Empowering Women and Providers for Improved Care of Urinary Incontinence (UI) [EMPOWER Study]

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Objectives:
Urinary incontinence (UI) affects over 50% of women. Its prevalence increases with age rendering up to 75% of women over age 65 with some degree of UI. Approximately 50% of women with UI experience daily symptoms, and an additional 30% have symptoms at least weekly. UI adversely affects the physical, psychological, and social well-being of millions.

Non-surgical treatment, including behavioral interventions or pharmacotherapy, is usually effective, but recognition in health care settings and evidence-based care for this condition remains suboptimal. In fact, only half of the estimated 40% of Medicare beneficiaries with UI who have spoken to a physician receive treatment. Treatment in primary care, with system support and availability of specialty care, has great potential. Unfortunately, a variety of patient, provider, and system-level barriers result in under-diagnosis and suboptimal management.

Using established patient-centered outcomes research evidence for nonsurgical treatments for urinary incontinence in women, we propose an integrated, multilevel (patient, provider, and system) approach that addresses key barriers to diagnosing and managing UI in the primary care setting. **Implementation strategies include large-scale screening, empowering patients to discuss UI with their providers, provider education and training, practice facilitation through nurse navigation, and a novel mobile platform "chatbot" named UI CeCe to engage patients in self-management of their UI.** A system-based strategy for streamlined specialist referral and treatment will also be implemented. The implementation plan is fully aligned with Agency for Healthcare Research and Quality's (AHRQ's) EvidenceNow framework as it encompasses practice facilitation, expert consultation, shared learning collaborative, data feedback and benchmarking, and health-information technology support.

To ensure the success of this project and its sustainability into primary care, we have created an inter-professional quality improvement team consisting of urinary incontinence specialists; primary care physicians; and implementation, dissemination, and evaluation scientists with complementary skills. Moreover, the implementation setting is an integrated healthcare system that has outstanding relationships with more than 100 community-embedded primary care practices. Our overall goal is to implement the multi-faceted Empowering for Improving-UI program and to measure its impact on rates of recognition and management, patient satisfaction, provider knowledge and confidence in managing UI, and impact on practice staff and providers' workflow and satisfaction.

Aims:
Specifically, we aim to:

1. **Implement the "Empowerment for Improving UI" program across a large network of primary care practices.** The program will involve systematic screening and identification of UI, patient empowerment, provider training and empowerment, nurse navigation, and simple and practical evidence-based technology. We hypothesize that the program will be implemented with fidelity to all planned elements and with local tailoring in all recruited practices.

2. **Create an evidence-based patient-centered care pathway** that minimizes burden on primary care and based on practices while optimizing health-information systems, including an embedded electronic screening tool, that lead to sustainable improvement in quality of care.
3. **Assess the impact of the Empowering for Improving UI intervention on:**
   a. **outcomes important to patients.** Compared with usual care, we hypothesize that Empowering for Improving UI will be associated with higher levels of UI diagnosis, non-operative treatment, improvement in symptoms, satisfaction with care, and streamlined referral to UI specialists by primary care providers.
   b. **provider knowledge and confidence, practice workflow and satisfaction among practice providers and staff.** We hypothesize that the intervention will minimally disrupt practice workflow, place a minimal burden upon practices overall, and be associated with a high level of satisfaction with the program. Providers will be more confident and knowledgeable about their management of UI, that practice personnel will be better able to systematically identify patients with IU and make appropriate referrals.

Through a systemic intervention that is multilevel, patient-oriented and supportive of primary care practice, and a rigorous mixed methods analysis, the proposed research has great potential to improve practice and patient outcomes and to generate transportable new knowledge to improve care for women with urinary incontinence.

AHRQ Grant Supplement: UI in African American Women

Specific Aim: Characterize the experience of illness, diagnosis and treatment among African American women suffering from urinary incontinence.

We will obtain and examine the qualitative reports of 30 African American women who reported symptoms of UI and enrolled in the EMPOWER clinical trial. We will use a semi-structured interview guide that will utilize a thematic analysis to investigate the experiences of African American women with symptoms of urinary incontinence to include the recognition of the problem, to communication of concern, and barriers to treatment. The subjective reports from African American women with urinary incontinence will give insight as to whether health disparities are accurately reflected in the quantitative data. The subjective reports may also lend a difference in perspective on the diagnosis and treatment process from a lens that is focused around their individual needs.

Quality Improvement and Clinical Trial occurring in parallel

The activities under this AHRQ grant consist of a quality improvement (QI) initiative and an interventional clinical trial running in parallel.

- **The portions of the project that are QI are under UH STUDY 20211635 Non Human Subject Research (NHR) submission.** The quality improvement initiatives will involve 1) systematic screening and identification of UI, 2) patient educational material, and 3) provider education through a seminar and a series of CME-credited interactive conferences called ECHO sessions.
- **The portions of the project that are human subjects research are under UH STUDY 20211420.** The clinical trial involves consenting patients to one of three cohorts, collection of UI-related data from the medical record, questionnaires, nurse navigators, and the mobile chatbot called UI CeCe.

Primary Care Institute:

Sixteen (16)-County Catchment Region: Population Demographics and Health Status, Health Care Environment and State of Primary Care

Population Demographics and Health Status: Although the symptoms of urinary incontinence (UI) significantly impact the quality of life, global prevalence estimates range dramatically. For example, the prevalence of UI has been estimated to range from 9.3-69% among women in the United States, thus reflecting the heterogeneity of the study population and the various definitions of UI.[1-4] These prevalence estimates have been primarily based on cross-sectional studies, including the population-based National Health and Nutrition Examination Survey (NHANES); a recent analysis of 25,553 NHANES participants spanning from 2005-2016 reported approximately 20% of individuals experienced any UI, 4.2% reported weekly, and nearly 2% reported dail.[4] While the impact of UI is substantial, unfortunately the number of modifiable risk factors is small. Currently, obesity (body mass index, BMI, > 30) has been identified as the strongest modifiable risk factor. The impact of obesity on UI seems to be increasing as suggested by an NHANES study contrasting BMI effects from 2001-2002 versus 2007-2008.[5] A recent NHANES study assessing the impact of socioeconomic status on UI reported a significant association with a poverty ratio, however, interactions with BMI or education level were not statistically significant.[4] This relationship is likely confounded, particularly due to women with less than a high school education are less likely to report UI than women with at least a high school education.[6] Lastly, the effects of smoking on UI appear to be equivocal, where some studies reported strong positive associations and others have reported no effect.

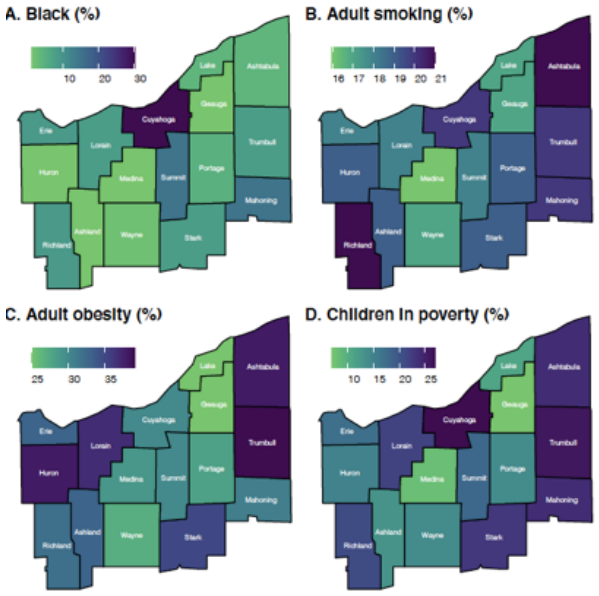


Figure 2. Prevalence e of urinary incontinence risk factors by counties across northeast Ohio: non-Hispanic black (**A**); adult smoking (**B**); adult obesity (**C**); and children in poverty (**D**). Source of data: https://www.countyhealthrankings.org/

As the discovery of modifiable risk factors for UI continues, several non-modifiable and clinical risk factors are well-established. Diabetic women have a significant increased risk of UI compared to women without diabetes. The risk impact seems to vary little by diabetic control, except for a reduction of BMI. Non-modifiable risk factors include parity, age, and self-reported race. Increased age and parity raises the likelihood of UI, where prevalence rates by race vary. Non-Hispanic white women had the greatest prevalence (41%) compared to non-Hispanic black (20%) and Mexican-American women (36%).[4] These prevalence rate differences, however, may be associated with the comfort level of patients discussing with their primary physician. Heterogenous study populations for modifiable and non-modifiable risk factors of UI will provide a generalizable setting to evaluate the implementation impact of novel non-surgical interventions.

Based on internally available primary care practice data from University Hospitals System, Primary Care Institute (PCI) that includes over 100 practices (N~109) in the 16 county catchment, we estimate that in 2019 there were over ***474 total primary care practices operated by multiple health care systems in the 16-county region***, given that the PCI's total market share is 23%.

Specialty Health Care Services Referrals and Community Support: All University Hospitals Health System (UHHS), Primary Care Institute practices (N=109), providers, and patients have

access to a wide variety of community and specialty care referral health services. Specialty referral health care services including pelvic floor rehabilitation and physical therapy, urology, female sexual health, urogynecology, and behavioral health & social work are key practice-, provider-, and patient-level supports that are important in the multi-level management and treatment of urinary incontinence in women, using evidence based implementation approaches/strategies that align system-wide resources and primary care practice. These referral services are particularly important since they reduce the potential burden on primary care practices and providers through referral linkages between primary care and needed specialty care supports and services.

