

Study Title: Online Trial Examining Validity of the Shared Decision Making Process Survey With Video Vignettes

Document Title: Design and Analysis plan for an online trial examining validity of the shared decision making process survey with video vignettes

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Purpose:

To examine the validity of the Shared Decision Making (SDM) Process scores in assessing SDM for cancer screening and medication decisions through standardized videos of good-quality and poor-quality SDM consultations.

Design:

Study staff are working with a national sampling firm to recruit subjects and obtain 400 responses. Subjects were randomly assigned to one of four arms. (1) Colorectal cancer screening good shared decision making video then poor video second (2) Colorectal cancer screening poor shared decision making video then good video (3) Treatment of high cholesterol good video then poor video and (4) Treatment of high cholesterol poor shared decision making video first then good video. Participants completed measures of Shared Decision Making after each video.

Randomization and Blinding:

Participants in each study were randomly assigned by the sampling firm to view videos of both good and poor-quality SDM conversations between a physician and patient actor in a specified order. Those randomized to the good-quality first group viewed the good quality SDM video followed by the poor-quality SDM video, while those randomized to the poor-quality first group viewed the poor-quality SDM video followed by the good-quality SDM video. Participants were blinded to their order, but no other blinding occurred.

Outcomes:

- SDM Process scale. The SDM Process scale measures the amount of SDM that occurs in an interaction. For this project, the scale items were adapted to be completed by an observer rather than a participant in the interaction. Scores range from 0 to 4; larger values indicate greater SDM occurred.
- Nine-Item Shared Decision Making Questionnaire. The 9-item Shared Decision Making Questionnaire (SDM-Q- 9) is a widely used patient-reported measure of SDM that focuses on the decisional process in a medical encounter. Scores range from 0 to 100; higher scores indicate more SDM occurred. The 9 items were adapted to reflect participants rating the SDM videos instead of rating their own experiences.
- Demographic and individual difference measures. Participants reported on their age, race, ethnicity, gender, income, and education. Participants were also asked to report on their health care utilization (a single item asking how many visits they had made to their health care provider in the past year; scores were truncated at 20 visits), physical health (1 = excellent, 5 = poor), and mental health (1 = excellent, 5 = poor), as well as to respond to the medical maximizer-minimizer single-item scale, a single item that measures the extent to which patients prefer to maximize or minimize the extent to which they have medical interventions.
- Individuals who watched the colorectal cancer screening videos were asked if they had ever been screened for colorectal cancer. Individuals who watched the high cholesterol videos were asked whether they have high cholesterol and if they had ever taken a medication for high cholesterol.

Sample Size:

The sample size was determined to ensure sufficient power to detect differences between the good and the poor shared decision making videos in this repeated measure design and analyses were

planned to be separate for each arm (i.e. one analysis for the colorectal cancer screening videos and a separate parallel analysis of the statins for high cholesterol video). To detect an eta² effect size of .04 with an alpha of 0.05 with 80% power would require 190 observations per clinical condition. Study staff rounded this to 200 observations per clinical condition, for a total required sample size of 400 patients.

Statistical Methods:

First, we examined descriptive statistics of the SDM Process items for the clinical conditions and orders. We examined rates of missing data to determine acceptability and descriptive results to see whether the scores span the range of total possible scores, are normally distributed, and whether there is evidence of floor or ceiling effects.

We examined the following hypotheses:

1. The good-quality SDM video will have higher mean SDM Process scores than the poor-quality SDM video in both colorectal cancer screening and high cholesterol studies, indicating discriminant validity. Multilevel models were used to test for impact of order (good quality first v. poor quality first), video (good quality v. poor quality), and the order-by-video interaction while adjusting for nesting of repeated videos within participant for the SDM Process scores.
2. The SDM Process and SDM-Q-9 scores will be at least moderately correlated (i.e., correlations $\geq .5$), indicating convergent validity. Pearson correlations were used to test for the relationship between the SDM-Q-9 and the SDM Process scores.

Heterogeneity of Treatment Effects (HTE):

Exploratory multilevel models were used to explore the relationship between order, video, and their interaction alongside other covariates, including mental and physical health status, number of visits to their health care provider in the past year, previous experience with screening (colorectal cancer screening only), previous diagnosis of high cholesterol (high cholesterol only), medical maximizer-minimizer single-item scale, education, race/ethnicity (i.e., white non-Hispanic compared to all others), income, age, and gender. All variables (except for gender, race/ ethnicity, and previous screening experience or high cholesterol diagnosis) were treated as continuous variables. All continuous variables were centered.