SUPPORTING STATEMENT

Part A

Evaluation of the SHARE Approach Model

Version Date: 04/06/2020

Agency of Healthcare Research and Quality (AHRQ)

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A. Justification

1. Circumstances that make the collection of information necessary

The mission of the Agency for Healthcare Research and Quality (AHRQ), set out in its authorizing legislation, The Healthcare Research and Quality Act of 1999 (see http://www.ahrq.gov/hrqa99.pdf), is to enhance the quality, appropriateness, and effectiveness of health services and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health systems practices, including the prevention of diseases and other health conditions. AHRQ shall promote health care quality improvement by conducting and supporting:

1. Research that develops and presents scientific evidence regarding all aspects of health care;

2. The synthesis and dissemination of available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

3. Initiatives to advance private and public efforts to improve health care quality.

Also, AHRQ conducts and supports research, evaluations, and demonstration projects, with respect to (A) the delivery of health care in inner-city areas and in rural areas (including frontier areas); and (B) health care for priority populations, which includes (1) low-income groups, (2) minority groups, (3) women, (4) children, (5) the elderly, and (6) individuals with special health care needs, including individuals with disabilities and individuals who need chronic care or end-of-life health care.

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 that includes exploring and comparing the benefits, harms, and risks of each option through meaningful dialogue about what matters most to the patient.

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 developed by AHRQ as a clinician-facing toolkit that teaches clinicians skills to facilitate shared decision-making (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 has the following goals:

1. Revise the SHARE Approach toolkit to remove outdated references and increase applicability for SDM in contexts involving problem solving

2. Evaluate the implementation of the SHARE Approach in eight primary care and four cardiology clinics

3. Evaluate the effectiveness of the SHARE Approach at improving SDM.

To achieve the goals of this project, AHRQ - in collaboration with its contractor the University of Colorado, has designed a SHARE Approach Implementation and Evaluation Plan that includes the following activities and data collections.

1. **Acquire feedback on SHARE Approach materials**: A panel of five clinician consultants with experience using the SHARE Approach will provide feedback about their experiences and recommendations for improvement. A separate panel of up to nine clinician stakeholders will review all SHARE Approach materials and evaluate them for applicability to situations involving problem-solving, and provide recommendations for improvement. We will additionally bring these materials to two standing patient advisory groups for a total of up to 9 patients who will provide feedback and recommendations for improving the SHARE Approach.

2. **Evaluation of SHARE Implementation**: We will recruit eight primary care and four cardiology practices to participate in a SHARE Approach implementation and effectiveness study. This evaluation shall support collection of information in diverse practice settings, including inner-city, rural, and low-income settings that provide care for minority groups, women and individuals with special health care needs with a particular focus on patients with multiple chronic conditions. SHARE training will be conducted in 2 half-day sessions and supplemental webinar sessions in all practices. Implementation will be assessed with a brief clinician and staff survey following training in each practice, semi-structured field notes recorded by all team members following interactions with clinics, and observations from SHAREd Learning Calls designed to support practices in implementation of the SHARE Approach.

3. **Evaluate SHARE Effectiveness.** To evaluate the effectiveness of the SHARE Approach at improving SDM in practices, we will conduct a short survey and audio recordings of clinical encounters. The survey and audio recordings will be conducted at three time points: in the month prior to SHARE implementation, in the month following SHARE implementation, and approximately six months following implementation. The short survey will include responses from both patients and clinicians. It will solicit patient and clinician perspectives on SDM in the encounter. A sample of patient-provider interactions

at each time point will be audio recorded to objectively evaluate whether SDM occurred using an a priori coding scheme.

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. A brief survey of physicians, advanced practice providers, other clinicians, nurses and other staff (clinicians) in 12 clinics following the SHARE Approach training in each clinic.

2. A brief survey of physicians, advanced practice providers, other clinicians, nurses and other staff (clinicians) in 12 clinics one month following the implementation of the SHARE Approach in each clinic.

3. A short survey completed by patients in the 12 clinics immediately following a clinic visit with a physician or advanced practice provider.

