Settings

- As described for KQ 1.

Key Question 4

What is the effect of vitamin D or combined vitamin D and calcium intake on serum 25(OH)D concentrations?

Populations

- As described for KQ 1.

Interventions

- Randomized controlled trials (RCTs) identified to answer all other KQs.

Comparators

- Placebo or lower dose supplement.

Outcomes

- Dose-response relationship between intake levels and indices of exposure.

Timing

- As described for KQs 1 and 2.

Settings

- As described for KQs 1 and 2.

Key Question 5

What is the association between serum 25(OH)D concentration and surrogate or intermediate outcomes?

Populations

- As described for KQ 2.

Interventions

- As described for KQ 2.

Comparators

- As described for KQ 2.

Outcomes

- As described for KQ 2.

Timing

- As described for KQ 2.

Settings

- As described for KQ 2.

Dated: June 21, 2013.

Carolyn M. Clancy,

Director, AHRQ.

[FR Doc. 2013–15730 Filed 7–2–13; 8:45 am]

BILLING CODE 4160–90–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Chronic Urinary Retention (CUR) Treatment

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 on medical devices to treat chronic urinary retention. Scientific information is being solicited to inform our review of chronic urinary retention (CUR) treatment, which is currently being conducted by the Evidence-based Practice Centers for the AHRQ Effective Health Care Program. Access to published and unpublished pertinent scientific information on medical devices to treat chronic urinary retention will improve the quality of this review. AHRQ is conducting this comparative effectiveness review pursuant to Section 1013 of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Public Law 108–173, and Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

DATES: Submission Deadline on or before August 2, 2013.

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: Robin Paynter, Research Librarian, Telephone: 503–220–8262 ext. 58652 or Email: *SIPS@epc-src.org.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a review of the evidence for chronic urinary retention (CUR) treatment.

The EHC 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 chronic urinary retention treatment, including those that describe adverse events, as specified in the key questions detailed below. The entire research protocol, including the key questions, is also available online at: *http://www.effectivehealthcare.AHRQ.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=1539*.

This notice is to notify the public that the EHC program would find the following information on medical devices to treat chronic urinary retention helpful:

- A list of completed studies your company has sponsored for this indication. In the list, 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, 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 your company 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 company for this indication and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. The contents of all 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 Effective Health Care 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 EHC 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/*.

Key Questions

KQ 1: What is the effectiveness and comparative effectiveness of treatments for CUR in adults:

- With male-specific etiologies?
- With female-specific etiologies?
- With non-sex-specific etiologies?

KQ 1a: What patient or condition characteristics (e.g., age, severity, etc.) modify the effectiveness of treatment?

KQ 2: What are the harms and comparative harms of treatments for CUR in adults:

- With male-specific etiologies?
- With female-specific etiologies?
- With non-sex-specific etiologies?

KQ 2a: What patient or condition characteristics (e.g., age, severity, etc.) modify the harms of treatment?

Dated: June 21, 2013.

Carolyn M. Clancy,

AHRQ, Director.

[FR Doc. 2013–15729 Filed 7–2–13; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30-Day 13–0106]

Agency Forms Undergoing Paperwork Reduction Act Review

The Centers for Disease Control and Prevention (CDC) publishes a list of information collection requests under review by the Office of Management and Budget (OMB) in compliance with the Paperwork Reduction Act (44 U.S.C. Chapter 35). To request a copy of these requests, call (404) 639–7570 or send an email to *omb@cdc.gov.* Send written comments to CDC Desk Officer, Office of Management and Budget, Washington, DC 20503 or by fax to (202) 395–5806. Written comments should be received within 30 days of this notice.

Proposed Project

Preventive Health and Health Services Block Grant (OMB No. 0920–0106, exp. 7/31/2013)—Revision—National Center for Chronic Disease Prevention and Health Promotion (NCCDPHP), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The Preventive Health and Health Services (PHHS) Block Grant program was established to provide awardees with a source of flexible funding for health promotion and disease prevention programs. Currently, 61 awardees (50 states, the District of Columbia, two American Indian Tribes, and eight U.S. territories) receive Block Grants to address locally-defined public health needs in innovative ways. Block Grants allow awardees to prioritize the use of funds and to fill funding gaps in programs that deal with the leading causes of death and disability. Block Grant funding also provides awardees with the ability to respond rapidly to emerging health issues, including outbreaks of diseases or pathogens. The PHHS Block Grant program is authorized by sections 1901–1907 of the Public Health Service Act.

CDC currently collects information from Block Grant awardees to monitor their objectives and activities (Preventive Health and Health Services Block Grant, OMB No. 0920–0106, exp. 7/31/2013). Each awardee is required to submit an annual application for funding (Work Plan) that describes its objectives and the populations to be addressed, and an Annual Report that describes activities, progress toward objectives, and Success Stories which highlight the improvements Block Grant programs have made and the value of program activities. Information is submitted electronically through the Web-based Block Grant Information Management System (BGMIS).

The Work Plan and Annual Report are designed to help Block Grant awardees attain their goals and to meet reporting requirements specified in the program's authorizing legislation. Block Grant activities adhere to the Healthy People (HP) framework established by the Department of Health and Human Services (HHS). The current version of the BGMIS associates each awardee-defined activity with a specific HP National Objective, and identifies the location where funds are applied. CDC is updating the BGMIS by replacing Healthy People 2010 objectives with Healthy People 2020 objectives.

CDC requests OMB approval to continue the Block Grant information collection for three years. CDC will continue to use the electronic BGMIS to monitor awardee progress, identify activities and personnel supported with Block Grant funding, conduct compliance reviews of Block Grant awardees, and promote the use of evidence-based guidelines and interventions. There are no changes to the number of respondents or the estimated annual burden per respondent. There are no changes to BGMIS data elements other than changes related to HP 2020 objectives and enhancements. The Work Plan and the Annual Report will be submitted annually. The estimated burden per response for the Work Plan is 20 hours and the estimated burden per response for the Annual Report is 15 hours.

Participation in this information collection is required for Block Grant awardees. There are no costs to respondents other than their time. The total estimated annualized burden hours are 2,135.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Block Grant Awardees	Work Plan	61	1	20
	Annual Report	61	1	15