PICOTS (POPULATIONS, INTERVENTIONS, COMPARATORS, OUTCOMES, TIMING, SETTINGS)—Continued

PICOTS	Inclusion key question 1: Prostaglandin inpatient vs. outpatient	Inclusion key question 2: Mechanical method inpatient vs outpatient	Inclusion key question 3: Outpatient comparison of methods	Inclusion key question 4: Fetal surveillance	Exclusion
Outcomes Maternal Harms	• Hemorrhage requiring transfusion [c]. • Postpartum hemorrhage by mode (vaginal, cesarean) [c]. • Uterine infection (i.e., choriamnionitis, administration of antibiotics in labor other than GBS prophylaxis) [c]. • Placental abruption, Uterine rupture. • Umbilical cord prolapse • Duration of time between hospital admission to birth that is insufficient to enable complete GBS prophylaxis antibiotics administration per CDC guidelines.	• Hemorrhage requiring transfusion [c]. • Postpartum hemorrhage by mode (vaginal, cesarean) [c]. • Uterine infection (i.e., choriamnionitis, administration of antibiotics in labor other than GBS prophylaxis) [c]. • Placental abruption • Uterine rupture • Umbilical cord prolapse • Duration of time between hospital admission to birth that is insufficient to enable complete GBS prophylaxis antibiotics administration per CDC guidelines.	• Hemorrhage requiring transfusion [c]. • Postpartum hemorrhage by mode (vaginal, cesarean) [c]. • Uterine infection (i.e., choriamnionitis, administration of antibiotics in labor other than GBS prophylaxis) [c]. • Placental abruption, Uterine rupture. • Umbilical cord prolapse • Duration of time between hospital admission to birth that is insufficient to enable complete GBS prophylaxis antibiotics administration per CDC guidelines.	• Hemorrhage requiring transfusion [c]. • Postpartum hemorrhage by mode (vaginal, cesarean) [c]. • Uterine infection (i.e., choriamnionitis, administration of antibiotics in labor other than GBS prophylaxis) [c]. • Placental abruption • Uterine rupture • Umbilical cord prolapse • Duration of time between hospital admission to birth that is insufficient to enable complete GBS prophylaxis antibiotics administration per CDC guidelines.	Outcomes not listed in inclusion criteria.
Timing	Maternal outcomes • From CR initiation to within 1-week following delivery. Infant outcomes • Immediately following delivery.	Maternal outcomes • From CR initiation to within 1-week following delivery. Infant outcomes • Immediately following delivery.	Maternal and additional outcomes (i.e., breastfeeding, maternal mood, mother-baby attachment). • From CR initiation to 1-year postpartum. Infant outcomes • Immediately following delivery.	Maternal outcomes • From CR initiation to within 1-week following delivery. Infant outcomes • Immediately following delivery.	KQ 1,2,4: Outcomes occurring after 1-week post delivery. KQ3: Outcomes for breastfeeding, mother-infant attachment, and maternal mood occurring after 1 year post-delivery.
Setting	• Inpatient versus outpatient settings.	• Inpatient versus outpatient settings.	• Outpatient setting	• Inpatient and outpatient settings.	
Study design	• Randomized Controlled Trials; recent high quality Systematic Reviews; if RCT evidence for benefits is insufficient, include large, high quality cohort studies comparing inpatient and outpatient setting. • Include high quality cohort and case-control studies for harms.	• Randomized Controlled Trials; recent high quality Systematic Reviews; if RCT evidence for benefits is insufficient, include large, high quality cohort studies comparing inpatient and outpatient setting. • Include high quality cohort and case-control studies for harms.	• Randomized Controlled Trials; recent high quality Systematic Reviews; if RCT evidence for benefits is insufficient, include large, high quality cohort studies comparing inpatient and outpatient setting. • Include high quality cohort and case-control studies for harms.	• Randomized Controlled Trials; recent high quality Systematic Reviews; if RCT evidence for benefits is insufficient, include large, high quality cohort studies comparing inpatient and outpatient setting. • Include high quality cohort and case-control studies for harms.	Case series, pre-post studies, case reports.

