NIDDK | NATIONAL INSTITUTE OF DIABETES AND DIGESTIVE AND KIDNEY DISEASES

Urology Interagency Coordinating Committee (UICC)

Friday, May 17, 2012
10:00 a.m. - 2:00 p.m.
6707 Democracy Blvd. Room 701 A-B
Bethesda, MD

Attendees:

L. Alekel (NCCAM)
R. Alexander (VA)
L. Begg (ORWH/NIH)
P. Donohue (NIDDK OSPPA)
E. Duggan (NIDDK/KUH)
M. Harris (NIDDK OCPL)
R. Higgins (NICHD)
K. Huntley (NCCAM/NIH)
Z. Kirkali (NIDDK/KUH)
S. Meikle (NICHD)
S. Moss (NICHD)
M. Murthy (NIA/NIH)
B. Polglase (NIDDK/OCPL)
M. Salive (NIA)
R. Star (NIDDK/KUH)
J. Thibadeau (NCBDDD/CDC)
R. Weiderhorn (FDA)
M. Worstell (HHS OWH)

Meeting Minutes

Welcome and Introductions
Tamara Bavendam, M.D.
National Institute of Diabetes and Digestive and Kidney Diseases

Dr. Bavendam opened the meeting and welcomed attendees. Meeting attendees introduced themselves.

Standardized Urological/Renal Management Plan for Spina Bifida
Judy Thibadeau,
Center for Disease Control

Dr. Thibadeau directed staff to the published article handout titled “Testing the Feasibility of a National Spina Bifida Patient Registry”. The purpose of this study was to describe the development and early implementation of a national spina bifida (SB) patient registry, the goal of which is to monitor the health status, clinical care, and outcomes of people with SB by collecting and analyzing patient data from comprehensive SB clinics. The creation of a National Spina Bifida Patient Registry partnership between the CDC and SB clinics has been feasible.
The citation for this paper is: Thibadeau JK, Ward EA, Soe MM, Liu T, Swanson M, Sawin KJ, Freeman KA, Castillo H, Rauen K, Schechter MS. Testing the feasibility of a National Spina Bifida Patient Registry. Birth Defects *Res A Clin Mol Teratol.* 2013 Jan;97(1):36-41.

Dr. Thibadeau presented plans for a prospective multisite study evaluating a protocol for Standardized Urological/Renal Management Plan for Spina Bifida children 0-5 years. The Plans’ standardized assessment includes:

- Renal Function Outcomes- DMSA scan, GFR and Creatinine
- Resource Utilization-renal/bladder ultrasound, urodynamics
- Management of UTIs, site and community
- Guideline adherence by family and clinician
- Clinician input when deviating from the guideline

She has been working with an external expert group and asked for group feedback.

Discussion

Participants offered the following feedback:

- Dr. Narva suggested reviewing data from the CKiD study. He noted that measuring creatinine is difficult in kids, but a new tool that measures standardized creatinine has been developed by Dr. Schwartz. However, the test has not been validated.
- Dr. Star noted that the RIVUR study has protocols for studying UTIs.
- The issue of addressing how to reach audiences that do not access clinics was raised. Would there be socioeconomic differences?
- The MOMS 2 study was discussed and it was noted that a urologic follow up is also being done in this study. However, the data will not be available until 2015 or 2016.
- Stratify children with and without reflux.
- Address the use of prophylaxis in clinics
- Adherence to behavioral interventions will be studied

Women`s Urology Research: How Important is Prevention?
Tamara Bavendam, M.D.
National Institute of Diabetes and Digestive and Kidney Diseases

Dr. Bavendam asked the group about prevention based efforts within their agencies. The Aging Institute noted that their focus in Alzheimer's Disease has shifted from treatment to prevention. The OWH noted interest in studying this to address needs with older women. Dr. Bavendam's presentation focused on several key points:

- Research investment thus far has been on a limited part of this population: treated patients.
- There are differences in clinician versus patient perspectives in understanding lower urinary tract symptoms (LUTS). Presence of LUTS is not equal to dysfunction of the LUT.
- When adopting a population perspective people can be divided into those with and without LUTS. Some of those without LUTS engage in behaviors that put them at risk for LUTS later in life. Two segments of population are easiest targets for prevention activities: early lower urinary tract dysfunction (LUTD) and those with symptom provoking behaviors.
- NIH LUTS prevention research is limited thus far.
- Efforts for prevention are limited by women not discussing it and by clinicians not being proactive (conflict over surgical versus nonsurgical interventions).
- LUTS/D prevention is broadly defined (i.e., target areas: difficult voiding and ancillary areas: sexual health).
- While urinary incontinence (UI) is a quality of life concern it is also an important medical condition which is overlooked.
- Overactive bladder (OAB) and UI are associated with other major comorbidities: cardiovascular disease, depress, diabetes, obesity, and bowel dysfunction.
- To garner the resources for the needed research UI should be reframed and presented as an important medical condition that is a barrier to successful treatment of priority, costly medical conditions such as obesity, diabetes risk, , cardiovascular risk, etc).
- Primary and secondary prevention should have a positive impact on priority medical conditions. Populations at risk for urinary incontinence should be exposed to a multidimensional educational initiative that would educate them about behaviors that promote healthy bladder function over a lifetime. This initiative would give participants the skills to increase or maintain physical activity and maintain social functioning and mental health. Maintenance of physical activity should reduce the incidence of priority medical conditions such as obesity, diabetes, cancer, depression, and cardiovascular disease.
- Opportunities for LUTS prevention strategy exist throughout a women's lifecycle and would benefit both the individuals, clinicians and payers.

