

Urology Interagency Coordinating Committee (UICC)

June 19, 2020

9:00 a.m. - 12:00 p.m.

Zoom Webinar

Meeting Minutes

Attendees:

K. Abbott (NIDDK)	D. Mazioomdoost (NICHD)
L. Banez (HRSA)	S. Mendley (NIDDK)
T. Bavendam (NIDDK)	D. Meyer (EPA)
L. Begg (ORWH)	C. Mullins (NIDDK)
A. Bierman (AHRQ)	J. Nagel (NCATS)
S. Brady (PLUS Network)	J. Norton (NIDDK)
P. Donohue (NIDDK)	T. Rankin (NIDDK)
E. Duggan (NIDDK)	J. Rymaruk (NIDDK)
B. Elwood (ORWH)	M. Salive (NIA)
M. Garzotto (VA)	V. Spruance (NIDDK)
S. Givens (NIDDK)	R. Star (NIDDK)
L. Halvorson (NICHD)	R. Thakar (Peer Review)
J. Huppert (HRSA)	M. Oldham (NIDDK)
K. Huss (NINR)	J. Weiss (HRSA)
C. Kerr (NIA)	M. Wilson (VHA)
Z. Kirkali (NIDDK)	

Welcome and Introductions

Dr. Star welcomed participants and discussed noncancerous genitourinary (NCGU) conditions as very costly conditions with impacts that go well beyond the individual's quality of life (QoL). The purpose of this meeting is to address these hidden burdens of NCGU conditions, across multiple levels biological, individual, and contextual levels.

Setting the Stage

Dr. Bavendam opened the meeting and welcomed participants. She noted research and clinical care for NCGU conditions is focused on the patient population that presents for care. However, there are a number of individuals who have conditions that go unreported, and these individuals experience reduced QoL. In addition, NCGU conditions have often unrecognized or "hidden" social, comorbid disease, economic, and environmental impacts. Dr. Bavendam described several NCGU conditions including urinary incontinence (UI), bladder infection, erectile dysfunction, overactive bladder (OAB), interstitial cystitis (IC), underactive bladder, nocturia, urinary stone disease, and prostate enlargement/inflammation, that represent clinical conditions in the NIDDK urology program. However, there is no cohesive theme for these GU conditions as they are treated by different medical specialties. Dr. Bavendam noted that there is also no routine screening or measurement tool and patients may feel stigma and underreport their impact on QoL.

Dr. Bavendam noted that screening is available for conditions such as UI in older persons, bladder infection during pregnancy, and prostate enlargement due to cancer. However, there are many NCGU conditions and populations where routine screening does not occur, and therefore identifying such

conditions relies largely on individual self-report, which is inhibited due to stigma surrounding these conditions.

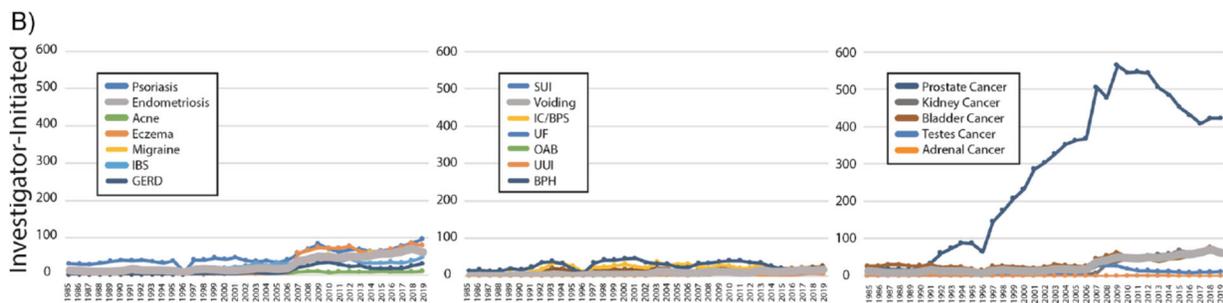
Dr. Bavendam detailed a list of conditions with the following characteristics, which may impede research and clinical care:

- Few are generally reflected in billing databases: only bladder infection, IC, and urinary stone disease (USD). These patients present with pain and discomfort.
- Few have surgical solutions: these include UI, OAB, USD, and prostate enlargement
- Most rely on self-report measures: UI, OAB, underactive bladder, IC, Erectile dysfunction, nocturia, and prostate enlargement/inflammation
- Most are perceived as quality of life conditions: UI, OAB, underactive bladder, nocturia, prostate enlargement/inflammation
- Most are associated with stigma: UI, bladder infection, erectile dysfunction, OAB, underactive bladder, prostate enlargement.