The Center for Female Pelvic Medicine & Surgery (FPMRS; i.e., urogynecology), housed within the UHCMC Urology Institute (as described below), directed by Dr. Adonis Hijaz, one of the study PIs, has a thriving, and ever-growing clinical practice with consistently increasing outpatient clinical volume, specializes in the advanced evaluation (urodynamic testing), surgical and non-surgical management of urinary incontinence and other disorders such as pelvic organ prolapse. Of all surgeries, 95% are performed on an outpatient basis.

Urology Institute of University Hospitals Cleveland Medical Center (UHCMC): Key to the success of the Urology Institute is the strategic integration of the departmental research efforts with other programs relevant to urologic health. Through seven centers of excellence, UH Urology Institute is strongly integrating services around patient needs and diagnosis to provide individuals with a comprehensive and personalized approach to meeting their urological health care needs. The centers are: Female Pelvic Medicine & Surgery, Chronic Pelvic Pain, Robotic & Minimally Invasive Surgery, Urologic Oncology, Pediatric Urology, Female Sexual Health, Men's Health and Stones. Every center contains clinics for specific patient problems, such as bladder and pelvic pain, to facilitate patient access. In addition, centers for Research and Innovation, and Quality and Outcomes have been created to promote the needed infrastructure for integration of new knowledge regarding patient care. The centers provide a vehicle for greater physician collaboration across multiple specialties, such as oncology, neurology, radiology, gastroenterology and gynecology—aligning our efforts to provide patients with state-of-the-art urology services, from the most basic to the most complex. Throughout the centers, teams of highly skilled physicians from multiple specialties and departments meet weekly to discuss specific cases, pose scientific queries and share information on best practices and ongoing or potential research initiatives --powerfully generating new ideas and potentially more advanced treatment options, in addition to promoting a greater understanding of urologic conditions, including female urinary incontinence

UH Primary Care Institute (PCI): Characteristics of Practices to be Recruited, Service Population Characteristics, Reflection of Diversity and Characteristics of Women most affected by urinary incontinence (UI) in the 16-county PCI geographic catchment

PCI Practice & Provider Characteristics: The UH Primary Care Institute (PCI) is an integrated network of 109 outpatient primary care practices that are owned and operated by the University Hospitals Health System (UHHS), UH Medical Practices; (UHMP), in a **16-county geographic service area subdivided into six (6) patient care regions** based on practice site location. In 2019, the largest proportion and number of PCI practices, in descending order, were located in the northwest (24%; N=25), southeast (20%; N=21), northeast (17%; N=18), south (13%; N=14), southwest (13%) and central (13%; N=13) regions, respectively, with nearly three-quarters (73%) of all practices located in urban settings, whereas 15% were in suburban and 12% in rural areas.

All PCI primary care health providers (N=395) are exclusively UH employed physicians (MD/DO; N= 318) or advanced practice providers (APPs; N= 77), and not affiliated with other health care systems or practices. Given the vast UHHS network of integrated specialty and other health care services (e.g., pelvic floor physical therapy, urogynecology, female sexual health, urology, etc), all PCI primary care provider referrals are within the UHHS network. All PCI practices and UH specialty services share an integrated UHHS-wide electronic medical record (EMR), that ensures high quality medical documentation, continuity of care, and access to patient care data. This enables high quality patient care, efficient provider communication, and high reliability medicine, which is all essential for the success of large scale quality improvement efforts.

In 2019, a total of 395 primary care providers, of whom 81% are board certified family medicine or internal medicine physicians and 19% APPs, had over 1,039,940 new and established patient office visits, of which 94% were established patient office visits, an average visit volume of 3,178 visits per provider. The number of PCI practices and providers has grown in 2020-2021 due to the recent UHHS acquisition of several large health care systems and their outpatient primary care practices.

PCI Primary Care Service Population Characteristics & Inclusion of Priority Populations:
The target *patient service population* for this study is women aged 18 years and older (N= 146,054; 59%) who receive outpatient primary care services from the PCI's network of 109 primary care practices. (see Figure 1) .The demographic and clinical characteristics, including estimates of the prevalence of urinary incontinence (UI) and UI-associated risk factors of this service population are presented in **Table 1.**

Although the racial/ethnic distribution and diversity of the female PCI service population generally reflects that of the catchment area (Black/African American: 14% vs 15%; White: 81% vs 76%), compared to the catchment region, the PCI female population has a larger proportion of elderly women ≥ 65 years; 41% vs 24%), and a **higher burden of UI risk factors**, notably for obesity (54% vs 31%) and diabetes (16% vs 12%), thus reflecting the characteristics of women at the highest risk for UI (i.e., elders, obese, diabetic).[1] All women receiving care from the PCI were insured through commercial or public insurance (Medicare or Medicaid), of whom over half (59%) were insured through commercial insurance/payors, while 37% and 4% were insured through Medicare and Medicaid, respectively. In the 16-county catchment, 92% of adult women were insured through public (Medicare, Medicare) or commercial payers.

Table 1: Demographic and Clinical Characteristics of PCI service population (2019) and adult women in 16-county PCI catchment area

Characteristics	PCI: Number of women (N) and Percent (%)	16-county region: Number of adult women and Percent (%)
Total	146,054 (100%)	2,097,024 (100%)
Age (years)		
18-64	86,126 (59%)	1,261,591 (76%)
> 65	59,928 (41%)	393,867 (24%)
Race & Ethnicity		
African American	20,905 (14%)	245,624 (15%)
White	118,935 (81%)	1,263,460 (76%)
Asian	1,291 (0.9%)	36,173 (2%)
Other	5,984 (4%)	
Hispanic/Latina	2,827 (2%)	74,719 (5%)

Data Source: PCI, UH Health System 2019 and publicly available for the 16 counties[CB1] . Urinary incontinence defined by ICD-10 diagnosis codes: R32, N39.46, N39.498, N39.45, N32.81, R39.81, N39.3, N31.9, N39.41, N39.43, N39.44, N39.490, N39.491. Diabetes defined by ICD-10 diagnosis codes: E 10-E11. Heart disease defined by ICD-10 diagnosis codes: I09.9, I11.0, I13.0, I13.2, I25.5, I42.0, I42.5, I42.6, I42.7, I42.8, I42.9, I43.*, I50*, P29.0.

The **prevalence of diagnosed urinary incontinence among adult women was 10% (N=14,291),** which is likely an ***underestimate of the true burden*** in this population given that the majority of women in the primary care setting are not screened for UI and diagnosed with UI, unless their symptoms are severe or bothersome. In one survey, 55% of women did not report their symptoms to a provider Although data were unavailable for the prevalence of UI among women in the 16-county catchment area, the estimated prevalence of UI is 20-30% (see Section B1;).[1, 4, 9] The characteristics of women with and without diagnosed UI in 2019 are presented in **Table 2**. In general, compared to women without UI, women with UI tended to have **higher prevalence rates of obesity** (63% vs 53%), **diabetes** (26% vs 15%), **age ≥ 65 years** (64% vs 39%), heart disease (9% vs 4%), and a larger percent of women self-identified as **Black/African American** (17% vs 14%) race. These data are consistent with known risk factors for UI, as described above.

Table 2: Demographic and Clinical Characteristics of Women in the PCI with and without Diagnosed Urinary Incontinence (2019)

Characteristics	UI (N= 14,291)	No UI (N=131,752)
Age >65 years	9,185 (64%)	50,773 (39%)
Race African American	2,352 (17%)	18,553 (14%)
White	11,653 (82%)	107,282 (81%)
Obesity	9,041 (63%)	69,927 (53%)
Diabetes	3,677 (26%)	19,878 (15%)
Heart Disease	1,256 (9%)	4,828 (4%)

The characteristics of PCI practices and its adult female service population generally reflects the characteristics of adult women in the 16-county PCI catchment region, and includes AHRQ defined **priority populations** (racial/ethnic minorities, older, and rural and inner city women). AHRQ priority populations will be targeted for project inclusion through a variety of recruitment and outreach strategies that leverage the PCI's leadership and administrative structure, centralized practice transformation facilitators within the Division of Population Health, and ongoing quality improvement and practice transformation initiatives (see Section B2) (https://www.ers.usda.gov/data-products/rural-urban-continuum-codes.aspx).

STUDY DESIGN

Engagement of Primary Care Practices

1. Expected Practice Participation: Participation in the EMPOWER project will be open to all 109 practices within the Primary Care Institute, which serves a diverse patient and geographic population, encompassing urban and rural areas within Northeast Ohio. Approximately 14% of established PCI patients are African American. Dr. Harwell will lead a focused outreach to practices with a high percentage of African American patients. As noted, the PCI is highly integrated within the University Hospitals Health System, and all PCI providers are employed by UH. Furthermore, large scale quality improvement and educational initiatives are coordinated centrally by PCI and UH leadership. As the project has already received the endorsement of PCI leadership and Dr. Rao serves as the academic leader for the PCI, we anticipate a high level of participation. The project will be described as a PCI initiative, rather than from an individual practice. Once practices have received detailed information about the project, they will have the option of opting out. This is a more effective engagement strategy than asking individual practices to voluntarily participate. As noted, we are able to pursue this strategy because the network of practices, PCI leadership, and health system leadership are all integrated and well-aligned in terms of priorities. We anticipate that roughly 80% practices (approximately 87 practices) will choose to participate and that we will be able to retain 70 of these throughout the course of the project (i.e. 17 dropouts), based on past PCI initiatives.

