Continence Begins with Prevention:
A New Paradigm Using a Transdisciplinary Science Approach

Bavendam, T., Newman, D., Lowder, J. L., Brady, S. S., Camenga, D., & Markland, A.D., on behalf of the PLUS Research Consortium
Acknowledgements

This work was completed for the Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium, which is supported by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) through cooperative agreements (grants DK106786, DK106853, DK106858, DK106898, DK106893, DK106827, DK106908, DK106892).
Workshop Overview

• Primary goal of the Prevention of Lower Urinary Tract Symptoms (PLUS) Consortium
  – A multi-center network funded by the NIH/NIDDK
  – Prevention of LUTS in women by advancing bladder health

• Transdisciplinary members
  – Includes physicians, nurses, psychologists, sociologists, prevention scientists, epidemiologists, and biostatisticians

• Workshop Goals
  – Provide an overview of the PLUS consortium, including ongoing efforts to define and measure bladder health
  – Introduce prevention science methods
  – Share strategies to implement collaborative team science
  – Seek input from audience members
Workshop Speakers & Main Objectives

1. Tamara Bavendam, MD - Describe the need for a paradigm shift to bladder health and a transdisciplinary approach
2. Diane Newman, DNP – Provide examples of continence promotion through prevention trials
3. Jerry Lowder, MD - Define bladder health and the relationship to other LUTS in women
4. Sonya Brady, PhD - Conceptualize bladder health in women using a social ecological and biopsychosocial model. And, apply a prevention science research paradigm to the study of risk and protective factors for bladder health using an interactive activity with discussion
5. Deepa Camenga, MD – Outline methodologic approaches for measuring bladder health across the life course in women and girls
Why bladder health?

Tamara Bavendam, MD, MS
Urologist/NIH NIDDK Project Scientist for the PLUS Consortium
Why Bladder Health: The Urologic Iceberg

* Iceberg concept adapted from Last (1963; 2001)
Women’s Bladder Health: Don’t Ask – Don’t Tell

“The bladder gets no respect!!!”
Reframing LUTS: Important Medical Condition with Tremendous Quality of Life Impact

Priority, Costly Medical Conditions
- Obesity
- Diabetes risk
- Cardiovascular risk
- Musculoskeletal risk
- Falls and Fractures
- Cancer risk
- Depression

LUTS

Decreased Physical Activity

Depression

Decreased Work Productivity
Opportunities Provided by a Bladder Health and LUTS Prevention Strategy

People With Bladders

Educate about bladder function, healthy behaviors and abnormal symptoms and spectrum of treatment options

More sufferers recognize their situation as abnormal and treatable

Opportunity to change unhealthy behaviors and incorporate behaviors that promote healthy bladder function

More sufferers seek evaluation and treatment with basic understanding of problem, treatment options and their role in treatment

Improve Overall Health
Opportunities Provided by a Bladder Health and LUTS Prevention Strategy

People With Bladders

Educate about bladder function, healthy behaviors and abnormal symptoms and spectrum of treatment options

More sufferers recognize their situation as abnormal and treatable

More sufferers seek evaluation and treatment with basic understanding of problem, treatment options and their role in treatment

Opportunity to change unhealthy behaviors and incorporate behaviors that promote healthy bladder function

IMPROVE OVERALL HEALTH
Opportunities Provided by a Bladder Health and LUTS Prevention Strategy

People With Bladders

Educate about bladder function, healthy behaviors and abnormal symptoms and spectrum of treatment options

More sufferers recognize their situation as abnormal and treatable

Opportunity to change unhealthy behaviors and incorporate behaviors that promote healthy bladder function

More sufferers seek evaluation and treatment with basic understanding of problem, treatment options and their role in treatment

IMPROVE OVERALL HEALTH
NIH “Bladder/Pelvic” Networks

NIDDK

MAPP (Urologic Chronic Pelvic Pain)

NICHID

PFDN (Pelvic Floor Disorders)

Pelvic Organ Prolapse

Anal Incontinence

Urinary Incontinence

LURN (LUTS except UCPP)

PRO

DEEP PHENOTYPING UCPPS

DEEP PHENOTYPING LUTS
Evolution from Treatment to Prevention

- Treated Patients
- Evaluated Patients
- Care Seeking Individuals
- Early Symptomatic Individuals
- Primary Prevention in Healthy Individuals

