BILLING CODE 4160-90-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Mobile Health Technology for Diabetes

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Request for supplemental evidence and data submissions.

SUMMARY: The Agency for Healthcare Research and Quality is seeking scientific information submissions from the public. Scientific information is being solicited to inform our review of *Mobile Health Technology for Diabetes,* 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER]**.

ADDRESSES:

E-mail submissions: SEADS@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

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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 (AHRQ) has commissioned the Evidence-based Practice Centers (EPC) Program to complete a review of the evidence for Mobile Health Technology for Diabetes. 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 *Mobile Health Technology for Diabetes*, including those that describe adverse events. The entire research protocol, including the key questions, is also available online at: http://www.effectivehealthcare.ahrq.gov/index.cfm/search-for-guides-reviews-and-reports/?pageaction=displayproduct&productid=2484

This is to notify the public that the EPC Program would find the following information on *Mobile Health Technology for Diabetes* 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. 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 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: 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 Guiding Questions

I. Which specific mobile health technology (mHealth) technologies for diabetes self-management have been researched?

II. What are the characteristics (e.g., interoperability, functions,

acceptability/usability, connection to electronic health records) of these specific mHealth technologies?

III. What patient outcomes are associated with the use of these specific mHealth technologies?

IV. What are the harms and costs associated with these specific mHealth technologies?

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