2. Challenges and Barriers to Recruitment: While we anticipate that relatively few practices will "opt out" of the project as this will be a network-wide initiative, we strongly believe there is a need to engage practices on a deeper level including generating enthusiasm for the project and increased recognition of the importance of urinary incontinence in women. Education for both providers and staff will be the primary mitigation strategy to address concerns about participation and to retain practices. The PCI has well-established mechanisms to inform and engage its providers which we will take advantage of.

a. *Information Sessions:* Information sessions will be held for all PCI leaders and providers through videoconference and/or in person in which the goals, expectations for participation, and anticipated outcomes of the project are described. Participants from PCI will be encouraged to ask questions and raise concerns. We will repeat the information sessions for each of the three Waves (Waves 1, 2 and 3). Individual Onboarding Visits at Primary Care Practices will be scheduled at sites considering participation for additional in person discussions about implementing the study.
b. *Individual Practice Outreach*: Finally, Drs. Hijaz, Rao, Sheyn, Conroy, Pope and Harwell will reach out to individual practice leaders and also to each physician leader in each participating PCI practice by phone and/or email and ask about any remaining concerns and questions about participation (even practices which have already agreed to participate). We believe this personal touch will be extremely helpful in further promoting engagement. All managers and providers will be encouraged to contact the project leadership at any time on their own to discuss the project.
c. *If any Wave has lower than expected recruitment outcomes, the EMPOWER team may add an extension period--a*n extended amount of time may be added to the end of any wave period to continue having primary care practices hand out Screening Questionnaires and engage patients in recruitment. This extension will be noted and identified with an "E" added to the end of the wave name (i.e. Wave 1E).

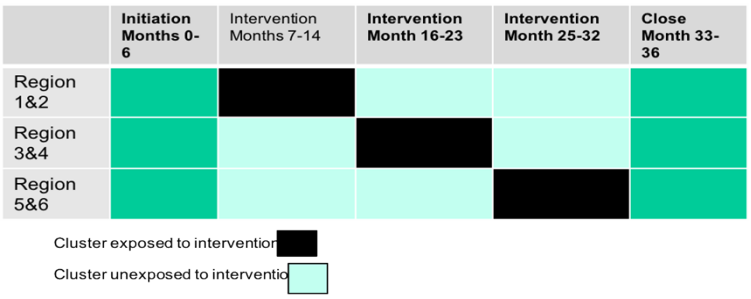
Randomization: Randomization software: R is the software (https://www.r-project.org/) that will be used for randomization. Randomizr is the package written for randomization. We will employ

a phased implementation of a cluster randomized trial. The clusters will be defined as the primary care practices and we will randomize an equal number of practices to the three study arms within each of six geographic regions (i.e., cohorts). The number of primary care practices assigned to each cluster will be a multiple of the number of intervention arms (N=3). Primary care practices within each cluster will be randomly assigned to the intervention arm using the R tool 'cluster_ra' in the *randomizr* package.

Primary Care Practices will be randomized by the study statistician into one of three arms of the study (shown in table below). All patients recruited from the same practice will have the same intervention.

Cohort 1 Practices	Cohort 2 Practices	Cohort 3 Practices
Usual care	Usual care + 4 calls with Nurse Navigator	Usual care + 4 calls with Nurse Navigator + 8 weeks using CeCe (chatbot)

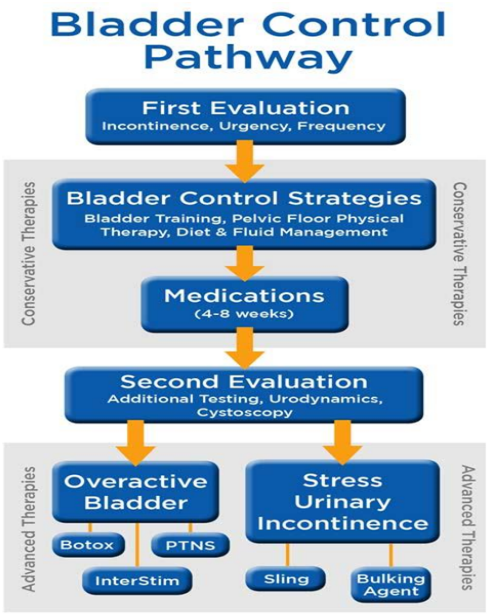
Clustered Design: Practices within the UH-PCI are clustered into 6 regions within the 16 counties (Central, Northeast, Northwest, South, Southeast and Southwest). We will adopt a Stepped Wedge design where the implementation plan will start in two regions at a time (*i.e.* Central+ South; Northeast+ Southeast; Northwest+ Southwest). Screening, recruitment and intervention (usual care, navigation, navigation+CeCe) will be done over a period of 8 months in each of the selected regions (i.e., Wave 1, Wave 2, Wave 3). Note that within each of the two regions, practices will be randomized to either of the three arms of the intervention. **All patients recruited from the same practice in the region will have the same intervention.** The stepped wedge design will allow the implementation and evaluation team the opportunity to adjust, refine, improve on work flow when we move the intervention to the next two regions according to the diagram below. Each of the two regions are separated by one month where the evaluation team will conduct interim analysis of the results (refer to the evaluation section).



Evidence-based Management (EBM) care pathway: The treatment of UI is dependent on the type that is present. Stress incontinence, SUI (leakage due to activities that increase intra-abdominal pressure), urge incontinence, UUI (leakage related to bladder over-activity) and mixed incontinence, MUI, together make up the majority of UI affecting women.[14] While advanced treatment for UUI, SUI, and MUI differs, there is significant overlap in the first line treatment for all three types of UI. The evidence-based care path for all three types consists of behavioral modification and pelvic floor exercise.

Behavioral modification includes initiating dietary changes that promote weight loss in obese and overweight women as well as identifying and minimizing intake of bladder irritants: including

caffeine, tobacco, carbonated beverages, acidic foods; together these interventions can account for >70% improvement in UI symptoms of all 3 types.[15-18] Self-directed pelvic floor exercises which consist of repeated levator ani contractions have also been shown to improve UI symptoms in the majority of women[19] Additionally, for UUI specifically, bladder training which consists of time voiding, distraction exercises to reduce urgency and increased time between voids has also found to be effective.[20] However, in the majority of cases patients need encouragement and reminders in order to be successful with these treatments, which is an aspect of conservative management that is currently not broadly applied.[21] Whereas Figure 3 represents the overall care pathway for the management of all incontinence, our team has built and will refine a EBM nonsurgical management care pathway that will guide the nurse navigator during the 6 months intervention phase.



Physician education- empowerment impact. The evidence based approach that we utilize in this project to achieve the goal of improving physician and office staff confidence and comfort in management of UI is through Project Echo. **Project ECHO** is a platform for practice-based education and training, service delivery, and outcomes evaluation developed at the University of New Mexico. The model has four components: 1) technology (multipoint video conferencing and internet) to leverage scarce healthcare resources; 2) disease management model focused on improving outcomes by reducing variation in processes of care and sharing best practices; 3) case-based learning to establish and develop communities of practice and encourage the collaborative management of patients between providers and subject matter experts and 4) monitoring outcomes using a web-based database.

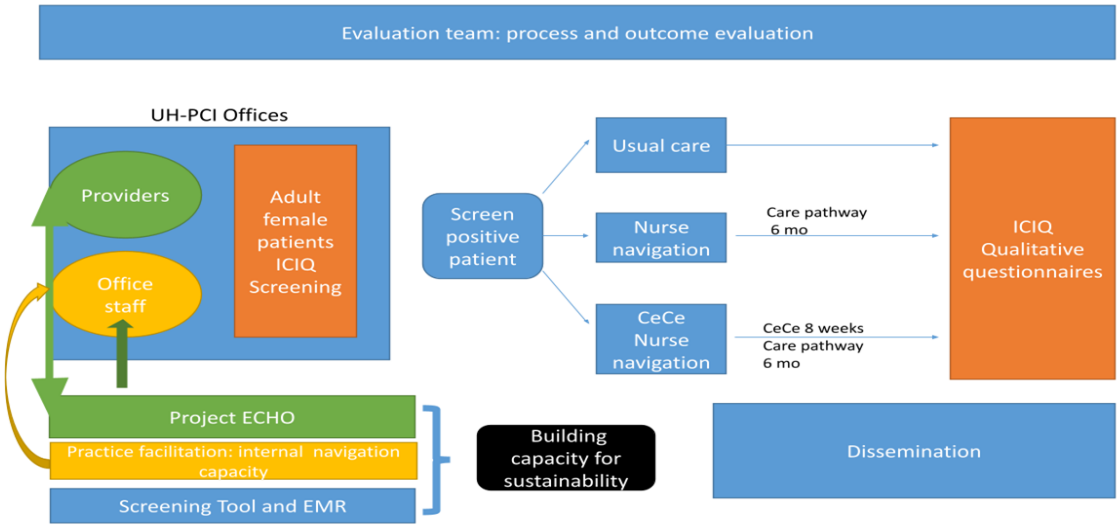
This project will pilot the Project ECHO model to increase the workforce capacity of nurse navigators and primary care physicians who are working with medically complex individuals with urinary incontinence. Funding from AHRQ will support planning and implementation of the UI series. The series is comprised of eight one hour-long sessions that will be facilitated by a team of subject matter experts every month. Sessions will consist of short didactic presentations (~20-30 minutes), followed by participant-led case presentations (new and follow-up cases). This structure, modeled after medical rounds, allows participants to apply the knowledge gained and openly discuss the real-world challenges of implementing recommended best practices. Through these discussions, the series facilitators and participants draw on their own experience to support each other and share strategies that they have found to be successful in navigating barriers.