4. A short 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 project 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 the quality, effectiveness, efficiency, appropriateness and value of health care services and with respect to quality measurement and improvement. 42 U.S.C. 299a(a)(1) and (2).

2. Purpose and Use of Information

Healthcare organizations have only recently begun to systematically incorporate shared decision making (SDM) into clinical encounters involving treatment decisions. To date, the SHARE Approach is unique in having developed clinician-facing shared decision-making training and tools that encourage a generic and highly generalizable approach to shared decision making in the context of both clinical treatment decisions and problem-solving. Only through systematic implementation and evaluation of the SHARE Approach toolkit will we identify effective implementation strategies and whether SHARE is effective at improving clinicians' shared decision-making skills. Therefore, the planned implementation and evaluation of the SHARE Approach will provide the information needed to:

1) Revise the SHARE Approach training materials to facilitate implementation in primary and specialty care practice settings, and

2) Establish effectiveness of the SHARE Approach for improving SDM in clinical encounters.

The findings from this research will be used, along with other activities described in Section 1, to identify implementation feasibility of the SHARE Approach, provide recommendations for improvements to the toolkit, and establish effectiveness of the approach for improving shared decision making. If the SHARE Approach proves to be a valid and reliable method for improving SDM it will be further disseminated by AHRQ to support health care organizations in their efforts to improve SDM nationwide.

3. Use of Improved Information Technology

The clinician and staff surveys will be completed immediately prior to the SHARE Approach training, immediately following the training, and one to two months after the training. The surveys will be conducted using multiple modes including an email request to complete an online survey form. In addition to in-person trainings, webinars will be hosted using Zoom video conference call technology to maximize the number of clinicians and staff exposed to the SHARE Approach training. After obtaining patient consent, audio recordings will be conducted using a small digital recording device.

4. Efforts to Identify Duplication

There are no existing data assessing the implementation and effectiveness of the SHARE Approach in primary care or specialty care ambulatory clinics. Work carried out under this clearance will be designed to evaluate the implementation and effectiveness of the program and will not duplicate any other evaluation or testing of the SHARE Approach sponsored by AHRQ or other Federal agencies. This is known from direct communication with AHRQ leadership, which would likely be involved in any such research efforts, and from literature searches conducted prior to submission of this information clearance request.

5. Involvement of Small Entities

Although we anticipate most of the primary care and specialty practices will be part of larger health care organizations, our purposive sampling will include one to three small private practices that are not affiliated with large health care organizations. The same information will be requested from all selected respondents, but smaller private practices are likely to have fewer clinicians and staff; thus, the reporting burden is expected to be less for these small entities. The information being requested from all respondents is the minimum required to achieve the project objectives.

6. Consequences if Information Collected Less Frequently

The evaluation of the implementation and effectiveness of the SHARE Approach is a one-time activity that involves collection of data at three time points for each of the 12 practices implementing the SHARE Approach. Data are collected immediately before and while the practice clinicians and staff participate in the training on the SHARE Approach, one month following the implementation and again approximately six months after implementation. A reliable and rigorous evaluation of the effectiveness of the SHARE Approach to SDM requires data collection before and after implementation to conduct a pre/post evaluation design to evaluate the implementation and maintenance of effectiveness. Less frequent data collection would significantly threaten the reliability and validity of the evaluation.

7. Special Circumstances

This request is consistent with the general information collection guidelines of 5 CFR 1320.5(d)(2). No special circumstances apply.

8. Federal Register Notice and Outside Consultations

8.a. Federal Register Notice

In accordance with the Paperwork Reduction Act of 1995 (Pub. L. 104-13) and Office of Management and Budget (OMB) regulations at 5 CFR Part 1320 (60 FR 44978, August 29, 1995), AHRQ published a notice in the Federal Register announcing the agency's intention to request an OMB review of this information collection activity. This notice was published on February 4, 2020, Volume 85, Number 23, pages 6193-6194, and provided a sixty-day period for public comment. A copy of this notice is attached as Attachment A. During the notice and comment period, AHRQ received no requests for information or substantive comments.