Discussion

- Identification of biomarkers may aid in diagnosis. The pelvic floor network is currently doing this work.
- Framework is good, but looking at multiple chronic conditions should be done. Aging Institute is working on mobility, improving interventions, rationalization of drug therapy. Consider putting individuals on high priority drugs rather than many different drugs.
- Not a good deal of research being conducted by the pharmaceutical industry. There are drugs in development for pain issues, but not incontinence.
- The issue of diet in UI was raised, but there is limited evidence about the impact of diet on UI.
- HHS Managing multiple morbidities initiative could be applicable to this prevention initiative.
- Patient centered orientation is a good setup. The magnitude of this problem is unknown. Having a standardized way of measuring this problem is needed. Biomarkers or clinical syndrome could be a good starting point.

Continence Across the Continents – An Example for Interagency Collaboration
Cara Tannenbaum, M.D
Associate Professor of Medicine
The Michel Saucier Endowed Chair in Geriatric Pharmacology, Health and Aging, Université de Montreal

Dr. Tannebaum requested that meeting attendees introduce themselves and detail what they would like to learn from this meeting. Meeting attendees expressed interest in cross collaborations and learning more about incontinence.

Dr. Tannebaum noted she developed her community-based research plan. Dr. Tannebaum's presentation focused on several key points:

- Dr Tannenbaum presented a research pipeline population based research to promote continence. It has 6 phases (discovery, feasibility, efficacy, effectiveness, implementation and sustainability) similar to drug development.
- Her phase 1 was. a cross-Canada survey of 5,000 women aged 55-95 years old of their health priorities. While over 50% had urinary incontinence, only 1 in 3 sought treatment.
- Her Phase 2 feasibility portion included an incontinence educational workshop and a evidence-based self-management tool. The workshop resulted in 85% of women had made efforts to improve their situation. The self –management tool was used by 95% of participants. Of self-management tool users, incontinence was reduced by 50% and self-efficacy significantly increased.
- The Continence across Continents trial was the Phase 3 efficacy study. This trial was a cluster randomized trial of three different community based continence promotion interventions to improve urinary incontinence among untreated older women. Recruitment for this trial was directed to women aged 60+ through community outreach efforts (advertisements and "cold" calls). The workshop and self-management tool were used for interventional efforts. During a three month telephone follow-up, over 65% reported successful treatment for incontinence symptoms through combined treatment (workshop and self-management tools). Over 59% of workshop only participants and over 40% of self-management tool users reported improvement.

In conclusion, Dr. Tannebaum delivered the following take home messages for inter-agency collaboration:

- Start small, think big!
- Many different formulas are available
- Goals can be tangential:
    - Populations (e.g., women, older population)
    - Conditions (e.g., incontinence, mental health, falls)

- Settings (e.g., community versus hospital versus long-term care)
    - Prevention (health services versus public health)
- No need to compromise on priorities or scientific rigor.
    - Let the researchers figure it out—creativity and innovation are the strong points.

Discussion

- Suggest use of collaboration through NIH Common Fund or PCORI funds
- CMS will announce innovation grants next week
- Aging is collaborating with PCORI; plan to design large trial on patient falls.
- Focus on quality measures to drive practice
- CMS has a huge initiative on preventing patient falls
- Incontinence affects length of stay in hospitals which increases costs. Possible focus for CMS.
- Collaboratively sponsoring training courses for PIs may help create interest for PIs to respond to these prevention based efforts.
- Office of Disease Prevention has recently expanded and is looking for collaborations
- HHS Community Living initiative was discussed as a research opportunity
- Dr. Wanda Jones is highly interested in the topic of incontinence.
- Examining the relationship between sexual activity and urinary tract infection may increase educational awareness. This could be done earlier to promote education amongst the younger population. There national office for organization of university study health services is in MD.
- CMMI (Medicare innovation center) is interested in new ways of treatment

"Healthy People" Objectives– Is there a Path to Integration of Benign Urological Conditions

Dr. Begg noted that she has spoken with HHS and there is no information about bladder or GI health in the 2020. HHS/ODPHP will require a working group to be formed and the group will have to develop measurable objectives. The group expressed interest in starting a working group for this task. Dr. Worstell suggested possibly associating bladder health with facility care. Dr. Worstell suggested inviting patient advocacy groups to the interagency meetings.

Agency Updates

- Rich Alexander (VA) noted limited activity in the benign urology. Lisa Begg (OWH) noted that there is a women's health group within the VA.
- DOD distributed a list of congressionally directed medical research programs in urology research.

Meeting Adjourned