Learning is acquired through “learning loops” as participants co-manage diverse patients in real-world situations and practice. Subject matter experts and participants draw on their own experience to support each other and share strategies that they have found to be successful in navigating barriers. Additionally, through support from the multidisciplinary team of subject matter experts, primary care providers (PCPs) gain skills and reinforcement in implementing practices extending beyond medical treatment, especially in under-resourced clinics. This longitudinal co-management of patients with specialists allows PCPs the opportunity to practice their expanded knowledge and skills in a fashion that builds their self-efficacy in handling real-world situations with their actual patients, while ensuring that they follow best practices as they learn. Providers also learn from each other as they hear consultations on cases by other

participants that may be similar to some of their own patients. Participants will complete a brief pre- and post- survey for the ECHO sessions and will receive additional support between sessions from the subject matter experts, as needed, via email and phone to help them navigate any challenges they encounter in implementing recommended practices.

Participation in the ECHO sessions will be encouraged, with a goal of at least one provider per site participating; however, participation in ECHO will not be a requirement for sites participating in the EMPOWER Study or for any individual providers. The ECHO sessions are being offered and encouraged by the study as part of the system-wide process improvement activities. The ECHO program utilizes a signed participant agreement that discusses expectations of participants and confidentiality. Providers from each site who decide to participate in some or all of the ECHO sessions are not considered study participants and the study will not obtain consent for these activities. These ECHO sessions have been approved as Not Human Subject Research for several other instances at UH and have not required written consent. These are meant to be flexible and completely voluntary, providers can join or drop out at any time, the pre- and post- surveys are not a requirement, and the same ECHO opportunity is being offered to all providers at all primary care sites that are part of the study.

Overall Study Diagram



Overall Project Timeline

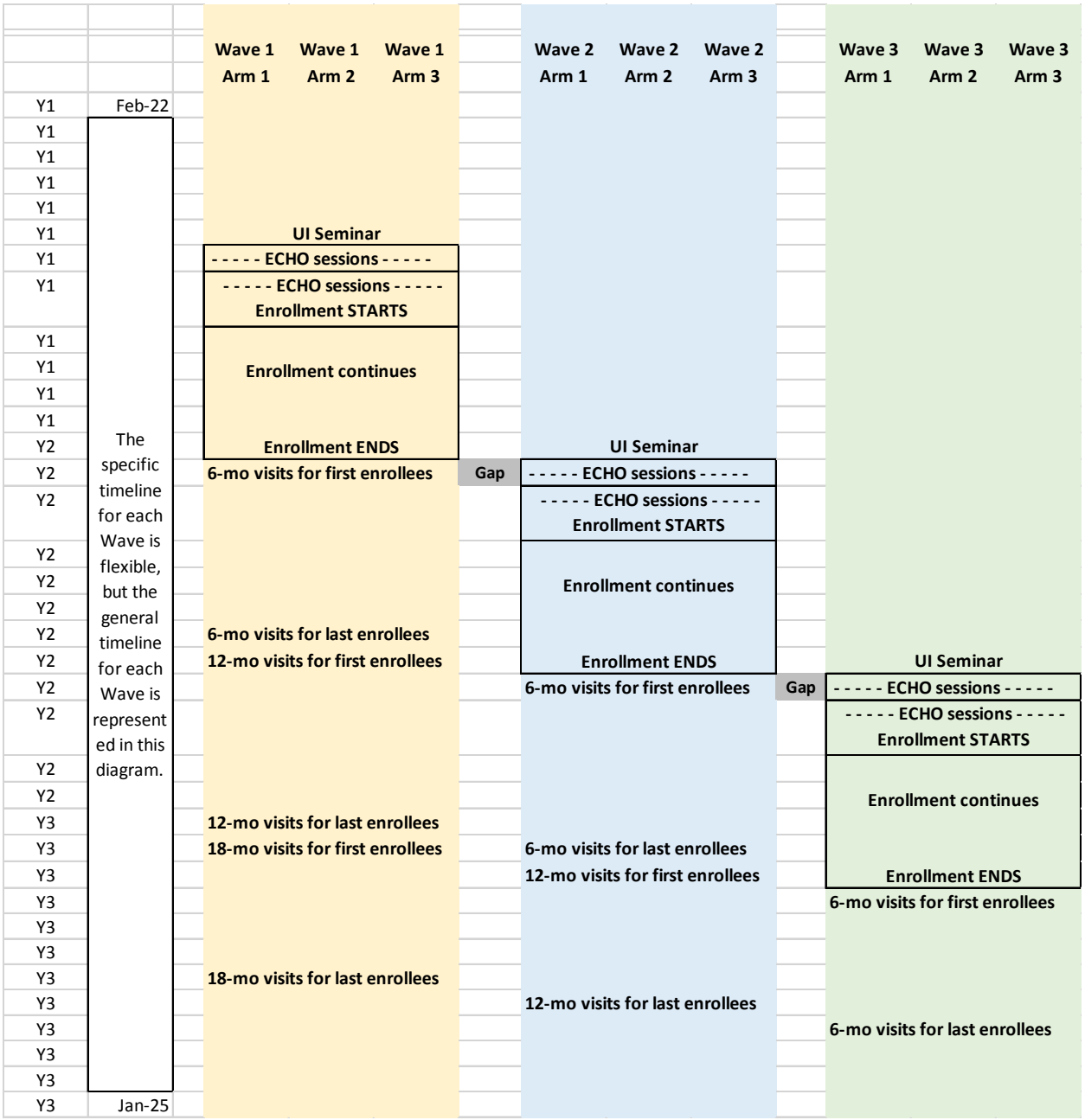
Following is a comprehensive timeline that incorporates the Start Up Activities, Implementation, Evaluation, and Dissemination efforts to be completed within the 3 year period of the project.

		Year 1				Year 2				Year 3			
		Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Start Up Activities	Design ECHO Program	**x**	**x**										
	Meet/Enroll PCPs	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**			
	IT Interface for Screening	**x**	**x**										
	Hire/Train Research Staff	**x**	**x**	**x**									
	Refine EBM care pathway	**x**	**x**	**x**									
	Train Nurse Navigators			**x**	**x**								
	Design targeted messaging to patients	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**		
Implementation	ECHO programing to PCPs			**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**
	Screen & Consent Patients			**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**		
	Nurse Navigator Intervention			**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	
Evaluation	Develop Surveys and Interview Guides	x	**x**										
	Obtain IRB approval	x	**x**										
	Collect and analyze data			**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**
	Report findings to I & D Teams				**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**	**x**
Dissemination	Interview Stakeholders		**x**			**x**	**x**			**x**			
	Focus Groups					**x**		**x**		**x**			
	Evaluate Metrics			**x**				**x**		**x**			
	Develop Tool-kits, marketing, & Website						**x**	**x**	**x**				
	Disseminate Tool-kits, marketing, and Website									**x**	**x**	**x**	**x**
	Abstracts, Presentations and Publications								**x**	**x**		**x**	**x**

Timeline of the approach for working with an individual primary care practice.

	Months											
	1	2	3	4	5	6	7	8	9	10	11	12
On board PCP and staff, ECHO Training	x	x										
Screen Patients			x	x	x	x	x	x				
Recruit and Enroll			x	x	x	x	x	x				
Navigator & Nav. + CeCe Implementation				x	x	x	x	x	x	x		
Navigator Follow up and Referral as needed.									x	x		
Patient, PCP and staff Evaluation									x	x		

Detailed Timeline for Sites in Waves 1-3



An extension period may be added to the end of any wave period to continue having primary care practices hand out Screening Questionnaires and engage patients in recruitment. Participants who enroll in an extension period may not have the same length of follow up as the participants in the main wave (in order to complete all activities by the end of the study time period); however, the consent form will be clear about the length of follow up.

