Street, NW, Washington, DC 20405, telephone 202–501–4755. Please cite OMB Control No. 9000–0066, Labor-related Requirements, in all correspondence.

Dated: February 15, 2019.

Janet Fry,

Director, Federal Acquisition Policy Division, Office of Governmentwide Acquisition Policy, Office of Acquisition Policy, Office of Governmentwide Policy.

[FR Doc. 2019–02990 Filed 2–20–19; 8:45 a.m.]

BILLING CODE 6820–EP–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Supplemental Evidence and Data Request on Use of Cardiac Resynchronization Therapy: A Systematic Review Update

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 *Use of Cardiac Resynchronization Therapy: A Systematic Review Update,* 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 Access to published and unpublished pertinent scientific information will improve the quality of this review.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 March 25, 2019.

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 *Use of Cardiac Resynchronization Therapy: A Systematic Review Update.* 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 *Use of Cardiac Resynchronization Therapy: A Systematic Review Update,* including those that describe adverse events. The entire research protocol is available online at: *https://www.ahrq.gov/research/findings/ta/index.html.*

This is to notify the public that the EPC Program would find the following information on Use of Cardiac Resynchronization Therapy: A Systematic Review Update 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 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.

The Key Questions

KQ1a: Is cardiac resynchronization therapy with defibrillator (CRT–D) effective in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with an LVEF ≤35% and a QRS duration ≥120ms?

KQ1b: Does the effectiveness of cardiac resynchronization therapy with defibrillator (CRT–D) vary by the following subgroups:

Age
Gender
Cardiomyopathy subtype
QRS morphology
Left ventricular ejection fraction
NYHA class
Atrial fibrillation

KQ2: What are the adverse effects or complications associated with CRT–D implantation?

KQ3a: Is cardiac resynchronization therapy in the absence of defibrillator capacity (CRT–P) effective in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with LVEF ≤35% and a QRS duration ≥120ms?

KQ3b: Does the effectiveness of cardiac resynchronization therapy in the absence of defibrillator capacity (CRT–P) vary by the following subgroups:

Age
Gender
Cardiomyopathy subtype
QRS morphology
Left ventricular ejection fraction
NYHA class
Atrial fibrillation

KQ4: What are the adverse effects or complications associated with CRT–P implantation?

KQ5: What is the effectiveness of CRT–D versus CRT–P in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with LVEF ≤35% and a QRS duration ≥120ms?

KQ6: What are the adverse effects or complications associated with CRT–D versus CRT–P implantation?

KQ7a: What is the effectiveness of alternative CRT techniques (adaptive CRT, multipoint pacing, His bundle pacing, quadripolar) versus conventional CRT techniques in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with an LVEF ≤35% and a QRS duration ≥120ms?

KQ7b: Does the effectiveness of alternative CRT techniques (adaptive CRT, multipoint pacing, His bundle pacing, quadripolar) vary by the following subgroups:

Age
Gender
Cardiomyopathy subtype
QRS morphology
Left ventricular ejection fraction
NYHA class
Atrial fibrillation

KQ8: What are the adverse effects or complications associated with alternative CRT techniques (adaptive CRT, multipoint pacing, His bundle pacing, quadripolar)?

KQ9: What is the effectiveness of His bundle pacing or CRT versus RV pacing in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with an LVEF between ≥36% to ≤50% and atrioventricular block?

KQ10: What are the adverse effects or complications associated with His bundle pacing or CRT versus RV pacing in reducing heart failure symptoms, improving myocardial function, reducing hospitalization and/or improving survival in patients with an LVEF between ≥36% to ≤50% and atrioventricular block?

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

Population(s)

KQ1–KQ8: Subjects of age ≥18, with a left ventricular ejection fraction ≤35% and a QRS duration ≥120 ms.

KQ9–10: Subjects of age ≥18, with an LVEF between ≥36% to ≤50% and atrioventricular block [We will use a recently published systematic review to address KQs 9–10].

Interventions

- Cardiac resynchronization therapy with a defibrillator (CRT–D)
- Cardiac resynchronization without a defibrillator (CRT–P)
- Alternative cardiac resynchronization therapy alternative CRT techniques (adaptive CRT, multipoint pacing, His bundle pacing, quadripolar)

Comparators

- CRT–D vs. implantable cardioverter defibrillator (ICD)
- CRT–P vs. optimal medical therapy
- CRT–D vs. CRT–P
- Alternative CRT techniques versus conventional CRT techniques

Outcomes

KQ1a, 3a, 5, and 7a (Effectiveness)

Clinical outcomes

- 6 minute hall walk distance
- Left ventricular end diastolic volume/volume index
- Left ventricular end systolic volume/volume index
- Left ventricular ejection fraction
- Packer Score [17]

Quality of life

- Minnesota Living with Heart Failure Inventory Score
- Kansas City Cardiomyopathy Score
- SF–36

Health outcomes

- Hospitalizations for heart failure
- All-cause mortality

KQ2, KQ4, KQ6, and KQ8 (Harms)

- Procedure related complications
- Length of hospital stay
- Pneumothorax
- Pocket hematoma
- Device Infection
- Cardiac perforation/tamponade
- Lead dislodgement
- Ventricular arrhythmias
- Death (within a week)
- Inappropriate ICD shocks (CRT–D and alternative CRT–D techniques only)

KQ1b, KQ3b, 7b (Subgroups)

- Age
- Gender
- Cardiomyopathy subtype
- QRS morphology
- Left ventricular ejection fraction
- NYHA class
- Atrial fibrillation

Timing

KQ1a, 3a, 5, and 7a, (Effectiveness)

- Outcomes from CRT–D, CRT–P, and alternative CRT techniques at 3–6 months, 1 year, and ≥2 year end-points

KQ2, 4, 6, and 8 (Harms)

- Outcomes from CRT–D, CRT–P, and alternative CRT techniques at any time point

Francis D. Chesley, Jr.,

Acting Deputy Director.

[FR Doc. 2019–02985 Filed 2–20–19; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

[60-Day–19–19SJ; Docket No. CDC–2019–0004]

Proposed Data Collection Submitted for Public Comment and Recommendations

AGENCY: Centers for Disease Control and Prevention (CDC), Department of Health and Human Services (HHS).

ACTION: Notice with comment period.

SUMMARY: The Centers for Disease Control and Prevention (CDC), as part of its continuing effort to reduce public burden and maximize the utility of government information, invites the general public and other Federal agencies the opportunity to comment on a proposed and/or continuing information collection, as required by the Paperwork Reduction Act of 1995. This notice invites comment on a proposed information collection project titled Preventive Health and Health Services Block Grant Center for State, Tribal, Local and Territorial Support (CSTLTS), Centers for Disease Control and Prevention (CDC). This study will allow CDC to monitor awardees progress, identify activities and personnel supported with Block Grant funding, conduct compliance reviews of Block Grant awardees, and promote the use of evidence-based guidelines and interventions.

DATES: CDC must receive written comments on or before April 22, 2019.

ADDRESSES: You may submit comments, identified by Docket No. CDC–2019–0004 by any of the following methods:

- *Federal eRulemaking Portal: Regulations.gov*. Follow the instructions for submitting comments.
- *Mail:* Jeffrey M. Zirger, Information Collection Review Office, Centers for Disease Control and Prevention, 1600 Clifton Road NE, MS–D74, Atlanta, Georgia 30329.

Instructions: All submissions received must include the agency name and Docket Number. CDC will post, without