chloride, trospium chloride, darifenacin, solifenacin succinate, fesoterodine, tolterodine, propiverine); calcium channel blockers (*e.g.,* nimodipine); botulinum toxin injections; TRPV1 antagonists (*e.g.,* resiniferatoxin); antidepressants (*e.g.,* tricyclics, SSRI, SNRI); beta-3 adeno-receptor agonists (*e.g.,* mirabegron).

Combinations of eligible nonpharmacological and pharmacological interventions.

Exclusion

Interventions not available in the United States and surgical treatments.

*Comparator*

Inclusion

Other eligible nonpharmacological interventions, other eligible pharmacological interventions, other eligible combination interventions, no active treatment or placebo.

Exclusion

Noneligible interventions, including surgery.

*Outcomes*

Inclusion

Measures of UI: Pad tests and other measures of leakage volumes; incontinence counts/frequency (*e.g.,* by diary), including urgency UI counts/frequency and stress UI counts/frequency; physical examination (*e.g.,* cough stress test); complete remission, improvement (partial remission), worsening, no change; subjective bladder control; patient satisfaction with intervention; need to use protection.

Quality of life and related questionnaires: Generic, validated; UI-specific, validated.

Other patient-centered outcomes, based on the findings of the contextual question (what defines a successful outcome).

Adverse events.

Exclusion

Bladder and pelvic tests that do not measure UI specifically or are used for diagnostic purposes (*e.g.,* urodynamic testing, pelvic muscle strength); urination measures that do not measure UI specifically (*e.g.,* total voids [that include nonincontinence voids], catheterization, postvoid residuals, urinary retention, perceived micturition difficulty).

*Timing*

Inclusion

Minimum 4 weeks follow up (since the start of treatment).

Exclusion

None.

*Settings*

Inclusion

Interventions provided in primary care or specialized clinic or equivalent by any healthcare provider; participants are community-dwelling.

Exclusion

Surgical, institutionalized, or in-hospital settings.

Country setting.

Inclusion

Any geographic area.

Exclusion

None.

*Study Designs*

Inclusion

For effectiveness outcomes: Randomized controlled trials (RCTs), with no minimum sample size, including pooled individual patient data from RCTs; nonrandomized comparative studies that used strategies to reduce bias (*e.g.,* adjustment, stratification, matching, or propensity scores), N≥50 women per group (N≥100 women total).

For harms outcomes: RCTs, with no minimum sample size; nonrandomized longitudinal comparative studies (regardless of strategies to reduce bias), including registries or large databases, N≥50 women per group (N≥100 women total); single arm longitudinal studies, including registries, large databases, and large case series N≥100 women; case-control studies (where cases are selected based on presence of harm), N≥50 female cases and ≥50 female controls (N≥100 women total).

All outcomes: Published, peer-reviewed articles or unpublished data from the Food and Drug Administration (FDA) or from the Web site *ClinicalTrials.gov.*

Exclusion

For effectiveness outcomes: Single group, case-control, and case report/series studies; nonrandomized comparative studies with only crude or unadjusted data.

Publication language.

Inclusion

Any.

Exclusion

Unable to read or translate.

**Sharon B. Arnold,**

*Deputy Director.*

[FR Doc. 2017–15799 Filed 7–26–17; 8:45 am]

**BILLING CODE 4160–90–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Agency for Healthcare Research and Quality, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ''*The AHRQ Safety Program for Improving Antibiotic Use.*''

This proposed information collection was previously published in the **Federal Register** on May 5, 2017, and allowed 60 days for public comment. AHRQ did not receive any substantive comments. The purpose of this notice is to allow an additional 30 days for public comment.

**DATES:** Comments on this notice must be received by August 28, 2017.

**ADDRESSES:** Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

**FOR FURTHER INFORMATION CONTACT:** Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

**Proposed Project**

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection. Antibiotics can have serious adverse effects including *Clostridium difficile* infections, organ dysfunction, allergic reactions, and the development of antibiotic resistance on both a patient level and population level. This project will assist acute care, long-term care and ambulatory care settings across the United States in adopting and implementing antibiotic stewardship

programs, which are coordinated efforts to improve the use of antibiotics by promoting the selection of the optimal antibiotic regimen, dose, route of administration, and duration of therapy.