ELIGIBILITY CRITERIA FOR PATIENT PARTICIPANTS IN MAIN STUDY AND PATIENTS FOR INTERVIEW ONLY

Inclusion Criteria:

1) Female patient having a primary care provider visit at UH Primary Care Institute (PCI)
2) ≥18 years old
3) Scores 1 or higher on the International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-SF)
4) Able to speak, read, understand English

Exclusion Criteria:
None

STUDY PROCEDURES FOR PATIENT PARTICIPANTS

Screening: A practical screening tool to use in primary care is the short 4-point **International Consultation on Incontinence Questionnaire- Short Form (ICIQ-SF)** to assess the presence of urinary incontinence in adult women presenting for non-incontinence related complaints to their primary care providers. This tool is validated and has been widely used to screen patients and to follow symptoms of incontinence after interventions. It is brief, takes 5 min or less time to administer and no training, and for this study may be answered in a written form or electronically. Cut-off scores for severity of UI in women have been reported by Klovning et al. in a cohort of 1,812 women responding to a general health questionnaire. Score ranges were 1 – 5 (slight), 6 – 12 (moderate), 13 – 18 (severe) and 19 – 21 (very severe).[11] A -2.52 score change in ICIQ-SF defined the minimally important difference in women with clinically relevant improvement in UI after 4 months of pelvic floor muscle training. [12]

All women ≥18 years who present to the enrolled PCI offices will be given a paper version of the **ICIQ-SF Screening Questionnaire with QR Code** that is part of routine practice/quality initiative along with their intake forms by the front desk or at the beginning of their visit. This sheet will have a QR code that will take the patient (via phone or tablet) to an electronic REDCap version of the ICIQ-SF Screening Questionnaire as the preferred option. If the patient is unable to use the electronic option, she will be directed to the other side of the sheet to answer the paper version of the questionnaire. The ICIQ-SF will be a standard of care UI screening measure offered to all female patients at the participating clinical sites and will be entered into the patient's EMR. The questionnaire will also serve as a recruitment method, inviting women to learn more about the study--at the end of ICIQ-SF (in both the electronic and paper versions), a patient is informed that there is a study opportunity and invited to provide her phone number if she'd like to be contacted with more information. Those who score 1 or above on the ICIQ-SF will be eligible for participation in the study. If a patient enrolls in the study, the patient's answers on this questionnaire will then be obtained from EMR and entered into the study dataset for the Baseline time point.

A small exam room poster is also being used in the Primary Care practices that prompts patients to do the screening questionnaire via REDCap with the QR code. The EMPOWER Study is not mentioned on the poster but, as described above, there is the invitation to the study at the end of the electronic questionnaire.

Additional recruitment details and consent details are in the Supplemental Form.

Summary of Procedures: Based on the office randomization into three cohorts, patients who screen positive and agree to participate in the study will be enrolled into either 1) usual care, 2) nurse navigation or 3) nurse navigation + CeCe. All patients will access their primary

care providers for usual care as they wish and patient data will be collected as described below. Patients in the second two cohorts will use CeCe and/or nurse navigation for 8 weeks. We will evaluate patient outcomes using **Patient Global Impression of Improvement (PGI-I)** and change in the score of the **ICIQ-SF**. Patient benefit will also be evaluated with **Overactive Bladder Symptom Score (OABSS), Urinary Distress Inventory, Short Form (UDI-6), Incontinence Questionnaire Lower Urinary Tract Symptoms Quality of Life Module (ICIQ-LUTSqol), and the study-specific EMPOWER** questionnaires. Participants in Cohort 3 will also complete the Michigan Incontinence Symptom Index within the CeCe chatbot. Depending on which Wave a participant is in, the questionnaire and follow-up period will be for 18 months (Wave 1), 12 months (Wave 2), or 6 months (Wave 3). All participants will be given printed educational material as part of the study (see **Educational Handout 1:** IUGA Non-surgical Approaches to Managing Bladder Problems) and will be advised to discuss their UI symptoms with their primary care provider (PCP). Some participants will be asked to participate in an optional qualitative interview about their experience in the study.

The questionnaires and interview guide are attached in Sparta.

Updates on the study's overall outcomes and progress will be IRB-approved in advance and then emailed to all participants enrolled to date (using the same email that participants are using to complete the study questionnaires). Each email will have instructions to opt out of receiving the updates if desired by replying "opt out."

Data Collection: Demographics and limited medical history will be collected from the participant directly and/or from the medical record. Study staff will use the "Intake Form for Patient Participants." The study will also collect data from the patient's medical record during their length of their participation in the study including: initial (baseline) ICIQ-SF, date of birth, height, weight, body mass index (BMI), UI-related diagnoses, UI-related test results, follow-up appointments, treatment recommendations, physical therapy, medications, referrals, etc.). All data to be collected in the study is listed in the Data Dictionary.

Questionnaires (administered by REDCap surveys via email to participant unless otherwise noted):

Questionnaire 1: International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF): This is a validated brief 4-item questionnaire for evaluating the frequency, severity and impact on quality of life (QoL) of urinary incontinence symptoms during the last 4 weeks in men and women in research and clinical practice across the world. It provides a comprehensive summary of the level, impact and perceived cause of symptoms of incontinence and may be used to facilitate patient-clinician discussions. Initial (baseline) ICIQ-SF is part of routine practice/quality initiative and the results will be collected from the medical record and entered into the study database. The questionnaire will be administered as part of the study at all subsequent timepoints. Estimated completion time is about 2 minutes.

Questionnaire 2: Overactive Bladder Symptom Score (OABSS): The validated OABSS has 4 questions to assess symptoms of overactive bladder during the last week[60]. Questions ask about daytime frequency, nocturia, urgency and urgency incontinence. Estimated completion time is about 2 minutes.

Questionnaire 3: Urinary Distress Inventory, Short Form (UDI-6): This validated questionnaire consists of 6 questions to measure how bothersome any urinary symptoms are during the last 3 months[61]. Estimated completion time is about 2 minutes.

Questionnaire 4: Incontinence Questionnaire Lower Urinary Tract Symptoms Quality of Life Module (ICIQ-LUTSqol): This validated questionnaire consists of 20

questions to assess the impact of urinary incontinence on quality of life during the last 4 weeks. Estimated completion time is about 10 minutes.

Questionnaire 5: Patient Global Impression of Improvement (PGI-I): This is a global index that may be used to rate the response of a condition to a therapy. The PGI-I is a transition scale that is a single question asking the patient to rate their urinary tract condition now, as compared with how it was prior to before beginning treatment on a scale from 1 "Very much better" to 7 "Very much worse." Estimated completion time is <1 minute.

Questionnaire 6: EMPOWER Questionnaire: These are additional questions including 5 questions from the validated Patient-perceived self-efficacy in patient-physician interactions (PEPPI)[58] and questions about the participant's thoughts on treatment options. Estimated completion time is about 3 minutes.

Questionnaire 7: Michigan Incontinence Symptom Index (M-ISI) for Cohort 3 participants only: This is a validated 10-item questionnaire to distinguish type of urinary incontinence, severity and bother[59]. This is administered via the chatbot and incorporated into the time the participant will be using the chatbot.

Nurse navigation: Nurse navigators are an innovation to integrate services and address the fragmented nature of health care systems.[23] This study will use nurse navigators to help coordinate care for participants in an effort to prevent patients from "falling through the cracks." Nurse navigators will connect with participants by phone or Zoom (with or without video) 4 times over 8 weeks and help guide participants in their UI management efforts. The Nurse Navigator can provide additional education about UI, discuss symptoms and treatment options, provide training on activities like completing a bladder diary, fluid and dietary management, bladder training, pelvic floor exercise (e.g., Kegels), referral options, and support for the recommendations made by the participant's provider.

Nurse navigators will create a "client" relationship and focus on promoting client self-sufficiency. Research has demonstrated that nurse navigators help patients utilize health care consumption optimally and are especially helpful for those with chronic or complex case.[24, 25]

The following patient-facing items uploaded in Sparta may be distributed to participants receiving nurse navigation as applicable to the individual participant's case:

- **Bladder Diary** -- document may be emailed or mailed to participant after consent in case it is utilized during Nurse Navigation visits; the diary may be determined to be an applicable recommendation during a Nurse Navigator visit; if patient opts to fill one out, the responses may be collected by participant completing a REDCap form, by emailing or mailing the completed document to the study team or by study team entering the participant's responses directly into the REDCap Form.
- Any websites from the list of **Educational Web References for Patient Participants**
- **Exercise Handouts** – may be emailed or mailed to participant. The 6 pages may be provided as a complete set or individual pages may be provided as selected by the Nurse Navigator.
- **Scheduling information** and provider lists for UH Urology and/or UH Physical Therapy (examples of these lists are provided but these lists are ever-changing and will be updated over time without IRB re-submission)

UI CeCe mobile chatbot: UI CeCe is the name of a novel mobile platform "chatbot" designed by the company Renalis to engage patients in self-management of their UI. Renalis is a digital

health company which has developed several digital technologies for managing pelvic health. The basic platform is based on an artificial intelligence (AI) conversational agent, called CeCe. The language used by the AI for each type of pelvic concern is based on health communication theories including Supportive Communication, Uncertainty Reduction Theory, and the Theory of Motivated Information Management. This allows the AI to build a relationship with the user by increasing knowledge, motivation and self-efficacy to accomplish their particular goals. The chatbot is not available to the public and is currently only available for research use.

The study team will provide participants the **CeCe Set up Instructions for Participants** by email and will also be available to help the participant through set-up as needed during study phone calls/Zoom sessions. The study team will coordinate having the participant start using CeCe on or near the same day as the first Nurse Navigator visit. Participants will interact with CeCe daily through SMS texting (or emails) and scripted responses to educate patients on pelvic floor anatomy as well as on pelvic floor exercises. Patients may learn more about UI management by viewing online videos or reading material outside of the medical setting. The chatbot will also collect bladder diary entries from the participants. The CeCe experience lasts 8 weeks (or up to 12 weeks if participants do not check in every day and there are gaps in completing the daily program).

