

**Urology Interagency Coordinating Committee (UICC)
Self-management of Urologic Conditions**

**Friday, June 9, 2017
9:00 a.m. - 12:00 p.m.
6707 Democracy Blvd. Room 7050, Bethesda, MD**

Meeting Minutes

KUH staff:

T. Bavendam (leader)	M. Moxey-Mims
K. Abbott	E. Newman
P. Donohue	T. Rankin
E. Duggan	R. Star

Welcome

Dr. Rob Star, M.D., Division Director for the National Institute of Diabetes and Digestive and Kidney Diseases, welcomed the group. Dr. Star noted that he is interested in working with other agencies to study shared interests.

Setting the Stage

Dr. Bavendam explained the differences in benign urology conditions for men and women in addition as it relates to self reporting and self management. There are 4 NIDDK Cooperative Research Networks: MAPP, LURN, PLUS and USDRN that focus on prevention and diagnosis. Dr. Bavendam noted that approximately half of all US adults has at least one chronic disease and one-fourth of these adults' chronic conditions endure limitations in daily living. Chronic diseases are among the most common and costly health problems. Self-management research has improved our ability to help people maintain a high quality of life in light of chronic conditions. The National Institute of Nursing Research (NINR) defines self management as: "Research that examines strategies that help individuals with chronic conditions, their families and caregivers better understand and manage their illness and enhance health behavior."

Self management is a constellation of mechanisms and processes that involve a patient and caregivers, cell and human biology, condition-specific peers, family, friends, healthcare providers and other groups. One example of self management was the African Americans with Type 2 diabetes. This was a feasibility study of 12-week, diabetes self-management intervention for middle-aged and older African Americans that was church-based, culturally targeted. Study results showed significant increases in medication adherence, healthier eating, and foot care adherence. This study also showed clinically significant effects on:

- Blood lipids
- Blood pressure

- Physical activity
- Waist circumference

In another study, Shirley Moore, Ph.D., RN, FAAN, from Case Western Reserve University looked neurological mechanisms and generalized anxiety disorder (GAD). Patients with GAD were examined for associations between baseline patterns of intrinsic functional connectivity (iFC) of the insula and of hubs within the DN (anterior and dorsal medial prefrontal cortex [MPFC] and posterior cingulate cortex [PCC]) and treatment-related changes in worry, somatic anxiety symptoms and decentering. The group conducted MRI scans before and after 16 sessions of Emotion Regulation Therapy. Greater treatment associated with reductions in worry, changes in iFC in insular and parietal cortices clusters. This adds to the growing body of research that disruptions in default and salience networks are promising treatment targets for GAD. This can be relevant to benign urology research as a method of treating patients with anxieties with benign urologic disorders.

As another potential invention, Frank Infurna, Ph.D. from Arizona State University, studied the effect of social influence (SI) on the individual. The study sought to discover if resilience to childhood adversity improved with social intelligence training. Among most reliable predictors of health declines are social stressors, including abusive social relations in childhood. The group studied if it was possible to interrupt cause-effect pairing through SI training to prompt lasting improvement in the ability to establish, maintain, and benefit from social relations in comparison to controls that lead to improved psychological and physical functioning. Specific aims of the study included:

1. Examining whether SI intervention can enhance capacity for rewarding social relations, especially for individuals with history of early life adversity.
2. Examining evidence for hypothesis that intervention-related gains in quality of social relationship will be responsible for improvements in psychological and physical functioning, and influence two biomarkers of health risk and resilience: interleukin 6 (IL-6) and DHEA-S.
3. Probing for individual differences in age, gender, abuse history, personality, and genetic markers of risk that identify participants most responsive to the intervention.

In another example of aging and care, Dr. Ananías Diokno, from William Beaumont Hospital Research Institute studied whether group learning achieves decreased incidents of lower urinary symptoms. The group also examined increased fall risk associated with increased nocturnal enuresis (NE), poorer upper- and lower-limb physical performance than women without NE and used a randomized controlled trial to compare effectiveness and cost-effectiveness of the group-administered behavioral treatment program.

Outcomes from the study included data regarding:

- Self-reported UI severity (ICI-Q)
- Frequency of UI episodes
- Volume of urine loss
- Incontinence type
- Pelvic floor muscle strength
- Patient satisfaction/perception of improvement, quality of life

In closing, Dr. Bavendam summarized self management studies in urologic health. As health conditions change, self-management behaviors fade or thrive. A self-management approach can help explain how a chronic condition interacts with human functioning over time and how biological, behavioral, and social factors interact, and synergistically influence overall health and well being

Meeting participants provided the following feedback and comments:

- Durability facing interventions is a critical issue
- Institutions can help self management practices in patient lives.
- Self management includes everyone: caregiver, nurse, etc
- Consider how you identify features to study for precision medicine and through prediction modeling? Perhaps through an electronic health record data set that could model symptoms presented and diagnoses could perform.
- Add chronic conditions to patient cohorts in the precision medicine initiative. For example, those in the brain initiative study.
- Self management approaches should be tailored and there should be a caregiver in that role.
- Consider studying precision behavioral medicine and how psychosocial profiling can match an intervention to the patient.
- Follow-up studies are needed to examine whether the patient continues with self-management practices after the initial study concludes.

