Telephone (local): (301) 427–1111; TTY (toll free): (866) 438–7231; TTY (local): (301) 427–1130; Email: *pso@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Background

The Patient Safety Act authorizes the listing of PSOs, which are entities or component organizations whose mission and primary activity is to conduct activities to improve patient safety and the quality of health care delivery.

HHS issued the Patient Safety Rule to implement the Patient Safety Act. AHRQ administers the provisions of the Patient Safety Act and Patient Safety Rule (PDF file, 450 KB. PDF Help) relating to the listing and operation of PSOs. The Patient Safety Rule authorizes AHRQ to list as a PSO an entity that attests that it meets the statutory and regulatory requirements for listing. A PSO can be ''delisted'' if it is found no longer to meet the requirements of the Patient Safety Act and Patient Safety Rule, or when a PSO chooses to voluntarily relinquish its status as a PSO for any reason. Section 3.108(d) of the Patient Safety Rule requires AHRQ to provide public notice when it removes an organization from the list of federally approved PSOs.

AHRQ has accepted a notification from the Northern Metropolitan Patient Safety Institute, PSO number P0021, which is a component entity of Northern Metropolitan Hospital Association, to voluntarily relinquish its status as a PSO. Accordingly, the Northern Metropolitan Patient Safety Institute was delisted effective at 12:00 Midnight ET (2400) on May 29, 2013. Northern Metropolitan Patient Safety Institute has patient safety work product (PSWP) in its possession. The PSO will meet the requirements of section 3.108(c)(2)(i) of the Patient Safety Rule regarding notification of providers that have reported to the PSO. In addition, according to section 3.108(c)(2)(ii) of the Patient Safety Rule regarding disposition of PSWP, the PSO has 90 days from the effective date of delisting and revocation to complete the disposition of PSWP that is currently in the PSO's possession.

More information on PSOs can be obtained through AHRQ's PSO Web site at *http://www.pso.AHRQ.gov/index.html.*

Dated: June 21, 2013.

Carolyn M. Clancy,

Director.

[FR Doc. 2013–15732 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 Vitamin D and Calcium

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 Vitamin D and Calcium. Scientific information is being solicited to inform the Vitamin D and Calcium: A Systematic Review of Health Outcomes project, 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 vitamin D and calcium will improve the quality of this systematic review. AHRQ is conducting this systematic 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.AHRO.gov/index.cfm/submitscientific-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 Vitamin D and Calcium: A Systematic Review of Health Outcomes.

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 vitamin D and calcium, 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://effectivehealthcare.AHRQ.gov/search-forquides-reviews-and-reports/?pageaction=displayproduct&productID=1529*

This notice is to notify the public that the EHC program would find the following information on Vitamin D and Calcium 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.
- A 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 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; pharmacoeconomic,

pharmacokinetic or pharmacodynamic studies; 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 Question 1

What is the effect of vitamin D intake or combined vitamin D plus calcium intake (but not calcium intake alone) on clinical outcomes, including cardiovascular diseases, cancer, immune function, pregnancy or birth outcomes, mortality, fracture, renal outcomes, and soft tissue calcification (the current report excludes two outcomes included in the original 2009 report: growth and weight management).

Population(s)

- The primary population of interest is generally healthy people with no known disorders, with the following exceptions. Studies that include broad populations might include some individuals with diseases or who are at risk for diseases.
- Studies of individuals with previous cancer, previous fractures, or precancerous conditions will be included.
- With the exception of studies of older adults, studies in which more than 20 percent of the participants have been diagnosed with a disease will be excluded.
- For clinical outcomes of cardiovascular disease (CVD), only studies of adults will be included (≥18 years of age).

Interventions

- For observational studies (exposures):
- Serum concentration of 25-hydroxyvitamin D [25(OH)D] or 1,25- dihydroxyvitamin D [1,25(0i1)2D] and method used
- Dietary intake of calcium from food and supplements
- Calcium balance
- For interventional studies:
- Vitamin D supplements with known doses
- Calcium supplements if co-administered with vitamin D
- Food-based interventions in which the doses of vitamin D and calcium were quantified and in which the doses differ between comparison groups

Comparators

- For observational studies:
  - Lower serum concentrations of vitamin D
- For interventional studies:
  - Placebo, non-fortified/supplemented food

Outcomes

- CVD clinical outcomes
- Cardiac events or symptoms
- Cerebrovascular events
- Peripheral vascular events or symptoms
- Cardiovascular death
- Study-specific combinations of cardiovascular events
- Total cancer
- Prostate cancer
- Colorectal cancer
- Breast cancer
- Pancreatic cancer
- Cancer-specific mortality
- Immune function clinical outcomes
- Infectious disease
- Autoimmune diseases
- Infectious disease-specific mortality
- Pregnancy-related outcomes
- Preterm birth or low birth weight
- Infant mortality
- Mortality, all cause
- Bone health, clinical outcomes
- Rickets
- Fracture
- Falls or muscle strength
- Adverse effects of intervention(s)
- All-cause mortality
- Cancer incidence and cancer-specific mortality
- Renal outcomes
- Soft tissue calcification
- (Other) adverse events from vitamin D or vitamin D plus calcium supplements

Timing

- Timing of interventions or exposures will not be pre-specified, with the exception that cross-sectional and retrospective case-control studies will not be included (nested case controls within prospective cohort studies will be included).
- For studies with multiple follow-up periods, the longest follow-up times will be preferentially considered.

Settings

- Settings will not be pre-specified.

Key Question 2

What is the effect of vitamin D or combined vitamin D and calcium intake on-surrogate or intermediate outcomes such as hypertension, blood pressure, and bone mineral density?

Populations

- As described for KQ 1, with the exception that for blood pressure and other CVD intermediate outcomes, only studies of adults 18 years of age or older will be included.

Interventions

- As described for KQ 1, with the following exceptions:
- For CVD outcomes, only randomized controlled trials (RCTs) will be included
- For bone health outcomes, only RCTs of greater than 1 year in duration will be included

Comparators

- As described for KQ 1.

Outcomes

- As specified in the original 2009 report, unless otherwise noted:
- CVD intermediate outcomes
- Cancer intermediate outcomes (colorectal adenoma, aberrant crypt cells, and mammographic breast density)
- Bone health intermediate outcomes (only bone mineral density/content)
- Pregnancy-related intermediate outcomes
- Pre-eclampsia
- High blood pressure with or without proteinuria

Timing

- As described for KQ 1, except for intermediate bone health for which studies of less than 1 year in duration will be excluded.

Settings

- As described for KQ 1.

Key Question 3

What is the association between serum 25(OH)D concentrations and clinical outcomes?*

Populations

- As described for KQ 1.

Interventions

- Serum concentration of 25(OH)D or 1,25 (OH)2D and the method used.

Comparators

- The serum concentration of 25(OH)D or 1,25 (OH)2D and the method used for the placebo or other comparison group.

Outcomes

- As described for KQ 1.

Timing

- As described for KQ 1.

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,