Dr. Bavendam noted that NCGU conditions impact federally recognized “high priority” diseases such as depression, cardiovascular disease, diabetes, obesity, and conditions related to decreased mobility as a result of falls and fractures. Yet, they are not themselves recognized as high priority or even important medical conditions, and federal research funding reflects this.

In October 2019, NIDDK held a meeting on the hidden burden of NCGU conditions and invited participation from participants with broad expertise in different GU areas, public health, economics, environment, nursing, social work, geriatrics, among others. Dr. Bavendam noted that the meeting led to the formation of working groups who are currently developing three manuscripts to address gaps in NCGU condition research. These manuscripts will be shared with the UICC community when available, likely in early 2021.

In closing, Dr. Bavendam displayed several graphs reflecting results from the following advance: Colby P Souders, Eric M Lo, A Lenore Ackerman. Underrepresentation of Functional Conditions of the Lower Urinary Tract in Adults in US Federal Research Funding. *Neurourol Urodyn.* 2020 Jun 7.



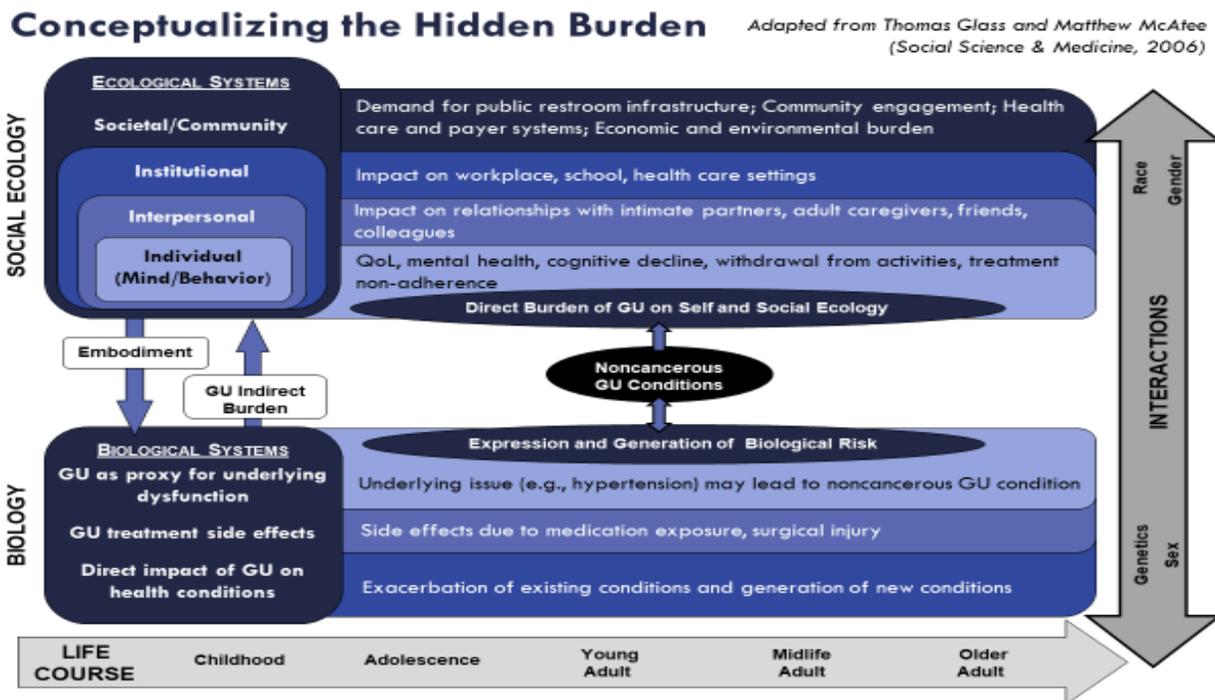
Illustrating the Benign GU Conceptual Model Framework

