



AGENCY FOR HEALTHCARE RESEARCH AND QUALITY



INTUIT-PC: Improving Nonsurgical Treatment of Urinary Incontinence Among Women in Primary Care: Dissemination and Implementation of PCOR Evidence (U18)

**Technical Assistance Call
February 25, 2021**

Agenda



- Zoom Logistics
- Introductions
- AHRQ context for this RFA
- RFA Guidance
- Q&A
 - ▶ Submit your questions in the Chat function

AHRQ Staff



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Purpose of this RFA



- To disseminate and implement the latest patient-centered outcomes research (PCOR) evidence about nonsurgical **treatments** for urinary incontinence (UI) to women in primary care practices
- To use lessons learned from previous AHRQ primary care practice improvement initiatives to implement and test implementation strategies

Context: Mission of Agency for Healthcare Research and Quality



www.ahrq.gov

To produce evidence to make healthcare safer, higher quality, more accessible, equitable and affordable

To work with HHS and other partners to make sure that the evidence is understood and used

Context: Dissemination of PCOR Findings



The Affordable Care Act of 2010 established a Patient-Centered Outcomes Research Trust Fund (PCORTF) to support comparative clinical effectiveness research

Section 937: AHRQ “shall **broadly disseminate the research findings** that are published by PCORI... and other government research relevant to comparative clinical effectiveness research.”

- **Patient-Centered Outcomes Research (PCOR)** is comparative clinical effectiveness research of the impact of two or more interventions on health outcomes
- PCOR produces not only **clinical findings**, but also evidence about the effectiveness of how health care is delivered, referred to in this RFA as **organizational practices**.

AHRQ D & I Initiatives

Learning While Implementing



- [Evidence Now: Cardiovascular Risk Reduction](#)
 - ▶ Building quality improvement capacity in small- to medium-sized primary care practices
- [TakeHeart: Cardiac Rehabilitation](#)
 - ▶ Scaling and spreading evidence-based strategies to increase cardiac rehab
- [Unhealthy Alcohol Use](#)
 - ▶ Integrating Behavioral Health and Primary Care
- [Managing Opioid Abuse in Rural Communities](#)
 - ▶ Increasing rural provider capacity to manage opioid use disorder
- Next generation of the [EvidenceNOW initiative](#)
 - ▶ Aligning primary care with public health and community services, building State capacity
- [INTUIT-PC: Urinary Incontinence:](#)
 - ▶ Aligning primary care with community services and specialty care, delivering patient-centered care to women in the context of multiple chronic conditions, potential for multilevel interventions

RFA Guidance

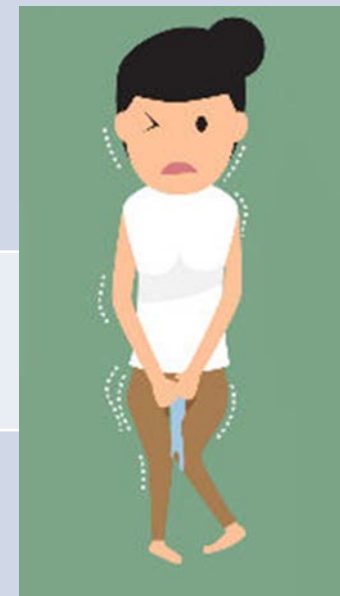


- ▶ Background
- ▶ Timeline
- ▶ Objectives
- ▶ Research Strategy
- ▶ Scored Review Criteria
- ▶ Specifics of this RFA

- ▶ **Note:** The RFA should be considered the source document for applications
- ▶ <https://grants.nih.gov/grants/guide/rfa-files/RFA-HS-21-001.html>

Background

Public Health Burden	✓ ~ 30% older women in U.S. report moderate to severe UI
Effective Nonsurgical Interventions	✓ Behavioral ✓ Medications ✓ Neuromodulation ✓ Combinations
Patient-Centered Outcomes	✓ Symptoms ✓ Cure
Evidence-Practice Gap	✓ <60% screened in Medicare ✓ <50% with symptoms seek care ✓ 30-50% treated
Fit with AHRQ	✓ Primary care improvement



