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Improving A Full Range of Advance Care Planning Behavior Change and Action Domains: the PREPARE Randomized Trial

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Abstract

Context

Advance care planning (ACP) engagement includes a wide range of behaviors and actions related to discussions and documentation, yet few ACP intervention studies measure the full process.

Objectives

To compare the effects of an easy-to-read advance directive (AD) versus an ACP website plus the AD (PREPARE+AD) on behavior change processes and actions, including discussions and documentation.

Methods

Secondary data were from a completed ACP trial. Participants were primary care patients, ≥60 years old, with ≥2 co-morbidities. We used the validated ACP Engagement Survey to examine 6-month change in subscales measuring Behavior Change Processes (knowledge, contemplation, self-efficacy, readiness) and Actions (decision makers, quality of life, flexibility for decision makers, asking clinicians questions), and specifically related to discussions and documentation. We used adjusted mixed effects linear models to compare mean change and engagement over time.

Results

Compared to the AD-only, PREPARE+AD resulted in greater increases in all Behavior Change Processes subscales and Actions related to decision makers, quality of life, and flexibility (all p-values≤0.005). Both interventions significantly increased the proportion of participants who engaged in ACP discussions (PREPARE+AD, 99.5%; AD-only, 93.3%) and documentation (PREPARE+AD, 99.5%; AD-only, 90.4%), with greater increases for PREPARE+AD (all p-values<0.001).

Conclusion

Both PREPARE plus an easy-to-read AD and an AD-only markedly increased ACP engagement in a full range of ACP behaviors, including discussions and documentation, and engagement was nearly 100% with PREPARE+AD. Future ACP studies should examine a full range of ACP behaviors beyond ADs and the impact of PREPARE and easy-to-read AD implementation on healthcare systems.

Key Words - Advance care planning; behavior change; advance directive; decision aid; communication

Running Title - Advance Care Planning Engagement with PREPARE

Introduction

Advance care planning (ACP) is a "process that supports adults in understanding and sharing their personal values, life goals, and preferences regarding future medical care,"(1) yet most ACP studies focus solely on advance directive (AD) completion. We have developed and validated a comprehensive ACP Engagement Survey(2) that assesses multiple behavior change processes, including self-efficacy and readiness, as well as specific ACP actions, including discussion and documentation.(2-4) It is important to comprehensively study the impact of ACP interventions on a full range of ACP behaviors because prior work has shown that patients move along a trajectory of behavior change for ACP from pre-contemplation to action, and individuals may differentially engage in discussions compared to documentation.(5-7) The ACP Engagement Survey can measure behavior change related to this full range of ACP behaviors.(2,8,9)

PREPARE (www.prepareforyourcare.org) is an evidence-based, interactive, online ACP program that uses behavior change techniques including video stories to prepare patients for medical decision making.(6) In a randomized trial, PREPARE plus an easy-to-read AD (PREPARE+AD) versus an AD-only, without clinician intervention, increased ACP documentation in the electronic health record 35% and 25%, respectively.(10) Additionally, PREPARE+AD increased overall ACP Behavior Change Process and Action scores from the validated ACP Engagement Survey.(10) However, that initial analysis did not examine the impact of PREPARE+AD on specific Behavior Change Process domains (i.e., knowledge, contemplation, self-efficacy, and readiness) and specific Action domains (i.e., decision makers,

quality of life, flexibility in surrogate decision making, and asking clinicians questions). Furthermore, that study did not explore the impact of the ACP interventions on discussion-specific or documentation-specific behaviors.

The goal of this study is to assess the impact of PREPARE+AD and the AD-only on a full range of ACP behavior change processes and actions. We hypothesized that PREPARE+AD would have higher Process and Action scores in all subscales of the ACP Engagement Survey and higher discussion-specific and documentation-specific behaviors compared to the AD-only. Measuring the impact of these interventions on a full range of behavior change processes and actions will provide a richer understanding of the degree to which these interventions can engage patients in the ACP process.