Recommendations from the H3Men Meeting

Dr. Zirkali, Senior Urologic Advisor at NIDDK, began his presentation by discussing the burden of LUTS/BPH, noting that these conditions prompt 8 million physician office visits/year, and one-fourth of this population is in their 50`s in 60`s; one-half is in their 80`s and these conditions account for \$1.1 B in direct health-care expenditures in 2000. In addition the healthcare and economic impact, these patients are suffer from increased mortality, depression, sleep disorders, falls, and a reduced QoL. Many male patients elect to undergo TURP surgery; however, in one study, of 1,068 men with Bladder Outlet Obstruction diagnosed with pressure flow studies: 428 (40%) died in the interim, while 217 underwent TURP with mean followup of 13 years. Of those men: 12.4% had obstruction, 36.5% had Detrusor Underactivity, and 63.5% had Detrusor Overactivity. Dr. Kirkali detailed the evolution of treatments of “BPH” with a diagramed chart and noted that the progression over the years from open surgery (1885) to Prostatic Urethral Life, Connective water Vapor Ablation Waterjet, Laparoscopic Prostatectomy, and Prostatic artery embolization in 2017. Dr. Kirkali noted that the AUA Guidelines on treatment are **lifestyle intervention** (fluid intake), **behavioral modification**, and **pharmacotherapy**. Symptom distress may be reduced with simple measures such as avoiding decongestants or antihistamines, decreasing fluid intake at bedtime and decreasing caffeine and alcohol intake generally. It is the expert opinion of the AUA Panel that some patients may benefit using a combination of all three modalities. Should improvement be insufficient and symptoms severe, then newer modalities of treatment such as botulinum toxin and sacral neuromodulation can be considered. The patient should be followed to assess treatment success or failure and possible adverse events

according to the section on basic management above.

Dr. Kirkali noted that, after the meeting, participants detailed future directions of research:

- Improve our understanding of LUTS and existing LUTS treatments
 - The relationship between LUTS and associated diseases e.g. diabetes
 - Symptoms most bothersome to men
 - Factors that encourage men to seek healthcare for LUTS
 - Better characterizing the LUTS patient by phenotyping men with LUTS to improve individualized treatment.
 - Gender differences
- Determine which patient subgroups will most benefit from which element of self-management
 - Factors that influence the likelihood of engaging in and responding to self-management for men with LUTS
 - The neurobiology that enables self-management behavior
 - Effectiveness of various elements of self-management in LUTS
- Develop strategies to successfully implement LUTS into urology practice
 - Ideal composition and organization of a LUTS self-management support team
 - Potential negative impact of delaying medical or surgical management

Dr. Kirkali noted that he is preparing a manuscript for publication with this information to help guide the field with future directions. The NIDDK urology team is interested in broad self management initiatives that will expand to caregivers as well.

Self-management in the USDRN

Dr. Kirkali, also discussed self-management practices with the urinary stone disease network (USDRN), formed in April 2015. The goals of the USDRN include informing clinical practice by 1) providing evidence for increasing adherence to fluid intake for stone prevention and studying effects of fluid intake on stone recurrence risk. The USDRN also seeks to understand and mitigate ureteral stent-associated symptoms and create data and biospecimen repository for future investigations. Dr. Kirkali noted that adherence was a very important issue for the prevention of stones. The USDRN focuses on behavioral economics (weight loss, smoking cessation, foster formation of new habits), and adherence improvement through structured problem solving (identify problem and create plan) that will result in the successful use in improving medication adherence and self management.

In addition to the NIDDK study underway, Dr. Kirkali discussed the Preventing Urinary Stones with Hydration (PUSH) trial. This is a randomized clinical trial to investigate the impact of increased fluid intake and increased urine output on the recurrence rate of urinary stone disease (USD) in adults and children. Researchers hypothesized that a program of robust behavioral intervention to increase fluid intake will reduce the risk of urinary stone disease recurrence/progression versus usual care. The PUSH study consisted of two patient groups: Control: self-monitoring only + usual care and Intervention: Behavioral intervention program + self-monitoring + usual care. Patients

were provided with a 1 liter water bottle and rewarded with financial incentives if they met the study water consumption criteria. The goal was for patients to form new habits. Dr. Kirkali noted that all fluids that a participant drank did not have to go through a bottle e.g., wine, coffee. There were 24 hour periodic urine collections. Dr. Kirkali noted that attrition rates in behavior modification studies are usually high at 20%; however, the PUSH study only reported 16.42% attrition.

