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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Scientific Information Request on Diagnosis of Gout

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 Diagnosis of Gout, 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES:
Online submissions:http://effectiveheathcare.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:

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 Effective Health Care (EHC) Program Evidence-based Practice Centers to complete a review of the evidence for Diagnosis of Gout.

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 Diagnosis of Gout, 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=1937.

This notice is to notify the public that the EHC Program would find the following information on Diagnosis of Gout 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 followup/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 EHC 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 EHC 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/.

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 also available online at:http://effectivehealthcare.ahrq.gov/search-for-guide-reviews-and-reports/?pageaction=displayproduct&productID=1937.

Key Questions

Key Question 1

· What is the accuracy of clinical signs and symptoms and other diagnostic tests (such as serum uric acid, ultrasound, CT scan, DECT, and plain x-ray), alone or in combination, compared to synovial fluid analysis in the diagnosis of acute gouty arthritis, and how does the accuracy affect clinical decision making, clinical outcomes and complications, and patient centered outcomes?

· How does the diagnostic accuracy of clinical signs and symptoms and other tests vary by affected joint site and number of joints?

· Does the accuracy of diagnostic tests for gout vary by duration of symptoms (i.e., time from the beginning of a flare)

· Does the accuracy of synovial fluid aspiration and crystal analysis differ by i) the type of practitioner who is performing the aspiration and ii) the type of practitioner who is performing the crystal analysis?

Key Question 2

What are the adverse effects associated with each diagnostic test (including pain, infection at the aspiration site, radiation exposure) or harms (related to false positives, false negatives, indeterminate results) associated with tests used to diagnose gout?

PICOTS (Population, Intervention(s), Comparator, Outcome, Timing, Setting)

Population(s) (KQ1 and 2)

· Adults (18 years and over) presenting with symptoms (e.g., an acute episode of joint inflammation) suggestive of gout, including the following subgroups:

  - o Male and female patients
  - o Older (65 and over) and younger patients

- Patients with comorbidities including hypertension, type 2 diabetes, kidney disease (renal insufficiency)
- Patients with osteoarthritis, septic arthritis, or previous joint trauma
- Individuals with a family history of gout

Interventions (KQ1, 2)

- Clinical history and physical exam
- Serum uric acid assessment
- US
- DECT
- Plain x-ray
- Joint aspiration by physicians and synovial fluid analysis using polarizing microscopy (by physicians or laboratory personnel)
- Combinations of these tests as identified in the literature

Comparators

- Joint synovial fluid aspiration and microscopic assessment for monosodium urate crystals (KQ1a-c, 2)
- Joint synovial fluid aspiration and microscopic assessment for monosodium urate crystals as performed by a practitioner with a different level of expertise or experience, e.g. rheumatologist, laboratory personnel (KQ1d)

Outcomes

- Diagnostic accuracy of clinical signs and symptoms, US, DECT, plain radiographs compared with joint aspiration and synovial fluid analysis (KQ1)
  - Sensitivity/specificity, true positives/true negatives, area under the curve
  - Positive, negative predictive value, positive/negative likelihood ratios (if prevalence known)
- Clinical decisionmaking
  - Additional testing
  - Pharmacologic/dietary management

· Intermediate outcomes

  - o sUA
  - o Synovial fluid crystals
  - o Radiographic or US changes

· Clinical outcomes

  - o Pain, joint swelling and tenderness
  - o Patient global assessment, and activity limitations (KQ1,2)

· Adverse effects of the tests, including

  - o Pain, infection, radiation exposure
  - o Effects of false positive or false negative (KQ2)

Timing

· For clinical outcomes of symptom relief: 1-2 days minimum (KQ1)

· Early in a flare vs. later or post-flare (KQ1c)

· For adverse events: immediate

Settings

· Primary care (outpatient) or acute care setting, preferentially

· Outpatient rheumatology practices/academic medical centers

Dated: August 26, 2014.

Richard Kronick,
AHRQ Director.

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