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Effect of the PREPARE Website vs an Easy-to-Read Advance Directive on Advance Care Planning Documentation and Engagement Among Veterans

A Randomized Clinical Trial

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IMPORTANCE Documentation rates of patients' medical wishes are often low. It is unknown whether easy-to-use, patient-facing advance care planning (ACP) interventions can overcome barriers to planning in busy primary care settings.

OBJECTIVE To compare the efficacy of an interactive, patient-centered ACP website (PREPARE) with an easy-to-read advance directive (AD) to increase planning documentation.

DESIGN, SETTING, AND PARTICIPANTS This was a comparative effectiveness randomized clinical trial from April 2013 to July 2016 conducted at multiple primary care clinics at the San Francisco VA Medical Center. Inclusion criteria were age of a least 60 years; at least 2 chronic and/or serious conditions; and 2 or more primary care visits; and 2 or more additional clinic, hospital, or emergency room visits in the last year.

INTERVENTIONS Participants were randomized to review PREPARE plus an easy-to-read AD or the AD alone. There were no clinician and/or system-level interventions or education. Research staff were blinded for all follow-up measurements.

MAIN OUTCOMES AND MEASURES The primary outcome was new ACP documentation (ie, legal forms and/or discussions) at 9 months. Secondary outcomes included patient-reported ACP engagement at 1 week, 3 months, and 6 months using validated surveys of behavior change process measures (ie, 5-point knowledge, self-efficacy, readiness scales) and action measures (eg, surrogate designation, using a 0-25 scale). We used intention-to-treat, mixed-effects logistic and linear regression, controlling for time, health literacy, race/ethnicity, baseline ACP, and clustering by physician.

RESULTS The mean (SD) age of 414 participants was 71 (8) years, 38 (9%) were women, 83 (20%) had limited literacy, and 179 (43%) were nonwhite. No participant characteristic differed significantly among study arms at baseline. Retention at 6 months was 90%. Advance care planning documentation 6 months after enrollment was higher in the PREPARE arm vs the AD-alone arm (adjusted 35% vs 25%; odds ratio, 1.61 [95% CI, 1.03-2.51]; $P = .04$). PREPARE also resulted in higher self-reported ACP engagement at each follow-up, including higher process and action scores; $P < .001$ at each follow-up).

CONCLUSIONS AND RELEVANCE Easy-to-use, patient-facing ACP tools, without clinician- and/or system-level interventions, can increase planning documentation 25% to 35%. Combining the PREPARE website with an easy-to-read AD resulted in higher planning documentation than the AD alone, suggesting that PREPARE may increase planning documentation with minimal health care system resources.

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Advance care planning (ACP) is a process whereby people communicate their goals and preferences for future medical care.¹ The Institute of Medicine recommends ACP as a means to provide patient-centered, value-aligned medical care.² In addition, Medicare and Medicaid Services (CMS) reimburse clinicians for ACP documentation because ACP conversations result in improved satisfaction with care, quality of life, and receipt of medical care aligned with patients' wishes.³⁻⁷

The ACP field has evolved to consider ACP as a process that involves a series of discussions over time in addition to advance directive (AD) completion.⁸ However, most older adults, even those with serious illness, have not engaged in ACP, and patients' wishes are often not documented.^{9,10} Clinician barriers to ACP include a lack of training and system resources, especially in busy outpatient clinics.¹¹⁻¹⁴ Patient barriers include difficulty understanding AD forms and feeling unprepared to make end-of-life medical decisions.^{9,11}

To help overcome some of these barriers, we first created an easy-to-read AD that significantly increased 6-month documentation.¹⁵ However, formative work among diverse populations demonstrated the need for more preparation for complex, ongoing medical decision making and communication of one's wishes.^{11,16,17} Therefore, we created the PREPARE website (<https://prepareforyourcare.org/>), which has been shown to empower older adults to engage in ACP through the use of a simple 5-step process and "how-to" videos.¹⁸ Both of these patient-facing ACP tools were designed to help older adults begin to engage in ACP outside the medical environment.

The objective of this randomized clinical trial was to compare the efficacy of PREPARE plus the easy-to-read AD (PREPARE plus AD) vs the AD alone (AD-only) on ACP documentation and engagement. We hypothesized that ACP documentation and engagement would increase in both arms but would be greater in the PREPARE plus AD arm.