Methods

Study Design

Data for this study are from a randomized trial conducted from 2013-2015 among primary care patients in the San Francisco Veterans Affairs Health Care System (SFVA). The trial compared the efficacy of PREPARE, a literacy and culturally appropriate, HIPAA-compliant, online, interactive ACP program (www.prepareforyourcare.org), plus an easy-to-read AD versus the AD-only on ACP engagement. Using a modified informed consent process for vulnerable populations, written informed consent was obtained.(12) This study was approved by University of California, San Francisco and SFVA institutional review boards.

Participants

The study population has been described.(10) Briefly, SFVA patients were eligible if they were at least 60 years of age, fluent in English, had at least two serious or chronic health conditions,(13-15) had two or more visits with a primary care clinician in the past year, and had at least two additional clinic, emergency department, or hospital visits in the past year. Patients with evidence of dementia, blindness, cognitive impairment, delirium, psychosis, or active substance abuse on screening were ineligible. Clinicians were not involved in the study other than providing permission to contact potential participants.

Interventions

The interventions have been described.(10, 11) Briefly, in the AD-only group, participants reviewed an evidenced-based easy-to-read AD in study offices for 5-20 minutes. In the PREPARE+AD group, in addition to AD review, participants reviewed PREPARE in study offices in its entirety. Reviewing PREPARE takes approximately 10 minutes per step or a mean (SD) of 57 (16) minutes.(6) PREPARE is a web-based guide to teach people the skills needed to identify their life goals and preferences for medical care within their clinical and social context, and to communicate these preferences to surrogate decision makers and clinicians. Using video stories, modeling of behaviors, and a 5-step process, PREPARE was designed to motivate and prepare individuals to discuss their values and care preferences, and using behavior change techniques, help individuals move along the ACP behavior change pathway.

Measures

Participants completed the 82-item ACP Engagement Survey, which includes 57 Behavior Change ACP "Process" measures and 25 ACP "Action" measures, at baseline, 1 week, 3 months, and 6 months after study enrollment. All survey items, response options, and subscales have been published.(4) Both PREPARE and the ACP Engagement Survey are based on Social Cognitive Theory and Behavior Change Theories, where behavior change processes, such as improvements in knowledge, contemplation, self-efficacy, and readiness are required to engage in ACP actions.(2, 6-9) ACP Actions include discussions and documentation concerning decision makers, quality of life preferences about acceptable health states and end-of-life care, flexibility in decision making for surrogate decision makers, and asking clinicians questions.(2)

The Behavior Change Process subscales of knowledge, self-efficacy, and readiness included 5-point Likert response option of ''not at all, a little, somewhat, fairly, extremely'' and the contemplation subscale included the 5-point response option of ''never, once or twice, a few times, several times, a lot''. The Action measures use yes/no response options. The ACP Engagement Survey has demonstrated feasibility and acceptability in multiple outpatient settings in the US and Canada (i.e., SFVA, safety-net, community and academic health systems and in primary care, cancer centers, and dialysis centers) suggesting generalizability and applicability for this study.(2,4,10,17) The survey has demonstrated high internal consistency (Process measures Cronbach's alpha 0.94) and test re-test reliability (Process measures intraclass correlation 0.70; Action measures 0.87).(2) Process subscales were calculated using the average 5-point Likert scale of each item in the domain. Action subscales were calculated by adding the subscale items for each Action measure (1 point for "yes" responses, 0 points for "no" responses)

at each time point, by study group. The quality of life subscale includes 10 items; the three other Action subscales include 5 items. Subscale items for each Process and Action measure are shown in Online Supplemental Table 1.

To specifically assess engagement in ACP discussions or documentation, we categorized Survey items into those related to Discussions (i.e. survey item referred to "ask" or "talk") and Documentation (i.e. survey item referred to "signing" or "documenting"). Forty Process measures and 17 Action measures were included in the Discussion-specific score. Four Process measures and 4 Action measures were included in the Documentation-specific score. Fifteen items from the original ACP Engagement Survey did not specifically focus on discussions or documentation (e.g., contemplation, knowledge, or decision making) and were not included in the Discussion or Documentation scores (Online Supplemental Table 1). We also assessed self-reported participant characteristics including health literacy (i.e., a one-item and 36-item validated surveys)(25), race/ethnicity, age, gender, health status, and social support as previously described.(11)