RFA: Timeline Important Dates



- Open Date (Earliest Submission Date) **January 13, 2021**
- Letter of Intent Due Date **February 24, 2021**
- Application Due Date **March 24, 2021**
 - ▶ All applications are due by 5:00 PM YOUR local time
- Peer Review (estimated) **July 2021**
- Award date (estimated) **November 2021**

RFA Specifications



- U18 mechanism – **Cooperative Agreement**, with substantial AHRQ programmatic involvement
- Up to **5 awards**
- Total costs (direct and indirect) \leq \$2,000,000 in any year and **\$3,000,000** for the entire project
- May not exceed 3 years

RFA: Five “Must” Objectives



- 1. Increase the delivery of evidence-based care for UI among women**
- 2. Improve linkages** between primary care settings and needed supports
- 3. Include patient-centered** care plans
- 4. Design a sustainable** implementation plan
- 5. Evaluate** the effectiveness and **disseminate** findings

Objective 1: Increase the delivery of evidence-based UI care



- ▶ Convene a **team** with expertise and experience
- ▶ Define the **targeted region(s)** with ≥ 50 primary care practices, or a mix of practices that together reach $\geq 50,000$ adult women
- ▶ Propose evidence-based **implementation strategies** to increase the delivery of evidence-based care (diagnosis and nonsurgical treatments) for UI
 - may include home care or referral to specialty care, but **MUST** focus primarily on providing nonsurgical treatments **within the primary care practice**

Objective 1 (cont): **Increase the delivery** of evidence-based UI care



- ▶ In addition to the evidence on nonsurgical treatments for UI, applicants may identify **other evidence-based research**
- ▶ **Address barriers to diagnosis and treatment**, especially among disadvantaged populations and those with competing needs, including multiple chronic conditions (**caregiver and patient burden**)
- ▶ Propose innovative strategies to **reduce the potential burden on practices** that add UI care to the services they offer

Objectives 2 - 4

- 2. Improve linkages** between primary care settings and needed supports, such as community-based resources and specialty care
- 3. Develop patient-centered care plans** in the context of co-existing illness(es); strategies must demonstrate how they will **integrate shared decision-making techniques into practice**
- 4. Design a sustainable** implementation plan, so that changes become a routine element of care delivery, and efforts last after the end of funding (both UI treatment and capacity for practice improvement)

Objective 5: **Evaluate** the effectiveness of implementation strategies and **disseminate** findings



- Propose a robust evaluation
- Participate in a comprehensive program evaluation conducted by an **external contractor** selected by AHRQ
- Identify an **evaluation liaison** with expertise across the project to serve as a chief informant and coordinator with the external evaluator
- Propose to measure **one or more health outcomes**
- Propose a **dissemination plan**, including interim findings

Research Strategy



The Research Strategy section must include the following sections:

- A. Project Team and Partnerships
- B. Access to and Recruitment of Primary Care Practices
- C. Approach to PCOR Dissemination and Implementation
- D. Evaluation Plan
- E. Dissemination Plan
- F. Project Timeline

25 total pages across all of the sections

Research Strategy A: Project Team and Partnerships



- A 1. The proposed leadership and **governance structure** for the project, the **roles and responsibilities** of each organization, and how to ensure **collaboration and coordination**
- A 2. History of working together and prior successful joint projects
- A 3. Existing **relationships with primary care practices** within the targeted region(s)
- A 4. The **resources and expertise** of organizations and key personnel

Access to and Recruitment of Primary Care Practices



- **B 1. Define the targeted region (s) or population to be served**
 - Population demographics, health status, and UI risk factors
 - The healthcare/primary care practice environment
- **B 2. Describe plans for practice **recruitment**, including:**
 - The number of practices
 - How practices will be recruited and engaged
 - Potential barriers to recruitment/retention and mitigation strategies
- **B 3. Describe the **characteristics** of the practices that will be recruited, including:**
 - How population reflects diversity within the region, those most affected by UI, and inclusion of priority populations