Methods

This is a single-blind, parallel-group, randomized comparative effectiveness trial. The conceptual framework and the full trial protocol,^{18,19} including inclusion and exclusion criteria; the study flow diagram; recruitment procedures; sample size estimates; and validity, reliability, and response options of all outcome measures have been previously published. Using a modified informed consent process for vulnerable populations,²⁰ written informed consent was obtained for all participants. Participants were compensated \$50 for the baseline interview and \$25 for all follow-up interviews. This study was approved by the University of California, San Francisco, and the San Francisco Veterans Affairs (VA) Medical Center institutional review boards. VA research audits were performed yearly.

Participants and Enrollment Criteria

Veterans were enrolled from a women's, geriatrics, and several general medicine clinics at the San Francisco VA from April

Key Points

Question Can a patient-facing, interactive advance care planning website called PREPARE plus an easy-to-read advance directive increase advance care planning documentation compared with an advance directive alone?

Findings In this randomized clinical trial that included 414 older veterans with chronic illness from multiple primary care clinics, PREPARE plus an easy-to-read advance directive resulted in statistically significant higher advance care planning documentation (35%) compared with an advance directive alone (25%).

Meaning Patient-facing advance care planning tools, including the PREPARE website and the easy-to-read advance directive, increased advance care planning documentation and engagement without additional clinician- or system-level interventions.

2013 through July 2016. A full table of inclusion and exclusion criteria has been published.¹⁹ In brief, veterans were included if they were 60 years or older, had at least 2 chronic medical conditions defined by *International Classification of Diseases, Ninth Revision (ICD-9)*, codes,^{21,22} had 2 or more visits with a primary care clinician in the past year (ie, a marker of established care) and had at least 2 additional VA clinic, emergency department, or hospital visits with any clinician in the past year (ie, a marker of frequent access). To be enrolled, veterans had to have an upcoming primary care appointment within 1 to 3 weeks.¹⁹ Exclusion criteria were determined by their clinician and study staff based on *ICD-9* codes, medical record review, and in-person screening and included dementia, moderate-to-severe cognitive impairment, blindness, deafness, delirium, psychosis, active drug or alcohol abuse within the past 3 months, plans to be out of town during the study, no telephone, or inability to answer informed consent teach-back questions within 3 attempts.¹⁹ Because people may change their medical preferences over time,²³ we did not exclude individuals who had previously engaged in ACP.

Recruitment and Data Collection

A Health Insurance Portability and Accountability Act (HIPAA) waiver was obtained to identify Veterans who met our inclusion and exclusion criteria and had upcoming appointments. As previously described,¹⁹ after clinicians gave permission for study staff to contact their patients, we sent recruitment letters and made phone calls to describe the study and assess eligibility and interest. Names were randomly listed to ensure random recruitment, with oversampling of women and nonwhite veterans. Staff screened participants prior to enrollment. Data were collected using Research Electronic Data Capture (REDCap); a secure, web-based application.²⁴

Interventions

Given the potential benefits of ACP, we decided with our VA stakeholders to perform a comparative effectiveness study and provide all veterans some form of ACP. Both PREPARE and the easy-to-read AD were designed with and vetted by older adults from several community and clinical settings and from diverse race/ethnicity and cultural backgrounds.^{15,18,19} Both tools

are patient-facing, meaning their use does not require clinician or systems-level involvement to begin the ACP process. No clinician-, electronic health record-, or systems-level changes were implemented as part of this trial.

AD-Only Intervention

In the AD-only arm, veterans were asked to review the easy-to-read AD for 5 to 20 minutes within research offices.¹⁵ Participants were called 1 to 3 days prior to their upcoming primary care visit to remind them about their visit.