Dr. Bavendam introduced Dr. Sonya Brady and added that she is an investigator working in the Scientific and Data Coordinating Center within the Prevention of Lower Urinary Tract Symptoms (PLUS) Research Consortium. Dr. Brady began her presentation on the need to develop a conceptual framework to understand the burden of NCGU conditions and commented that this need was identified during the October 2019 NIDDK meeting on this topic. Dr. Brady noted that she received her training in clinical and health psychology, and she identifies as a prevention, behavioral, and social scientist with a focus on primary and secondary prevention.

Dr. Brady displayed the Social and Ecological Model and described how interpersonal, institutional, community, and society/public policy factors influence individual health and added that GU research has broadened to focus on how individuals impact social ecology, including social relationships and public policy. Dr. Brady also commented on the need to fully explore data for both upstream (i.e., risk factors) and downstream (i.e., consequences) factors related to NCGU conditions, but acknowledged the focus of this meeting is on **downstream** impacts such as obesity & related diseases, reduced physical activity, poor diuretic adherence, falls, and fractures.

Dr. Brady noted that the use of the term “benign” to describe NCGU conditions (while clinically intended to mean non-cancerous), implies a need for “less concern,” suggesting the conditions are not harmful. However, in addition to the substantial QoL burden, individuals may also experience impacts such as an exacerbation of existing biological risks, generation of new biological risks, and/or an impact on the individual’s interpersonal, institutional, community, and societal relationships.

Dr. Brady directed participants to the full framework (below) that was adapted from a 2006 paper by Glass and McAtee (Reference: <https://pubmed.ncbi.nlm.nih.gov/16198467/>) focusing on a life course approach using ecological and biological systems that impact individual GU conditions.



Dr. Brady discussed how the NCGU conditions can generate risk to the individual through the individual’s biological systems. An initial conceptualization of these impacts included the biological multi-organ systems, how the body functions at the cellular and molecular level, and the individual’s genomic substrate. Individuals diagnosed with NCGU can experience co-morbidities, biologic dysfunction, tissue injury/inflammation, and hormonal changes. Dr. Brady detailed a list of health conditions that may lead to, be exacerbated by, or be caused by NCGU conditions:

- Obesity
- Diabetes
- Cardiovascular function

- Mental health
- Geriatric health

Dr. Brady noted that the observation of how these other conditions impact the individual’s noncancerous GU condition led to a revised conceptualization that is now focusing on the mechanistic links between noncancerous GU conditions and other clinically relevant conditions. The revised framework looks at GU within three potential biological pathways: GU as proxy for underlying dysfunction, GU treatment side effects, and direct impact of GU on health conditions. Additionally, the revised framework uses the social ecology model that draws attention to the importance of NCGU conditions by assessing levels of impact at different levels of social ecology.

Although it is still a work in progress, the revised framework focuses on embodiment which includes the individual’s access to toilets and GU indirect burden to the extent that GU exacerbates conditions such as obesity. Dr. Brady also discussed how biological and socially constructed factors such as genetics, sex, gender, and race may be sources of vulnerability and protection.

Dr. Brady also called out that these impacts may vary over the life course. For example, urgency will have greater impact on falls and fractures in the elderly. This concept is reflected in the framework by the “Life Course” bar running across the bottom of the figure. In addition, impacts may vary based on underlying genetics and biological sex, as well as across social constructs of race and gender. For example, women often experience longer bathroom wait times and trans-gender individuals and lower income, ethnic minority individuals have reported greater difficulty accessing public restrooms—all of which could exacerbate impacts of urinary symptoms on quality of life.