Research Strategy C: Approach to PCOR D&I



- C 1. Include a **preliminary list of important PCOR evidence on nonsurgical treatment of UI** for women in primary care practices
- C 2. Describe an evidence-based, comprehensive approach to implementation using **strategies to accelerate incorporation** of nonsurgical treatment of UI in women and other clinical and organizational findings into practice
 - ▶ Also describe how the implementation will be **tailored** for practices that serve diverse populations

Research Strategy C (Cont): Approach to PCOR D&I



- C3. Provide the **conceptual** and/or **logic** model for the overall approach
- C4. Discuss **potential challenges and barriers** to executing the D&I approach and proposed **mitigation** strategies
- C5. Describe how the strategy will address **barriers to diagnosis and treatment in populations served**
- C6. Describe how implementation of evidence-based nonsurgical treatment of UI in women will be **sustained**
 - ▶ Both helping practices maintain improvements in UI care delivery and their capacity for change

Research Strategy D: **Evaluation Plan**



- D 1. Describe the **mixed-methods evaluation** approach, data sources, data collection, and analysis plan
- D 2. Work with AHRQ's external evaluator on the **cross-grant evaluation**, including allocating a team member as a liaison
- D 3. Examples of the cross-grant evaluation questions are
 - Process: How were strategies implemented?
 - Reach: Who was reached by the project?
 - Impact: Applicants must propose to measure one or more health outcomes

Research Strategy E: **Dissemination Plan**



- E 1. Describe plans for **sharing project progress**, insights into the implementation, and/or findings from the evaluation
- E 2. Describe how the project could be **replicated** in other regions/practice groups
- E 3. Document a commitment to **cooperating** with AHRQ and its contractors in disseminating information about the project

Research Strategy F: **Project Timeline**



- F 1. Provide a **project timeline** showing the major scheduled activities and milestones for the project
 - Startup activities (e.g., hiring and training staff)
 - Practice recruitment
 - Implementation of intervention
 - Data collection
 - Project closeout (e.g., completion of project within 36 months)
- F 2. Include an example timeline for working with an **individual primary care practice**

Scored Review Criteria Categories

- **Significance**
- **Investigator(s)/Personnel**
- **Innovation**
- **Approach**
- **Environment**

Review Criteria to Highlight for this RFA



- **Significance**

- Is the proposed project likely to result in D&I of PCOR findings **directly to primary care practices**?
- Is the proposed project likely to improve **implementation** of nonsurgical treatment of UI to **women in primary care practices**?

- **Investigator/Personnel:**

- Is the single PI (or multiple PI(s) combined) devoting at least **20% FTE** ?
- Is there an **evaluation liaison**, and is this individual devoting at least **10% FTE**?

Review Criteria to Highlight for this FOA (cont)



- **Innovation**

- In this FOA, using an established implementation strategy in a new context (e.g., among women, for urinary incontinence, or in primary care) is considered innovative

Review Criteria to Highlight for this FOA (cont)



● Approach

- Does the team have **existing relationships** to ensure that the project can start quickly and deliver within the proposed timeline?
- Is the **recruitment plan** realistic and likely to succeed ?
- Does the **patient population** served reflect the **diversity** within the region and/or the populations most affected by UI, and underserved communities?
- Do they include an appropriate plan to **identify and select interventions** to implement to improve UI in women?
- Do they describe how they will **identify and incorporate changing evidence** as guidance and findings evolve?
- Do they address **sustainability** beyond the project timeframe?
- Do they articulate a **robust evaluation plan** that will produce results that are meaningful and valid?

Review Criteria to Highlight for this FOA (cont)



Environment

- Does the project benefit from **features of the region**?
- Have potential environmental **obstacles** and the means for **avoiding or mitigating** their effects been identified?
- If D&I expansions are proposed, have problems or learning from **prior experience** been acknowledged/properly anticipated, and are **possible resolutions proposed**?