Once this research receives funding, Renalis and the EMPOWER study team will collaborate to build a customized UI CeCe chatbot that will apply to the needs of this study. The design of the CeCe chatbot for use in the EMPOWER Study will fall under the category of non-significant risk, medical mobile device under FDA enforcement discretion. More information about the CeCe chatbot, sample scripts and screenshots is attached as a PDF in Sparta.

Under the agreement with UH, Renalis is permitted to use de-identified data from approximately 50 participants in the UI CeCe arm, gathered strictly through interaction with the software, to present it to the FDA in a pre-submission meeting related to potential FDA-clearance for this technology in the future. Renalis has confirmed that if the FDA's review is favorable, Renalis would then conduct its own pivotal trial for the chatbot, completely outside of this AHRQ grant.

Optional Interview: Participants who agree to the optional interview on the consent form may be asked to do one (but not both) of the following types of interviews.

Primary Interview: Forty-five (45) enrolled participants will be asked to participate in an optional qualitative interview about their experience in the study. The interview will be conducted via Zoom (with or without video) and be recorded and transcribed. Study staff will utilize the "Interview Guide – Patient Participants." Up to 15 non-enrolled patients will be asked to participate in the interview as well using the "Interview Guide – Patients Declining Main Study." We will only invite patients who initiated and completed a recruitment contact and was informed about the study but then declined to enroll. The interview will take about 30 minutes and may occur any time at or after the Month 6 time point.

Diversity Interview (for AHRQ Grant Supplement): Thirty (30) African American women who are enrolled in the EMPOWER study and with positive urinary incontinence screening results will be asked to participate in an optional qualitative interview about their experience with the diagnosis and treatment process (if applicable). The interview will be conducted via Zoom (with or without video) and will be recorded and transcribed. Study staff will utilize the "Diversity Interview Guide." We will only invite patients who consented to recruitment contact and was informed about the study. The interview will take about 30 minutes and may occur any time at or after the Week 8 time point.

Primary and Diversity interviews will be done by the participant phoning in to a Zoom session, joining a Zoom session online, or in person. If the interview is completed by an online Zoom session, the participant can choose whether they want to be on video or not and if their name is displayed or not. However the interview is completed, it will be recorded to the UH Zoom Cloud. If the participant chooses to be on video during the online Zoom session, the recording feature automatically records both audio and video; however, the study team will immediately delete the video recording file. The audio recording/transcription files will be transferred to a secure computer drive with access limited to study team members only. The audio recording will then transcribed into a final transcription document that will be used for the study analyses. We will remind participants prior to the recording to not provide any identifying information during the interview, but if they do mention anything that is identifiable, we will NOT include it in the transcription document.

See Schedule of Activities and Assessments for frequency, timing and length of procedures.

Schedule of Activities & Assessments for Patient Participants

		Waves 1, 2 & 3			Waves 1 & 2 Only	Wave 1 Only
Study Visit	Screening	Baseline	Week 8	Month 6	Month 12	Month 18
Visit Windows		Within 30 days post-enrollment*	56 days post-enrollment (+14 days)	180 days post-enrollment (+30 days)	365 days post-enrollment (+30 days)	548 days post-enrollment (+30 days)
Eligibility confirmation	X					
Cohort 1: Abbreviated consent via Information Sheet	X					
Cohorts 2 & 3: Informed consent	X					
Interview-only patients: Informed consent	X					
(Q1) International Consultation on Incontinence Questionnaire-Short Form (ICIQ-SF)	X (from medical record)		X	X	X	X
(Q2) Overactive Bladder Symptom Score (OABSS)		X	X	X	X	X
(Q3) Urinary Distress Inventory, Short Form (UDI-6)		X	X	X	X	X
(Q4) Incontinence Questionnaire Lower Urinary Tract Symptoms Quality of Life Module (ICIQ-LUTSqol)		X	X	X	X	X
(Q5) Patient Global Impression of Improvement Questionnaire (PGI-I)			X	X	X	X
(Q6) EMPOWER Questionnaire		X	X	X	X	X
Study-specific data collection from participant (e.g., demographics, limited medical history)		X				
For Cohorts 2 & 3 Only: Nurse Navigator introduction & continued follow-up/coaching at 4 time points over 8 weeks. The date of NN Visit 1 is considered Week 1, Day 1. Suggested Visit Schedule (no specific visit windows) Week 1: Day 1 Week 2: Day 7 Week 4: Day 28 Week 8: Day 56		X----------X				
For Cohort 3 Only: Daily use of CeCe phone chatbot for 8 weeks (including instruction on accessing and using CeCe at Baseline)		X----------X				
Data collection from medical record/clinical care -- outpatient/inpatient clinical encounter information related to incontinence (e.g., urinary incontinence (UI) diagnosis, UI recommendations and referrals, UI medications prescribed, UI-related test results, UI surgery, etc.)		X----------X				
Primary Interview: Semi-structured Qualitative Interview, optional				X		

		Waves 1, 2 & 3			Waves 1 & 2 Only	Wave 1 Only
Study Visit	Screening	Baseline	Week 8	Month 6	Month 12	Month 18
Visit Windows		Within 30 days post-enrollment*	56 days post-enrollment (+14 days)	180 days post-enrollment (+30 days)	365 days post-enrollment (+30 days)	548 days post-enrollment (+30 days)
for a sub-set of up to 45 enrolled participants (up to 15 participants per Wave, ideally consisting of 5 participants from each of the three cohorts)						
Diversity Interview: Semi-structured Qualitative Interview, optional for a sub-set of up to 30 enrolled participants (ideally consisting of 10 participants from each of the three cohorts)			X			
Semi-structured Qualitative Interview, for up to 15 non-enrolled patients (ideally consisting of 5 patients per Wave who decline participation in the main study)		X				
Estimated length of time for questionnaires and study-specific data collection for participants in Cohorts 1, 2 & 3		30 minutes	20 minutes	20 minutes	20 minutes	20 minutes
Estimated addition time for Nurse Navigator contact for participants in Cohort 2 & 3		10 minutes per contact (40 minutes in total)				
Estimated additional time for CeCe interaction for participants in Cohort 3		5 minutes per day (about 5 hours in total over 8 weeks)				
Estimated additional time for the optional Qualitative Interview		30 minutes (non-enrolled patients)		30 minutes (enrolled patients)		

*The enrollment date is the date that both eligibility is confirmed and consent is complete.

Total time involved for participants in Wave 1: Cohort 1: 2 hours, Cohort 2: 3 hours, Cohort 3: 8 hours

Total time involved for participants in Wave 2: Cohort 1: 1.5 hours, Cohort 2: 2.5 hours, Cohort 3: 7.5 hours

Total time involved for participants in Wave 3: Cohort 1: 1.25 hours, Cohort 2: 2.25 hours, Cohort 3: 7.25 hours

Total duration of participant involvement for each Wave: Wave 1: 18 months, Wave 2: 13 months, Wave 3: 6 months

ELIGIBILITY CRITERIA FOR SITE STAKEHOLDERS

Inclusion Criteria:

1) Provider or administrative staff at UH Primary Care Institute office

Exclusion Criteria:
None

STUDY PROCEDURES FOR THE SITE STAKEHOLDERS

Recruitment details and consent details regarding enrollment of the Site Stakeholders (providers and administrative staff) are in the Supplemental Form.

Study staff will use the "Intake Form for Stakeholder Participants" to collect the minimum enrollment data required by the grant (age, gender, race, ethnicity) and the stakeholder's practice information. The form will be in REDCap and will be emailed to the participant or completed in a proctored fashion by the study staff after consenting the participant.

Surveys: At least one provider and one office manager/administrative staff from each participating site will be asked to complete surveys throughout and after the enrollment/implementation period at their site. The survey is titled "Surveys for Stakeholders."

Optional Interview: Ninety (90) stakeholders will be asked to participate in an optional semi-structure qualitative interview about their experience in the study.

- Two stakeholders from up to 15 sites that opted out of study participation (up to 5 sites in each wave)
- Two stakeholders from up to 15 sites that opted in to study participation and then dropped out (up to 5 sites in each wave)
- Two stakeholders from up to 15 sites that opted in to study participation and are continuing in the study (up to 5 sites in each wave)

The interview will be conducted via Zoom (with or without video) or in person (at a PCI location) and will be recorded and transcribed. Study staff will utilize the "Interview Guide - Stakeholders."

The interview will take about 30 minutes and be done by the participant phoning in to a Zoom session, joining a Zoom session online, or in person. If the interview is completed by an online Zoom session, the participant can choose whether they want to be on video or not and if their name is displayed or not. However the interview is completed, it will be recorded to the UH Zoom Cloud. If the participant chooses to be on video during the online Zoom session, the recording feature automatically records both audio and video; however, the study team will immediately delete the video recording file. The audio recording/transcription files will be transferred to a secure computer drive with access limited to study team members only. The audio recording will then transcribed into a final transcription document that will be used for the study analyses. We will remind participants prior to the recording to not provide any identifying information during the interview, but if they do mention anything that is identifiable, we will NOT include it in the transcription document.

The survey and interview guide are attached in Sparta.

See Schedule of Activities and Assessments for frequency, timing and length of procedures.