Meeting participants offered the following feedback:

- Mark Garzotto noted the thought across disciplines is helpful to describe the framework of conditions and noted that this highlights need for collective thinking versus individualized thinking. He also commented that this framework reflects what he sees in clinical practice and added that there is not enough emphasis in clinics on screening for NCGU conditions. This leads to social impacts that affect community and family members through behaviors such as patient disengagement. He described an example of a patient who presented with difficulties urinating. Although the patient requested that his urinary symptoms be addressed, the medical system was only interested in treating the patient’s cancer.
- Donna Mazioomdoost commented that there is often a delay from the time of symptom onset to when women come in to get screened/treated for urinary symptoms, and she added that most women have had symptoms for years and are embarrassed to discuss symptoms. She commented that she felt this was an educational barrier and emphasized the need to educate patients that these are conditions that are treatable.
- Bill Elwood commented how this model reflects biomedicine, life course, and patient experience over the life course in society.

Federal Agency Comments—Identifying gaps and opportunities in the federal response to address NCGU conditions across levels of the framework:

Several agencies reported activities they are engaged in, as well as “in mission” areas across levels of the framework.

- Lisa Begg (Office of Research on Women's Health [ORWH])—Noted ORWH partners with NIDDK on efforts such as the Prevention of Lower Urinary Tract Symptoms (PLUS) Consortium and the Multidisciplinary Approach to the Study of Pelvic Pain (MAPP) Network. ORWH seeks

to address conditions that disproportionately affect women with a focus on biological effects and the female life course, and other research where it is important to study sex differences.

- Jill Huppert (Agency for Healthcare Research and Quality [AHRQ]): Noted AHRQ's mission is to produce evidence to make health care safer and ensure that evidence is understood and used. AHRQ implements findings from patient centered outcomes that are meaningful to patients and collaborate with the Patient-Centered Outcomes Research Institute (PCORI). AHRQ NGCU research focuses on the diagnosis and nonsurgical treatment for women in UI in the primary care setting.
- Dave Meyer (Environmental Protection Agency [EPA]): Noted his agency serves in a regulatory capacity and funds research related to the link between chemicals and NCGU conditions and evaluates risk assessment (toxic substance control act) from establishing credible links. He also noted that EPA receives requests from the state government to investigate water quality and from NIH to provide information about the environmental impact of health conditions.
- Joan Weiss (Health Resources and Services Administration [HRSA]): Noted HRSA focuses on increasing access to healthcare for underserved and underinsured populations. HRSA's Geriatrics Workforce Enhancement Program grant recipients partner with academia, primary care sites/delivery systems, and community-based organization to educate the workforce to provide value-based care that maximizes patient and family engagement to improve health outcomes for older adults by integrating geriatrics and primary care. She noted that HRSA provides training within the social ecology component, but is less involved in biological components.
- Jane Chang (Patient-Centered Outcomes Research Institute [PCORI]): Noted PCORI's mission is to help individuals make informed health decisions. She stated that PCORI establishes programs that address NCGU conditions within social ecology networks and focus on QoL, outcomes for caregivers, and individual burden and behavior. PCORI currently has nine studies related to UI disorders.
- Donna Mazloomdoost (National Institute of Child Health and Human Development [NICHD]): Noted that NICHD sponsors the Pelvic Floor Disorders Network as well as some studies on UI. She noted that the NICHD Strategic Plan focuses on health disparities (racial/ethnic/gender), disease prevention (for maternal health, pediatric, pelvic floor conditions), promoting reproductive and gynecological health to manage fertility to support lifelong health such as pelvic floor disorders, and understanding basic biology and expanding basic and translational research efforts.
- Karen Huss (National Institute of Nursing Research [NINR]): Noted the NINR's mission is to promote and improve the health of individuals, families, and communities. NINR programmatic areas of science include self-management, symptom science and genetics, wellness, and end of life and palliative care. Within the GU framework, NINR focuses on upstream factors such as the impact of relationship with partners and families and downstream factors such as comorbid conditions and preventing dysfunction. NINR also partners with OBSSR to address gaps in research related to social isolation.
- Joan Nagel (National Center for Advancing Translational Sciences [NCATS]): Noted that the NCATS mission scope is disease neutral but looks at commonalities across diseases and how to best translate findings into implementation. She noted that NCATS sponsors competitive FOAs for kidney disease within the NIDDK mission as well as FOAs for biostatistics, multi institutional studies, and PIs who want to work across institutions. She highlighted two NCATS FOAs for the group and noted these are opportunities to leverage CTSA resources and bring in outside investigators:
 - Limited Competition: National Institute of Dental and Craniofacial Research (NIDCR) Supplements to NCATS CTSA Programs for Scholars Pursuing Dental, Oral and Craniofacial Clinical and Translational Research Career Development (Admin Supp): <https://grants.nih.gov/grants/guide/rfa-files/RFA-DE-17-008.html>.

