Method of Collection

To achieve the goals of this project, the following data collections will be implemented:

AHRQ Research Reporting System (ARRS)—Grantees and vendors use the ARRS system to report project progress and important preliminary findings for grants and contracts funded by the Agency. Grantees and vendors submit progress reports on a monthly or quarterly basis which are reviewed by AHRQ personnel. All users access the ARRS system through a secure online interface which requires a user I.D. and password entered through the ARRS login screen. When status reports are due AHRQ notifies principal investigators and vendors via email.

The ARRS is an automated, user-friendly resource that is utilized by AHRQ staff for preparing, distributing, and reviewing reporting requests to grantees and vendors for the purpose of information sharing. AHRQ personnel are able to systematically search the information collected and stored in the ARRS database. Personnel will also use the information to address internal and/or external requests for information regarding grant progress, preliminary findings, and other requests, such as Freedom of Information Act requests and producing responses related to federally mandated programs and regulations.

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated annualized burden hours for the respondents. It will take grantees and vendors an estimated 10 minutes to enter the necessary data into the ARRS System and reporting will occur four times annually. The total annualized burden hours are estimated to be 333 hours.

Exhibit 2 shows the estimated annualized cost burden for the respondents. The total estimated cost burden for respondents is $12,454.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Form name	Number of respondents	Number of responses per respondent	Hours per response	Total burden hours
Data entry into ARRS	500	4	10/60	333
Total	500	N/A	N/A	333

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Form name	Number of respondents	Total burden hours	Average hourly wage rate *	Total cost burden
Data entry into ARRS	500	333	$37.40	$12,454
Total	500	333	N/A	12,454

* Based upon the average wages for Healthcare Practitioner and Technical Occupations (29–0000), ''National Compensation Survey: Occupational Wages in the United States, May 2015,'' U.S. Department of Labor, Bureau of Labor Statistics, *http://www.bls.gov/oes/current/oes_nat.htm#29-0000.*

Request for Comments

In accordance with the Paperwork Reduction Act, comments on AHRQ's information collection are requested with regard to any of the following: (a) Whether the proposed collection of information is necessary for the proper performance of AHRQ health care research and health care information dissemination functions, including whether the information will have practical utility; (b) the accuracy of AHRQ's estimate of burden (including hours and costs) of the proposed collection(s) of information; (c) ways to enhance the quality, utility and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information upon the respondents, including the use of automated collection techniques or other forms of information technology.

Comments submitted in response to this notice will be summarized and included in the Agency's subsequent request for OMB approval of the proposed information collection. All comments will become a matter of public record.

Sharon B. Arnold,

Acting Director.

[FR Doc. 2017–07156 Filed 4–10–17; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Systematic Review of Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries

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

ACTION: Request for supplemental evidence and data 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 *Systematic Review of Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries,* which is currently being conducted by the AHRQ's Evidence-based Practice CentersProgram. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before May 11, 2017.

ADDRESSES:

Email submissions: SEADS@epc-src.org.

Print submissions: Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, P.O. 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. 51723 or Email: *SEADS@epc-src.org.*

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 *Systematic Review of Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries.* AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

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 *Systematic Review of Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries,* including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *https://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2455*

This is to notify the public that the EPC Program would find the following information on *Systematic Review of Breastfeeding Programs and Policies, Breastfeeding Uptake, and Maternal Health Outcomes in Developed Countries* 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 follow-up/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 EPC Program. The contents of all submissions will be made available to the public upon request. 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 indications 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 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: *https://www.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 Key Questions

KQ 1a. What is the effectiveness and harms of programs and policies on initiation, duration, and exclusivity of breastfeeding?

KQ 1b. To what extent do the effectiveness and harms of programs and policies on initiation, duration, and exclusivity of breastfeeding differ for subpopulations of women defined by sociodemographic factors (*e.g.,* age, race, ethnicity, socioeconomic status)?

KQ 1c. To what extent do intervention-related characteristics (*e.g.,* type of breast pump provided—manual or electric; delivery personnel) influence the initiation, duration, and exclusivity of breast feeding?

KQ 2a. What are the comparative benefits and harms for maternal health outcomes among women who breastfeed for different intensities and durations?

