the individual under evaluation's separation from employment, or three years—whichever occurs first. Longer retention is authorized if required for business use.

ADMINISTRATIVE, TECHNICAL, AND PHYSICAL SAFEGUARDS:

Paper records are secured by lock and key and electronic files are stored on secure servers. The system has the ability to track individual user actions within the system. The audit and accountability controls are based on National Institute of Standards and Technology (NIST) and Board standards, which, in turn, are based on applicable laws and regulations. The controls assist in detecting security violations and performance or other issues in the system. Access to the system is restricted to authorized users within the Board who require access for official business purposes. Users are classified into different roles and common access and usage rights are established for each role. User roles are used to delineate between the different types of access requirements such that users are restricted to data that is required in the performance of their duties. Periodic assessments and reviews are conducted to determine whether users still require access, have the appropriate role, and whether there have been any unauthorized changes.

RECORD ACCESS PROCEDURES:

The Privacy Act allows individuals the right to access records maintained about them in a Board system of records. Your request for access must: (1) contain a statement that the request is made pursuant to the Privacy Act of 1974; (2) provide either the name of the Board system of records expected to contain the record requested or a concise description of the system of records; (3) provide the information necessary to verify your identity; and (4) provide any other information that may assist in the rapid identification of the record you seek.

Current or former Board employees may make a request for access by contacting the Board office that maintains the record. The Board handles all Privacy Act requests as both a Privacy Act request and as a Freedom of Information Act request. The Board does not charge fees to a requestor seeking to access or amend his/her Privacy Act records.

You may submit your Privacy Act request to the—Secretary of the Board, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue NW, Washington, DC 20551.

You may also submit your Privacy Act request electronically by filling out the required information at: *https://foia.federalreserve.gov/.*

CONTESTING RECORD PROCEDURES:

The Privacy Act allows individuals to seek amendment of information that is erroneous, irrelevant, untimely, or incomplete and is maintained in a system of records that pertains to them. To request an amendment to your record, you should clearly mark the request as a ''Privacy Act Amendment Request.'' You have the burden of proof for demonstrating the appropriateness of the requested amendment and you must provide relevant and convincing evidence in support of your request.

Your request for amendment must: (1) provide the name of the specific Board system of records containing the record you seek to amend; (2) identify the specific portion of the record you seek to amend; (3) describe the nature of and reasons for each requested amendment; (4) explain why you believe the record is not accurate, relevant, timely, or complete; and (5) unless you have already done so in a related Privacy Act request for access or amendment, provide the necessary information to verify your identity.

NOTIFICATION PROCEDURES:

Same as ''Access procedures'' above. You may also follow this procedure in order to request an accounting of previous disclosures of records pertaining to you as provided for by 5 U.S.C. 552a(c).

EXEMPTIONS PROMULGATED FOR THE SYSTEM:

Certain portions of this system of records may be exempted from 5 U.S.C. 552a(c)(3), (d), (e)(1), (e)(4)(G), (H), and (I), and (f) of the Privacy Act pursuant to 5 U.S.C. 552a(k)(5).

HISTORY:

This SORN was previously published in the **Federal Register** at 73 FR 24984 at 25003–04 (May 6, 2008). The SORN was also amended to incorporate two new routine uses required by OMB at 83 FR 43872 (August 28, 2018).

Board of Governors of the Federal Reserve System.

Ann E. Misback,

Secretary of the Board.

[FR Doc. 2024–28926 Filed 12–9–24; 8:45 am]

BILLING CODE 6210–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Recurrent Nephrolithiasis in Adults and Children: Comparative Effectiveness of Preventive Medical Strategies

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

ACTION: Request for supplemental evidence and data submission.

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 on *Recurrent Nephrolithiasis in Adults and Children: Comparative Effectiveness of Preventive Medical Strategies,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers (EPC) Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before January 9, 2025.

ADDRESSES:

Email submissions: epc@ahrq.hhs.gov.

Print submissions:

Mailing Address: Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E53A, Rockville, MD 20857.

Shipping Address (FedEx, UPS, etc.): Center for Evidence and Practice Improvement, Agency for Healthcare Research and Quality, ATTN: EPC SEADs Coordinator, 5600 Fishers Lane, Mail Stop 06E77D, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kelly Carper, Telephone: 301–427–1656 or Email: *epc@ahrq.hhs.gov.*

SUPPLEMENTARY INFORMATION: The Agency for Healthcare Research and Quality has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for *Recurrent Nephrolithiasis in Adults and Children: Comparative Effectiveness of Preventive Medical Strategies.* AHRQ is conducting this review pursuant to Section 902 of the Public Health Service Act, 42 U.S.C. 299a.