Funding Decisions

The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review
- Availability of funds
- Responsiveness to goals and objectives of the FOA
- Relevance and fit within AHRQ research priorities, as well as overall **programmatic and geographic balance** of the proposed project to program priorities

Requirements of Note

- Single IRB requirements
 - ▶ **Reliance on a single IRB of record in cooperative research is required beginning January 20, 2020**, unless the study meets the criteria for an exception described in §46.114(b)(2) of the Revised Common Rule
 - ▶ Details on slide 41
- Program planning and performance reporting requirements

Program Planning and Performance Reporting Requirements:



Recipients' performance will be measured based on success in the following program goals:

Goal	Question	Performance measures	Timeline:
Reach	Who was reached by the project?	Number of practices, clinicians, and patients reached by the implementation	Reach target by year 3
Process	How were strategies implemented?	Number and types of personnel working with practices to support implementation, List of strategies implemented	Reach target by year 3
Impact	Do health outcomes improve?	One or more health outcomes (such as UI symptoms or patient satisfaction) will be collected for the evaluation	Specific outcomes determined in year 1, Data collected through year 3

These are in line with the proposed evaluation questions described in Research Plan Section D: Evaluation

Q. Who can apply?

1. Can we apply as a non-U.S. organization?
2. Is the announcement targeted to PIs/Institutions with prior AHRQ primary care funding (Evidence Now, Unhealthy Alcohol)?

A:

1. AHRQ FOAs do not allow foreign institutions to submit grant applications but **do allow** foreign institutions to participate in projects as members of consortia or as subcontractors only.
2. All eligible institutions listed in Section III of the RFA are encouraged to apply.

Q: What evidence-based interventions can we propose to include as care for UI?

1. Are we limited to the evidence-based interventions listed in the 2018 systematic review referenced in the RFA?
2. Is any nonsurgical protocol appropriate for the trial, or only protocols that would be appropriate for generalist care?

A:

Applicants may propose any nonsurgical care or treatment for UI that is evidence-based (shown to be effective and safe in women with UI).

Q. What implementation strategies can be used?

- If an intervention or strategy is proven effective in one setting, can we apply to a new setting?
- Can we propose strategies using mobile technology?

A. Yes, using an established implementation strategy in a new context (e.g., among women, for urinary incontinence, or in primary care) is considered innovative.

FAQ-4

Q: Can we propose linking patients to community resources and specialists? Can we target interventions to women in the community?

A: Grantees must improve linkages between primary care settings and needed supports.

- ▶ Grantees may include home care, community, or referral to specialty care, but **MUST** focus primarily on providing nonsurgical treatments **within the primary care practice.**

Q: Should we measure patient-centered outcomes?

A. Yes. This is a measure of the impact of the FOA.

- Since improving health outcomes is an important ultimate goal of PCOR and this FOA, applications must propose to measure one or more health outcomes.
 - ▶ (for example, UI symptoms, patient satisfaction, and surgical intervention rates)

Q: Can we provide incentives/compensation to patients or providers?

A: The RFA does not specify.

- However, the objectives, research strategy, and review criteria state that the grantee is expected to design a **sustainable** implementation plan, so that changes become a routine element of care delivery, and efforts last after the end of funding (for both UI treatment implementation and capacity for practice improvement).

Q: Who will perform the outside evaluation?

A: AHRQ expects to award a separate contract to an independent entity to manage the evaluation. All grantees are required to participate in the evaluation.

Other Questions?



OTHER QUESTIONS?

Submit your questions using the Chat function

Q: Would OB/Gyn practices count as primary care?

A: We did not exclude them, and some OB/GYN practices provide primary care.

- The RFA describes primary care practices as those who are accountable for addressing a large majority of personal healthcare needs, including prevention and health promotion, developing a sustained partnership with patients, and practicing in the context of family and community.
- The RFA states : Primary care practice settings may include community health centers and women’s health providers that serve adult women in that region.