PREPARE Plus AD Intervention

The PREPARE plus AD arm included the literacy and culturally appropriate, HIPAA-compliant PREPARE website¹⁸ plus the easy-to-read AD.¹⁵ Briefly, we reconceptualized ACP as a process that evolves over time and includes many behaviors.⁸ 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 with their family, friends and clinicians. Through tailored algorithms, PREPARE asks individuals about their values and helps them make a commitment (ie, action plan) to do 1 ACP step. PREPARE then creates a unique, printed “Summary of My Wishes” and has the capacity to save individual’s preferences. Reviewing PREPARE takes a mean (SD) of 57 (16) minutes or approximately 10 minutes per step.¹⁸

PREPARE was administered within research offices, and participants were asked to review PREPARE in its entirety. Participants were instructed to complete PREPARE on their own. Research staff intervened only if there were technological issues and the study could not move forward. After viewing PREPARE, participants were given a copy of their action plan; the AD; their website login; and a PREPARE pamphlet, booklet, and DVD to take home. Participants were called 1 to 3 days prior to their upcoming primary care visit and reminded to bring the “Summary of My Wishes” and action plan to their medical visit.

Outcomes

Our primary outcome was any new ACP documentation in the electronic medical record (EMR) 9 months after study enrollment.¹⁹ Because legal forms (eg, ADs, living wills, a durable power of attorney for healthcare, and physicians’ orders for life-sustaining treatment [POLST] forms) and documented discussions can be used to direct medical care, we created a composite variable of any ACP documentation (forms and/or discussions). All medical review data were double-coded by 2 independent research assistants. Discrepancies were adjudicated by the principal investigator (R.L.S.).

Secondary outcomes, measured at 1 week, 3 months, and 6 months, included the validated, patient-reported ACP Engagement Survey. This questionnaire includes both process measures of knowledge, contemplation, self-efficacy, and readiness assessed on an average 5-point Likert scale and action measures such as discussing and documenting ACP wishes using “yes” or “no” response options on a 0- to 25-point scale.^{18,19,25} All questions are published.²⁶ Clinically meaningful effect sizes were defined based on commonly

used criteria (ie, 0.50-0.79 was considered a moderate effect).²⁷ We also measured ease of use, “How easy was it to use this guide?” on a 1 (very hard) to 10 (very easy) point scale, and satisfaction, “How comfortable were you reviewing this guide?”, “How helpful was this guide?”, and “How likely are you to recommend this guide to others?” using “not-at-all” to “extremely” 5-point Likert scale after viewing the interventions.

Other Measures

We assessed participant characteristics using self-report at baseline including age, gender they most identified with (male, female, other), race/ethnicity, and validated measures of health status, health literacy, social support, and social standing.¹⁹ We also assessed the presence of a possible surrogate decision maker (yes or no), whether they had funeral plans or a will, and whether they had internet access in the home (yes or no).¹⁹ Two research assistants conducted independent medical record review to determine prior ACP documentation up to 5 years before the baseline interview. We also administered the Patient Health Questionnaire (PHQ)-4 at baseline and at each follow-up interview. The PHQ-4 includes the PHQ-2 for depression and the Generalized Anxiety Disorder (GAD)-2 anxiety screening tool.²⁸ A score of 3 or greater on a 0 to 6 scale suggests possible depression or anxiety.

Sample Size

We estimated that 350 veterans would provide 92% power with a 2-tailed $\alpha = .05$ to detect ACP documentation (primary outcome) from 15% in the AD-only arm to 30% in the PREPARE plus AD arm. We oversampled to 415 veterans to account for up to 15% attrition.

Randomization, Allocation Concealment, Blinding, and Fidelity

Because we hypothesized that literacy and cultural differences may be important determinants of ACP engagement,^{15,18,29} participants were block randomized, using a computer-based random number generator, by health literacy (adequate vs limited),³⁰ and race/ethnicity (nonwhite vs white) in random block sizes of 4, 6, and 8 by a statistician (J.B.) who was not involved in recruitment. The initial visit included consent, baseline assessments, and the interventions, which were longer in the PREPARE plus AD arm. Because of the need to schedule interview rooms to accommodate longer PREPARE plus AD interviews, randomization occurred at the time of scheduling.

Although participants could not be blinded to the intervention, they were told during the consent process that they had a “50/50 chance” of getting 1 of 2 different ACP guides. However, the nonassigned intervention was not described. The staff member who administered the intervention and baseline interview was not blinded. However, all follow-up outcome ascertainment was conducted by different staff blinded to group allocation. Research staff asked participants at each follow-up to not disclose the materials they reviewed, and staff documented whether they became unblinded. If unblinding occurred, a third blinded staff member conducted all subsequent interviews. Clinicians were blinded to patient group assignment; we obtained clinicians’

permission to recruit their patients, but the interventions were not described, and no clinician education was provided.