- National Center for Complementary and Integrative Health (NCCIH) Supplements to NCATS CTSA Programs for Scholars Pursuing Complementary Health Research Career Development (Admin Supp Clinical Trial Optional):
<https://grants.nih.gov/grants/guide/pa-files/pa-18-920.html>.
- Mark Garzotto (Veterans Health Administration [VHA]): Noted the VHA’s mission focuses on veterans and added that this population experiences an increase in GU conditions with age. Other high priority areas for research within the VHA include urologic conditions that develop with age, recruitment and retention of urologists, and investments in women’s health and health care services provided by women. He noted that the VHA has a large collection of data at and a system in place that collects data that can be mined to check upstream or downstream effects and collects data longitudinally.
- Marcel Salive (National Institute on Aging [NIA]): Noted the NIA’s mission focuses on the aging process and improving the health of adults as they age for conditions such as UI, geriatric syndromes, and multiple chronic conditions. Primarily, NIA funds non-surgical UI treatment trials. NIA also sponsors a career development program (Grants for Early Medical/Surgical Specialists' Transition to Aging Research (GEMSSTAR) to draw specialists into field. He also commented that the framework should include drug-disease interaction and disease to disease interaction. He highlighted a recent FOA: Advancing Research to Develop Improved Measures and Methods for Understanding Multimorbidity (R01 Clinical Trial Optional) at <https://grants.nih.gov/grants/guide/pa-files/PAR-20-179.html> and added that this FOA focuses on R01 grants and NIDDK can sign on.
- Jenna Norton (National Institute of Diabetes and Digestive and Kidney Diseases [NIDDK]): Noted NIDDK traditionally focused on the upstream management of GU conditions. However, there is a new shift that focuses on biology, QoL, and individual mind and behavior. NIDDK also supports research related to urologic conditions on obesity, diabetes, and other conditions.
- Bill Elwood (ORWH): Noted a recent FOA titled “Research on biopsychosocial factors of social connectedness and isolation on health, wellbeing, illness, and recovery (R01 Basic Experimental Studies with Humans Required)” at <https://grants.nih.gov/grants/guide/pa-files/PAR-19-384.html>.
- Joan Nagel (National Center for Advancing Translational Sciences [NCATS]): Noted NCATS can be included in the framework for institutional, workforce, and education across the entire spectrum.
- Attendees also suggested NIDDK reach out to the Agency for Community Living (ACL), who was not represented at the meeting, but may have a strong interest in the subject.

Interactive Working Session: Mapping How Federal Agencies Could and Should Address GU and Other Chronic Conditions (from non-GU centric perspectives, e.g., incorporating in MCC)

Framework Level	Sublevel	Agency & Mission
Societal/Community	Environmental	<ul style="list-style-type: none"> ● Environmental Protection Agency (EPA) – regulatory (risk assessments [prevention]); state-level up (water use, waste management, end-of-life material streams [Burden]); ● Agency for Healthcare Research and Quality (AHRQ) – Medical Expenditure Panel Survey (MEPS); Healthcare Cost and Utilization Project (HCUP) (emergency care + ambulatory)
	Economic	<ul style="list-style-type: none"> ● Agency for Healthcare Research and Quality (AHRQ) – Medical Expenditure Panel Survey