Note: Line reflects size of population
NIH “Bladder/Pelvic” Networks

NIDDK

PLUS

Define Bladder Health and LUTS Risk Factors

DEEP PHENOTYPING UCPPS

MAPP

Urinary Incontinence

LURN

DEEP PHENOTYPING LUTS

PRO

NICHID

PFDN

Pelvic Organ Prolapse

Anal Incontinence

Urinary Incontinence
PLUS Evolution at NIDDK

- Urology Interagency Coordinating Committee (2012)
- LUTS Prevention Think Tank (2013)
- UICC Adhoc Meeting Women's Urology Research (2014)
- NIDDK Path to Prevention Workshop (2015)
PLUS Considers Bladder Health Holistically

Considering Ages from adolescent girls to older women

LUTS=Lower Urinary Tract Symptoms
UI=Urinary Incontinence
ISD=Intrinsic Urethral Dysfunction
UTI=Urinary Tract Infection
VD=Voiding Dysfunction
IC/BPS=Interstitial Cystitis/Bladder Pain Syndrome
Define Healthy Bladder

Expand Understanding of Factors

RFA: Prevention of Lower Urinary Tract Symptoms (PLUS)
PLUS Evolution at NIDDK

- Urology Interagency Coordinating Committee
- LUTS Prevention Think Tank
- UICC Adhoc Meeting Women’s Urology Research
- NIDDK Path to Prevention Workshop
- RFAs Published; Applications Submitted
- Applications Reviewed; Council Concurrence
- PLUS Consortium Launched

Year:
- 2012
- 2013
- 2014
- 2015
PLUS Research Center and Investigator Locations

Total Investigators = 53

- UMinn
- Loyola
- UMich
- WashU
- UAB
- UCSD
- Yale
- UPenn
- NIDDK

= NIDDK
= Research Center
= SDCC
= Investigator

Total Investigators = 53
Two Years Ago We Started with an Empty Stage
PLUS Consortium Nov 2016
PLUS Research Consortium Investigators
Developed Transdisciplinary Research Approach
(Continuum of integration – An Analogy)

- **Unidisciplinary research**

- **Three cross-disciplinary research orientations**
  - **Multidisciplinary**
    - Independent, Sequential, Divisional
    - Exchange
  - **Interdisciplinary**
    - Joint, Interactive, Partnership
    - Dialogue, Exchange, Hybridization, Complementary
  - **Transdisciplinary**
    - Integrative, Interdependent, Immergent
    - Reciprocity, Discourse, Share Vocabulary, Extends

Adapted from Holly J. Falk-Krzesinski, 2012; Austin et al., 2008; Nissani, 1995
PLUS is Rapidly Evolving

- FLEXIBILITY
- BUILDING TRUST
- Listening to ALL Voices
- Defining Terms
Why we should care about prevention?

Diane K. Newman, DNP ANP-BC FAAN
Adjunct Professor of Urology in Surgery
Research Investigator Senior, Perelman School of Medicine
University of Pennsylvania
Co-director Penn Center for Continence & Pelvic Health
PENN Medicine
Philadelphia Pennsylvania
Why?

- **Incontinence:**
  - Is prevalent worldwide.
  - Incidence is high.
  - Is a chronic condition with known risk factors.
  - Severity is graded.
  - Affects social, emotional and physical well being.
  - Is costly to manage.

*An Issue for Women Across their Lifespan*
Purpose of prevention: to reduce movement down the causal chain
The Prevention Pyramid: Targeting different populations

- **Primordial Prevention**: Healthy & apparently healthy people without symptoms, disease, or RFs
- **Primary & Secondary Prevention**: Women not seeking care who may have symptoms, unidentified disease, and/or RFs
- **Primary & Secondary Prevention**: Women (may have Sx Asymptomatic, Diag, Risk Factors (RFs))
- **Treatment**: Health Promotion
Prevention of UI in Women: What is the evidence?