To ensure fidelity, staff followed study scripts and used checklists for every study phase.¹⁹ Staff had to demonstrate an ability to adhere to the protocol in role-playing exercises, 10% of all interviews and data capture were observed for accuracy, and ongoing training was provided.

Statistical Methods

Variables were assessed for distributional and outlier values using standard summary statistics. Baseline participant characteristics were compared between arms using unpaired *t* tests, χ^2 , or Fisher exact tests. Using *t* tests or χ^2 tests, we also compared, by intervention group, veterans' age, race/ethnicity, and gender between those who refused vs those who enrolled and between those who withdrew vs those who remained in the study. We used intention-to-treat analysis using SAS statistical software (version 9.4; SAS Institute Inc). All *P* values were 2-tailed and set at a significance level of .05. We used mixed-effects logistic and linear regression with fixed effects for time (baseline and 9 months for ACP documentation and 1 week, 3 months, and 6 months for secondary outcomes of the ACP Engagement Survey modeled using dummy variables), group (AD-only vs PREPARE plus AD) and group \times time interaction as well as blocking variables of literacy (adequate or limited) and race/ethnicity (white or nonwhite). We also adjusted all models for prior ACP documentation and potential clustering by physician. We tested for interactions by adding interaction terms to the group \times time variable for age (<65 years and \geq 65 years), gender (women and men), race/ethnicity (white and nonwhite), health literacy (adequate and limited), presence of a possible surrogate decision maker (yes or no), health status (fair-to-poor or good-to-excellent), and internet access at home (yes or no). A *P* value for interaction <.05 was considered statistically significant. Ease-of-use, satisfaction, depression, and anxiety measures were assessed using the Wilcoxon rank test.