[c] (Bolded) items indicate Primary Outcomes.
CR = cervical ripening; CD = cesarean delivery; KQ = Key Question; ROM = rupture of membrane; CDC = Centers for Disease Control and Prevention; L&D = labor and delivery; RCTs = randomized controlled trials.

Dated: January 29, 2020.

Virginia L. Mackay-Smith,

Associate Director, Office of the Director, AHRQ.

[FR Doc. 2020–02058 Filed 2–3–20; 8:45 am]

BILLING CODE 4160–90–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project: ‘‘*Evaluating the Dissemination and Implementation of PCOR to Increase Referral, Enrollment, and Retention through Automatic Referral to Cardiac Rehabilitation (CR) with Care Coordination.*’’ In accordance with the Paperwork Reduction Act, AHRQ invites the public to comment on this proposed information collection.

DATES: Comments on this notice must be received by 60 days after date of publication.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov.*

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by email at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Evaluating the Dissemination and Implementation of PCOR to Increase Referral, Enrollment, and Retention through Automatic Referral to Cardiac Rehabilitation (CR) With Care Coordination

The aim of AHRQ's TAKEheart project is to (a) raise awareness about the benefits of cardiac rehabilitation (CR) after myocardial infarction or coronary revascularization, then to (b) disseminate knowledge about the best practices to increase referrals to CR, and, finally, (c) to increase CR uptake.

Currently over two-thirds of eligible cardiac patients are not referred to CR despite extensive evidence of its effectiveness in preventing subsequent morbidity; national estimates of referral range from 10–34%. To help improve CR rates, the Million Hearts® Cardiac Rehabilitation Collaborative—an initiative co-led by the Centers for Disease Control and Prevention (CDC) and the Centers for Medicare & Medicaid Services (CMS)—developed a Cardiac Rehabilitation Change Package (CRCP) and established a national goal of 70% participation in CR by 2022 for eligible patients. Recognizing that widespread adoption of the CRCP could help hospitals enhance CR rates, the CDC turned to AHRQ with a request that AHRQ consider disseminating and implementing evidence for CR and practices that promote CR. The CRCP is designed to facilitate this dissemination and implementation process.

AHRQ reviewed this request in the context of its Patient Centered

Outcomes Research Dissemination and Implementation initiative and judged the CDC nomination to have a high level of fit with AHRQ's criteria of having a substantial evidence base, high potential impact, and high feasibility for wide dissemination and implementation Outreach with stakeholders indicates that this initiative aligns well but does not duplicate work by NIH; PCORI; CMS and CDC.

The core recommendations in the CDC package are, first to spread adoption of automatic referral system—where patients after cardiovascular events are referred by the Electronic Health Record to rehabilitation unless the cardiologist actively decides not to refer because of medical ineligibility. The second core recommendation is use of a care coordinator to guide patients through referral has resulted in the most significant increases in referral to CR. TAKEheart will facilitate dissemination and implementation of Automatic Referral with Care Coordination in selected, diverse hospitals nationwide which demonstrate their readiness.

AHRQ will evaluate TAKEheart to assess:

- the extent and effectiveness of the dissemination and implementation efforts
- the uptake and usage of Automatic Referral with Care Coordination and
- levels of referral to CR at the end of the intervention.

Evaluation results will be used to improve the intervention and to provide guidance for future AHRQ Dissemination and Implementation projects. Two cohorts of ''Partner Hospitals,'' up to 125 hospitals in total, will receive training that disseminates the importance of CR and ways to enhance CR referral and then engages them in efforts to implement Automatic Referral with Care Coordination over twelve month periods. The evaluation will ascertain the diversity of hospitals engaged, the activities that contributed to (or hindered) their efforts, and the types of support which they report having been most (and least) useful. This information will be used to improve recruitment, technical assistance, and tools for the second cohort.

In addition, hospitals—including those involved in the dissemination and implementation support for Partner Hospitals—will be invited to attend Affinity Group virtual meetings organized around specific topics of interest which are not intrinsic to Automatic Referral with Care Coordination. Hospital staff engaged in Affinity Groups will create a vibrant Learning Community. The evaluation will determine which Affinity Groups engaged the most participants of the Learning Community, and which resources participants determined the most useful. This information will be used to develop resources which will be available on a new, permanent website dedicated to improving CR.