		(MEPS); Healthcare Cost and Utilization Project (HCUP)
	Restroom infrastructure	
	Community engagement	<ul style="list-style-type: none"> • Patient-Centered Outcomes Research Institute (PCORI) – engagement award funding mechanism – opportunity for future. • National Center for Advancing Translational Sciences (NCATS) – community engagement studios – future opportunity (recruitment) • Administration for Community Living (ACL) – (Arlene to follow up)
	Healthcare system	<ul style="list-style-type: none"> • Agency for Healthcare Research and Quality (AHRQ) – Funding Opportunity Announcement on urinary incontinence practices and health systems implementing best evidence
	Payer systems	<ul style="list-style-type: none"> • Centers for Medicare & Medicaid Services (CMS) – (Arlene to follow up)
Institutional	Workplace	<ul style="list-style-type: none"> • National Institute for Occupational Safety and Health (NIOSH) • Department of Labor - management of public restrooms as people return post-covid
	School	<ul style="list-style-type: none"> • Department of Education – suggested contact: Liz Albro
	Healthcare settings	<ul style="list-style-type: none"> • Agency for Healthcare Research and Quality (AHRQ) – implementation/dissemination • Health Resources and Services Administration (HRSA) – workforce development Patient-Centered Outcomes Research Institute (PCORI) – (implementation projects)? • Veteran’s Health Administration (VHA) • National Institute on Aging (NIA) – career development • National Center for Advancing Translational Sciences (NCATS) – integrating investigators
	Insurance providers	<ul style="list-style-type: none"> • Patient-Centered Outcomes Research Institute (PCORI) – payers forum, potential for future discussion
Interpersonal	Intimate relationships	<ul style="list-style-type: none"> • National Institute of Mental Health (NIMH) • Office of Research on Women's Health (ORWH) – partner violence (upstream) • Veteran’s Health Administration (VHA) – Lifestyle Questionnaire on companionship (Q34) • Agency for Healthcare Research and Quality (AHRQ)
	Adult caregivers	<ul style="list-style-type: none"> • Patient-Centered Outcomes Research Institute (PCORI) • National Institute of Nursing Research (NINR)

		<ul style="list-style-type: none"> • National Institute on Aging (NIA) – independence in aging • Agency for Healthcare Research and Quality (AHRQ) • National Cancer Institute (NCI) – translation/adaptation from cancer context • Health Resources and Services Administration (HRSA)
	Friends	<ul style="list-style-type: none"> • National Institute of Nursing Research (NINR)
	Colleagues	
Individual - Mind	Quality of life	<ul style="list-style-type: none"> • Agency for Healthcare Research and Quality (AHRQ) – evidence reviews (e.g., systematic review on non-surgical interventions); AHRQ data: Medical Expenditure Panel Survey (MEPS) and the Healthcare Cost and Utilization Project (HCUP) – surgical procedures; Potential for a urology survey question; Suggested contact for MEPS: Dr. Arlene Bierman. • Centers for Disease Control and Prevention (CDC) — Behavioral Risk Factor Surveillance System (BRFSS) (no urologic measures); National Health and Nutrition Examination Survey (urinary incontinence) – cross sectional. Suggested contact: Dr. Lisa McGuire is the Lead for the CDC’s Alzheimer's Disease and Healthy Aging Program. • Health Resources and Services Administration (HRSA) – patient education • Patient-Centered Outcomes Research Institute (PCORI) – comparative effectiveness research consortium, systematic review on non-surgical treatments • National Institute of Nursing Research (NINR) • Veteran’s Health Administration (VHA) - addressing normalization
	Mental health	<ul style="list-style-type: none"> • Agency for Healthcare Research and Quality (AHRQ) • Patient-Centered Outcomes Research Institute (PCORI) • National Institute of Nursing Research (NINR) • Veteran’s Health Administration (VHA) - addressing normalization
	Cognitive health	<ul style="list-style-type: none"> • Agency for Healthcare Research and Quality (AHRQ) • Patient-Centered Outcomes Research Institute (PCORI) • National Institute of Nursing Research (NINR)
Individual-Behavior	Withdrawal from activities	<ul style="list-style-type: none"> • National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)

