- For tumor response, no minimum follow-up
- For harms due to overtreatment or undertreatment, no minimum follow-up
- For survival and quality of life, at least six months minimum follow-up

Setting

Any setting.

Dated: December 29, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2015–00762 Filed 1–20–15; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Treatments for Fecal Incontinence

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS

ACTION: Request for scientific information submissions.

SUMMARY: The Agency for Healthcare Research and Quality (AHRQ) is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of Treatments for Fecal Incontinence, which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Programs. Access to published and unpublished pertinent scientific information will improve the quality of this review. AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: Submission Deadline on or before February 20, 2015.

ADDRESSES:

Online submissions: http://effectivehealthcare.AHRQ.gov/index.cfm/submit-scientific-information-packets/. Please select the study for which you are submitting information from the list to upload your documents.

Email submissions: SIPS@epc-src.org.

Print submissions:

Mailing Address:

Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, PO Box 69539, Portland, OR 97239.

Shipping Address (FedEx, UPS, etc.):

Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, 3710 SW U.S. Veterans Hospital Road, Mail Code: R&D 71, Portland, OR 97239.

FOR FURTHER INFORMATION CONTACT: Ryan McKenna, Telephone: 503–220–8262 ext. 58653 or Email: *SIPS@epc-src.org.*

SUPPLEMENTARY INFORMATION:

The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Programs to complete a review of the evidence for Treatments for Fecal Incontinence.

The EPC Program is dedicated to identifying as many studies as possible that are relevant to the questions for each of its reviews. In order to do so, we are supplementing the usual manual and electronic database searches of the literature by requesting information from the public (*e.g.,* details of studies conducted). We are looking for studies that report on Treatments for Fecal Incontinence, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2013.*

This notice is to notify the public that the EPC Program would find the following information on Treatments for Fecal Incontinence (FI) helpful:

- A list of completed studies that your organization has sponsored for this indication. In the list, please indicate whether results are available on *ClinicalTrials.gov* along with the *ClinicalTrials.gov* trial number.
- For completed studies that do not have results on ClinicalTrials.gov, please provide a summary, including the following elements: study number, study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, primary and secondary outcomes, baseline characteristics, number of patients screened/eligible/enrolled/lost to follow-up/withdrawn/analyzed, effectiveness/efficacy, and safety results.
- A list of ongoing studies that your organization has sponsored for this indication. In the list, please provide the ClinicalTrials.gov trial number or, if the trial is not registered, the protocol for the study including a study number, the study period, design, methodology, indication and diagnosis, proper use instructions, inclusion and exclusion criteria, and primary and secondary outcomes.
- Description of whether the above studies constitute all Phase II and above clinical trials sponsored by your organization for this indication and an index outlining the relevant information in each submitted file.

Your contribution will be very beneficial to the EPC Program. The contents of all submissions will be made available to the public upon request. Materials submitted must be publicly available or can be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on indications not included in the review cannot be used by the EPC Program. This is a voluntary request for information, and all costs for complying with this request must be borne by the submitter.

The draft of this review will be posted on AHRQ's EPC Program Web site and available for public comment for a period of 4 weeks. If you would like to be notified when the draft is posted, please sign up for the email list at: *http://effectivehealthcare.AHRQ.gov/index.cfm/join-the-email-list1/.*

The systematic review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions. The entire research protocol, is available online at: *http://effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2013.*

The Key Questions

Key Question 1

What is the comparative effectiveness of treatments to improve quality of life and continence and lessen the severity of FI in affected adults?

Key Question 2

What adverse effects are associated with specific treatments for adults with FI?

PICOTS

The PICOTS Framework (Population, Intervention, Comparator, Outcomes, Timing, Setting) will be identified for each key question.

Population

We will include adults with FI and classify them within the etiologic categories listed below, and by adult age groups (geriatric versus other). Whenever possible, we will examine treatment effects within etiologic subgroups of adults, since affected individuals are highly heterogeneous and not all treatments are feasible for specific subgroups. Patients with FI due to spinal cord injury will be separately evaluated. Adults with fistulas will be excluded. The possible associations of

treatments and etiologic subgroups are shown in Appendix A of the research protocol.