KQ 2b. To what extent do benefits and harms for maternal health outcomes differ for subpopulations of women defined by age, race, ethnicity, and comorbidity?

Population(s)

KQs 1, 2: Childbearing women and adolescents; we will also search for evidence on subgroups of women defined by age, race, ethnicity, comorbidity, and socioeconomic status (including insurance status and payer type).

Interventions/Exposure

KQ 1: Community, workplace, and health care system-based interventions aimed at promoting and supporting breastfeeding, including the following: Health plan benefits, state and federal policies or programs (*e.g.,* WIC programs), hospital implementation of the BFHI, workplace or school-based programs, and others. For studies assessing the effectiveness of BFHI, we will include studies evaluating full and partial implementation (at least 3 steps) of the 10 steps.

KQ 2: Exposure to breastfeeding.

Comparators

KQ 1: No intervention (or usual practice); comparisons of two interventions that differ in content or intensity.

KQ 2: No breastfeeding; shorter duration of breastfeeding (*e.g.,* breastfeeding for 1 month vs. 12 months) and/or less intensive breastfeeding (*e.g.,* exclusive breastfeeding vs. mixed feeding or formula feeding).

Outcomes

KQ 1: Rates of breastfeeding initiation; duration and exclusivity of breastfeeding, adverse effects of interventions (*e.g.,* guilt about not breastfeeding, workplace discrimination, and other reported harms).

KQ 2: Postpartum depression, breast cancer, ovarian cancer, osteoporosis, cardiovascular outcomes (*e.g.,* stroke, myocardial infarction), postpartum weight change, type 2 diabetes, hypertension.

Timing

KQs 1, 2: We will have no minimum study duration or length of follow up.

Settings

KQs 1, 2: Studies conducted in a developed country [''very high'' (KQs 1, 2) and ''high'' (KQ 1) human development index per the United Nations Development Programme 40.

Study Design

KQ 1: Randomized and non-randomized controlled clinical trials; prospective cohort studies with concurrent control groups; systematic reviews; for studies assessing policy or system-level interventions, we will also include pre-post studies with repeated outcome measures before and after the intervention.

KQ 2: Randomized and non-randomized controlled clinical trials; cohort studies; case-control studies; systematic reviews.

Sharon B. Arnold,

Acting Director.

[FR Doc. 2017–07157 Filed 4–10–17; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Lower Limb Prosthesis

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

ACTION: Request for supplemental evidence and data 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 *Lower Limb Prosthesis,* which is currently being conducted by the AHRQ's Evidence-based Practice Centers Program. Access to published and unpublished pertinent scientific information will improve the quality of this review.

DATES: *Submission Deadline* on or before May 11, 2017.

ADDRESSES:

Email submissions: SEADS@epc-src.org.

Print submissions:

Mailing Address: Portland VA Research Foundation, Scientific Resource Center, ATTN: Scientific Information Packet Coordinator, P.O. 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. 51723 or Email: *SEADS@epc-src.org.*

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 *Lower Limb Prosthesis* (LLP). AHRQ is conducting this systematic review pursuant to Section 902(a) of the Public Health Service Act, 42 U.S.C. 299a(a).

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 *Lower Limb Prosthesis,* including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: *https://effectivehealthcare.ahrq.gov/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productID=2451*

This is to notify the public that the EPC Program would find the following information on *Lower Limb Prosthesis* 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 follow-up/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 EPC Program. The contents of all submissions will be made available to the public upon request. 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 indications 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 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: *https://www.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 Key Questions

Key Question 1

What assessment techniques used to measure functional ability of adults with major lower limb amputation have been evaluated in the published literature?

I. What are the measurement properties of these techniques, including: Reliability, validity, responsiveness, minimal detectable change, and minimal important difference?

II. What are the characteristics of the participants in studies evaluating measurement properties of assessment techniques?

Key Question 2

What prediction tools used to predict functional outcomes in adults with major lower limb amputation have been evaluated in the published literature?

I. What are their characteristics, including technical quality (reliability, validity, responsiveness), minimal detectable change, and minimal important difference?

II. What are the characteristics of the participants in these studies?

Key Question 3

What functional outcome measurement tools used to assess adults who use a lower limb prosthesis (LLP) have been evaluated in the published literature?

I. What are their characteristics, including technical quality (reliability,