This study is being conducted by AHRQ through its contractor, Abt Associates Inc., pursuant to AHRQ's statutory authority to disseminate government-funded research relevant to comparative clinical effectiveness research. 42 U.S.C. 299b-37(a).

Method of Data Collection

To collect data on the many facets of the intervention, we will use multiple data collection tools, each of which has a specific purpose and set of respondents.

1. *Partner Hospital Champion Survey.* Each Partner Hospital will designate a ''Champion,'' who will coordinate activities associated with implementing Automatic Referral with Care Coordination at the hospital, and provide the Champion's name and email address. The Champion may have any role in the hospital, although they are expected in relevant positions, such as cardiologists or quality improvement managers. We will conduct online surveys of 125 Champions (one Champion per hospital). We will use the email addresses to send the Champion a survey at two points: Seven months after the start of dissemination and implementation to the Partner Hospitals and at the end of the 12-month dissemination and implementation period. The first survey will focus on four constructs. First, it will capture data about the hospital context, such as whether it had prior experience customizing an electronic medical record (EMR) or is a safety net hospital. Second, it will address the hospital's decision to participate in TAKEheart. Third, it will capture data on the CR programs the hospital refers to, whether the number or type has changed, and why. Fourth, it will collect feedback on the training and technical assistance received. The second survey will focus on three constructs. First, it will collect feedback on the TAKEheart components, including training, technical assistance, and use of the website. Second, we will ask about the hospitals' response to participating in TAKEheart, such as changes to referral workflow or CR programs. Third, we will ask those Partner Hospitals which have not completed the process of implementing Automatic Referral with Care Coordination whether they anticipate continuing to work towards that goal and their confidence in succeeding.

2. *Partner Hospital Interviews.*

a. *Interviews with Partner Hospital Champions.* We will select, from each cohort, eight Partner Hospitals that demonstrated a strong interest in addressing underserved populations or reducing disparities in participation in cardiac rehabilitation. We will conduct a key informant interview with the Champion of each selected Partner Hospital to delve into their response to the information and guidance that was disseminated to them and to describe how they are addressing the needs of underserved populations by implementing Automatic Referral with Care Coordination.

b. *Interviews with Partner Hospital cardiologists.* We will select, from each cohort, eight hospitals based on criteria such as hospitals which serve specific populations, or have the same EMRs, which will inform their experience customizing the EMR. We will conduct semi-structured interviews with one cardiologist at each of the selected hospitals twice. In the second month of the cohort for dissemination and implementation, we will ask about their needs, concerns, and expectations of the program. In the 11th month of the cohort implementation, we will determine whether their concerns were addressed appropriately and adequately.

c. *Interviews with Partner Hospitals that withdraw.* We expect that a small number of Partner Hospitals may withdraw from the cohort. We will identify these hospitals by their lack of participation in training and technical assistance events; technical assistance providers will confirm their withdrawal. We will interview up to nine withdrawing hospitals to better understand the reason for withdrawal (*e.g.,* a merger resulted in a loss of support for the intervention, Champion left), as well as facilitators of, and barriers to, each hospital's approach to implementing Automatic Referral with Care Coordination. If more than nine hospitals withdraw, we will cease interviewing.

3. *Learning Community Participant Survey.* We will conduct online surveys of 250 currently active Learning Community participants at two points in time, in months 18 and 31 of the project. We will administer the survey by sending a link to an online survey to email addresses entered by virtual meeting participants during registration. The email will describe the purpose of the survey.

4. *Learning Community Follow-up Survey.* We will conduct a brief online survey with up to 15 Learning

Community participants following the final virtual meeting for each of 10 Affinity Groups, to ascertain whether the hospitals were able to act on what they learned during the session. The total sample will be 150 Learning Community participants.

Estimated Annual Respondent Burden

Exhibit 1 presents estimates of the reporting burden hours for the data collection efforts. Time estimates are based on prior experiences and what can reasonably be requested of participating health care organizations. The number of respondents listed in column A, Exhibit 1 reflects a projected 90% response rate for data collection effort 1, and an 80% response rate for efforts 3 and 4 below.

1. *Partner Hospital Champion Survey*. We assumed 113 hospital champions will complete the survey based on a 90% response rate. It is expected to take up to 45 minutes to complete for a total of 169.5 hours to complete.