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 *Recurrent Nephrolithiasis in Adults and Children: Comparative Effectiveness of Preventive Medical Strategies.* The entire research protocol is available online at: *https://effectivehealthcare.ahrq.gov/products/kidney-stones/protocol.*

This is to notify the public that the EPC Program would find the following information on *Recurrent Nephrolithiasis in Adults and Children: Comparative Effectiveness of Preventive Medical Strategies* helpful:

- A list of completed studies that your organization has sponsored for this topic. 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,* a summary, including the following elements, if relevant: 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 topic.* In the list, please provide the *ClinicalTrials.gov* trial number or, if the trial is not registered, the protocol for the study including, if relevant, 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 topic and an index outlining the relevant information in each submitted file.

Your contribution is very beneficial to the Program. Materials submitted must be publicly available or able to be made public. Materials that are considered confidential; marketing materials; study types not included in the review; or information on topics 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 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 email list at: *https://effectivehealthcare.ahrq.gov/email-updates.*

The review will answer the following questions. This information is provided as background. AHRQ is not requesting that the public provide answers to these questions.

Key Questions (KQ)

KQ 1: What is the comparative effectiveness of preventive treatment with diet or pharmacologic agents in nonpregnant children and adults with history of nephrolithiasis?

a. Does effectiveness vary by stone composition, diet assessment, blood or urine chemistry, or genetic testing performed prior to treatment?

b. Does effectiveness vary by blood or urine chemistry or genetic testing performed as followup after treatment is initiated?

KQ 2: What are the comparative harms of preventive treatment with diet or pharmacologic agents in nonpregnant children and adults with history of nephrolithiasis?

a. Do harms vary by stone composition, diet assessment, blood or urine chemistry, or genetic testing performed prior to treatment?

b. Do harms vary by blood or urine chemistry or genetic testing performed as followup after treatment is initiated?

KQ 3: What is the comparative effectiveness of surveillance imaging strategies in nonpregnant children and adults with history of nephrolithiasis?

a. Does effectiveness vary with preventive treatment?

b. Does effectiveness vary by timing of imaging?

KQ 4: What are the comparative harms of surveillance imaging strategies in nonpregnant children and adults with history of nephrolithiasis?

a. Do harms vary with preventive treatment?

b. Do harms vary by timing of imaging?

Contextual Question (CQ)

CQ 1: What is the natural history of kidney stone recurrence in children and adults?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, and Setting)

DETAILED INCLUSION AND EXCLUSION CRITERIA FOR SYSTEMATIC REVIEW

Category	Include	Exclude
Populations	*All KQs:* Nonpregnant children and adults with a history of nephrolithiasis.	*All KQs:* Children and adults without a history of nephrolithiasis; pregnant persons; persons receiving treatment for acute renal colic or for stone removal or expulsion.
Interventions	*KQ 1, 1a, 1b, 2, 2a, 2b:* Dietary and/or pharmacological treatment, including dietary supplements and FDA-approved prescription or OTC drugs (Appendix A). *KQ 1a, 2a:* Eligible interventions along with evaluation of stone composition, dietary intake, genetic testing, or blood or urine chemistries before treatment is started. *KQ 1b, 2b:* Eligible interventions along with evaluation of genetic testing or blood and urine chemistries after treatment initiation. *KQ 3, 3a, 3b, 4, 4a, 4b:* Followup imaging when used for routine surveillance (CT scan, renal ultrasound, abdominal radiograph) to detect radiographic stone recurrence, size, composition, location, or shape.	*KQs 1, 2:* Nondietary and nonpharmacological interventions, including behavioral interventions aimed to improve treatment adherence; interventions for the acute treatment of kidney stones (*e.g.,* surgery, lithotripsy, medical expulsion therapy). Prescriptions drugs and OTC medications that are not FDA-approved or available in the United States. *KQ 3, 4:* Imaging not used specifically for surveillance of kidney stones.
Comparators	*KQ 1, 1a, 1b, 2, 2a, 2b:* Placebo, usual diet, no preventive treatment (for effectiveness); other eligible intervention (for comparative effectiveness).	*All KQs:* No comparator (single arm study).