Potential Subgroups Include:

- Structural (damage or variants)
  - Anal sphincter
    - Injury (often due to episiotomy): from muscle damage and/or nerve damage
    - Damage from surgery (for hemorrhoids or cancer [after anal, rectal or colon resection]) or underlying systemic condition (such as scleroderma)
  - Pelvic floor
    - Weakening (atrophy), prolapse (pelvic organs, rectal), or stretching (chronic constipation)
  - Rectal
    - Post-radiation (mainly for prostate and rectal cancer)
    - Rectal filling and storage problems
    - Hemorrhoids
    - Rectocele
  - Congenital malformations (anorectal, anal sphincter)
- Alterations in gastrointestinal motility or fecal texture (due to conditions or ingestibles)
  - Crohn's disease, ulcerative colitis, irritable bowel syndrome
  - Medications
  - Autoimmune disorders (such as systemic lupus erythematosus)
- Neurogenic etiologies
  - Nerve injury to pelvic floor
  - Spinal cord injury, spina bifida
  - Traumatic brain injury
  - Stroke
  - Neurodegenerative diseases (such as multiple sclerosis, multiple system atrophy, Shy-Drager syndrome, etc.)
- Multiple
  - Any combination of above etiologies
- Unknown
  - FI etiology(ies) unknown or not reported

Interventions

We will include FDA-approved treatments for FI and FDA-approved medications used off-label (not specifically approved for the treatment of FI) and available for use in the United States. Interventions that do not require FDA approval and are used in the United States will be included. Since a number of treatments that are not FDA-approved are commonly used in Europe, the following additional specifications will apply:

- If the device is FDA approved for an indication and is used off label for FI, we will include the studies (*e.g.,* rectal irrigation).
- If a device is FDA approved under a certain brand name for FI (*e.g.,* anal plugs), and there are studies that compare it to other brands approved only in Europe, we will include those studies.

Colostomy, treatments for diarrhea (not FI), and laxatives used to treat stool impaction will be excluded.

- Nonsurgical
  - Functional enhancement therapies (muscle training/biofeedback/electrostimulation):
    - Pelvic floor muscle training exercises (PFMT)
    - PFMT with biofeedback (using electrical or ultrasound sensors) EMG
    - PFMT with biofeedback, plus electrostimulation
  - Dietary modifications: Fiber, probiotic supplements, other
  - Medications: such as
    - Antidiarrheal or constipating drugs (such as loperamide hydrochloride [*e.g.,* Imodium®], diphenoxylate plus atropine [*e.g.,* Lomoti1®], codeine)
    - Sphincter function enhancers (topical phenylepinephrine gel, sodium valproate)
    - Other bowel-affecting drugs: Anticholinergics (hyoscyamine sulfate), tricyclic agents (amitriptyline, imipramine)
  - Behavior modification
  - Stool consistency management
  - Devices: anal plugs
  - Rectal irrigation
  - Injections of local biocompatible tissue-bulking agent (into the anal canal walls)
    - Dextranomer in stabilized sodium hyaluronate (Solesta®)
- Surgical
  - Implanted neurostimulation (sacral nerve stimulators)
  - Radiofrequency anal sphincter remodeling (SECCA)—(may be in-office procedure)
  - Anal sphincter repair (sphincteroplasty or muscle transposition)
  - Sphincter replacement (artificial anal sphincter)
  - Surgical correction of condition that led to FI (such as rectal prolapse, hemorrhoids, or rectocele)
- Combined treatments: any combination

Comparators

All other treatment options, alone or in combination. Where available, trials with placebo or sham controls will be included.

Outcomes

The review will focus on patient-important outcomes as listed below. Intermediate outcomes, such as physiologic measures of sphincter function (electromyography (EMG) recruitment, direct EMG [pudendal nerve terminal motor latency test], anorectal manometry, defecography, etc.), will not be examined due to the lack of correlation with patient-important outcomes.