Schedule of Activities & Assessments for Site Stakeholders

In this table, the timing for the study activities/visits is from the opening of patient enrollment at the practice for each Wave.

		Waves 1, 2 & 3							
			Patient Enrollment Period						
Study Visit #	Estimated Time	Up to 2 Months Prior to Start of Enrollment	Month 1	Month 2	Month 3	Month 4	Month 5	Month 6	Month 7
Consent to participate in surveys and/or interviews (PCP and Office Manager at all participating sites and some non-participating sites)	15 minutes	X							
Monthly surveys of Lead PCP and Office Manager at all participating sites	5 minutes per survey (30 minutes total over 6 months)		X	X	X	X	X	X	
Post-implementation survey of Lead PCP and/or Office Manager at all participating sites	5-10 minutes								X
Semi-structured Qualitative Interview with Lead PCP and Office Manager from up to 45 sites (90 participants): • Up to 15 sites that opted out of study participation (up to 5 sites in each wave) • Up to 15 sites that opted in to study participation and then dropped out (up to 5 sites in each wave) • Up to 15 sites that opted in to study participation and are continuing in the study (up to 5 sites in each wave)	20-30 minutes	X • For sites that opt out, interview can occur at any time. • For sites that opt in and then drop out, interview can occur at any time after drop out. • For sites that opt in and are continuing in the study, interview can occur any time after 4 months of the Patient Enrollment Period have been completed							

POTENTIAL RISKS

This study is not greater than minimal risk.

Questionnaires/surveys & use of CeCe Chatbot
Answering the questionnaires and interacting with the CeCe chatbot may be boring or tiring. Individuals may feel uncomfortable or feel stress from some of the questions on the surveys. Individuals will be informed that they can skip any questions if they don't want to answer them.

Optional Interviews
Individuals may feel uncomfortable or feel stress from the questions in the interview setting as they are personal in nature and centered on the patient's condition or the stakeholder's opinions. Participants will be assured of a private setting and data confidentiality and can skip any questions in the interview.

Data Collection and Confidentiality
There is a risk of loss of confidentiality with any study and data collection. We are protecting against this by keeping all of the data separate from participants' name and in password protected documents/databases on secure computers/systems.

Unknown Risks: There may be risks that we do not know about at this time.

Potential Benefits to Research Participants
There may or may not be direct benefits to the patient participants within all cohorts of this study including interacting with their providers, some of whom have engaged in supplemental urinary incontinence training. Patients will receive an educational handout and some patients will receive additional education and support from a Nurse Navigator and/or the CeCe chatbot. Study participation may improve a patient's chances of having significant improvement with these symptoms.

There are no direct benefits to the stakeholder participants or to the non-enrolled patients who consent to the interview.

Alternatives to Participation
Participation in this study is voluntary. Subjects can refuse to participate or stop at any time without stating a reason. Non-enrollment or withdrawal from the study will not affect access to medical care which would otherwise be entitled. If subjects wish to be screened for urinary incontinence without participating in the study, they may fill out these questionnaires in a clinical setting.

Evaluation Plan

Guided by the RE-AIM model, the evaluation of the EMPOWER study will use mixed methods to assess study Reach, Effectiveness, Adoption, Implementation, and Maintenance as well as the inner and outer context from the Practical, Robust Implementation and Sustainability Model.[42] The evaluation will use an iterative process (Harden) during each of the implementation Waves to provide quarterly evaluation feedback to the program implementation team to inform subsequent implementation Waves.

Data Collection

Reach of the program will be assessed by the following:

Under the Quality Improvement Component (separate NHR IRB submission): number of PCP offices participating in the program as documented in memorandums of understanding, number of female patients screened in each office, assessment from the EMR of number of patients screened positive for UI, number of participants in the Project ECHO sessions as documented in session attendance logs, and characteristics of patients in offices opting in to the program (such as age, gender, race, ethnicity, insurance status, parity, menopausal status, current smokers, UI diagnoses, UI referrals, and co-occurring diagnoses such as obesity, diabetes and heart disease).

Under the EMPOWER Study: number of patients participating in the study as documented in the enrollment database as well as characteristics of patients participating in the intervention (same characteristics as described above).

The process evaluation will also include an assessment of the representativeness of the reach of the study, through examination of the characteristics of patients from the EMR as described above in offices participating in the study (**data from the Quality Improvement Component (separate NHR IRB submission))** and patients enrolling in the study (**data from the EMPOWER Study)** as compared to the PCI overall. The representativeness of the EMR will be defined based on patient demographics from the previous year, as well as an average of the previous three and five years, to avoid any bias arising from the COVID19 pandemic.

Under the Quality Improvement Component (separate NHR IRB submission):
In the process evaluation, information seminars and session logs will be used to assess the date of seminars/sessions, # of participants attending each seminar/session, role of those attending seminars/sessions, the implementation team members involved in the information seminars/sessions, seminar/session topics, as well as questions asked in each session. Meeting logs will also document all efforts to engage and recruit offices, such as calls to lead physicians and managers, emails, as well as individual meetings. The implementation meeting logs will include the date of engagement, the members of the implementation team and office staff involved, discussion topics, and questions asked.

The process evaluation will assess program fidelity. Implementation of the screening process will be assessed by the % of female patients screened for urinary incontinence in each participating office. To assess the office staff education the % of participating offices with a champion identified will be monitored through a list of office champions

maintained by the implementation team and the % of office champions trained will be assessed through training attendance logs.

To assess the education and empowerment of PCPs, the evaluation will include % of PCP offices participating in ECHO and % of ECHO sessions attended by PCPs through data provided by University of Chicago.

The impact evaluation will also include assessment of the outcomes of PCP Participation in Project ECHO, including increased knowledge and confidence. Results from surveys of ECHO sessions will be provided by the University of Chicago.

Under the EMPOWER Study:
To assess the nurse navigator component, the evaluation will include monitoring the # of nurse navigators trained through training logs, the # of times the nurse navigator interacts with the office and the content of those meetings through meeting logs, as well as using fidelity checklists and EMR log of nurse navigator contacts to examine the number of calls made with patients, time between screening and contact by the nurse navigator, time between each contact by the nurse navigator, treatment plan followed for each patient, education provided to each patient, and planned follow-up contacts. The UI CeCe chatbot will be monitored through bladder diary data, behavioral modifications when applicable and symptomatic changes provided by Renalis.

To assess intervention adoption and engagement from the patient perspective as well as factors that impact adoption, engagement, and satisfaction with treatment, a semi-structured interview will be conducted with 60 patients (20 during each intervention Wave). This sample will include 15 participants in the usual care cohort, 15 participants enrolled in the nurse navigator component, 15 participants enrolled in the nurse navigator+chatbot cohort, and 15 patients who declined to enroll in the study after recruitment discussion.

In an assessment of time and roles of individuals involved in the implementation, the implementation team members and the time spent by them engaging practices, recruiting, training, and engaging in research enrollment will be monitored through meeting logs as well as training logs and agendas.

Empowerment of patients in the usual care treatment will be assessed for participants enrolled in the study through EMR notes of whether UI is discussed at the patients visit after screening.

Health impacts and satisfaction of enrolled participants will be measured by UI diagnoses and UI referrals through the EMR and ICIQ-SF, OABSS, UDI-6, ICIQ-LUTSqol, PGI-6 and study-specific EMPOWER questionnaires completed by patients 8 weeks and 6 months after enrollment. Additionally, patients in implementation Wave 1 will receive an additional set of surveys at 12 months and 18 months post-enrollment, and patients in implementation Wave 2 will receive an additional set of surveys 12 months post-enrollment.

To better understand factors that impact adoption of the program, semi-structured interviews will be conducted with the lead PCP and manager at up to 15 offices that opt-

out of participating in the program (up to 5 offices from each implementation Wave), up to 15 offices that drop-out of participating in the program (up to 5 offices from each implementation Wave), and 15 offices that participate in the program (5 offices from each implementation Wave). This will include questions to assess barriers and facilitators to adoption of QI projects overall, projects addressing UI, and this study specifically.

The interviews with the 15 offices participating in the program and with those that drop out of the study will also examine barriers and facilitators to implementation of the project. Factors that impact the intervention implementation will also be examined through short surveys completed by a primary care provider and manager at all offices participating in the study. Participating offices will complete monthly surveys during the implementation. To examine barriers and facilitators to implementation from the perspective of the nurse navigators, interviews will be conducted with the nurse navigator during each implementation Wave.

The time spent by office staff on study implementation will be examined in the interviews and surveys with participating offices.

To monitor program maintenance, intention to maintain program components will be included in the interviews with participating offices and in the final monthly survey with participating offices during implementation. The interviews with participating offices will also include questions to assess factors that may impact maintenance. The evaluation will also assess the % of champions trained as nurse navigators through the training attendance log.

As part of the impact evaluation, a survey with all participating offices one month post implementation will assess the components that have been maintained by the participating offices.

Data Analysis

Quantitative: Although the stepped wedge cluster randomized trial is relatively new, its popularity and use has been steadily increasing, and serves as an alternative to parallel cluster trial designs.[43] [44, 45] Our application of the stepped wedge cluster randomized trial involves the randomization of all medical practices encompassed in two regions to one of the three study arms – 1) Usual care, 2) Nurse navigation, and 3) Nurse navigation and CeCe. Two regions will be added to the stepped wedge cluster randomized trial every 9 months. Overall, a baseline and 6-month evaluation for each participating patient will be measured and outcomes will be evaluated as a cross-sectional assessment by study arm where the difference between the baseline and follow-up evaluation will be determined. The observed difference as well as the percentage change will be analyzed to assess statistically significant differences.