8.b. Outside Consultations

During the initial revision phase of the SHARE Approach Evaluation, AHRQ and the University of Colorado will engage up to five (5) clinician consultants that have experience implementing the SHARE Approach in their encounters with patients. These five consultants will review the SHARE Approach training materials and toolkits and provide feedback for shortening, improving, and increasing relevance of the materials based on their experience using the materials.

To ensure the perspectives of diverse stakeholders are represented, the University of Colorado will also coordinate and receive feedback from up to nine (9) clinician stakeholders and members of standing patient advisory groups. The clinician stakeholders will review the SHARE Approach training materials and toolkits and provide feedback for shortening, improving, and increasing relevance of the materials for shared decision making in the context of complex problem solving. The patient advisory groups will represent a diverse array of perspectives (e.g. patients with different co-morbidities) and provide feedback and recommendations for improving the SHARE Approach materials that is needed to implement effective shared decision making.

9. Payments/Gifts to Respondents

Patients agreeing to participate in clinical encounter audio recordings will be offered a $25 Amazon gift card as a token of appreciation for their time and participation in the study. This decision is based on experience with other AHRQ data collection and findings from the published literature showing that modest incentives can improve response rates (Ryu, Couper & Marans, 2006).[1] Card survey respondents will not be provided an incentive due to the very low burden of the survey.

Ryu, E., Couper, M.P. & Marans, R.W. (2006). Survey Incentives: Cash vs. In-Kind; Face-to-Face vs. Mail; .1[1] .Response Rate vs. Nonresponse Error. *International Journal of Public Opinion Research, 18(1),* 89-106

10. Assurance of Confidentiality

Individuals and organizations will be assured of the confidentiality of their replies under Section 944(c) of the Public Health Service Act at 42 U.S.C. 299c-3(c). In accordance with this law, individuals and organizations will be informed of the purposes for which the information is collected and that any identifiable information about them will not be used or disclosed for any other purpose unless they consent to the use of the information for another purpose.

The following personally identifiable information (PII) will be collected during the SHARE Evaluation project from practices and clinical staff: names, clinical role and email addresses. This information will be collected and stored separately from other information. Names of practices and clinical staff will be replaced with anonymized practice IDs and staff IDs. Clinical staff email addresses are needed to share information about the training and survey questionnaires and needed if staff choose to complete these online. Clinician and staff surveys will include the anonymized practice and staff IDs and the clinician version of the card surveys will be assigned an unique anonymized card survey identification number that is linked to clinicians using the clinician anonymized ID.

Patient versions of the card surveys will be linked to clinician card surveys using the unique anonymized card survey identification number. No patient PII will be collected as part of the card survey.

For the patients agreeing to have their clinician encounter audio recorded, patient PII will be obtained to provide documentation for the payment of the $25 dollar incentive. This information will be collected and stored separately from all other information. The audio recordings will not be linked to this patient PII and will be identified by an anonymized recording identification number. However, during the course of the audio-recorded clinician encounter it is possible the patient and/or the clinician will discuss patient PII. As stated, the audio recordings will only be identified with the anonymous recording identification number and these recordings will be transcribed and coded by University of Colorado research staff that will not have access to the payment documentation. Transcripts and coded information will be purged of all PII and any other information that could identify an individual.

No practice, clinician, staff, or patient names or other PII will be included in any reports, presentations, or other publications emerging from this project without the express consent of the individual or organization. Only aggregated, de-identified results will be displayed in any reports, presentations, or other publications.

All project data, including the files linking practice and staff names and study IDs, will be stored in a secure, password-protected electronic shared folder with secure access granted only to specified project staff with a need to know each type of information. The practice and staff names, roles and email addresses, as well as the audio recordings, incentive payment information and crosswalks with study IDs, will only be accessible by the Principal Investigator, Project Director and Project Manager. Data identifiable with only the study IDs will be stored in a secure folder with access limited to project staff who need to use the data, including the Principal Investigator, Project Director and Project Manager. Protocols for data collection, storage, and analyses will be approved by the Colorado Multiple Institutional Review Board (COMIRB) that oversees research conducted at the University of Colorado Anschutz Medical Campus.

