD. She wondered whether the urological issues were sequelae to obesity associated with NAFLD or independent issues. Dr. Assimos explained that the connection between NAFLD and urological symptoms has not yet been clarified. He noted that a member of his group has found a connection between hepatic fibrosis and increased oxalate in a mouse model of non-alcoholic steatohepatitis and plans to investigate this connection in humans. His group has developed a noninvasive method to estimate alanine-glyoxylate aminotransferase activity, which will be important in future translational studies.

### **Obesity and Female LUTS**

*H. Henry Lai, M.D., Professor of Surgery, Washington University School of Medicine in St. Louis*

Dr. H. Henry Lai shared details about obesity and LUTS in women. The most common LUTS in women are stress UI and overactive bladder (OAB). He presented cross-sectional population surveys from the Netherlands and Sweden that demonstrated associations between obesity and several bladder symptoms (i.e., OAB, urgency, frequency, urgency UI, stress UI) in women. A U.K. longitudinal cohort study of more than 12,000 women age 40 and older showed a positive association between obesity and stress UI

and a negative association between obesity and OAB. An epidemiological survey of more than 5,000 Bostonians also showed a positive correlation between central obesity and OAB in women. Data from the LURN-I observational cohort study showed that general obesity correlates with OAB, urgency UI, and stress UI in women. The LURN-I study also demonstrated a positive relationship between central obesity and OAB, urgency UI, stress UI, and nocturia in women. (Nocturia was not associated with general obesity in women.) Dr. Lai called on the meeting participants to consider interventional and preventive strategies for LUTS in the context of obesity.

**Using Agency for Healthcare Research and Quality (AHRQ) Databases to Examine UI and Obesity**  
*Jill Huppert, M.D., M.P.H., Program Officer, Evidence-Based Practice Center Division, AHRQ*  
*Cleothia Alford, M.P.S., M.Sc., Oak Ridge Institute for Science and Education Research and Evaluation Fellow, Evidence-Based Practice Center Division, AHRQ*

Dr. Jill Huppert discussed AHRQ databases containing information related to UI and obesity. The [Medical Expenditure Panel Survey](#) (MEPS) is a set of large-scale surveys of people, their families, their medical providers, and employers that collect data on the cost and use of health care services and health insurance coverage. The MEPS House Component (MEPS-HC) is an annual survey of approximately 15,000 households, and the MEPS Medical Provider Component (MEPS-MPC) collects data from all hospitals, emergency rooms, home health care agencies, outpatient departments, long-term health care facilities, and pharmacies reported by MEPS-HC respondents. The objective of the MEPS-MPC is to compare provider data with household data collected in the House Component before normalizing the data for reporting. The MEPS Insurance Component survey collects information from employers in the private sector and state and local governments on the health insurance coverage offered to their employees. MEPS data are used in large health policy simulation models and to calculate the gross domestic product, National Health Expenditure Accounts, and tax credits for small businesses offering health insurance.

Dr. Huppert described the AHRQ's Managing Urinary Incontinence Initiative. AHRQ has funded a U18 cooperative effort to help primary care practices implement patient-centered outcomes research on effective nonsurgical interventions for UI, such as behavioral approaches, medications, and neuromodulation.

Ms. Cleothia Alford described her efforts to use MEPS data to estimate total and out-of-pocket costs of health care events related to UI in women, for which current data were lacking and would be beneficial as baseline information for systematic reviews and implementation projects. The goal of the project was to conduct an exploratory analysis of a nationally representative sample of patients with a health care event related to UI. To meet the objectives of the UICC meeting, the data were stratified by obesity. Data were compiled from MEPS data files (full-year consolidated data files and medical conditions files) for the years 2017–2019. Survey responses were recorded verbatim and encoded using International Classification of Diseases, Tenth Revision (ICD-10) codes. Ms. Alford noted the limitations of ICD-10 codes used in MEPS data, because ICD-10 collapses multiple conditions into a single code. Limitations on code captures per event guarantee the loss of important information. Despite these considerations, MEPS data showed that most respondents had no care related to UI (ICD-10 code N39) or obesity (ICD-10 code E66). The prevalence of patients with health care events related to both UI and obesity was much smaller than the prevalence of patients with health care events related to either UI or obesity. Despite being in the least prevalent category, patients with health care events related to UI and obesity incurred the highest out-of-pocket and total expenses of any category.