Statistical Analysis

The study was adequately powered to determine significant differences in the ACP Engagement Survey scores between study arms.(10, 11) We conducted mixed effects linear models to compare the Process or Action subscale scores, the ACP Discussion-specific score, and the ACP Documentation-specific score including terms for group (study arm), time and group-by-time interaction, adjusting for the block randomization factors of race/ethnicity and

health literacy,(25) baseline ACP documentation, and clustering by primary care physician.(10, 11) Individual slopes were estimated for each participant, and we determined the percentage of participants who had an overall positive slope from baseline to 6-months for Discussion-specific and Documentation-specific behaviors. Percentages were compared between groups using Chi-squared tests. Effect sizes (Cohen's *d*) for 6-month follow up compared to baseline by study group were calculated.(18) Clinically meaningful effect sizes were defined based on commonly used criteria (small, 0.20-0.49; moderate, 0.5-0.79; large, ≥0.80).(18) The percent change for each Process or Action subscale score from 6-month follow up compared to baseline was calculated as the difference between the 6-month value minus the baseline value divided by the baseline value*100. No individual ACP Engagement Survey question was missing greater than 10%; therefore, we used all available data in the mixed effects models for the average 5-point Process scores. As the Action scores were a count of individual items, we used a mean imputation approach where scores were pro-rated based on the number of items available. All analyses were conducted using statistical software SAS 9.4 (SAS Institute, Cary, North Carolina) and STATA 15 (College Station, TX). All tests of statistical significance were two-sided.

Results

Study Participants

This analysis includes 414 enrolled participants; 205 randomized to the PREPARE+AD group and 209 in the AD-only group. The mean age of participants was 71.1 years, 9% were

women, and 43% were nonwhite. Other participant characteristics and the trial consort figure have been published.(11)

Specific Advance Care Planning Behavior Change Processes

Figure 1 shows changes over time in the Behavior Change Process subscales of knowledge, contemplation, self-efficacy, and readiness for PREPARE+AD and AD-only groups. Scores were not significantly different at baseline for each subscale, except self-efficacy, which was higher in the AD-only group (mean score 4.0 AD-only versus 3.8 PREPARE+AD, p=0.02). Both groups showed statistically significant increases from baseline over time for each Process subscale; however, PREPARE+AD showed greater increases in each subscale than the AD-only (Group*Time $p \leq 0.005$). The PREPARE+AD effect sizes in the Process subscales at 6-months compared to baseline were moderate for knowledge (0.6) and contemplation (0.7), and small for self-efficacy (0.44) and readiness (0.44).

Specific Advance Care Planning Actions

Figure 2 shows changes over time of ACP Action subscales of decision makers, quality of life, flexibility, and asking clinicians questions by PREPARE+AD and the AD-only group. There were no significant differences between study groups at baseline for any Action subscale ($p>0.05$). Scores increased significantly over time for the decision maker, flexibility, and quality of life action subscales, with significantly greater increases in PREPARE+AD compared to AD-only group (all group*time $p \leq 0.005$) (Figure 2). The subscale concerning asking clinicians questions decreased in both groups over time and did not differ between groups (Group*Time

p=0.27). The greatest magnitude of change over time was seen in the flexibility for surrogate decision-making subscale, with PREPARE+AD resulting in a 100% increase in actions related to flexibility from baseline to 6 months compared to 60% in the AD-only group. The effect sizes for PREPARE+AD Action subscales at 6-months compared to baseline were strong for flexibility 0.87, moderate for decision maker 0.56 and quality of life 0.53, and small and negative for asking clinicians questions -0.33.