COMIRB's Federal-wide Assurance (FWA) with the Office for Human Research Protections of the U.S. Department of Health and Human Services provides that the organization will assure compliance with the Terms of Assurance for Federally-supported research.

11. Questions of a Sensitive Nature

While there are no questions of a sensitive nature, the audio recordings of patient-clinician encounters may include information of a sensitive nature. The consent process will include a statement that participants may ask that the audio recording be stopped at any time. In addition, the card survey will include instructions that participants may skip any question they choose to not answer.

12. Estimates of Burden Hours and Costs

Exhibit 1 shows the estimated burden hours for the respondents' time to participate in the research activities that will be conducted under this clearance. Data collection will occur between September 2020 and October 2021. Surveys of physicians, advanced practice providers, other clinicians, nurses and other staff in each of the 12 practices will be conducted at the time of SHARE training and again approximately 1 to 2 months following training. These will be conducted with no more than 100 physicians, advanced practice providers, other clinicians, nurses and other staff for each survey and will require no more than 10 minutes to complete.

Brief card surveys will be completed by both patients and clinicians. We estimate the maximum number of patients participating in the card survey as follows: A maximum of 100 clinicians will see a maximum of 20 patients per day, of which half (n=10) will agree to complete the card survey, over 6 days of data collection, totaling N=6,000 patient respondents (100 x 10 x 6). The patient card survey will take a maximum of 2 minutes per completed survey. Clinicians will complete a card survey for every patient they see during the 6 days of data collection, or a total of N=12,000 card surveys (100 clinicians x 20 patients per day x 6 days). The clinician card survey will require a maximum of 1 minute per completed survey.

Audio recordings of up to 260 clinical encounters will be obtained with burden not to exceed 10 minutes to obtain patient informed consent.

Exhibit 1. Estimated respondent burden hours

Type of Information Collection	Number of Respondents	Number of Responses per Respondent	Hours per Response	Total Burden Hours
Card survey (patient)	6,000	1	2/60	200
Card survey (clinician)	100	120	1/60	200
Audio recorded encounters	260	1	10/60	43
Clinician survey*	100	2	10/60	33
Totals	6,460	na	na	476

* May include telephone non-response follow-up in which case the burden will not change

Exhibit 2 shows the estimated cost burden of respondents for these data collection activities, based on the respondent's time to participate in these data collection activities. The total cost burden is estimated to be $29,831.

Exhibit 2. Estimated cost burden

Type of Information Collection	Number of Respondents	Total Burden Hours	Average Hourly Wage Rate*	Total Cost Burden
Card survey (patient)	6,000	200	$24.98	$4,996
Card survey (clinician)	100	200	$101.43	$20,286
Audio recorded encounters	260	44	$24.98	$1,100
Clinician survey	100	34	$101.43	$3,449
Totals	6,460	478	na	$29,831

*Based upon the average wages for 29-1060 Physicians and Surgeons (broad) and 00-0000 All Occupations, "National Compensation Survey: Occupational Wages in the United States, May 2018," U.S. Department of Labor, Bureau of Labor Statistics https://www.bls.gov/oes/current/oes_nat.htm#29-0000.

13. Estimates of Annualized Respondent Capital and Maintenance Costs

There are no respondent capital and maintenance costs, which include the purchase of equipment, computers or computer software or services, or storage facilities for records, as a result of participating in this data collection. The only cost to respondents will be that associated with their time to respond to the information collection as shown in Exhibits 1 and 2.

14. Estimates of Annualized Cost to the Government

Information collections conducted under this clearance will be carried out under contract with the University of Colorado.

The project and aspects of data collection related activities will occur in each of the three (3) years of the project. Exhibit 4 shows the total cost and annualized cost for the overall project. The estimated annualized cost of $399,982 includes all components of the project to update and evaluation the SHARE Approach model. Although not shown in the exhibit, the annualized cost of all data collection related activities is $160,543.