FAQ-9

Q: Can we incorporate primary care practices in the Department of Veterans Affairs Health Care System?

A: VA sites are not excluded. The RFA describes primary care practices as those who are accountable for addressing a large majority of personal health care needs, including prevention and health promotion, developing a sustained partnership with patients, and practicing in the context of family and community.

FAQ-10

Q: We have found there is no or very little regional data on Women with Incontinence. How do we overcome this lack of data in completing section B. that asks for information on

“Population demographics, particularly with regard to urinary incontinence or risk factors for urinary incontinence”?

A: The RFA asks for data on the population that might be at increased risk for UI, such as older women, or those with obesity. Some regions might be able to estimate that data, or even data on surgical procedures for UI as a proxy measure.

FAQ-11



Q: If AHRQ will provide an external evaluator, should we still include an external evaluator in our budget?

A: AHRQ will be conducting an overarching, cross-grantee evaluation. Each applicant will need to designate an evaluation liaison at 10% FTE to support the overarching evaluation. In addition, you may propose whatever personnel you need to accomplish your own project's evaluation as described in section D of the research strategy.

FAQ-12

Q: Does the 50K women, mean all women served by the practices or 50k women with UI? Do we have to collect UI on 50,000 women? Can we include patients who are provided with educational materials in addition to women who are directly treated with the nonsurgical methods of treatment?

A:

- The RFA requires 50,000 adult women to be available in the mix of practices, that is: 50,000 who could be reached by an implementation strategy.
- Not all of them will have UI, or will have outcomes collected.
- Providing educational materials does not meet the definition of an evidence-based strategy in this RFA.

Q: Should the 50 primary care sites be within a single geographic region, or could our sites be spread across a few locations?

A:

- The RFA does not require a contiguous geographic location. All proposed locations should be justified by strong relationships or a system that will enable success.

Single IRB Requirement



- <https://www.ahrq.gov/funding/policies/human-subjects/index.html>
- The Revised Common Rule, at 45 CFR 46.114 (b) (**cooperative research**), requires all institutions located in the United States that are engaged in cooperative research conducted or supported by a Common Rule department or agency **rely upon approval by a single IRB for the portion of the research that is conducted in the United States.**
- The reviewing IRB will be identified by the Federal department or agency supporting or conducting the research or **proposed by the lead institution** subject to the acceptance of the Federal department or agency supporting the research.
- **Reliance on a single IRB of record in cooperative research is required beginning January 20, 2020**, unless the study meets the criteria for an exception described in §46.114(b)(2) of the Revised Common Rule.
- [AHRQ Guide Notice on Implementation of the Use of a Single Institutional Review Board \(IRB\) for Cooperative Research at 45 CFR 46.114 \(b\).](#)
- [AHRQ Guide Notice on Exception to the Use of the Single IRB Review Requirements During the Coronavirus Disease 2019 \(COVID-19\) Public Health Emergency.](#)

Links of Interest

- <https://www.ahrq.gov/evidencenow/index.html>
- <https://takeheart.ahrq.gov/>
- <https://integrationacademy.ahrq.gov/about/initiatives/alcohol>
- <https://integrationacademy.ahrq.gov/about/initiatives/opioid>
- <https://www.ahrq.gov/pcor/dissemination-of-pcor/ahrq-pcor-dissemination-investments.html>
- <https://www.pcori.org/research-results/2017/nonsurgical-treatments-urinary-incontinence-women-systematic-review-update>
- <https://www.pcori.org/research-results/evidence-synthesis/evidence-maps-and-evidence-visualizations/effect-pelvic-floor>

Final Comments



- Application Due Date **March 24, 2021**

- Questions:

UI_grant@ahrq.hhs.gov

- This presentation will be posted on the AHRQ website
- Refer to the RFA as the final source

<https://grants.nih.gov/grants/guide/rfa-files/RFA-HS-21-001.html>