2. *Partner Hospital Interviews*. In-depth interviews will occur with select Partner Hospital staff.

a. *Interviews with Partner Hospital Champions*. We will have a single, 90 minute interview with eight Partner Hospital Champions, in each cohort, from Partner Hospitals that have a common characteristic of particular interest, for a total of 24 hours.

b. *Interviews with Partner Hospital cardiologists*. We will hold individual, up-to-30 minute interviews with eight cardiologists, twice in each cohort, for a total of 16 hours.

c. *Interviews with Partner Hospitals that withdraw*. We will interview up to nine withdrawing hospitals for no more than 20 minutes to better understand the reason for withdrawal as well as facilitators and barriers, for a total of 2.7 hours.

3. *Learning Community Participant Survey*. We assumed 200 Learning Community participants will complete the survey based on an 80% response rate. It is expected to take up to 15 minutes to complete each survey for a total of 100 hours.

4. *Learning Community Follow-up Survey*. We will conduct a brief, up to 10 minute, online survey of participants of each of just ten selected Affinity Groups at two months after the virtual meeting. We assumed 120 Learning Community participants will complete the survey based on an 80% response rate. It is expected to take up to 15 minutes to complete each survey for a total of 20.4 hours.

EXHIBIT 1—ESTIMATED ANNUALIZED BURDEN HOURS

Data collection method or project activity	A. Number of respondents	B. Number of responses per respondent	C. Hours per response	D. Total burden hours
1. Partner Hospital Champion Survey*	113	2	0.75	169.5
2a. Interviews with Partner Hospital Champions	16	1	1.5	24.0
2b. Interviews with Partner Hospital Cardiologists	16	2	0.5	16.0
2c. Interviews with Partner Hospitals that withdraw	9	1	0.3	2.7
3. Learning Community Survey**	200	2	0.25	100.0
4. Learning Community Follow-up Survey**	120	1	0.17	20.4
Total	474	.....	.....	332.6

* Number of respondents (Column A) reflects a sample size assuming a 90% response rate for this data collection effort.
** Number of respondents (Column A) reflects a sample size assuming an 80% response rate for this data collection effort.

Exhibit 2, below, presents the estimated annualized cost burden associated with the respondents' time to participate in this research. We obtained median hourly wage rates for relevant occupations from the Bureau of Labor & Statistics on ''Occupational Employment Statistics, May 2018 Occupation Profiles'' found at the following URL on October 1, 2019: *https://www.bls.gov/oes/current/oes_stru.htm#15-0000.* We assumed that half the Partner Hospital Champions will be cardiologists and half will be Quality Improvement managers. We calculated the hourly rate of $72.27 by averaging the median hourly wage rate for cardiologists ($96.58, occupation code 29–1069) and medical and health services managers ($47.95, occupation code 11–1141). The occupation of medical and health services managers has been used for quality improvement staff in other AHRQ projects. The total cost burden is estimated to be about $21,497.

EXHIBIT 2—ESTIMATED ANNUALIZED COST BURDEN

Data collection method or project activity	A. Number of respondents	B. Total burden hours	Average hourly wage rate	Total cost burden
1. Partner Hospital Champion Survey*	113	169.5	$72.27	$12,250
2a. Interviews with Partner Hospital Champions	16	24.0	72.27	1,734
2b. Interviews with Partner Hospital Cardiologists	16	16.0	96.58	1,545
2c. Interviews with Partner Hospitals that withdraw	9	2.7	72.27	195
3. Learning Community Survey**	200	100.0	47.95	4,795
4. Learning Community Follow-up Survey**	120	20.4	47.95	978
Total	474	332.6	.....	21,497

* Number of respondents (Column A) reflects a sample size assuming a 90% response rate for this data collection effort.
** Number of respondents (Column A) reflects a sample size assuming an 80% response rate for this data collection effort.

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 healthcare 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.

Dated: January 29, 2020.

Virginia L. Mackay-Smith,

Associate Director.

[FR Doc. 2020–02112 Filed 2–3–20; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Agency for Healthcare Research and Quality, HHS.

ACTION: Notice.