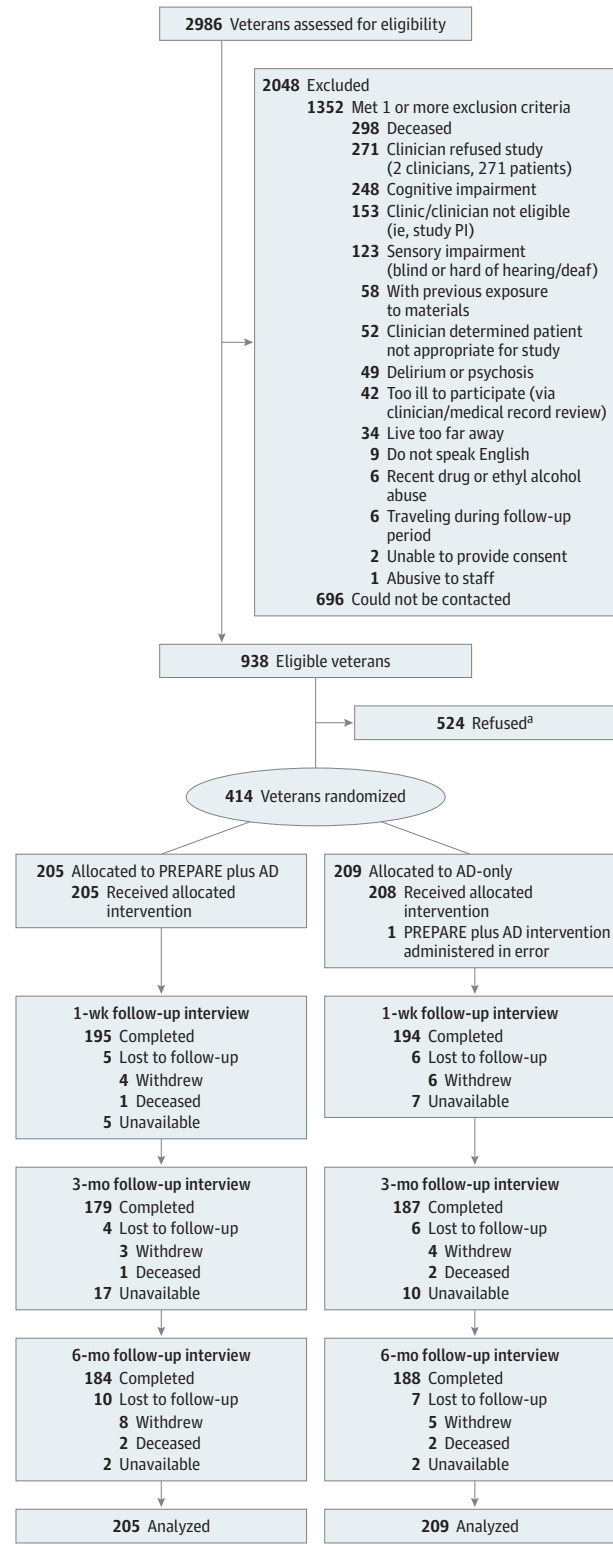
Missing Data

There were no missing data for the primary outcome (ie, all medical records were reviewed). For secondary outcomes, less than 10% of interviews were missing at any time point, and all available data were included in the mixed-effects models. No individual ACP Engagement Survey question was missing greater than 10%; therefore, we used a mean imputation approach. If bias were to occur using this conservative approach, it would tend toward the null.³¹ We conducted sensitivity analysis and excluded data for veterans whose research assistants became unblinded.

Results

Of 938 eligible veterans, 414 (44%) enrolled; 205 were randomized to the PREPARE plus AD and 209 to the AD-only arm (Figure 1). There were no differences in gender or race/ethnicity of veterans who refused; however, those who refused were older than those who enrolled (mean [SD], 74.6 [9.1] years vs 71.1 [7.8] years; *P* < .001. The mean age of enrolled par-

Figure 1. CONSORT Flow Diagram



AD indicates advance directive; PI, principal investigator; PREPARE, patient-centered, advance care planning website.

^a One person consented but did not undergo any study procedures and was excluded from the analysis.

Table. Baseline Participant Characteristics

Participant Characteristic	No.	No. (%)	
		AD-only (n = 209)	PREPARE Plus AD (n = 205)
Demographics			
Age, mean (SD)	414	71.5 (7.9)	70.7 (7.7)
Women	414	19 (9)	19 (9)
Race/ethnicity			
	413		
White		122 (59)	113 (55)
African American		42 (20)	46 (22)
Latino/Hispanic		17 (8)	16 (8)
Native American		2 (1)	3 (1)
Asian/Pacific Islander		13 (6)	13 (6)
Multiethnic/other		12 (6)	14 (7)
Education ≤high school	413	40 (20)	34 (16)
Limited health literacy	411	44 (21)	39 (19)
Finances, not enough to make ends meet	412	25 (12)	24 (12)
Social standing 1-10 score, mean (SD)	407	6.6 (2.0)	6.5 (2.0)
Religious, fairly to extremely	410	77 (37)	75 (37)
Spiritual, fairly to extremely	412	130 (63)	125 (61)
Social support			
In a married/long-term relationship	414	100 (48)	87 (42)
Have adult children	413	141 (67)	133 (65)
Have a potential surrogate	414	198 (95)	184 (90)
Health status			
Self-rated health, fair-to-poor	412	55 (27)	65 (32)
IADL difficulty score 0-8, mean (SD)	413	1.1 (1.8)	1.0 (1.5)
ADL difficulty score 0-7, mean (SD)	412	1.1 (1.4)	1.1 (1.3)
Depression, PHQ2 score 0-6, mean (SD)	413	0.8 (1.3)	1.0 (1.5)
Anxiety, GAD2 PHQ2 score, 0-6, mean (SD)	413	1.1 (1.6)	1.2 (1.7)
Prior planning activities			
Completed a will	407	104 (51)	94 (46)
Made funeral arrangements	408	62 (30)	65 (32)
Prior ACP documentation	414	109 (52)	103 (50)
Legal forms (ie, advance directives) and orders (ie, POLST)		89 (43)	73 (36)
Documented discussions about ACP		61 (29)	63 (31)
Internet access			
Access to the internet	414	79 (38)	87 (42)

Abbreviations: ACP, advance care planning; AD, advance directive; ADLs, activities of daily living; GAD2, generalized anxiety disorder 2-question anxiety screening measure; IADL, instrumental activities of daily living; PHQ2, Patient Health Questionnaire, 2-question depression screening measure; POLST, physician's orders for life-sustaining treatment; PREPARE, patient-centered, advance care planning website.