• Prior work shows effectiveness of a face-to-face Bladder Health (BH) class for preventing urinary incontinence (UI)
  
  — Class content included the education on healthy bladder habits, dietary and fluid modification, behavioral techniques of bladder training and the pelvic floor muscle training techniques of repetitive exercise and knack squeeze trick

Educating Adult Women about Bladder Health: the Translating Unique Learning for UI Prevention (TULIP) Project

• Multi-site, randomized, two arm, parallel design:
  – University of Michigan School of Nursing (Detroit)
  – University of Pennsylvania Division of Urology (Philadelphia)

• Aim: To compare early- and long-term primary prevention of UI of women > age 55 with no LUTS randomized to:
  – Face-to-face bladder health class (2-hrClass) OR
  – Abbreviated video of same content on DVD (20-minVideo)
Educating Adult Women about Bladder Health: the Translating Unique Learning for UI Prevention (TULIP) Project

• Intent-to-treat analysis to compare the effect of each intervention group across time & also with each other

• Study was powered for non-inferiority

• Able to test the hypothesis that there would be no difference in incidence of UI at 2 year post intervention.
  – Did not know at the inception of the study if the 2hrClass would be superior, inferior, or non-inferior to the 20minVideo.
Materials and Methods: Recruitment Strategy

  – Commercial mailing list of 50,000 per sites with enriched sampling from urban settings and representation of African American women by zip code indicators

• Inclusion criteria included community-dwelling females, continent, and > 55 years old.

• Pre-screening initiated via telephone interview (N=2230) and finalized by baseline screening visit (N=1074).
Study Flow

1. Telephone Screen of Responders to Mass Mailing/Flyers/Referrals
2. Clinical Screening/Baseline at Site
3. Randomization
4. 2hrClass and 20minVideo
5. 3 Months Assessment
6. 12 and 24 Months Assessment
Baseline Screening (N=814)

- Eligible by physical examination (n=647)
- International Continence Consultation Questionnaire-Short Form (ICIQ-SF)
  - Sum of questions 1-3. \( \leq 5 \) (Avery et al., 2004)
  - Primary Outcome
- Indevus Urgency Severity Scale (IUSS) (Nixon et al., 2005)
- Paper Towel Test (PTT). (Miller et al., 1988)
  - No more than a few drops leaked on PTT
- Brink Test: PFM muscle pressure/displacement
- Negative for UTI or hematuria by dipstick
- Negative for POP beyond introitus
Materials and Methods: Intervention

- **2hrClass (Bladder Health Class)**
  - Two-hour face-to-face taught by professional
  - Content, practice, & take-home instructions on
    - Pelvic Floor Muscle Exercise
    - Bladder Training with urgency suppression techniques
    - Squeeze Trick (the Knack)
- **20minVideo (BH Class content abbr. to 20 minutes)**

Followed (seen) for 3 months, 1-yr, 2-yrs post-intervention
## TULIP Participant Breakdown by Race and Site (N=647)

<table>
<thead>
<tr>
<th></th>
<th>University of Pennsylvania</th>
<th>University of Michigan</th>
</tr>
</thead>
<tbody>
<tr>
<td>Caucasian</td>
<td>200</td>
<td>239</td>
</tr>
<tr>
<td>African American</td>
<td>105</td>
<td>76</td>
</tr>
<tr>
<td>Hispanic</td>
<td>5</td>
<td>2</td>
</tr>
<tr>
<td>Other</td>
<td>10</td>
<td>10</td>
</tr>
</tbody>
</table>
# TULIP Participant Demographics and Body Mass Index by Study Group (N=647)

<table>
<thead>
<tr>
<th>Variable</th>
<th>2-hrClass</th>
<th>20-minVideo</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Age</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. 55-87 Years</td>
<td>332</td>
<td>314</td>
</tr>
<tr>
<td>Mean ± SD</td>
<td>63.03 (5.43)</td>
<td>62.79 (5.91)</td>
</tr>
<tr>
<td><strong>Race/Ethnicity</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No. Race/Non-Hispanic White</td>
<td>332/214</td>
<td>315/225</td>
</tr>
<tr>
<td>No. Race/Non-Hispanic Black</td>
<td>332/101</td>
<td>315/80</td>
</tr>
<tr>
<td><strong>Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No./HS or less</td>
<td>332/31</td>
<td>315/32</td>
</tr>
<tr>
<td>No./Some College to Grad Degree</td>
<td>332/301</td>
<td>315/283</td>
</tr>
<tr>
<td><strong>Employment Status</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Employed full time</td>
<td>95</td>
<td>102</td>
</tr>
<tr>
<td>Employed part-time</td>
<td>49</td>
<td>46</td>
</tr>
<tr>
<td>Unemployed/Disabled</td>
<td>34</td>
<td>33</td>
</tr>
<tr>
<td>Retired</td>
<td>154</td>
<td>133</td>
</tr>
<tr>
<td>Prefer not to answer</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td><strong>BMI</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>328*</td>
<td>314</td>
</tr>
<tr>
<td>Mean (SD)</td>
<td>29.1 (SD 6.4)</td>
<td>28.8 (6.3)</td>
</tr>
</tbody>
</table>
Materials and Methods: Statistical Procedures