Dr. Kirkali noted that the expected contribution to science from the PUSH trial was:

- Evidence for behavioral change program to:
 - Increase fluid intake/urine output (surrogate)
 - Modify health outcome (stone recurrence)
- Evidence to support increased fluid intake to reduce stone recurrence

Meeting participants provided the following feedback

- Did patients express concern about the time of water consumption?

For more information, please visit: www.usdrn.org.

Economic Incentives for Self-management

Dr. Peter Reese, Associate Professor of Medicine & Epidemiology at the University of Pennsylvania Perelman School of Medicine, began his discussion of bringing behavioral economics to health. Dr. Reese commented that individual behavior is key to the health of the US population. Despite public outreach campaigns: 1% of US population overweight or obese, Smoking is the leading cause of preventable mortality – 438,000 deaths per year and 50% of patients put on statins after heart attack stop taking it within 2 years.

Rather than focusing on treating patient conditions in the ER or at the clinic, the effort should be devoted to unobserved health behaviors that take place between visits. Variables such as medication adherence and tobacco use are strongly associated with key outcomes. Novel technologies permit health care teams – including transplant staff – to monitor these behaviors in real-time and intervene. This new emphasis is also being driven by increasing interest by insurance companies to compensate physicians for performance. Providers are increasingly reimbursed according to their success in getting patients to meet process or outcome based metrics such as blood pressure control, smoking cessation, lipid lowering, hemoglobin A1c reductions, and kidney allograft survival.

These economic incentive programs are becoming increasingly popular with employers who may offer employees perks such as fee gym memberships, higher insurance premiums for smokers, deposits into health savings accounts for undergoing health screening. Dr. Reese discussed leveraging novel technology to improve adherence through the use of wireless pill bottle, pedometers, scale, CPAP, blood pressure monitor, and glucometers. For example, a test at the Cleveland Clinic designed a pill bottle with an interface alarm that can chime and even text the caretaker with information. Linking biometric devices such as smartphones or other platform and providing patients with real time payments such as direct deposits may increase patient adherence. Another example

included testing patient versus provider incentives to improve lipids where cardiovascular disease was the focus. In this example, the patients who successfully adhered to their medication saw bigger gains than the group who did not. However, some obstacles to this approach are factors such as the inability for the patient to focus on their health 20 years down the road and competing demands for attention.

The pressure for health systems to perform well is increasing and corporations are also highly interested in motivating employees to lead healthier lives. Dr. Reese provided an example of General Electric, who had undergone a successful behavioral intervention with employees. General Electric provided economic incentives for employees to complete a smoking cessation program with a follow up of 6 months in compensation.

Dr. Reese also discussed some plausible self-management domains in urologic health:

- Medication adherence
- Fluid intake for kidney stone prevention (PUSH trial)
- Self-catheterization for voiding dysfunction (U-REACT)

Dr. Kirkali had covered the PUSH trial in his talk, so Dr. Reese focused on the U-REACT trial that focused on adolescents and young adults, kidney transplant recipients and need for immunosuppression adherence, spina bifida patients with neurogenic bladder and need for self-catheterization, and mobile health based intervention (i.e. text messaging, tailored feedback and financial incentives). For the adolescent spina bifida population, self catheterization was a very large issue. Outcomes showed adherence over time; the outcome at 1 year was that urodynamic studies will test the change in bladder wall compliance.

In summary, Dr. Reese noted that behavior is vital to diverse health outcomes, including several in the urologic domain. New tools and novel application of theory are reinvigorating a field that seemed resistant to intervention for many years, and new, interesting experiments are underway to try to figure out how to improve adherence. The field should be creative in figuring out how to use technologies and theory-based interventions to engage our patients between visits. Dialysis providers in particular have to be innovative to engage patients between visits. While privacy concerns remain, the norm is changing with smartphones. Engaging the “unengaged” remains an obstacle.

National Institute of Nursing Research Self-management Portfolio

Dr. Rebecca Roof, from the National Institute of Nursing Research (NINR), noted that the NINR mission is to promote and improve the health of individuals, families, and communities. To achieve this mission, NINR supports and conducts clinical and basic research and research training on health and illness at all stages of life. Dr. Roof noted that in September 2016 released a 5-year strategic plan includes their areas of scientific focus: symptom science, wellness, self-management, end-of-life and palliative care, training, and technology. NINR defines self-management as “Self-Management is the ability of the individual, in conjunction with family, community, and healthcare professionals, to manage symptoms, treatments, lifestyle changes, and psychosocial,

cultural, and spiritual consequences associated with chronic illness.” There is a focus on providing support for the caregivers as well.