DETAILED INCLUSION AND EXCLUSION CRITERIA FOR SYSTEMATIC REVIEW—Continued

Category	Include	Exclude
	KQ 3, 3a, 3b, 4, 4a, 4b: Eligible followup imaging for routine surveillance of kidney stones, no followup imaging.	
Outcomes	*All KQs:* Patient-centered health outcomes: Incident symptomatic stones, urinary tract obstruction with acute renal impairment, end-stage renal disease, urinary tract infection, stone-removal procedures/surgery, procedure-related morbidity, emergency department visits and hospitalizations, quality of life, missed school or work, preventive treatment-related adverse events, imaging-related adverse events, serious adverse events, discontinuations due to adverse events. *Intermediate outcomes:* Growth of existing stones, incident radiographic stones, radiation exposure, incidental imaging findings.	*KQ 1, 1a, 1b, 3, 3a, 3b:* Blood or urine chemistry measures, urine supersaturation measures, acute pain.
Timing	*KQ 1, 3:* Studies that measure outcomes at least 12 months after baseline. *KQ 2, 4:* Followup not limited.	*KQ 1, 3:* Studies of less than 12-months duration.
Setting	Outpatient clinical settings including primary care, urology, nephrology, or other specialty stone clinics; countries with HDI[12] of *very high* (Appendix B).	Inpatient settings; Countries with HDI other than *very high.*
Study Designs, Publication Types, and Language.	*All KQs:* Published in peer-reviewed literature, unpublished studies with enough information about methods to determine risk of bias; English language. RCTs; for comparisons lacking sufficient RCT evidence, NRSIs with concurrent comparator group and primary study aim/outcome to assess a dietary or pharmacologic intervention or surveillance imaging approach are eligible.	*All KQs:* Interrupted time series, case series, narrative reviews, editorials, and commentaries are not eligible; systematic reviews are not eligible but will be reviewed to determine whether any included studies are eligible. Studies with fewer than 30 participants at baseline per study arm. Studies published in languages other than English. *KQ 2:* Studies designed to report epidemiologic associations between dietary factors and stone incidence.

CT = computed tomography; FDA = U.S. Food and Drug Administration; HDI = United Nations Development Programme Human Development Index; KQ = key question; NRSI = nonrandomized study of intervention; OTC = over-the-counter; RCT = randomized controlled trial.

Dated: December 4, 2024.

Marquita Cullom,

Associate Director.

[FR Doc. 2024–28933 Filed 12–9–24; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Government-Owned Materials; Availability for Access

AGENCY: National Institute of Allergy and Infectious Diseases, National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The material listed below is owned by an agency of the U.S. Government and is available for transfer to achieve expeditious use and/or commercialization of results of federally funded research and development.

FOR FURTHER INFORMATION CONTACT: Access information may be obtained by communicating with the Technology Transfer and Intellectual Property Office, National Institute of Allergy and Infectious Diseases, 5601 Fishers Lane, Rockville, MD 20852 by contacting Benjamin Hurley at 240–669–5092 or *benjamin.hurley@nih.gov.*

SUPPLEMENTARY INFORMATION:

Royalty-Free Starting Material (MVA-clone 1) for the Clinical Development, Evaluation, and Commercialization of a Viable Mpox Vaccine

Worldwide, leading health authorities have cited the growing need for a commitment to equitable vaccine access and its role in curtailing future epidemics—a vision that cannot be realized without significant improvements in the speed, scale, and access of vaccine manufacturing and deployment in historically underserved regions. For at-risk populations and those with contraindications to commonly deployed vaccines, such initiatives are even more vital.

Modified vaccinia virus Ankara (MVA), developed more than 30 years ago as a highly attenuated candidate smallpox vaccine, was recloned at the U.S. National Institute of Allergy and Infectious Diseases (NIAID) (referred to here as ''MVA clone-1'') from a 1974-originating passage and evaluated for safety and immunogenicity in both normal and partially immune-deficient animals. Subsequent studies verified the protective ability of this attenuated vaccine against mpox in non-human primates, and clinical efforts since have resulted in FDA approval and availability of a two-dose MVA vaccine in the U.S.

In support of the global humanitarian effort to achieve equitable vaccine access and in light of the current public health emergency of international concern (PHEIC) declared by the World Health Organization in 2024—which has resulted in more than 500 deaths in the Democratic Republic of the Congo since the beginning of this year—the National Institute of Allergy and Infectious Diseases (NIAID) is seeking inquiries from parties interested in independent R&D and/or collaborative research to further develop, evaluate, and commercialize a viable mpox vaccine for distribution (particularly in developing nations/regions currently having minimal access to mpox vaccines) using NIH-provided starting material (MVA clone-1). While traditional licensing opportunities related to mpox detection are also available (*e.g.,* antibodies, neutralization assays), NIAID will transfer the MVA clone-1 material in question on a royalty-free basis to qualified partners in an effort to combat the current PHEIC. In the event that NIAID has limited ability to distribute material, or if supply approaches exhaustion, priority will be given to collaborators with a proposed plan demonstrating, in