• Time to follow-up calculation based on viewing date of 20minDVD or 2HrClass attendance
• Intent-to-treat analysis performed to compare outcomes controlling for age, Race, BMI, etc.
• Multiple imputation using IVEWare software used to handle missing data (Raghunathan et. al., 2001)
Results

• Sample of 647 enrolled
  – Age mean 63 years (range 55-87 years)
  – Nearly 28% African American
  – BMI 29 (SD 6.35)

• No significant differences between groups on the ICIQ-SF, PTT, and IUSS demonstrates equally efficacious interventions
  – Both ICIQ-SF and IUSS were lower than baseline at 24-months follow-up, but difference did not reach significance

• Pattern differences between groups
## ICIQ-SF Comparison by Randomized Group

<table>
<thead>
<tr>
<th></th>
<th>20minVideo Mean or mean diff (SE)</th>
<th>2hrBH Mean or mean diff (SE)</th>
<th>Mean difference</th>
<th>P-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baseline</td>
<td>3.1 3(0.15)</td>
<td>3.11 (0.15)</td>
<td>-0.095</td>
<td>0.92</td>
</tr>
<tr>
<td>3-mo vs Baseline</td>
<td>-0.44(0.2)</td>
<td>0.39 (0.45)</td>
<td>1.69</td>
<td>0.09</td>
</tr>
<tr>
<td>12-mo vs Baseline</td>
<td>-0.23(0.2)</td>
<td>-0.30(0.19)</td>
<td>0.24</td>
<td>0.81</td>
</tr>
<tr>
<td>24-mo vs Baseline</td>
<td>-0.37 (0.23)</td>
<td>-0.05 (0.31)</td>
<td>0.78</td>
<td>0.44</td>
</tr>
</tbody>
</table>
ICIQ-SF by Group from Baseline to 24 Months
IUSS by Group from Baseline to 24 Months

![Graph showing IUSS by Group from Baseline to 24 Months]

- **Baseline**: Both Class and Video groups show similar IUSS values.
- **3-month**: slight increase in IUSS for both groups, with Video slightly higher than Class.
- **12-month**: IUSS values continue to rise, with Video remaining slightly ahead of Class.
- **24-month**: IUSS values continue to increase, with Video consistently higher than Class.
TULIP Project Conclusion

- Study was able to recruit and retain a sample of community-dwelling adult continent women, to compare two delivery methods of health education for UI prevention.
- No differences in the ICIQ-SF between the two groups over the 24 months of the study
  - Adjusted for BMI at baseline, age, race/ethnicity, education, employment status, income, and marital status
- 20minDVD-video was equally efficacious to a 2hrclass
- Persuasive evidence of the benefits to be obtained by women who have access to instruction in self-management practices to prevent UI
Discussion

• Outcomes for BOTH groups demonstrated a prevention effect at 2 year follow-up

• Reported annual UI incidence rates: 4-16.5%
  – Both TULIP groups had lower values at 2 yrs.

• The essentially unchanged IUSS and PTT scores for both groups at 2 years are opposite reported UI and OAB increases with age
Conclusions

- The 2-hrClass and the 20 minute Video are useful for LUTS prevention
- For the purposes of primary prevention, the fact that outcomes were similar (and even somewhat better) with a learning method that does not require a trained professional has ramifications for public health initiatives
Future Needs

- Prevention of other LUTS, along with UI
- Prevention in high risk groups
- Prevention in adolescents/younger women
What is bladder health?

Jerry L. Lowder, MD, MSc
Associate Professor
Director, Division of Female Pelvic Medicine &
Reconstructive Surgery
Washington University in St. Louis
Disclosures

• None
“The beginning of wisdom is to call things by their proper name.”

Confucius
Definitions – Lower Urinary Tract Symptoms

• Well-defined
Definitions – LUTS Terminology
“In modern medicine, we have a name for everything, but a cure for nothing.”

Charles F. Glassman
Definitions – Measurement of LUTS
“The desire to take medicine is perhaps the greatest feature which distinguishes man from animals.”