		<ul style="list-style-type: none"> • Patient-Centered Outcomes Research Institute (PCORI) • National Institute of Nursing Research (NINR) • National Institute on Aging (NIA) – National Health and Aging Trends Study (NHATS) (nursing home); Health & Retirement Survey • Health Resources and Services Administration (HRSA) – workforce development • Agency for Healthcare Research and Quality (AHRQ) – especially in nursing home entry • National Cancer Institute (NCI) – translation/adaptation from cancer context
	Treatment adherence	<ul style="list-style-type: none"> • National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) - obesity, diabetes, kidney outcomes • National Institute of Nursing Research (NINR) • Veteran’s Health Administration (VHA) - data, Million Veterans program • Health Resources and Services Administration (HRSA) – workforce development • Agency for Healthcare Research and Quality (AHRQ) • National Cancer Institute (NCI) – translation/adaptation from cancer context
	Physical activity	<ul style="list-style-type: none"> • National Institute of Nursing Research (NINR) • Veteran’s Health Administration (VHA) – data, Million Veterans program • Health Resources and Services Administration (HRSA) – workforce development • Agency for Healthcare Research and Quality (AHRQ)
	Diet	<ul style="list-style-type: none"> • National Institute of Nursing Research (NINR) • Veteran’s Health Administration (VHA) – data, Million Veterans program • Health Resources and Services Administration (HRSA) – workforce development • Agency for Healthcare Research and Quality (AHRQ)
	Independence	<ul style="list-style-type: none"> • National Institute on Aging (NIA) • Veteran’s Health Administration (VHA) – lifestyle survey has Q on independence (Q29)
Individual - Biology	Comorbidities	<ul style="list-style-type: none"> • National Institute of Child Health and Human Development (NICHD) – health disparities / disease prevention. • National Institute of Child Health and Human Development (NICHD) – rehab center (contact: Theresa Cruz) – potential for long-term conversations.

		<ul style="list-style-type: none"> • Office of Research on Women's Health (ORWH) • National Institute of Nursing Research (NINR) • Veteran's Health Administration (VHA) – data, Million Veterans program • National Institute on Aging (NIA) – geriatric syndromes, UI (GU as discordant conditions)
	Function/ dysfunction	<ul style="list-style-type: none"> • National Institute of Child Health and Human Development (NICHD) • National Institute of Nursing Research (NINR) • National Institute on Aging (NIA) • Veteran's Health Administration (VHA) - data, Million Veterans program - lifestyle
	Microbiome	<ul style="list-style-type: none"> • National Institute of Child Health and Human Development (NICHD) - prevention/treatment • National Institute of Nursing Research (NINR) • National Institute on Aging (NIA)
	Tissue injury/ inflammation	<ul style="list-style-type: none"> • National Institute on Aging (NIA) – “inflammaging” • National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) – urinary tract infections, prostatic disease (upstream) • National Institute of Child Health and Human Development (NICHD) – stem cells – individualized response
	Hormonal environment	<ul style="list-style-type: none"> • National Institute of Child Health and Human Development (NICHD) • National Institute on Aging (NIA) • National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) – prostatic (upstream) • National Institute of Child Health and Human Development (NICHD)
	Epigenetics (Genetics)	<ul style="list-style-type: none"> • Veteran's Health Administration (VHA) - data, Million Veterans program • National Institute on Aging (NIA) • National Institute of Child Health and Human Development (NICHD) stem cells, individualized response – upstream

Conclusion

Ms. Norton thanked attendees for their participation and noted that she will send out a doodle poll to identify a time for a 1-hour WebEx to discuss the Potential Impacts of COVID 19 on NCGU Research and Care that was originally planned for today's meeting. Dr. Bavendam also thanked attendees for their participation and added that she will circulate the meeting minutes to ensure all Federal agency contributions are correct. She also requested information on Federal agencies that were not represented at this meeting. Dr. Bavendam noted that this will be a standing agenda item for the urology interagency coordinating committee meetings.