More specifically, this project has the following goals:

- Identify best practices in the delivery of antibiotic stewardship in the acute care, long-term care and ambulatory care settings.
- Adapt the Comprehensive Unit-Based Safety Program (CUSP) model to enhance antibiotic stewardship efforts in the health care settings.
- Assess the adoption of CUSP for antibiotic stewardship and evaluate the effectiveness of the intervention in the participating health care systems.
- Develop a bundle of technical and adaptive interventions and associated tools and educational materials designed to support enhanced antibiotic stewardship efforts.
- Provide technical assistance and training to health care organizations nationwide, using a phased approach, to implement effective antibiotic stewardship programs and interventions.
- Improve communication and teamwork between health care workers surrounding antibiotic decision-making.
- Improve communication between health care workers and patients/families surrounding antibiotic decision-making.

This study is being conducted by AHRQ through its contractor Johns Hopkins University, with subcontracted partner NORC. The *AHRQ Safety Program for Improving Antibiotic Use* is being undertaken pursuant to AHRQ's mission to enhance the quality, appropriateness, and effectiveness of health services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. 42 U.S.C. 299.

**Method of Collection**

To achieve the goals of this project the following data collections will be implemented:

(1) *Structural Assessments:* A brief (five to seven questions), online Structural Assessment Tool will be administered in all settings at baseline (pre-intervention) and at the end of the intervention period to obtain general information about facilities and existing stewardship infrastructure and changes in stewardship infrastructure and interventions as a result of the AHRQ Safety Program.

(2) *Team Antibiotic Review Form:* The Stewardship Team will conduct monthly reviews of at least 10 patients who received antibiotics and fill out an assessment tool in conjunction with frontline staff to determine if the ''four moments of antibiotic decision-making'' are being considered by providers. The four moments are (1) Is an infection present requiring antibiotics? (2) Were appropriate cultures ordered and best initial choice of antibiotics made? (3) (after at least 24 hours) Are changes in antibiotic orders appropriate? (4) What duration of therapy is appropriate?

(3) The AHRQ Surveys on Patient Safety Culture will be administered to all participating staff at the beginning and end of the intervention. Each survey asks questions about patient safety issues, medical errors, and event reporting in the respective settings.

a. The Hospital Survey on Patient Safety Culture will be utilized to evaluate safety culture for acute care hospitals.

b. The Nursing Home Survey on Patient Safety Culture will be administered in long term care.

c. The Medical Office Survey on Patient Safety Culture will be administered in ambulatory care centers.

(4) *Semi-Structured Qualitative Interviews:* In-person and/or telephone discussions will be held before and after implementation with stewardship champions/organizational leaders, physicians, pharmacists, nurse practitioners, physician assistants, nurses, certified nursing assistants and others deemed relevant, to learn about the facilitators and barriers to a successful antibiotic stewardship program. Specific areas of interest include stakeholder perceptions of implementation process and outcomes, including successes and challenges with carrying out project tasks and perceived utility of the project; staff roles, engagement and support; and antibiotic prescribing etiquette & culture (*i.e.,* social norms and local cultural factors that contribute to prescribing behavior at the facility/unit-level).

(5) *Electronic Health Record (EHR) Data:* Unit-level antibiotic usage and clinical outcomes will be extracted from the EHRs of participating health care facilities and used to assess the impact of the AHRQ Safety Program for Improving Antibiotic Use.

**Estimated Annual Respondent Burden**

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

| Form name | Number of respondents | Number of responses per respondent | Hours per response | Total burden hours |
|---|---|---|---|---|
| 1. Structural Assessment | 500 | 2 | 0.2 | 200 |
| 2. Team Antibiotic Review Form | 333 | 90 | 0.2 | 5,994 |
| 3. Surveys on Patient Safety Culture (SOPS) | | | | |
| a. HSOPS | 4,167 | 2 | .5 | 4,167 |
| b. NHSOPS | 4,167 | 2 | .5 | 4,167 |
| c. MOSOPS | 4,167 | 2 | .5 | 4,167 |
| 4. Semi-structured qualitative interviews (Physicians—line 1; Other Health Practitioners—line 2 | 30 | 2 | 1 | 60 |
| | 60 | 2 | 1 | 120 |
| 5. EHR data | 500 | 12 | .5 | 3,000 |
| Total | 13,924 | N/A | N/A | 21,875 |