William Osler
LUTS Treatments

PTNS
Toviaz
Sanctura
Dstropan
Detro
Vesicare
Interstimchloride
oxybutynin
Enablex
tolterodine
Ditropan
Solifenacin
Myrbetriq
fesoteridine
Gelnique
Darifenacin
trospium
desipramine
mirabegron
Elavil
Detrol
Fluvoxate
Botox
November is Bladder Health Month

This month serves as a reminder to get the facts about common bladder health problems and to take an active role in your health. During November, the Urology Care Foundation will highlight a different bladder health theme and related resources.

**Week 1 Theme: Incontinence, OAB and SUI**
November 1-5

**Week 2 Theme: Nocturia and Bedwetting**
November 6 - 12

**Week 3 Theme: Bladder Cancer**
November 13 - 19

**Week 4 Theme: Bladder Infection/Urinary Tract Infection (UTI)**
November 20 - 26
Current uses of “bladder health”

Bladder Health Tips

- Drink plenty of water. Strive to drink 6 to 8 cups of water each day.
- Cut down on the amount of caffeine and alcohol you drink - these may upset your bladder. Limit your intake of coffee, tea or cola as these can heighten bladder activity and lead to leakage.
- Women should sit to go to the toilet - they should not hover over the toilet seat.
- Take your time when on the toilet so that your bladder can empty - if you rush, and do not empty your bladder fully, over time, you could get a bladder infection.
- Stay away from foods that bother the bladder. Some foods can worsen incontinence. Skip foods like chocolate (also a source of caffeine), as well as spicy or acidic foods like tomatoes and citrus fruits.
- Keep your pelvic floor muscles strong with pelvic floor muscle training.
- Stop smoking. It is of great value to stop smoking for your bladder health - using tobacco is a major cause of bladder cancer.

For more information on bladder health facts, read the Bladder Health Infographic:
• While there are effective treatment options for LUTS, few incontinence prevention programs studied
  – In part due to no definition of Bladder Health

• A standardized Bladder Health definition can aid in identifying:
  – factors to promote health
  – factors to modify to prevent LUTS
To date, bladder health has been framed in terms of absence of LUTS.

PLUS Research Consortium looked to:
- the WHO definition of health:
  - “Health is a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity”
- Huber et al. for perspective on aging and chronic disease where complete well-being is unattainable
  - Health as “the ability to adapt and to self-manage”
- the concept of allostasis to capture resilience to short term physical, social, and environmental stressors

http://www.who.int/about/mission/en/
Bladder Health: More than the absence of LUTS

• Working definition
  – A complete state of physical, mental, and social well-being related to bladder function, and not merely the absence of LUTS
  – Function that permits daily activities, adapts to short term physical or environmental stressors, and allows optimal well-being (e.g. travel, exercise, social, occupational activities)

• Functions of the bladder
  – Storage
  – Emptying
  – Bioregulatory (protection from infection, inflammation, etc.)

• Consortium in process of identifying normative “stressors” or “challenges” to which most girls and women can rebound

Definitions: Bladder Health to Healthy Bladder Functions

- Drafted framework table of bladder functions:
  - Storage
  - Emptying
  - Bioregulatory
    - Novel function to recognize bladder physiology in health and dysfunction

- Reviewed literature for accepted LUTS definitions associated with bladder dysfunctions

- Developed elements of bladder function based on LUTS definitions
Understanding of storage and emptying cycle of a healthy bladder: Expert consensus 1.0

- To be included during workshop
Definitions: Bladder Health to Healthy Bladder Functions

• “Bladder Health” definitions proposed for each indicator of bladder function
  – Definitions took into account variation across lifecourse

• Included available subjective and objective measurements for bladder dysfunction and health
  – guide for research and future instrument development

• PLUS TCFM – worked in groups & subgroups to develop and refine definitions
  – Input from entire PLUS Consortium obtained at various stages
Definitions: Bladder Health to Healthy Bladder Functions

• PLUS categorization of bladder functions *differs* from previously described bladder phases:
  – storage, emptying, and post-micturition

• In health, post-micturition is a time period where dysfunction in emptying or storage *could* occur (not a stand-alone “function”)
  – The healthy bladder should transition from emptying to storage without a defined “post-micturition” state
    • *i.e.* Post-void dribble is in both storage and emptying *dysfunctions,* acknowledging that this condition is likely multifactorial and may represent dysfunction in storage, emptying or both
Definitions: Bladder Health to Healthy Bladder Functions

