DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Platelet-rich Plasma for Wound Care in the Medicare Population

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 on *Platelet-rich Plasma for Wound Care in the Medicare Population,* 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 30 days after the date of publication of this notice in the **Federal Register**.

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: Jenae Benns, Telephone: 301–427–1496 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 Platelet-rich Plasma for Wound Care in the Medicare Population. 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 *Platelet-rich Plasma for Wound Care in the Medicare Population,* including those that describe adverse events. The entire research protocol is available online at: *https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/topicrefinement/platelet-rich-plasma-protocol.pdf.*

This is to notify the public that the EPC Program would find the following information on *Platelet-rich Plasma for Wound Care in the Medicare Population* 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,* 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 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 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 email list at: *https://www.effectivehealthcare.ahrq.gov/email-updates.*

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.

Key Questions (KQ)

Comparative Effectiveness Questions

KQ 1. What are the benefits and harms of treatment strategies including PRP alone with or without other wound care treatments compared to other wound care treatments in patients with diabetic, venous and pressure chronic wounds, for patient oriented outcomes such as at least the following: Completely closed/healed wounds (skin closure with complete re-epithelialization without drainage or dressing requirements), time to complete wound closure, wound reoccurrence, risk of developing wound infection, amputation, hospitalization (frequency and duration), return to baseline activities and function, reduction of wound size, pain, opioid medication use, exudate and odor, quality of life and adverse effects.

KQ 1.a. Describe the risk of bias in the studies examined by chronic wound type and study design.

KQ 1.b. What are the differences in formulation techniques and components between these preparations? What are the differences in application techniques, frequency of application and ''dosage'' (amounts applied)?

KQ 1.c. What are the study characteristics (such as those listed below) in each included investigation for each chronic wound type treated by PRP?

a. Comparator (if standard care, describe in detail)

b. Study inclusion/exclusion criteria and patient characteristics of enrollees, including at least age, gender, and general health (*e.g.,* status of HbA1c, diabetes, peripheral vascular disease, obesity, smoking, renal), wound characteristics, and prior and concurrent wound treatments.

c. Wound characteristics of enrollees including at least wound type, wound size/depth/duration/severity, vascular status, infection status and whether there were inter- and intra-rater checks of wound measurements.

d. Basic study design and conduct information including at least method of patient enrollment, care setting, and use of run-in period

e. Definition of wound characteristics: Definition of ''failure to heal'', and

definition of a successfully healed wound (re-epithelialization)

f. Method of applying skin PRP including provider, frequency of application, definition of standard of care, and handling of infections

g. Measurement and assessment methods including method of assessment(s); frequency and time points for assessment(s) (including long term assessments for durability of heal); and blinding of assessors

KQ 1.d. Based on the included studies, what are the patient characteristics commonly considered for the initiation and continuation/discontinuation of PRP in patients with chronic wounds?

Contextual Questions

KQ 2. What types of PRP preparations are currently being marketed in US medical practices (gel, liquid, etc.)?

Future Research Questions:

KQ 3. What PRP preparations are currently being investigated in ongoing trials?

KQ 4. What best practices in study design could be used to produce high quality evidence on PRP?

KQ 5. What are the evidence gaps found in this body of research?

PICOTS (Populations, Interventions, Comparators, Outcomes, Timing, Settings)

