SUPPORTING STATEMENT

Part B

Evaluation of the SHARE Approach Model

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Agency for Healthcare Research and Quality (AHRQ)

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B. Collections of Information Employing Statistical Methods

The project objectives are to:

1. Evaluate the implementation of the SHARE Approach in 12 primary care and specialty care practices in Colorado, and;

2. Evaluate the effectiveness of the SHARE Approach for improving shared decision making in clinical encounters.

The application of statistical methods in achieving these objectives are related to evaluating the SHARE Approach's effectiveness at improving shared decision making in clinical encounters. The project design is driven by a current lack of information on the contextual factors that facilitate or impede implementation of the SHARE Approach and the effectiveness of the SHARE Approach in improving shared decision making. The data collection activities and the design of the analysis of these data include semi-structured field notes completed by study team members who are in direct contact with the practices will document implementation of the SHARE Approach and practice specific contextual factors. Specifically, field notes will document observations relevant to the adoption, implementation and maintenance of the SHARE Approach across the duration of the project. Content analysis of field notes will use qualitative analysis methods. Additional data collection will involve systematic collection of information from 10 or more respondents:

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

1. Respondent universe and sampling methods

The brief surveys of clinicians (#1 and 2 in the above list of data collection involving 10 or more respondents) will be provided to all practice staff that have clinical contact with patients in the 8 primary care and 4 cardiology practices implementing the SHARE Approach. Clinician surveys will be collected at two different time points from each practice. The first survey will be conducted immediately following the SHARE Approach training to assess clinician's evaluation of the training. The second survey will be conducted one month later to assess clinician use of

the SHARE Approach in their clinical encounters. As such, the potential respondent universe for these Clinician Surveys will be the number of clinicians in the 12 practices. The 8 primary care practices and 4 cardiology practices will be purposively identified and recruited for this study to provide geographic diversity and a variety of practice characteristics. For statistical analysis purposes we are estimating that each of the 12 practices will have, on average, 8.33 clinicians that receive the SHARE training for a total potential respondent universe of 100.

The **Card Surveys** of patients and clinicians (#3 and 4 in the above list of data collection involving 10 or more respondents) will be conducted in all 12 practices and will be administered at three different data collection periods. The first data collection period will occur over a 2-day period one month prior to a practice receiving the SHARE training. The second data collection period will occur over a 2-day period one month after a practice received the SHARE training. The third data collection period will occur over a 2-day period six months after a practice received the SHARE training. Over the course of each 2-day data collection period, clinicians will be expected to complete the card survey after each patient encounter, and a member of the study team will approach as many patients as possible following their encounter and ask them to complete the patient card survey. As such, the potential respondent universe for the Patient and Clinician Card Surveys will be all patients with a clinic visit in each 2-day data collection period and all clinicians seeing patients in practices over the course of each 2-day data collection period. Assuming all clinicians will see at least one patient over the course of each 2-day data collection period, the potential respondent universe of clinicians is 100, which is the same potential respondent universe as the Clinician Survey. Estimating that each of the clinicians in the 12 practices will on average, see 20 patients per day, the total potential patient respondent universe equals 12,000 patients (100 clinicians x 20 patients per day x 6 days of data collection). As the specific days of each 2-day data collection period will be scheduled independent of other factors the total potential patient respondent universe represents a random sample of patients in each practice.

The **Audio Recordings** of patient-clinician encounters (#5 in the above list of data collection involving 10 or more respondents) will also be conducted in all 12 practices and will be administered over the same 2-day data collection periods at three different time points (i.e., one month prior, one month after and six months after a practice receives the SHARE Approach training). A subset of all patients with a clinic visit in each 2-day data collection period will be approached prior to their appointment to request their informed consent to have their encounter audio recorded. Patients with visits that are the most likely to involve shared decision making will be identified by clinic staff at the beginning of each day of data collection in a practice. As such, the potential respondent universe for the Audio Recordings is the same as the Patient Card Surveys (i.e., 12,000). Practices will be asked to identify 10 patients per day whose visits will likely involve shared decision making as determined by patients with multiple, active chronic conditions. A project team member working on-site at the clinic will approach 7 to 8 patients each day resulting in a sample size of 520 patients across the 12 practices and the 6 days of data collection. The selection of patients for the Audio Recordings that are most likely to involve shared decision making conversations results in a purposive sample of all patients with visits to the practice in each 2-day data collection period.

Exhibit 1 summarizes the information on the respondent universe and the sampling methods for this data collection activity.

Exhibit 1. Respondent Universe and Sampling Methods

Data Collection Activity	Respondent Universe	Sample Description	Sampling Method	Sample Size	Projected Response Rate	Projected Number of Respondents
1. Clinician survey immediately following SHARE training	100	Clinicians who work in the 12 recruited practices and take part in SHARE training	Purposive Sample	100	100%	100
2. Clinician survey 1 month following SHARE training	100	Clinicians who work in the 12 recruited practices and take part in SHARE training	Purposive Sample	100	100%	100
3. Clinician card survey	100	All clinicians who see patients on the days of data collection	Purposive Sample	100	90%	90
4. Patient card survey	12,000	All patients who have appointments in the practice on the days of data collection	Universe of patients with appointments	12,000	50%	6,000
5. Audio Recordings	12,000	All patients who have appointments in the practice on the days of data collection likely to involve shared decision making	Purposive Sample	520	50%	260

As described in Exhibit 1, this information collection activity uses non-probability based samples. The objectives of the study are most efficiently achieved through the use of non-probability based samples to assess the implementation of the SHARE Approach and evaluate the effectiveness of the SHARE Approach in practices that have an interest in enhancing shared decision making. As such, statistical inferences related to the underlying population of all primary care and cardiology practices will not be made using the information collected.