• Bioregulatory function – Novel
  – Subdivided into three main functions:
    • 1) host defense/biosis barrier
    • 2) physical/chemical barrier
    • 3) cancer barrier
  – Considered a bidirectional communications between
    the bladder and the environment
    • prevent systemic or local infection, transmit appropriate
      physiologic signals or regulate cellular function
  – In health, the bladder barrier protects the individual
    from pathogens, chemicals, and malignancy
    • is adaptable to short term physical or environmental
      stressors; and is able to recover from disruption without
      long-term or persistent sequelae
# Overview of PLUS Consortium Bladder Dysfunction and Health in Women and Girls

<table>
<thead>
<tr>
<th>Bladder Function</th>
<th>Elements of Function</th>
<th>Lower Urinary Tract Symptom(s)</th>
<th>Bladder Health</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Subjective Experience(s)</td>
<td>Objective Measure(s)</td>
</tr>
<tr>
<td>Storage</td>
<td>Capacity</td>
<td>Examples will be given during workshop for each component</td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Day/Waking</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Night/Sleeping</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Continence</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Day/Waking</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Night/Sleeping</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sensation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Urge</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Comfort</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Emptying</td>
<td>Initiation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Stream Flow</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Speed</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Character</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Continuity</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Ease</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Efficacy</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Sensation</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Relief of urge</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Completeness</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>- Comfort</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Bioregulatory</td>
<td>Biosis Barrier</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Physical/Chemical</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Barrier</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>Cancer Barrier</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Timeline to Definitions of Bladder Health & Healthy Bladder Functions

- TCFM charged with defining bladder health
- Bladder Health Table drafted based on known functions
- LUTS definitions mapped to bladder health functions
- Final Definition Presented
- Consensus Gained

- TCFM Meetings
- In Person Meetings

Nov 2015 to Feb 2017
“The best way to reduce the cost of medical care is to reduce the illness.”

Arlen Specter
What is a prevention science approach?

Sonya Brady, PhD
Associate Professor
School of Public Health, Division of Epidemiology and Community Health
University of Minnesota
What is a prevention science approach?

• Underlying premise:
  – One must understand what leads to disease and how disease can be prevented in order to promote and preserve health.

• Systematic study of potential precursors to human dysfunction and health
  – *Risk factors* are those attributes, characteristics, or exposures of an individual that increase the likelihood of developing a disease.
  – *Protective factors* enhance health and lessen the likelihood that dysfunction will occur in response to risk factors.
  – Risk and protective factors at different levels of social ecology have also been referred to as *social determinants of health*

(Coie et al., 1993; Heller, 1996; Viner et al., 2012; WHO, 2014)
What is a prevention science approach?

• **What do prevention scientists do?**
  – Conduct etiologic studies to identify risk and protective factors
  – Develop and test prevention interventions aimed at modifying risk and protective factors
    • **Goal is to promote health and prevent major dysfunction before onset of a disease or disorder**

• **Prevention science applies a life course developmental perspective**
  – Dissemination of findings are expected to impact health promotion programs, practices, and policies, and in turn, the health of populations across the life course

(Coie et al., 1993; Heller, 1996; Society for Prevention Research, 2013)
Social Ecological Model
(McLeroy, Bibeau, Steckler, & Glanz, 1988)
Biopsychosocial Model
(Engel, 1977; Engel, 1980)

Biological

Social

Psychological

Health & Illness

Biospheres
Society-Nation
Culture-Subculture
Community
Family
Two-Person
Person
(Experience & Behavior)
Nervous System
Organs/Organ Systems
Tissues
Cells
Organelles
Molecules
Atoms
Subatomic Particles
Society-Behavior-Biology Nexus
(Glass & McAtee, 2006)
Working PLUS Conceptual Framework

Adapted from Thomas Glass and Matthew McAtee (Social Science & Medicine, 2006)

• Will include during workshop
Interactive Exercise

1. **Brainstorming**
   - What are risk factors for LUTS?
   - What protective factors should promote bladder health?
   - Write a single risk or protective factor on the colored notes at your table.

2. **Organizing factors by level of social ecology**
   - Place each of your colored post-its on one of the giant post-its in the room
   - Levels of social ecology
     - Individual – Biology/Body
     - Individual – Mind/Behavior
     - Interpersonal
     - Institutional
     - Societal/Community
Interactive Exercise - Debriefing

• What was the experience like for you?
  – What was challenging?
  – What insights did you gain?