Exhibit 3. Estimated Annualized Cost

Cost Component	**Total Cost**	**Annualized Cost**
Updating the SHARE Approach	$72,565	$24,188
Preparation for Implementation	$65,699	$21,900
Evaluation Plan	$73,655	$24,552
Implementation of SHARE Approach	$407,160	$135,720
Data Analysis and Reporting	$367,685	$122,562
Project Management	$213,182	$71,061
Total	$1,199,946	$399,982

Exhibit 4 shows the estimated annual cost for AHRQ staff overseeing this project. With approximately 40% of the overall project related to data collection activities an additional annual cost of $12,134 for agency staff would be associated with data collection related activities on this project. The total annual cost to the government for the data collection related activities on this project is estimated to be $172,677.

Exhibit 4: Annual Cost to AHRQ for Contract Oversight

Tasks/Personnel	Staff Count	Hourly Rate	Estimated Hours	Estimated Annual Cost
Management and Research Support: GS-13, Step 8	1	$60.67	500	$30,335
Grand Total				$30,335

Annual salaries based on 2020 OPM Pay Schedule for Washington/DC area: https://www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/pdf/2020/DCB_h.pdf

15. Changes in Hour Burden

This is a new data collection effort and does not modify any previous submission.

16. Time Schedule, Publication and Analysis Plans

16.a. Time Schedule

The timing of major project-related activities are presented in Exhibit 5. The timing of the collection of data for the evaluation and the implementation of the SHARE Approach in the 12 practices is dependent on receipt of OMB clearance, which we expect to receive by August 28, 2020. Assuming clearance is received by that date, the following schedule of project activities will be followed:

Exhibit 5. Project Timeline

Activity	Start Date	End Date
Update the SHARE Approach curriculum, tools, and implementation material	12/02/2019	08/04/2020
Obtain IRB approval	12/18/2019	02/21/2020
Develop provider survey, card surveys, audio recording protocols, and observation guides	12/19/2019	03/18/2020
Recruitment of practices	03/03/2020	08/11/2020
Collect data for evaluation	09/01/2020	11/29/2021
Implement SHARE Approach in 12 practices	10/01/2020	11/29/2021
Data coding, transcription and quality checks	03/30/2021	01/17/2022
Data analysis	01/18/2022	04/18/2022
Final Report	04/19/2022	10/27/2022
Manuscript for peer-reviewed publication	06/21/2022	11/14/2022
Revise SHARE tools, resources, training, and implementation material	04/19/2022	11/14/2022

16.b. Publication and Use of Findings

AHRQ plans to submit at least one manuscript describing project findings to a peer-reviewed journal.

16.c. Analysis Plans

Survey data will be analyzed using statistical methods as follows: Initially, descriptive statistics will be computed to describe baseline clinician/practice and patient characteristics. In addition,

chi-squares and t-tests will be used to determine whether there are differences between: (1) complete and incomplete reports, and (2) clinician dropouts vs non-dropouts over time. Clinician/practice characteristics as well as patient sociodemographic characteristics will be included as covariates in subsequent analyses if associated with report completion or outcomes at $p<.15$. For longitudinal clinician data, we will employ methods that utilize all available data, assuming ignorable missingness (MCAR or MAR). Primary outcome variables for most analyses will be continuous (or ordinal); secondary outcomes may be dichotomous. We will employ general linear mixed model approaches (random effects for clinician) that incorporate multilevel data structures with fixed effect terms for observation (pre-training, post-training, follow-up) to facilitate hypothesis testing and estimation. In the event normality assumptions are not met we will utilize generalized linear mixed models with the appropriate link function (e.g. logit link for dichotomous). All hypothesis tests will be two-sided with alpha=.05 or p values reported. Statistical analysis will be carried out using SAS 9.4. Goodness of fit statistics (e.g. AIC, deviance, -2 log likelihood and change in –2LL for nested models) and model fitting diagnostics to assess for influential points, outliers, over dispersion and heteroscedasticity will be used to evaluate alternative model specifications (below). Analysis of audio recording data will use the OPTIONS coding scheme for quantifying objective use of shared decision making in the clinical encounter.

17. Exemption for Display of Expiration Date

No exemption is being requested.

List of Attachments:

Attachment A – Federal Register Notice
Attachment B – SHARE Approach evaluation clinician and staff surveys
Attachment C – Clinician card survey
Attachment D – Patient card survey
Attachment E – Audio recording coding scheme