

Urology Interagency Coordinating Committee (UICC)

Friday, December 13, 2013
9:30 a.m. - 1:00 p.m.
6707 Democracy Blvd. Room 701 A-B
Bethesda, MD

Meeting Minutes

Welcome and Introductions

Tamara Bavendam, M.D.

National Institute of Diabetes and Digestive and Kidney Diseases

Meeting participants introduced themselves. Dr. Bavendam noted that the purpose of this meeting was to provide input and feedback for urology research programs and to foster interagency communications and collaborations.

Report: UICC Ad hoc Ad Hoc Women's Urologic Health Research Program Planning Meeting

Tamara Bavendam, M.D.

National Institute of Diabetes and Digestive and Kidney Diseases

Dr. Bavendam provided a summary of the recent UICC Ad hoc women's urology health research program planning meeting. Topics of presentations in this meeting included:

- Framing Lower Urinary Tract Symptoms (LUTS) in Women
- LUTS Epidemiology
- LUTS Impact
- Surgical Treatment of Female LUTS
- LUTS Treatment – Behavioral and Pharmacological
- Management of LUTS – Role of Physical Therapy
- Prevention Research
- LUTS Prevention Intervention Research
- LUTS Risk Factors – Nonbiologic and Behavioral
- LUTS Risk Factors - Biological

Emphasis was also placed on challenges to bladder health throughout the lifespan of the female, data and knowledge gains from the Boston Area Community Health Study survey.

During the group discussion individuals expressed that these various knowledge gaps were consistent with a goal to establish a knowledge base that will allow for future primary and secondary LUTS prevention research. Because of the overlapping of symptoms and the potential for continuation of risk factors from childhood to adulthood into old age, there was a general recognition by participants that the knowledge base should be established broadly – understanding risk factors for LUTS across the lifespan,

recognizing that future prevention intervention efforts would be targeted at specific high-risk populations for specific aspects of LUTS.

A comment from a UICC meeting participant noted that the Ad hoc group's suggestions were varied and "all over the map".

Women's Urology Research: Next Steps

Tamara Bavendam, M.D.

National Institute of Diabetes and Digestive and Kidney Diseases

Dr. Bavendam discussed the latest NIDDK urology initiative focused on the prevention of lower urinary tract symptoms (LUTS). Based on discussion from the Ad Hoc meeting, Dr. Bavendam noted that the following were identified as research needs:

- What females across the lifespan do not know about their bodies/bladders
- What we do not know about females' bladders across the lifespan
- What clinicians do not know about LUTS
- Epidemiology-Risk Factors
- Obesity
- Prevention of recurrent Urinary Tract Infections
- Better understanding of the role of LUTS in falls and fractures
- Impact of LUTS on sexual function and vice versa
- Activation of sufferers to do something
- Effective management of LUTS
- Defining needs in underserved populations (Non English speaking, LGBTQ)
- Sex and Gender differences in LUTS - occurrence and impact
- Defining and testing models for prevention
- Expanded the understanding of detrusor and urothelium

Following the report back from the Ad Hoc meeting, Dr. Bavendam presented the bladder health initiative concept proposal. The purpose of this initiative is to clarify normal lower urinary tract function and factors and behaviors that contribute to normal function, further identify and establish the modifiable risk factors important for the development of UI/LUTS in women, as the first steps in a longer range plan that should:

- allow for basic mechanistic research with translational potential
- lead to a cohort study seeking identifiable subgroups amenable to prevention,
- set a foundation for future prevention studies and an prevention education programs

The proposed approach would create a multi-disciplinary consortium that will

- Leverage Ongoing Studies: Analyze literature and existing data, and collect new data from on-going epidemiological studies and longitudinal cohort studies (e.g. WHI, NHANES, SWAN, BLAS, LookAHEAD, EDIC, BACH Survey). Form associations between measures of UI/LUTS symptoms, and identify modifiable and non-modifiable risk factors for UI/LUTS.
- Conduct new studies:

- Conduct a national cross-sectional population survey of women to assess the association of UI/LUTS symptoms, bladder knowledge, voiding patterns and toileting behaviors.
- Improve/modify the LURN patient-reported symptom measurement tools in populations not included in LURN.
- Conduct clinical research studies to characterize normal bladder function and normal and abnormal voiding behaviors.