SUMMARY: This notice announces the intention of the Agency for Healthcare Research and Quality (AHRQ) to request that the Office of Management and Budget (OMB) approve the proposed information collection project ''Evaluation of the SHARE Approach Model.''

DATES: Comments on this notice must be received by 60 days after date of publication.

ADDRESSES: Written comments should be submitted to: Doris Lefkowitz, Reports Clearance Officer, AHRQ, by email at *doris.lefkowitz@AHRQ.hhs.gov*.

Copies of the proposed collection plans, data collection instruments, and specific details on the estimated burden can be obtained from the AHRQ Reports Clearance Officer.

FOR FURTHER INFORMATION CONTACT: Doris Lefkowitz, AHRQ Reports Clearance Officer, (301) 427–1477, or by emails at *doris.lefkowitz@AHRQ.hhs.gov.*

SUPPLEMENTARY INFORMATION:

Proposed Project

Evaluation of the SHARE Approach Model

Shared decision making (SDM) occurs when a health care provider and a patient work together to make a health care decision that is best for the patient. Implementing SDM involves effective communication between providers and patients to take into account evidence-based information about available options, the provider's knowledge and experience, and the patient's values and preferences in reaching the best health care decision for a patient. To facilitate SDM in all care delivery settings, AHRQ developed the five-step SHARE Approach, which includes exploring and comparing the benefits, harms, and risks of each option through meaningful dialogue about what matters most to the patient. Using the SHARE Approach also builds a trusting and lasting relationship between health care professionals and patients.

SDM is increasingly included in clinical care guidelines, and in some cases is even mandated. While there is considerable interest in improving SDM across broad health care settings, less is known about how to effectively implement SDM. There is evidence that SDM is often not conducted effectively in practice, and identifying ways to improve SDM has therefore become an imperative. Lack of clinician support and education have been identified as important barriers to SDM.

The SHARE Approach was released in 2015 by AHRQ as a clinician-facing toolkit that teaches clinicians skills to facilitate SDM across a broad range of clinical contexts. While several implementation success stories have been shared with AHRQ, to date there has been no formal evaluation of the effectiveness of the SHARE Approach materials for improving SDM in primary and specialty care settings for which it was designed. As a result, challenges that may be faced by practices who wish to implement the SHARE Approach are currently unknown. Without research to identify and address these issues, practices and organization may be unable to effectively implement the SHARE Approach and may be unwilling to do so absent evidence of its effectiveness at improving SDM outcomes.

The Evaluation of the SHARE Approach Model project aims to revise the SHARE Approach toolkit to remove outdated references and increase applicability for SDM in contexts involving problem solving, evaluate the implementation of the SHARE Approach model in eight primary care and four cardiology clinics, and evaluate the effectiveness of the SHARE Approach model at improving SDM.

Method of Collection

The purpose of this clearance request is to collect the information needed to evaluate the implementation and effectiveness of the modified SHARE Approach materials. Specifically, the data collection activities requested in this clearance are:

1. Brief surveys of physicians, advanced practice providers, other clinicians, nurses and other staff in 12 clinics immediately following the SHARE Approach training in each clinic.
2. A brief survey of physicians, advanced practice providers, other clinicians, nurses and other staff in 12 clinics one month following the SHARE Approach training in each clinic.
3. A short card survey completed by patients in the 12 clinics immediately following a clinic visit with a physician or advanced practice provider.
4. A short card survey completed by physicians or advanced practice providers in the 12 clinics immediately following a clinic visit with a patient.
5. Audio recordings of patient-provider (physician or advanced practice provider) encounters in clinic examination rooms in the 12 clinics.

This study is being conducted by AHRQ through its contractor, the University of Colorado, pursuant to AHRQ's statutory authority to conduct and support research on health care and on systems for the delivery of such care, including activities with respect to clinical practice, including primary care and practice-oriented research. 42 U.S.C 299a(a)(4).

Estimated Annual Respondent Burden

Exhibit 1 shows the estimated burden hours over the full 3 years of this clearance for the respondents' time to participate in the research activities that will be conducted under this clearance. Brief card surveys will be completed by both patients and clinicians. The physician/advanced practice provider card survey will require a maximum of 60 seconds. The patient card survey will take a maximum of 2 minutes. Number of observations will include a maximum