PICOTS elements	Inclusion criteria	Exclusion criteria
Populations	Adult patients (18 years and older) with • Lower extremity diabetic wounds • Lower extremity venous ulcers • Pressure wounds in any location	• Animals. • Children (age <18 years). • Wounds of other etiologies. • Studies with mixed, non stratified diabetic wounds/venous ulcers/pressure wounds. • Traumatic wounds. • Peripheral arterial disease (PAD) related wounds in non diabetics (i.e., diabetic wounds are to be included regardless of the presence of PAD, but PAD alone wounds without diabetes are a reason of exclusion). • Wounds <4 weeks.
Intervention	Any preparation of autologous platelet-rich plasma with or without other treatments.	
Comparators	Any other wound care without PRP	None.
Outcomes	• Completely closed/healed wounds (skin closure with complete re-epithelialization without drainage or dressing requirements versus failure to heal). • Time to complete wound closure. • Healing durability (Time to wound reoccurrence). • Wound infection (improvement of wound infection or reduced risk of developing wound infection). • Amputation. • Hospitalization. • Return to baseline activities of daily living and function. • Wound size. • Pain. • Opioid medication use. • Quality of life. • Adverse effects.	None.
Timing		None.
Settings	Any	None.
Study design	KQ 1 • Original data • Any sample size • RCTs • Comparative observational studies • Relevant systematic reviews, or meta-analyses (used for identifying additional studies).	*In vitro* studies, non-original data (*e.g.*narrative reviews, editorials, letters, or erratum), single-arm observational studies, case series, qualitative studies, cost-benefit analysis, cross-sectional (*i.e.,* non-longitudinal) studies, before-after studies that do not have a comparison group, survey.
Subgroup analysis	• Age. • Gender. • Settings. • Comorbidities (*e.g.,* status of HbA1c, diabetes, peripheral vascular disease, obesity, smoking, renal disease, liver disease). • Wound characteristics (wound type, area, depth, volume, duration, severity, vascular status, infection status, and prior and concurrent wound treatments). • Anatomical location (lower extremity diabetic wounds only). • PRP formulation techniques. • PRP components. • PRP application techniques. • PRP frequency. • PRP ''dosage'' (amounts applied). • PRP offloading procedures (*e.g.,* total contact casting, removable CAM WalkerTM, irremovable offloading devices). • Use of immunosuppressant medication. • Nutrition status. • Pain medication (opioids, others).	

PICOTS elements	Inclusion criteria	Exclusion criteria
Publications	Studies published in English only	Foreign language studies.

Abbreviations: KQ = key question; PICOTS = populations, interventions, comparators, outcomes, timing, and settings; RCT = randomized controlled trial.

Dated: March 17, 2020.

Virginia Mackay-Smith,

Associate Director, Office of the Director, AHRQ.

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BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[30Day–20–0881]

Agency Forms Undergoing Paperwork Reduction Act Review

In accordance with the Paperwork Reduction Act of 1995, the Centers for Disease Control and Prevention (CDC) has submitted the information collection request titled ''Data Calls for the Laboratory Response Network'' to the Office of Management and Budget (OMB) for review and approval. CDC previously published a ''Proposed Data Collection Submitted for Public Comment and Recommendations'' notice on October 18, 2019 to obtain comments from the public and affected agencies. CDC did not receive comments related to the previous notice. This notice serves to allow an additional 30 days for public and affected agency comments.

CDC will accept all comments for this proposed information collection project. The Office of Management and Budget is particularly interested in comments that:

(a) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information will have practical utility;

(b) Evaluate the accuracy of the agencies estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used;

(c) Enhance the quality, utility, and clarity of the information to be collected;

(d) Minimize the burden of the collection of information on those who are to respond, including, through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.,* permitting electronic submission of responses; and

(e) Assess information collection costs.

To request additional information on the proposed project or to obtain a copy of the information collection plan and instruments, call (404) 639–7570. Comments and recommendations for the proposed information collection should be sent within 30 days of publication of this notice to *www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under 30-day Review—Open for Public Comments'' or by using the search function. Direct written comments and/or suggestions regarding the items contained in this notice to the Attention: CDC Desk Officer, Office of Management and Budget, 725 17th Street NW, Washington, DC 20503 or by fax to (202) 395–5806. Provide written comments within 30 days of notice publication.

Proposed Project

Data Calls for the Laboratory Response Network (OMB Control Number 0920–0881, Exp. 3/31/2020)—Extension—National Center for Emerging and Zoonotic Infectious Diseases (NCEZID), Centers for Disease Control and Prevention (CDC).

Background and Brief Description

The LRN Program Office maintains a database of information for each member laboratory that includes contact information as well as staff and equipment inventories. However, during emergency response, the LRN Program Office may conduct a Special Data Call to obtain additional information from LRN Member Laboratories in regards to biological preparedness. The LRN has not used the Generic 0920–0881 in the previous three years but it is critical that the LRN retain its ability to survey its members in a timely fashion during emergencies. Special Data calls may be conducted via queries that are distributed by broadcast emails or by survey tools (*i.e.,* Survey Monkey). This is a request for an extension to this generic clearance. CDC requests approval for 68 annual burden hours. There is no cost to respondents other than their time to respond to the data call.

ESTIMATED ANNUALIZED BURDEN HOURS

Type of respondents	Form name	Number of respondents	Number of responses per respondent	Average burden per response (in hours)
Public Health Laboratorians	Special Data Call	136	1	30/60