• What questions do you have?
Generation of Risk and Protective Factors

- Nested levels of influence served as a prompt to consider factors outside of one’s expertise / “comfort zone”
- Consortium generated over 600 factors
- Over 400 factors remained after prioritization
- Prioritized factors clustered into 8 broad research themes
PLUS CONSORTIUM
Research Themes – will present during workshop
Synthesized Rankings of Prioritized Risk and Protective Factors

• Will include during workshop
Sample of Prioritized Risk and Protective Factors

• Will include during workshop
How do we implement a prevention approach?

Deepa Camenga, MD
Assistant Professor
Adolescent Medicine, Emergency Medicine, Research Division
Yale University
Today’s Presentation

• Why bladder health?
• Why should we care about bladder health and prevention?
• What is bladder health?
• What is a prevention science approach?
  – We got your input!
• How can we implement a prevention approach to study bladder health?
Our Path to Prevention
The GOAL

• To obtain the necessary information to plan future interventions to promote bladder health and prevent LUTS.
Our Path Map for Prevention
The Map

Create PLUS Measurement Toolbox

- Conduct PLUS FOUNDATIONAL STUDY (Cross-sectional & Longitudinal)
- Develop and Implement Prevention Intervention for Bladder Health Promotion
- Develop and Validate Measures of Risk and Protective Factors
- Develop and Validate Measure of Bladder Health
Our Guiding Principles

• Foster trans-disciplinary perspective

• Use terminology, definitions, conceptual frameworks, and research themes PLUS developed/identified

• Set priorities for risk and protective factors

• Focus on Measurement
  • The measures we know exist
  • The measures that need modification
  • The measures we know doesn’t exist, and need
The Bladder Health Roadmap

Create PLUS Measurement Toolbox

Develop and Validate Measures of Risk and Protective Factors

Conduct PLUS FOUNDATIONAL STUDY (Cross-sectional & Longitudinal)

Develop and Implement Prevention Intervention for Bladder Health Promotion

Develop and Validate Measure of Bladder Health
Bladder Health Measurement Roadmap

- Conceptualize Bladder Health
- Determine Components of Bladder Health

What components should we include?
Bladder Health Measurement Roadmap

- Conceptualize Bladder Health
- Determine Components of Bladder Health
- Determine How to Measure Components
- Select/Develop Measurement Approach
- Develop and Validate Measure of Bladder Health

What components should we include?
Bladder Health Measurement Roadmap

1. Conceptualize Bladder Health
2. Determine Components of Bladder Health
3. Determine How to Measure Components
4. Select/Develop Measurement Approach
5. Validate Measures
6. Administer Measurement Tool

Develop and Validate Measure of Bladder Health

What components should we include?
Bladder Health Measurement Roadmap

1. Conceptualize Bladder Health
2. Determine Components of Bladder Health
3. Determine How to Measure Components
4. Select/Develop Measurement Approach
5. Validate Measures
6. Administer Measurement Tool

What components should we include?
Conceptualize Bladder Health

Bladder Health Measurement Roadmap

- Develop and Validate Measure of Bladder Health
- Select/Develop Measurement Approach
- Determine Components of Bladder Health
- Determine How to Measure Components
- Validate Measures
- Administer Measurement Tool

Develop and Validate Measure of Bladder Health
Determine how to Measure Components

• Our Plan
  1. Evaluate quality of existing tools
  2. Identify gaps in existing tools
PLUS CONSORTIUM
Research Themes

• Will include during workshop
Gaps- some examples

- **Toileting environment – Access to toilets**
  - School (students and teachers)
  - Workplace via occupation
  - Public spaces

- **Musculoskeletal Function**
  - Low back pain
  - Prior lumbar/sacral surgery

- **Stress and Mental Health**
  - Anxiety
  - Children/adolescents
Bladder Health Measurement Roadmap

- Conceptualize Bladder Health
- Determine Components of Bladder Health
- Determine How to Measure Components
- Select/Develop Measurement Approach
- Validate Measures
- Administer Measurement Tool
- Develop and Validate Measure of Bladder Health
Conceptualize Bladder Health

Determine Components of Bladder Health

Determine How to Measure Components

Select/Develop Measurement Approach

Validate Measures

Administer Measurement Tool

Gaps in Knowledge

PLUS Activities

- Qualitative Studies
- Quantitative Studies
- Existing Database Analyses
- Innovative Methods

Conceptualize Bladder Health

Select/Develop Measurement Approach

Validate Measures

Administer Measurement Tool

Determine How to Measure Components

Gaps in Knowledge

PLUS Activities

- Qualitative Studies
- Quantitative Studies
- Existing Database Analyses
- Innovative Methods
PLUS Studies and Projects to inform gaps in bladder health measurement