Dr. Roof noted that examples of self-management studies include:

- Margaret Grey: R01-NR-04009, Coping Self-Management, and Adaptation in Adolescents with Type 1 Diabetes. Findings: Low-income and minority status were related to lower levels of primary control coping (e.g., problem solving) and secondary control coping (e.g., not set up to self-manage because of coping skills), and higher levels of disengagement coping (e.g., avoidance). Self-management mediated the relationship between coping and stress reactivity with quality of life and metabolic control.
- Carolyn Sampselle: R01-NR-012011, Translating Unique Learning for Incontinence Prevention the TULIP Project. Findings: Yielded comparable levels of knowledge and self-efficacy in preventing urinary incontinence in both interventions.
- Self-management: Spinal cord injury. This was a web-based intervention that paired nurse coaching with a support network. This was a feasibility trial that can now support evidence for a larger trial. Findings: Yielded comparable levels of knowledge and self-efficacy in preventing urinary incontinence in both interventions.
- Grayson Holmbeck: R01-NR-016235, Self-Management in Adolescents and Young Adults with Spina Bifida. This study focuses on neurological problems, birth defects and is associated with transitional health care. Purpose: To understand self-management and medical adherence of adolescents and emerging adults with SB (ages 16-23 years) in the context of past and present biological, neuropsychological, and social functioning. It also aims to understand the transition to adult health care. This study is ongoing.

In conclusion, Dr. Roof presented NINR’s self-management science of the future:

- Translating scientific evidence-based interventions to community and home settings
- Working with communities
- Promoting use of available and affordable technologies
- Maintaining self-management behaviors in the long-term
- Self-management in the context of multiple comorbid conditions
- Biopsychosocial approaches

Discussion: Self-management in Benign Urology

- Dr. Abbott commented on the pairing of doctors and patients. Some patients have difficulty achieving the recommended activity level because of occupation (inability to use the bathroom as needed) or caretaker resistance to take the patient to the restroom.
- Have physicians advise realistic caretaker responsibilities to the caregivers. For example, advise caregivers that they will have to take patients to the restroom 10-15 times per day not just two.
- Dr. Elwood, from the NIH Office of Behavioral and Social Sciences Research spoke about the need to account for behavior and chronic behaviors in urologic conditions. He noted that the population most compliant with their medications had a 24 hour hotline problem solving such as helping with loss of job and helping with patient

resistance. This was also true for those who were about to receive bimonthly text messaging.

- Dr. Reese also commented on the effectiveness of behavioral financial interventions with those who are affected with dementia and those who are truly willing to be adherent to medications regardless of other comorbidities and side effects.
- Dr. Kirkali noted that there are a number of adaptable options for the PUSH trial. If one item does not work, there are alternatives.
- Staff commented on the effectiveness of smart trial designs and short term effectiveness/success as a motivation to continue self management practices.
- Dr. Reese also commented on pilot data from tech companies. For example, Paypal did not begin with the intention of becoming Paypal. Sometimes the big trial and big power can be achieved through P&F projects.
- Dr. Reese noted that financial incentives can be relevant neutral if they still maintain the same health goals.
- Dr. Elwood suggested presenting efficacy studies that have been funded and completed at professional, practice association meetings. Publications of effective studies can take years to be recognize.
- Dr. Abbott noted issues with patient engagement.
- NCI's representative asked if the AUA's Aqua Development System could be helpful for these efforts? Dr. Kirkali noted that the AUA began with prostate cancer and is now beginning with other fields.
- Dr. Bavendam asked Dr. Elwood how this research could be synthesized. Dr. Elwood noted that disseminating information to the public has been extremely helpful. Also, by packaging information with partnerships and implementing this work. Dr. Star noted that this would be helpful for NIDDK to develop partnerships for this effort other than through large scale clinical trials.
- Focus of between visits is intriguing and can be helpful for data mining.

Dr. Bavendam noted that participation comments have resulted in a robust conversation.

Agency Updates – Round Table

- Dr. Ross noted an upcoming “Science of Caregiver” submit. Aug 7 and 8. Focus on caregiver health. Also, science of self management discussed.
- Dr. Elwood suggested a self management study group amongst Institutes.
- NINR suggested monthly science techniques to discuss this topic.
- Dr. Star suggested a journal club to highlight different areas of research that discusses strengths of some studies and highlight non effectiveness of other studies.
- Dr. Banez from AHRQ noted that the protocol for the AHRQ systematic review update titled “Nonsurgical Treatments for Urinary Incontinence in Adult Women: A Systematic Review Update” has been posted on the Effective Health Care website: <https://effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=2479>. The draft evidence report will be posted for public comment around October-November this year. This project is funded through a collaboration between the AHRQ Evidence-based Practice Center (EPC) program and PCORI.
- Dr. Ross suggested a follow up meeting from this self management meeting.

12:00 p.m. Meeting Adjourned