The first step in gaining momentum for this initiative is the “Path to Prevention of LUTS workshop” to be held on February 14-15, 2014. This meeting will bring together medical, nursing, physical therapy, patient education, behavior change, epidemiology, public health, and prevention experts in a scientific workshop framed around defining bladder health as a first step along this path. The meeting objectives included:

- To review what we know, what we don’t know, what we need to know about healthy bladder behaviors and risk factors for lower urinary tract symptoms in women
- To describe the essential features of NIH prevention research
- Identify key features and challenges of implementing a research program in prevention of lower urinary tract symptoms in women
- To review current evidence for LUTS prevention educational interventions and the discuss the level of evidence needed for specific aspects of the intervention

The goal of this workshop is to provide a scientific background that can inform research to identify and establish modifiable risk factors for LUTS in women and help lay the foundation for future prevention studies.

Another NIDDK-sponsored meeting, the Urinary Incontinence Research Summit is being held on March 20, 2014 at the Natcher Conference Center on the NIH Main Campus in Bethesda. The objectives of the urinary incontinence research summit are to bring together health care professionals from a variety of disciplines, consumer advocates and governmental agencies with interest in the treatment of urinary incontinence to achieve the following goals:

1. Determine the key scientific advances in the treatment of urinary incontinence in women made by the Urinary Incontinence and Pelvic Floor Research Networks and other NIH funded clinical research (i.e. PRIDE)
2. Identify how their findings have impacted treatment of patients, been adopted by physicians and other health care professionals, other researchers and insurers
3. Determine the audience specific messages that will facilitate dissemination and uptake of the results of NIDDK studies
4. Define unmet needs in urinary incontinence research to stimulate the submission of investigator initiated (R01) and other grant applications Studies of particular interest would have broad applicability to the affected population.
5. Broadly disseminate summit findings to appropriate audiences

Meeting participants offered the following comments:

- There is a random controlled trial “TULIP (Translating Unique Learning for Incontinence Prevention) study” studying primary prevention and secondary prevention for mild urinary incontinence. This study uses a diary and video. The interest for the LUTS initiative would be treatment/intervention based.
- NCCAM noted focus on treatment; however, they are interested in promoting more research efforts related to health promotion. Interest in dietary habits should be studied. Also, interested in patient centered care.
- One institute noted interest in calculation studies. GWAS study looking at urge, incidence, etc. Descriptive study of women who are asymptomatic.

Urology Diseases in America Update

Paul Eggers, PhD.

National Institute of Diabetes and Digestive and Kidney Diseases

Following Dr. Bavendam’s presentation, Dr. Eggers provided an overview and results from the Urologic Diseases in America (UDA) project. Dr. Eggers noted that UDA goals included the overall documentation and analysis of current and retrospective data related to particular benign urologic diseases for the following areas:

1. Descriptive analyses of various urologic diseases, symptoms and conditions in the United States. This includes demographic variations in the incidence and prevalence of these conditions, as well as changes that may be occurring over time;
2. Physician and other provider practice patterns. This includes variation and changes in the use of surgical, medical, and pharmaceutical interventions for the treatment of urological conditions;
3. Outcome analyses. This includes the assessment of clinical, quality of life and economic results of therapeutic interventions in the treatment of urologic conditions. To the extent possible, this should also include comparative effectiveness analyses;
4. Access to and use of medical care by minority populations and those who may be otherwise disadvantaged due to income and/or health care insurance coverage issues.

Data sources for the UDA project included National Center for Health Statistics (Healthcare Cost and Utilization Project [HCUP], National Ambulatory Medical Care Survey [NAMCS], and National Health and Nutrition Examination Survey [NHANES]); the Centers for Medicare and Medicaid Services (CMS), and Economics Datasets (MarketScan: Captures absentee data, Ingenix: Data on medical claims for 25 Fortune 500 companies, and MEPS: Survey of health care service use and expenditures). Dr. Eggers noted two comparisons in top total annual expenditures:

- For urinary tract infections, females totaled \$956,500,000 versus \$480,200,000 for males.
- For urinary incontinence, females totaled \$234,400,009 versus \$39,000,000 for males.

Dr. Eggers noted the following prevalence highlights for urinary incontinence:

- UI is one of most prevalent chronic diseases
- Past prevalence estimates
 - Large variations
 - Definition-reliant (i.e., whether daily, weekly, ever)
- UDA measured prevalence using NHANES
 - Among women, 38% reported having UI
 - Among men, 17% reported having UI
- Urinary incontinence was reported as more common in females through the age of 85.