- Focus group study
- Systematic and rapid literature reviews
- Secondary analyses of existing databases
- Community Engagement
- Innovative data collection methods (EMA)
• Will include during workshop
PLUS Studies and Projects to inform gaps in bladder health measurement

- Focus Group Study
- Systematic and rapid literature reviews
- Secondary analyses of existing databases
- Community Engagement
- Innovative data collection methods (EMA)
Ongoing Literature Reviews

- Bladder Function in School-Aged Girls and Women: A Systematic Review and Meta-Analysis

- Occupation and LUTS: A Systematic Review and Meta-Analysis
Secondary Data Analysis

• Insight into the concept of a “healthy bladder”: Secondary data analyses in the Boston Area Community Health (BACH) Survey
  – To describe LUT characteristics/LUTS in women with and without interference from urinary experiences.

• The Relation between Common Workforce Groups and LUTS: Cross-Sectional and Longitudinal Analyses in the BACH Survey
  – To describe LUTS (including UI and OAB) according to workforce groups in community-dwelling adult women.
Secondary Data Analysis

- Early-life predictors of child, adolescent and young adult LUTS in the Avon Longitudinal Study of Parents And Children cohort

- Perceptions and Contextual Experiences of Bladder Health: A Content Analysis of LURN Interviews with Women
  - to understand the subjective experience of healthy bladder from the lay perspective
PLUS Studies and Projects to inform gaps in bladder health measurement

- Focus Group Study
- Systematic and rapid literature reviews
- Secondary analyses of existing databases
- Community Engagement
- Innovative data collection methods (EMA)
Community Engagement (CE) Mission

- Establish Best Practices
- Provide guidance and guidelines
- Add a CE foundation for the development of a prevention research agenda for bladder health across the life course.
PLUS Community Engagement Committee
Community Conversation
6:30-8pm May 15, 2017
333 W. Wacker Drive, Suite 2600, Chicago, IL

Purpose: Community conversation with Individuals who represent PLUS stakeholders groups in Chicago area.

Who: Representatives from: a) community-based organizations, 2) local health department, 3) CTSI and other community-academic health partnerships.
C³ Discussion Questions

– How would you describe how bladder health is experienced/addressed by the women/girls in the communities you serve?

– What resources do you know about that address bladder health in your communities?

– What opportunities do you see in collaborating with the PLUS Research Consortium?
Examples of C³ Discussion

• Community Health Workers need to be involved in dissemination

• Get more community level data

• Disseminate Information Early
  – Community Grand Rounds – churches/other places.
Ongoing CE Activities

- Continue education on CE research methods
- Establish process to review research protocols to recommend CE research activities – i.e. recruitment strategies and dissemination
- Determine process for formation of a PLUS Consortium Community Advisory Group (CAG)
Innovative Bladder Health Measurement

• To develop a smartphone bladder application for discovery and dissemination of information
  – E.g., assess bladder health, risk/protective factors, EMA
  – Provide information to user: measurement, recommendations
Bladder Health Measurement Roadmap

1. Conceptualize Bladder Health
2. Determine Components of Bladder Health
3. Determine How to Measure Components
4. Select/Develop Measurement Approach
5. Validate Measures
6. Administer Measurement Tool
7. Future Directions

Concepts:
- Determination
- Selection/Development
- Administration
- Validation
- Measurement

Future Directions:
Future Activities

1. Evaluate quality of existing tools
2. Identify gaps in existing tools
3. Prioritize development of new measurement items
4. Determine appropriateness of survey items for full age spectrum
Planned Impact

• Development and testing of evidence-based prevention interventions
  – Broad dissemination to the public
  – Integration into health care systems
  – Shaping of health-promoting policies within schools, workplaces, public spaces, and public health agencies

• Promoting the health equity and overall well-being of girls and women in diverse communities
Summary: A Transdisciplinary Science Approach

• Promoting bladder health
  – Opportunity exists
  – Holistic approach

• Understanding bladder health
  – Key component to prevention
  – More evidence needed

• Defining bladder health
  – Not just the absence of disease/symptoms
  – Bladder function is complex and multifaceted

• Conceptualizing bladder health
  – Framework to study novel risk and protective factors

• Implementing bladder health interventions
  – Foundation-building approach
  – Simultaneous effort
• On behalf of the PLUS Consortium, we say THANK YOU