Dr. Huppert described the Healthcare Cost and Utilization Project (HCUP). HCUP databases are derived from administrative billing data (rather than claims data) and contain clinical and nonclinical information, including diagnoses and procedures; discharge status; patient demographics; and charges for all patients,

regardless of payer (e.g., Medicare, Medicaid, private insurance, uninsured) beginning in 1988. Data are not collected from federal facilities (e.g., Indian Health Service, prisons, U.S. Department of Defense, Veterans Health Administration [VHA]). Currently, 48 states participate in HCUP. HCUP databases comprise the National (Nationwide) Inpatient Sample, Kids' Inpatient Database, Nationwide Emergency Department Sample, Nationwide Readmissions Database, State Inpatient Databases, State Ambulatory Surgery and Services Databases, and State Emergency Department Databases. [HCUP-NET](#) is a free website for querying the HCUP databases. Dr. Huppert noted that she could not find any reports on incontinence when searching HCUP data.

### ***Discussion***

- In response to a question from Dr. Kevin Abbott, Dr. Huppert clarified that HCUP data are not related to the National Hospital Discharge Survey, which was managed by the Centers for Disease Control and Prevention.
- Dr. Abbott asked whether HCUP data include Medicaid patients. Dr. Huppert affirmed that HCUP data include Medicaid, self-pay, and no-charge patients.

### **General Discussion**

- Dr. Candace Price commented on the connection between ED and vascular function and asked about associations between ED and cardiovascular risks. Dr. Sarma answered that several epidemiological studies show a connection between ED and cardiovascular disease that is not yet entirely clear. She noted the likelihood that ED was an early marker (rather than a cause) of changes that ultimately lead to cardiovascular disease and added that longitudinal studies of natural studies are needed to clarify these associations.
- When asked about the appropriateness of BMI for measuring obesity, Dr. Sarma noted that many studies have shifted their focus to measures of central obesity. She agreed that fat composition and location should be phenotyped in more depth. Dr. Assimos commented that his group is using DEXA scanning to study obesity and added that magnetic resonance imaging also could be beneficial.

### **Adjournment**

Dr. Barthold thanked the presenters and attendees for their participation. She announced that the closed session with federal partners would convene at 11:00 a.m. EDT and adjourned the open meeting.

### **CLOSED SESSION**

#### **Around the Table: Improving Awareness of Correlations between Obesity and Urologic Conditions** *Julia Barthold, M.D., Program Director, KUH, NIDDK, NIH*

Dr. Barthold explained that the objective of the roundtable was to discuss ways to improve the understanding and awareness of correlations between obesity and urologic conditions, with the goal of influencing behavior and facilitating weight loss. The UICC requests input to formulate optimal research strategies that will begin to incorporate such urologic outcomes as urinary stone disease, benign prostatic hyperplasia, ED, LUTS, and UI.

Before the meeting, the following questions were shared with agency partners for their consideration:

1. How can we increase awareness, measurement, and accurate tracking of the effects of obesity on urologic outcomes among clinicians and affected individuals?
2. Can associated potential positive effects on urologic outcomes motivate sustained and effective treatment of obesity?
3. How can we best address the cyclical nature of urologic conditions and barriers to weight loss (e.g., associated limitations to physical activity)?
4. How could consideration of urologic conditions as comorbidities of obesity shift the cost–benefit calculation of treatment options?

Agency partners shared their thoughts on how clinical and translational studies could inform individualized care and improve outcomes in obese populations with comorbid urologic conditions.

***Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD), NIH***

Dr. Candace Tingen presented on behalf of Dr. Donna Mazloomdoost, an NICHD program scientist and member of the Pelvic Floor Disorders Network steering committee. Dr. Mazloomdoost is increasing awareness about UI as a pelvic floor disorder. Dr. Tingen will consider additional NICHD priorities in this area.

***Agency for Healthcare Research and Quality***

Dr. Huppert noted that AHRQ’s main activity in this area is managing the U18 cooperative effort. She noted the difficulty in screening for urological conditions in primary care and added that a request that grantees harmonize their data collection resulted in major challenges (e.g., pushback for the use of more than two screening questions). The consortium is trying to develop a short questionnaire that is acceptable to all the grantee institutes.