Other findings included:

- Trends in Surgical Procedures among Female Medicare Beneficiaries: any procedure per 100,000 diagnosed persons remained flat from 1002 to 2007.
- In trends of the type of Surgical Procedures among Female Medicare Beneficiaries, the pubovaginal sling rose in 2000 with significantly higher rate in 2004 and 2007 while the Raz type suspension declined.

In conclusion, Dr. Eggers discussed what will be included in the 2014 UDA urinary incontinence tables:

For male and female urinary incontinence:

- NHANES tables:
prevalence, frequency, bother, activity limitations, stress, urgency and mixed
- Over 65 – Medicare tables:
Percent of beneficiaries seeking care, hospitalizations, physician visits, hospitalizations, surgical procedures, and costs
- Under 65 – I3 data base tables
Percent of beneficiaries seeking care, hospitalizations, physician visits, hospitalizations, surgical procedures, and costs

For pediatric urinary incontinence:

- NHANES tables: - None
0 to 17 – 7 data base tables
Percent of children seeking care, hospitalizations, physician visits, hospitalizations, surgical procedures, and costs

Meeting participants noted that the UDA data presented was informative and useful for planning future efforts.

DoD Urology Interests

Carolyn J. Best, PhD

Program Manager

Department of Defense

Dr. Best discussed the DoD's congressionally directed medical research programs (CDMRP). The CDMRP is the second largest funder in the United States for research in prostate cancer. The hallmarks of the CDMRP include:

- Disease-specific research funds added to DOD budget by Congress
- Program-specific vision is adapted yearly; award mechanisms are changed as needed
- Consumer advocates involved throughout process
- Fund highly innovative research
- Fill unfunded/unmet gaps and niches
- Two-tier formal review of applications – Institute of Medicine model
- Awards fully obligated at outset; no continuation funding

Dr. Best noted that the scope of CDMRP award mechanisms support differing stages of career including pre- and postdoctoral fellowship, new investigator, and innovator. The award mechanisms also support individuals and teams such as investigator-initiated research, synergistic idea development, center of excellence, and consortium. Finally, the CDMRP award mechanisms serve to support the spectrum of research through concept and exploration – hypothesis development, idea development, advanced technology/therapeutic development, and clinical trials.

In particular, Dr. Best highlighted three research programs of relevance to urology. The CDMRP's Prostate Cancer Research Program (PCRP) was awarded over \$1 billion in funds since Fiscal Year 2007. From Fiscal Year 1997 to 2013, there have been 2,650 awards made so far. The award mechanisms used in this research program support early discovery, idea development, team science, clinical trials, consortia, and training.

The second program Dr. Best discussed was the Peer Reviewed Medical Research Program (PRMRP). Applications to the PRMRP also solicited under research topic areas included: interstitial cystitis, polycystic kidney disease, kidney cancer, and chronic kidney disease (new in FY13). The award mechanism used in this program supports early discover and therapeutic/technology development. Of the total PRMRP awards made from FY99-12, \$18.4 million was dedicated to urology research and \$32.5 million went to support non-urology research.

Lastly, Dr. Best presented information about the Spinal Cord Injury Research Program (SCIRP). Since FY10 this program has encouraged applications addressing topic areas including bladder, bowel and sexual dysfunction as a result of SCI. The award mechanisms used in this program support investigator-initiated research and translational/qualitative research. From FY09-12 \$4.6 million was used from urology research versus \$55 million for non-urology research.

Of particular interest, Dr. Best noted that \$5.2 million is allocated for interstitial cystitis within the CDMRP urology portfolio. For more information about the CDMRP program, meeting participants are encouraged to visit the website at: <http://cdmrp.army.mil>.

Meeting participants offered the following comments:

- Research outcomes database is not publicly available, but could be useful if more visible on website.
- Introduce military population of women to urology research. Some studies could be funded through core research funds.

Agency Updates – Round Table

- Dr. Kirkali noted work on the LURN study group has started working and have finalized protocol 1. Also, another set of PIs joined this effort to assist with phenotyping.
- NIDDK new website will launch December 16.
- NCCAM noted the annual pain consortium meeting will take place on May 28 and 29, 2014.
- DoD is working with NIH to get data into the NIH reporter.
- Dr. Rankin noted a recent Urology Centers Directors meeting.
- NIA funded a multicenter trial on behavioral therapy in UI. Also, NIA will be funding an R13 meeting in Feb 20-21 on underactive bladder.
- Dr. Bavendam noted the following resources: the TULIP and Group Learning to Accomplish Decreased Incidents of Lower Urinary Symptoms (GLADIOLUS) trials.

Meeting Adjourned