Key Question 1 (Final health outcomes)

- Quality of Life (multiple scales, such as the Fecal Incontinence Quality of Life [FIQL],25 Gastrointestinal Quality of Life Index, or the Medical Outcomes Survey 36-item health survey (SF–36), others)
- Reduced frequency of incontinence episodes (bowel diaries, episode counts, etc.)
- Reduced severity of incontinence (volume and type of leakage; the use of coping behaviors): multiple scales such as the Fecal Incontinence Severity Index [FISI], Jorge/Wexner (Cleveland Clinic) Incontinence Score, Vaizey/St. Mark's Hospital incontinence score, Pescatori, Miller Incontinence Score, and others.
- Urgency
- Emotional and psychological outcomes (fear, shame, embarrassment, depression, humiliation, anger, etc.): FIQL subscales, Euro-QoL 5D (anxiety/depression subscale)
- Change (reduction) in coping behaviors relative to FI management
- Social activity
- Sexual function

Key Question 2 (Adverse effects of specific treatments)

- Pain: abdominal, other
- Worsening of FI (frequency, severity)
- Constipation and/or diarrhea
- Other gastrointestinal symptoms (such as cramping, bloating, etc.)
- Difficulty evacuating bowels
- Headache
- Nausea
- Change in appetite
- Local dermatitis
- Surgical complications (infection, revision surgery, etc.)
- Negative emotional/psychological effects (depression, anger, etc.)
- Other adverse effect(s) related to treatment (skin breakdown, urinary tract infection, etc.)

Timing

Duration of follow up: Since FI is a chronic condition, studies with at least 3 months of follow up after treatment initiation are the main focus of the review. However, since some interventions may have only short follow up (such as medications or

dietary interventions), we will include all studies that otherwise meet the selection criteria to allow us to make overarching comments about the status of the FI treatment-outcomes literature in the final report.

Setting

Any setting (community dwelling, long-term care, other).

Dated: December 30, 2014.

Richard Kronick,

AHRQ Director.

[FR Doc. 2015–00764 Filed 1–20–15; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Performance Measures for Community-Centered Healthy Marriage, Pathways to Responsible Fatherhood and Community-Centered Responsible Fatherhood Ex-Prisoner Reentry grant programs.

OMB No.: 0970–0365—Reinstatement with changes of a previously approved collection.

Description: The Office of Family Assistance (OFA), Administration for Children and Families (ACF), U.S. Department of Health and Human Services (HHS), intends to request approval from the Office of Management and Budget (OMB) to renew OMB Form 0970–0365 for the collection of performance measures from grantees for the Community-Centered Healthy Marriage, Pathways to Responsible Fatherhood and Community-Centered Responsible Fatherhood Ex-Prisoner Reentry discretionary grant programs. The performance measure data obtained from the grantees will be used by OFA to report on the overall performance of these grant programs.

Data will be collected from all 60 Community-Centered Healthy Marriage, 54 Pathways to Responsible Fatherhood and 5 Community-Centered Responsible Fatherhood Ex-Prisoner Reentry grantees in the OFA programs. Grantees will report on program and participant outcomes in such areas as participants' improvement in knowledge skills, attitudes, and behaviors related to healthy marriage and responsible fatherhood. Grantees will be asked to input data for selected outcomes for activities funded under the grants. Grantees will extract data from program records and will report the data twice yearly through an on-line data collection tool. Training and assistance will be provided to grantees to support this data collection process.

Respondents: Office of Family Assistance Funded Community-Centered Healthy Marriage, Pathways to Responsible Fatherhood and Community-Centered Responsible Fatherhood Ex-Prisoner Reentry Grantees.

ANNUAL BURDEN ESTIMATES

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total annual burden hours
Performance measure reporting form (for private sector affected public)	110	2	0.8	176
Performance measure reporting form (for State, local, and tribal government affected public)	9	2	0.8	14
Estimated Total Annual Burden Hours				190

In compliance with the requirements of Section 506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Planning, Research and Evaluation, 370 L'Enfant Promenade SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. Email address: *infocollection@acf.hhs.gov.* All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 2015–00809 Filed 1–20–15; 8:45 am]

BILLING CODE 4184–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–N–0500]

Agency Information Collection Activities; Proposed Collection; Comment Request; Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of