Advance Care Planning Engagement in Discussions and Documentation

Both ACP interventions resulted in nearly all participants (PREPARE+AD 99.5% vs AD-only 92.9%) reporting an increase in either discussion-specific or documentation-specific Behavior Change Processes and Actions (Table 1). However, increases were significantly greater in PREPARE+AD ($p<0.001$). The proportion of participants with increased Discussion-specific Process scores (PREPARE+AD 98.5% vs AD-only 90.4%, $p<0.001$) and increased Discussion-specific Action scores (PREPARE+AD 91.2% vs AD-only 82.8%, $p=0.011$), was high for both interventions, but significantly higher in PREPARE+AD. The proportion of participants with increased Documentation-specific Process scores (PREPARE+AD 99.5% vs AD-only 88.5%, $p<0.001$) and Documentation-specific Action scores (PREPARE+AD 94.6% vs AD-only 68.9%, $p<0.001$) was also high for both interventions and significantly higher in PREPARE+AD.

Discussion

This is the first study to comprehensively describe a full range of ACP Behavior Change Processes (i.e., knowledge, contemplation, self-efficacy, and readiness) and ACP Actions (i.e.,

discussions and documentation of surrogate decision makers, quality of life preferences, flexibility for surrogate decision making, and asking clinicians questions) after the use of the interactive, online ACP PREPARE program and the easy-to-read AD compared to the AD-only. Both PREPARE+AD and the AD-only interventions were powerful tools to help increase nearly all measured Behavior Change Process and Action subscales. Both interventions also significantly improved overall engagement in ACP discussion-specific behaviors, as well as documentation-specific behaviors over 6 months, with PREPARE+AD demonstrating an increase in ACP engagement in nearly 100% of participants. The added and synergistic benefit of PREPARE to the easy-to-read AD versus the AD-only is likely related to the provision of theory-based narratives, stories, and "how to videos" designed to prepare patients for medical decision making.

This is also the first longitudinal study to use the ACP Engagement Survey to detect the impact of ACP interventions in diverse primary care patients with chronic illness. Compared to using a single outcome of AD completion to define successful ACP, use of the patient-reported ACP Engagement Survey enabled detection of the process of ACP over time for a full range of ACP behaviors.(4) The ACP Engagement Survey was able to detect rich engagement in the ACP process related to documentation-specific behaviors such as completing a legal from to designate a healthcare decision maker. For example, nearly 95% of PREPARE+AD participants self-reported an increase in Action measures related to new ACP documentation after viewing PREPARE, whereas a cross-sectional evaluation of AD completion in the medical record only found 35% of participants had ACP documentation at the end of the trial.(21) PREPARE and the

easy-to-read AD, and likely other evidence-based ACP tools,(22) may increase engagement in a broad range of important discussion-specific and documentation-specific ACP outcomes that are often unmeasured but are critical steps in the ACP process.

Neither PREPARE+AD or the AD-only interventions improved actions related to asking clinicians questions. There are several possible explanations for these findings. First, based on a well-described learning phenomenon,(23,24) it is possible participants reported asking questions about ACP at baseline and later learned that their questions were about something else, resulting in a decline over time.(6) Second, Asking Questions is the last step in the PREPARE program, and because participants watched all five steps at once, it is possible participants could not maintain full attention through the 5th step.(6) Although the PREPARE steps were meant to be watched individually, the updated PREPARE website has been shortened to decrease cognitive burden for individuals who prefer to watch all five steps together. Third, in subsequent analysis of the ACP Engagement Survey among US and Canadian participants, the psychometric properties of the Asking Clinicians Questions subscale items were less robust, and these questions have been dropped from shorter versions of the Survey.(4) Finally, it is possible that patients truly asked fewer questions because they were more engaged with other aspects of ACP, such as discussing and documenting their decisions.

This study has several limitations including the predominantly older and male population of Veterans recruited from a single medical center, which may restrict generalizability. Additionally, this study used all 82 items from the original ACP Engagement Survey, which may

not be possible in community-based settings or pragmatic trials. Future studies can consider shorter versions of the Survey that have been shown to be valid, internally consistent, and able to detect change across a full range of ACP behaviors.(4) Furthermore, as participants were chronically, but not terminally, ill primary care patients followed for 6 months, this study could not assess impact on end-of-life care.