Drs. Huppert and Kirkali discussed screening tools. Dr. Robert Star, Director, KUH, NIDDK, NIH, commented that the involvement of patients in research efforts from the beginning can help minimize such challenges. He recommended including patients on steering committees and establishing consortium monitoring boards consisting of outside experts. Funding opportunities should include language indicating oversight by external committees.

***Veterans Health Administration***

Dr. Mark Wilson introduced Dr. Susan Raffa, the national program director for the MOVE! Weight Management Program. Dr. Raffa noted evidence that even modest weight loss, if sustained, can have significant health benefits. MOVE! is a lifestyle intervention program that combines behavioral, dietary, and physical activity components with the aim of improving health conditions through weight loss. The program can be accessed via in-person visits, telehealth visits, use of an app, or a text messaging service and has involved more than 1 million participants since 2006. More than 25 percent of all participants achieve clinically meaningful weight loss, and customer satisfaction is high compared with other VHA programs.

In response to a question from Dr. Abbott about urology symptoms before and after intentional weight loss, Dr. Raffa noted that discussions about incorporating these measures currently are taking place.

In response to a question from Dr. Star, Dr. Raffa explained that veterans can refer themselves to the program or be enrolled by any clinic. She added that VHA is trying to increase awareness about MOVE!

### ***NIH Office of Research on Women's Health (ORWH)***

Dr. Lisa Begg explained that ORWH is part of the NIH Office of the Director, which manages strategic planning and coordinates programs and activities across the NIH. ORWH co-funds \$40 million per year for research, including studies of obesity and urological symptoms. Dr. Begg noted that the *2024–2029 NIH-Wide Strategic Plan for Women's Health Research* (including research on sex and gender differences) will be released on January 1, 2024. This 5-year plan was discussed at a coordinating committee meeting on June 14, 2023.

### ***NIH Office of Behavioral and Social Sciences Research (OBSSR)***

Dr. William Elwood informed the UICC that OBSSR will be appointing a new director and, subsequently, developing a new strategic plan. He noted that OBSSR has an ongoing collaboration with NIDDK on the self-management of chronic conditions, including LUTS and other urinary challenges. Like ORWH, OBSSR co-funds research opportunities and is interested in bio-social interactions affecting physical activity and/or diet that contribute to weight changes and downstream health effects.

### ***National Heart, Lung, and Blood Institute (NHLBI), NIH***

Dr. Price described ongoing NHLBI projects that are relevant to enhancing awareness and management of urological conditions in the context of obesity. The PALS (Prostate Cancer Active Lifestyle Study) study is a randomized phase III trial assessing a diet and exercise program to promote weight loss and improve health in men with low-risk or low-intermediate-risk prostate cancer on active surveillance. The goal is to learn whether weight loss will affect cancer and other health outcomes. The Accumulating Data to Optimally Predict Obesity Treatment (ADOPT) Core Measures project aims to better understand individual differences in response to a wide range of obesity treatments by identifying and instituting a standard set of 50 core measures that can be analyzed across studies. Additionally, NHLBI will soon announce a new [notice of funding opportunity](#) to better understand the heterogeneity of obesity risk and related health outcomes.

### **General Discussion**

- Dr. Kirkali commented that NIDDK is supporting a clinical trial investigating the LURN Symptom Index-10 as an outcome.
- The group discussed the lack of public awareness of the connection between obesity and poor urologic outcomes. Dr. Huppert commented that urological issues are assumed to be a normal part of aging. Some might consider UI a mere nuisance, but it is a primary cause of nursing home admissions and individuals' forgoing exercise because they are worried about leaks.
- The group discussed the need for powerful patient advocacy groups for UI. Dr. Abbott noted that this topic might be of interest to the older members of Congress.
- Ms. Andrea Brandau commented that the urologic conditions and obesity portfolio at the Patient-Centered Outcomes Research Institute (PCORI) was thin. She added that PCORI is working to ensure that urologic and obesity measures are included in future studies.

### **Adjournment**

Dr. Barthold thanked attendees for their participation and adjourned the meeting.



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