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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 Access to published and unpublished pertinent scientific information on medical devices to treat chronic urinary retention will improve the quality of this review.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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

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.

E-mail 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 website 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 e-mail 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

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