A standard parallel trial compares intervention arms, whereas the stepped wedge study considers exposed (intervention) and unexposed (control) observation periods. Thus, the distribution of results across unexposed observation periods is compared with that across the exposed observation periods. Following an intention to treat principle, clusters should be analyzed according to their randomized crossover time irrespective of whether crossover was achieved at the desired time. A sensitivity analysis of the intent to treat schedule to true

occurrence will be conducted.[46] Characteristics of the individuals and clusters will be summarized by exposure status so as to allow consideration of selection biases and lack of balance for categorical (*e.g.* Chi-squared) and continuous (*e.g.* t-tests) variables. This contrast will include the numbers analyzed, the average cluster size, cluster characteristics, and important patient characteristics. The overall analysis of randomized arms will be conducted employing a generalized linear regression with multinomial outcome structure, utilizing a logit function, contrasting the 'Usual Care' arm with the two treatment arms, and a contrast between the treatment arm of 'Nurse navigation' versus 'Nurse navigation and CeCe'. A multivariable model adjusting for potential confounding variables (*e.g.* race, SES, geospatial residence, *etc*) will be used, as well as the evaluation for statistical interactions. All statistical tests will be two-sided and an alpha level of 0.05 will be used to determine statistical significance.

Given the stepped wedge design occurs over a period of time, during which the proportion of clusters exposed to the intervention gradually increases, this means a calendar time effect could be introduced. Although a two month window between recruitment of new regions will unlikely introduce a calendar bias, we will assess for confounding by calendar time and incorporate into the final model if it significantly affects our intervention (*i.e.* 10% change in the beta estimate). Lastly, a stepped wedge design also allows exploration of heterogeneity in treatment effects between clusters, using within cluster comparisons of exposed and unexposed periods. Although we may be underpowered due to the intra-correlative structure of the data, we will evaluate heterogeneity across clusters as a secondary analysis.

Several references have described formal methods to determine the necessary sample size and expected power for cross-sectional stepped wedge design.[47, 48] In a stepped wedge study, sample size and power calculations are complicated given the potential confounding effect from calendar time and the intercorrelation structure within clusters. For example, a simple randomized parallel study where time is not a confounding factor the precision will be greater than a stepped wedge study. However, the contribution of both exposed and unexposed observations will off-set this decrease of precision in a stepped wedge study given the confounding effect from time is minimal. Furthermore, the precision will be enhanced with the increase of cluster effects, *i.e.* intra-clustering is large.[49] For comparison, the estimated power is presented in Table 3 for three designs: simple parallel design, parallel with baseline period, and stepped wedge. The table uses the method of Hussey and Hughes and refers to a trial with 10 clusters and total cluster size of 1,000 designed to detect a standardized effect size of 0.3 (at 5% significance).[47, 48] The stepped wedge design is assumed to have six steps and an intra-cluster correlation of 0.10 with no confounding from time. As observed, the power for our proposed study is estimated to be 93%, greater than both the simple parallel design (62%) and parallel with baseline period (81%).

Table 3. Statistical power comparison for three study designs.

	Simple Parallel Design	Parallel with Baseline Period	Stepped Wedge Design
Number of clusters	10	10	10
Cluster size	1,000	1,000	1,000
Total sample size	10,000	10,000	10,000
Power	**0.62**	**0.81**	**0.93**

Qualitative:
A content analysis will be conducted on meeting notes, training notes and agendas, as well as fidelity checklists.[50]

Interview sample sizes have been selected to achieve thematic saturation.[51] All interviews will be audio-recorded and transcribed verbatim. A codebook will be developed using inductive and deductive methods.[52] Using NVivo qualitative software, interview transcripts will be coded and a thematic analysis will be conducted to identify factors that impact program adoption, implementation, maintenance, and health impacts, such as patient satisfaction (QSR International Pty Ltd. NVivo. https://www.qsrinternational.com/nvivo-qualitative-data-analysis-software/home).[53]

The primary analysis will include all randomized patients, excluding only those who were lost to follow-up or requested to be withdrawn from the analysis. The analysis for each primary and secondary outcome will be undertaken on an 'intention-to-treat' basis, where patients will be included in the assigned randomization. Since the clusters are defined as physician practices, we do not anticipate cross-over across the randomized groups. Any known cross-overs will be documented. All analyses will include individuals with both the baseline and follow-up measures obtained using the ICIQ-SF screening questionnaire. Positive scores, i.e. follow-up subtracted from baseline, will indicate an improvement whereas negative scores will represent worsening.

Baseline characteristics, such as age, BMI, and race, will be cross-tabulated according to the randomized group to ensure appropriate balance. Unbalanced groups will be further scrutinized by downstream analyses, sensitivity analysis, and adjustment. The primary analysis of the ICIQ-SF will be implemented using random effects regression, allowing for the clustering by primary care physician practice, and adjusted for relevant covariates. Statistical significance will be determined based on an alpha threshold of 0.05 and two-sided statistical tests will be utilized.

Power: Under similar assumptions as outlined in the proposal, based on a t-test (2-sided; 0.05 alpha-level) where the outcome is approximately normally distributed and assuming an ICC = 0.1, then we will be able to detect an effect size of 0.18 with 85% power recruiting 2,016 patients per study intervention arm (*i.e.* control, navigation and navigation/CeCe) across a total of 60 primary care offices (20 primary care offices per arm) assuming no covariate adjustment. However, the inclusion of covariates capturing 10% of the outcome variation for both group and member level covariates (3 degrees of freedom each), respectively, marginally decreases our detectable effect size to 0.16. This statistical power is based on a physician practice recruitment rate of 55% (60/109 - see below for recruitment strategy), however, we anticipate >70% of primary care offices will participate, yielding 72 primary care practices and >6,000 patients, thus significantly improving our estimated statistical power.

The logic model for the overall approach to dissemination and implementation, which are in alignment with our specific aims, is in the figure below.

INPUTS	ACTIVITIES	OUTPUTS	OUTCOMES
What we invest (resources)	What we do:	Direct products of program activities	Changes in behavior, knowledge, attitudes, conditions:
Study Leadership Team Implementation Team Evaluation Team Dissemination Team Study Advisory Committee **Collaborating institutions and Departments:** **University Hospitals** • Center of Female Pelvic Medicine and Reconstructive Surgery • Family Medicine and Community Health • Population Health Services Organization • Primary Care Institute • Urology Institute • UH Marketing • UH research & education • UH informatics **Case Western Reserve University** • Prevention Research Center of Health Neighborhoods • Quantitative and Population Health Sciences • School of Medicine • School of Nursing • Hirsh Institute for EBP implementation **Consultants** Kurt Stange, MD, PhD; ECHO-Chicago; Nursing Navigators Solutions; Renalis – CeCe Chatbot	**Start Up Activities:** Tailor ECHO program Meet with PCPs. Enroll PCPs. IT interface for screening tool Tailor CeCe Chatbot Hire research staff and train. Train Nurse Navigators. Design targeted messaging to patients. **Implement:** Screen patients Consent patients Randomize to 1 of 3 arms: Care under PCP, Navigator, Navigator + CeCe Chatbot **Evaluate** Develop surveys and interview guides to use with PCPs, office managers, nurse navigators, and patients. Obtain IRB approval. Collect and analyze quantitative and qualitative data to assess study reach, effectiveness, adoption, implementation, and maintenance. Report findings to implementation and dissemination teams. **Disseminate** Develop interview guides for Navigators, Patients and PCPs, organization. Conduct focus groups. Obtain metrics. Develop tool-kits and web-access. Abstracts and publications.	PCPs Engaged (# outreach to PCP, # completed ECHO, # enrolled) Project champion at each practice site identified. # patients screened + for UI # patients enrolled # patients retained/arm of study/ region Navigator metrics (# calls, referrals, barriers, successes) Health outcomes and demographic data Patient satisfaction Provider satisfaction survey Qualitative data from PCPS, Navigators and Patients # & type of revisions to work flow # advisory sessions and feedback provided **Dissemination:** Interview guide to use with stakeholders. Identified preferred communication strategies to stakeholders. Research findings and products to disseminate. # targeted communication strategies to providers and patients. # of presentations, publications, organizations reached, informal opinion leader communications, PCP communications. Evaluations from end-users.	Delivery of Care • Incontinence screening embedded in EMR Intake • Internal navigators manage UI in PCP offices • PCP adapted care pathway • Adoption of interactive web-based tool • Penetration of changes to all PCP geographic regions Satisfaction • Improved PCP comfort with evaluation/ management of UI • Improved patients perception of UI management • Patient satisfaction with treatment within PCP space • Improvement of quality of life as related to UI Health • Increased diagnosis of UI within community • Improved health seeking behavior • Improvement in individual UI scores • Increase number of people on indicated medications Transitions of Care (Specialty Care) • Indications for referrals • Decrease referral to specialist of index UI cases • Increased referral to specialist of complex UI cases • Increased utility of allied services through direct referral from PCP

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