2. Information Collection Procedures

The brief survey of clinicians immediately after and one-month following SHARE training will collect information about clinicians' experience with the SHARE Approach training and their successes, failures, and willingness to implement the skills and tools taught in the SHARE Approach training in their daily practice. All clinicians in the 12 practices will have the option of completing these surveys on paper or electronically using an emailed survey link to a website. The survey questions include closed-ended Likert scale and open-ended response formats. We will ask clinicians to report their opinions about the most and least valuable components of the

SHARE Approach training, and later on report how or whether they use the approach in their daily practice.

Card surveys: The **Clinician card survey** will collect information about satisfaction with discussion, whether the clinical encounter involved decision-making or problem solving with the patient, and if so, the clinician's evaluation of shared decision making in the encounter as measured by a standard scale instrument. Paper and pencil surveys will be provided to all clinicians in each practice immediately following every patient encounter in the 2-day data collection period. These surveys provide clinicians' subjective assessment of shared decision making during the patient encounter. The **Patient card survey** will collect patient provided information on the purpose of their clinical visit, a standardized measure of patients' preferred role in decision-making, patient demographics, and the same information as the clinician card surveys. Paper and pencil surveys will be provided to every patient with a clinical visit in each practice immediately following their clinical encounter in the 2-day data collection period. These surveys provide patients' subjective assessment of shared decision making during their encounter with a clinician.

Audio recordings will capture the verbal exchanges between a patient and a clinician in the examination room. A project team member who is on-site for the 2-day data collection period will turn on an audio recording device in the exam room as a patient that has provided informed consent for the recording enters the exam room and leave the room. The project team member will retrieve the audio recording device as soon as the patient leaves the exam room. The audio recordings will be transcribed and coded using a validated coding scheme to provide an objective assessment of shared decision making during clinical encounters.

The brief surveys of clinicians and audio recordings will be analyzed with qualitative and descriptive methods to assess implementation of the SHARE Approach. Audio recordings will additionally be coded using the OPTIONS coding scheme for quantifying shared decision making in clinical encounters. The clinician and patient card surveys will be analyzed initially using descriptive statistics to describe baseline clinician/practice and patient characteristics. In addition, chi-squares and t-tests will be used to determine whether there are significant differences between responses from complete and incomplete surveys and over time. Clinician/practice characteristics as well as patient sociodemographic characteristics will be included as covariates in subsequent analyses if significantly associated with survey completion or outcomes at p-value less than 0.15. Primary outcome variables, including patient and clinician self-reported shared decision making and objective shared decision making obtained from audio recordings, 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.

3. Methods to Maximize Response Rates

Several methods will be used to enhance participation rates in the SHARE Approach training and surveys, including the following:

- Recruiting primary care and cardiology practices that have worked with members of the project team, including members of the practice-based research networks managed by the University of Colorado.
- Establishing a practice participation agreement that describes the objectives of the project, the benefits to the practice and its patients from implementing the SHARE Approach, the expected amount of time required in training and responding to data collection requests, the types of data collected, and the implications of the implementation and evaluation findings to improve dissemination of shared decision making.
- Offering two in-person opportunities to participate in the SHARE Approach training and an online webinar for practice staff not able to attend one of the in-person trainings.
- Ensuring the survey protocols are limited to information that is required to achieve project objectives, not excessively lengthy, and minimizes burden on participants.
- Involving knowledgeable project staff in data collection procedures.
- Providing support to practices in implementing the SHARE Approach through multiple SHAREd Learning Calls.
- Offering $25 incentive to patients who consent to audio recording of their interactions with the rendering clinician.
- Thanking respondents for their time and reinforcing the benefits of the project results to the health care organization, the respondent, and patients.

4. Tests of Procedures

Primary outcome measures for the card survey, including the OPTION scale for self-reported shared decision making, and the OPTION coding framework for documenting shared decision making in clinical encounters, are scales that have been used and validated in previous research. All other card survey questions come from scales used in prior research. The card survey outcomes have been extensively discussed by the research team and received input from a local patient panel at the University of Colorado. Brief clinician surveys to assess SHARE training incorporate both qualitative outcomes and standard Likert scale outcomes, and assess attitudes and experiences with the SHARE Approach that are unique to this study and therefore were created for this study through discussion between members of the research team and AHRQ. Our team has extensive experience with qualitative and quantitative data collection, data collection from both clinicians and patients, and data collection in multi-site studies.

5. Statistical Consultants

Exhibit 2 provides information on the individuals consulted in the design and data analysis plans for the project. The exhibit provides information on the name, contact information, organizational affiliation, area of expertise, and role of each individual.

Exhibit 2. Expert Consultants

Name	Contact Information	Organization	Area of Expertise	Role in Collection and Analysis of Information
Miriam Dickinson, PhD	301-427-1444 Miriam.dickinson@cuanschutz.edu	University of Colorado	Biostatistician	Analysis plan
Mark Gritz, PhD	303-724-8359 mark.gritz@cuanschutz.edu	University of Colorado	Econometrics, Survey research methods	Instrument review, Analysis plan
Laura Scherer, PhD	303-724-5749 Laura.scherer@cuanschutz.edu	University of Colorado	Experimental designs, Survey research methods	Instrument design, Analysis plan, Analysis