Participants was 71.1 (7.8) years, 38 (9%) were women, 179 (43%) were nonwhite, 120 (29%) reported fair-to-poor health status, and 212 (51%) had evidence of prior ACP documentation (Table). The mean ACP documentation rate 6 months prior to intervention exposure was 0.8% (0.6%) for both groups. There were no differences in participant characteristics between arms (Table), and the number of enrolled veterans per clinician was 5 (6) [range, 1-28]. At 6 months, 184 participants in the PREPARE plus AD arm and 188 in the AD-only arm completed follow-up interviews (a 90% retention rate). There were no significant differences between groups in the rates of, or reasons for, withdrawal (9 patients [7%] in each arm) (see the eTable in the Supplement).

At 9 months, in mixed-effects adjusted analysis, new overall ACP documentation was higher in the PREPARE plus AD vs the AD-only arm (unadjusted analyses, 37% vs 27%, $P = .04$; and adjusted analyses, 35% vs 25%, adjusted odds ratio [OR], 1.61; 95% CI, 1.03-2.51, $P = .04$), including higher documenta-

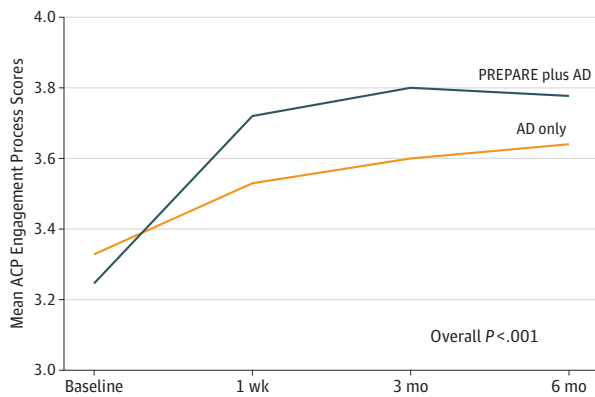
tion for legal forms and orders (20% vs 13%; $P = .04$) and for documented discussions (26% vs 20%; $P = .13$).

Self-reported ACP engagement including mean process and action scores increased significantly more in the PREPARE plus AD arm compared with the AD-only arm, group \times time $P < .001$ (Figure 2 and Figure 3). Effect size estimates were moderate for PREPARE plus AD (0.59 to 0.68 SDs for process scores, 0.49 to 0.59 SDs for action scores) and were small for the AD-only arm (0.24 to 0.39 for process scores, 0.20 to 0.39 SDs for action scores).²⁷

There were no significant interaction effects observed for ACP documentation or ACP engagement as a function of age, gender, race/ethnicity, US acculturation, health literacy, presence of a surrogate decision maker, health status, access to or confidence using the internet, or prior ACP documentation.

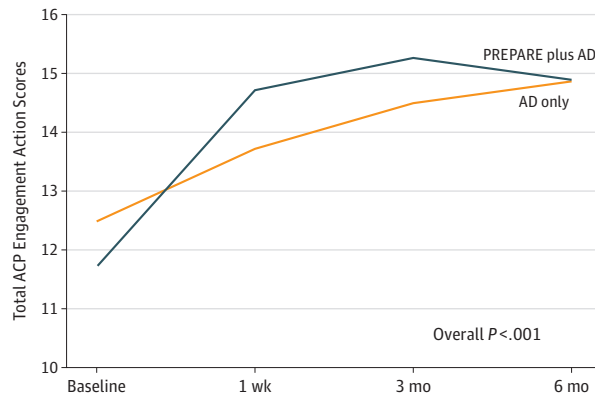
There were no significant differences in the 10-point self-reported ease-of-use scales for PREPARE plus AD vs the

Figure 2. Values Reflect Mean Advance Care Planning (ACP) Engagement Process Scores From Repeated Measures, Mixed-Effects Linear Regression Models Adjusted for Race, Literacy, Baseline ACP Documentation, and Clustering by Physician



P values reflect significance for overall group \times time interactions. AD indicates advance directive; PREPARE, patient-centered, advance care planning website.

Figure 3. Values Reflect Total Advance Care Planning (ACP) Engagement Action Scores From Repeated Measures, Mixed-Effects Linear Regression Models Adjusted for Race, Literacy, Baseline ACP Documentation, and Clustering by Physician



P values reflect significance for overall group \times time interactions. AD indicates advance directive; PREPARE, patient-centered, advance care planning website.