In conclusion, the PREPARE website and an easy-to-read AD were powerful tools which helped increase nearly all measured ACP Behavior Change Process and Action subscales, with the combination of PREPARE+AD resulting in significantly greater increases. By measuring a full range of ACP behaviors, beyond AD completion only, this study demonstrated that PREPARE+AD resulted in increased ACP engagement in nearly 100% of participants. Understanding how these interventions affect specific processes and actions can help clinicians tailor their use to patients' readiness and needs and help them understand how the tools may fit into clinical or educational programs. Future studies should examine a full range of ACP behaviors beyond ADs. In addition, because PREPARE and the easy-to-read AD are likely to be synergistic with other clinician or health system interventions, future studies should examine use of PREPARE in group medical visits(19,20) or clinician prescribing of particular PREPARE steps tailored to patients' needs and readiness.

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Conflict of Interest Disclosures: None reported.

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Figure Legends

Figure 1. Impact of PREPARE plus Advance Directive (AD) compared to an AD-only on Advance Care Planning Behavior Processes.

Process subscale scores for PREPARE+AD (n=205, solid line) versus an AD-only (n=209, dashed line) over 6-months and showing percent change in scores. A) Knowledge Subscale, PREPARE+AD effect size 0.60; B) Contemplation Subscale, PREPARE+AD effect size 0.70; C) Self-Efficacy Subscale, PREPARE+AD effect size 0.44; D) Readiness Subscale, PREPARE+AD effect size 0.44. All scores are on a Likert scale 0-5. P values reflect significance for group x time interactions, using repeated measures, mixed-effects linear regression models, adjusted for race, health literacy, baseline ACP documentation, and clustering by physician. AD indicates advance directives; PREPARE indicates a patient-centered ACP website. The percent change for each study group is calculated as the difference between the 6-month value minus the baseline value divided by the baseline value*100.

Figure 2. Impact of PREPARE plus Advance Directive (AD) compared to an AD-only on Advance Care Planning Actions.

Action subscale scores for PREPARE+AD (n=205, solid line) versus an AD-only (n=209, dashed line) over 6-months and showing percent change in scores. A) Decision Maker Subscale (range 0-5), PREPARE+AD effect size 0.56; B) Quality of Life Subscale (range 0-10), PREPARE+AD effect size 0.53. Quality of Life includes acceptable health states and care desired at the end of life. C) Flexibility in Decision Making Subscale (range 0-5),

PREPARE+AD effect size 0.87; D) Ask Clinicians Questions Subscale (range 0-5), PREPARE+AD effect size -0.33. P values reflect significance for group x time interactions, using repeated measures, mixed-effects linear regression models, adjusted for race, health literacy, baseline ACP documentation, and clustering by physician. AD indicates advance directives; PREPARE indicates a patient-centered ACP website. The percent change for each study group is calculated as the difference between the 6-month value minus the baseline value divided by the baseline value*100.

Table 1. Percent of Participants with Increased Engagement in Advance Care Planning Discussion-specific and Documentation-specific Behaviors

	Increase in either Process or Action Measures N (%)			Increase in Process Measures N (%)			Increase in Action Measures N (%)		
	AD-only	**PREPARE+AD**	**p-value**	**AD-only**	**PREPARE+AD**	**p-value**	**AD-only**	**PREPARE+AD**	**p-value**
Overall Engagement	192 (92.9%)	204 (99.5%)	<.001	186 (89.0%)	203 (99.0%)	<.001	173 (82.8%)	191 (93.2%)	.0012
Discussions	195 (93.3%)	204 (99.5%)	<.001	189 (90.4%)	202 (98.5%)	<.001	173 (82.8%)	187 (91.2%)	.011
Documentation	189 (90.4%)	204 (99.5%)	<.001	185 (88.5%)	204 (99.5%)	<.001	144 (68.9%)	194 (94.6%)	<.001

AD-only, n = 209; PREPARE+AD, n=205. Engagement is defined as a positive slope from baseline. Engagement in Discussion-specific behaviors includes 57 survey items that referred to “ask” or “talk.” Engagement in Documentation-specific behaviors includes eight survey items that referred to “signing” or “documenting.” Overall Engagement assessment includes 65 survey items related to either Discussions or Documentation (online Supplemental Appendix).