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

| Form name | Number of respondents | Total burden hours | Average hourly wage rate* ($) | Total cost burden ($) |
|---|---|---|---|---|
| 1. Structural Assessment | 500 | 200 | [a] 98.83 | 19,766 |
| 2. Team Antibiotic Review Form | 333 | 5,994 | [a] 98.83 | 592,387 |
| 3. SOPS | | | | |
| a. HSOPS | 4,167 | 4,167 | [b] 27.87 | 116,134 |
| b. NHSOPS | 4,167 | 4,167 | [b] 27.87 | 116,134 |
| c. MOSOPS | 4,167 | 4,167 | [b] 27.87 | 116,134 |
| 4. Semi-structured qualitative interviews (Physicians—line 1; Other Health Practitioners—line 2 | 30 | 60 | [a] 98.83 | 5,930 |
| | 60 | 120 | [b] 27.87 | 3,344 |
| 5. EHR data | 500 | 3,000 | [b] 27.87 | 83,610 |
| Total | 13,924 | 21,875 | N/A | 1,053,439 |

National Compensation Survey: Occupational wages in the United States May 2016 ''U.S. Department of Labor, Bureau of Labor Statistics:'' *http://www.bls.gov/oes/current/oes_stru.htm*

[a] Based on the mean wages for *29–1069 Physicians and Surgeons, All Other*

[b] Based on the mean wages for *29–9099 Miscellaneous Health Practitioners and Technical Workers: Healthcare Practitioners and Technical Workers, All Other*

**Request for Comments**

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology. Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

**Sharon B. Arnold,**

*Deputy Director.*

[FR Doc. 2017–15796 Filed 7–26–17; 8:45 am]

**BILLING CODE 4160–90–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Agency for Healthcare Research and Quality

### Agency Information Collection Activities: Proposed Collection; Comment Request

**AGENCY:** Agency for Healthcare Research and Quality, HHS.

**ACTION:** Notice.

**SUMMARY:** This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project ''*Implementation of TeamSTEPPS in Primary Care Settings (ITS–PC).*'' This proposed information collection was previously published in the **Federal Register** on May 5, 2017 and allowed 60 days for public comment. No substantive comments were received.

**DATES:** Comments on this notice must be received by August 28, 2017.

**ADDRESSES:** Written comments should be submitted to: AHRQ's OMB Desk Officer by fax at (202) 395–6974 (attention: AHRQ's desk officer) or by email at *OIRA_submission@omb.eop.gov* (attention: AHRQ's desk officer).

**FOR FURTHER INFORMATION CONTACT:** Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

**Proposed Project**

''*Implementation of TeamSTEPPS in Primary Care Settings (ITS–PC)*''

In accordance with the Paperwork Reduction Act, 44 U.S.C. 3501–3521, AHRQ invites the public to comment on this proposed information collection. As part of its effort to fulfill its mission, AHRQ, in collaboration with the Department of Defense's (DoD) Tricare Management Activity, developed TeamSTEPPS® (Team Strategies and Tools for Enhancing Performance and Patient Safety) to provide an evidence-based suite of tools and strategies for training teamwork-based patient safety to health care professionals. TeamSTEPPS includes multiple toolkits which are all tied to, or are variants of, the core curriculum. In addition to the core curriculum, TeamSTEPPS resources have been developed for primary care, rapid response systems, long-term care, and patients with limited English proficiency.

The main objective of the TeamSTEPPS program is to improve patient safety by training health care staff in various teamwork, communication, and patient safety concepts, tools, and techniques and ultimately helping to build national capacity for supporting teamwork-based patient safety efforts in health care organizations.

Created in 2007, AHRQ's National Implementation Program has trained Master Trainers who have stimulated the use and adoption of TeamSTEPPS in health care delivery systems. These individuals were trained using the TeamSTEPPS core curriculum at regional training centers across the U.S. AHRQ has also provided technical