AD-only intervention (9.0 [1.4] vs 8.7 [1.7]; $P = .31$) or for the 5-point satisfaction scales including comfort reviewing the interventions (4.5 [0.7] vs 4.4 [0.8]; $P = .57$); helpfulness (4.4 [0.8] vs 4.3 [0.9]; $P = .19$); and likelihood of recommending the guides (4.4 [0.9] vs 4.2 [1.1]; $P = .10$).

No adverse events were reported. After controlling for baseline scores, there were no differences in depression or anxiety between arms at 6 months. One participant assigned to the AD-only arm was given PREPARE plus AD; however, this individual was analyzed in their assigned group. Outcomes did not differ after excluding 7 individuals whose research assistants became unblinded (5 PREPARE plus AD, 2 AD-only).

Discussion

In the absence of clinician- or systems-level interventions, the easy-to-read AD (AD-only) increased new ACP documentation to 25%. PREPARE plus AD increased ACP documentation to 35%. Both tools were rated highly in terms of ease-of-use, satisfaction, and helpfulness, suggesting that PREPARE and the easy-to-read AD could serve as scalable, easy-to-disseminate tools to improve the ACP process, especially in busy and resource-poor primary care clinics.

Prior studies have shown that passive ACP education with written materials is less effective than ongoing education by a trained health care professional.⁹ One reason may be the use of ADs and other materials written beyond a 12th grade reading level.³² The success of both PREPARE and the easy-to-read AD may be explained by their attention to both literacy and cultural considerations designed with and for diverse communities.^{15,18} The PREPARE website may also help patients engage in ACP owing to the inclusion of “how-to” videos that model behavior based on behavior change and social cognitive theories.¹⁸ In addition, videos have been shown to help patients make end-of-life medical decisions.³³

The easy-to-read AD-alone increased ACP documentation similar to a 52-page ACP workbook used among veterans (easy-to-read AD, 25%; workbook, 23%), although the workbook study included mostly educated, white men compared with our diverse sample.³⁴ In addition, in general, facilitator-based models have shown marked improvement in clinical communication and ACP documentation, well over 50%.^{6,35,36} In the VA workbook study, the addition of a social worker intervention increased documentation to 48%, while the addition of PREPARE increased documentation to 35%. While all care plans should eventually be reviewed by a clinician regardless of whether they are initiated by patient-facing or facilitator-level interventions, these studies suggest that some individuals may need a facilitator to begin to engage in the ACP process. However, because it may not be feasible to provide a facilitator for all patients, especially in resource-limited health systems, the ACP documentation gains demonstrated in this patient-facing only intervention study of 25% (AD-alone) and 35% (PREPARE plus AD) could have large public health implications. While combining the patient-facing tools with clinician-, facilitator-, and system-level models would likely be highly synergistic, further research is needed.

Limitations

Older veterans, including only 9% women, were recruited from several clinics from the San Francisco VA, potentially limiting generalizability. However, the sample was diverse. We did not collect reasons for refusal, and it was not possible to blind patients to treatment. However, all staff conducting follow-up interviews were blinded to group allocation, and sensitivity analysis did not change our findings. Also, the materials were viewed in study offices with computer access, potentially limiting generalizability to viewing at home. Furthermore, study interviews and reminder calls may be activating. Although reminder calls are a routine part of primary care at the VA, other programs may need to include reminders to obtain similar results, specifically reminders to bring in ADs.

Conclusions

Easy-to-use, patient-facing ACP tools, without clinician- and system-level interventions, can increase ACP documentation by 25% to 35%. Combining PREPARE plus an easy-to-read AD re-

sulted in higher ACP documentation and engagement than the AD alone. This study suggests that PREPARE and the easy-to-read AD may be useful ACP interventions on a population level, especially in resource-limited health systems. Although these tools are likely to be synergistic with other clinician- and system-level interventions, more research is needed.

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Study concept and design: Sudore, McMahan, Barnes.

Acquisition, analysis, or interpretation of data: All authors.

Drafting of the manuscript: Sudore, Feuz, McMahan.

Critical revision of the manuscript for important intellectual content: All authors.

Statistical analysis: Sudore, Boscardin, McMahan.

Obtained funding: Sudore.

Administrative, technical, or material support: Sudore, Feuz, McMahan, Katen.

Study supervision: Sudore, Feuz, McMahan.

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