1. **Study title**

Deferring Agency at End-of-Life: The Role of Information and Advance Directives

1. **Principal investigator**

Ben Handel, handel@berkeley.edu, UC Berkeley

1. **Co-investigators**

Allyson Root, a\_barnett@berkeley.edu, UC Berkeley

Callie Scott, Callie.Scott@providence.org, Providence St. Joseph Health

1. **Geographic location of study**

Oregon, United States

1. **Keyword(s)**

Advance Directives

1. **Abstract (300 word maximum)**

We propose to pilot a randomized evaluation of strategies to facilitate advance directive completion in the 65+ patient population of our partner, Providence St. Joseph Health. Despite the significant economic and personal implications of end-of-life health care decisions, many people fail to document their wishes or to select a representative who can make medical decisions on their behalf. Descriptive evidence suggests that this results in sub-optimal outcomes including dissatisfaction and potentially unnecessary medical spending. However, it is not well understood why patients fail to engage in this apparently high-value planning. Our trial will pilot two interventions with roughly 4,000 patients, with intention to scale the evaluation to include over 70,000 patients across 64 clinics. We will evaluate the effects of (i) an in-person drive to facilitate advance directive completion, (ii) an informational video on advance directives that will be electronically distributed to patients, and (iii) the interaction of these two interventions. Key outcomes will include advance directive completion rates, decisions made on advance directive forms, and eventually observed care decisions. We will also leverage surveys and granular data on patient health to better understand barriers to advance care planning and relate to underlying economic theory that explains behavior.

1. **Projected timeline for the study:**

Funding: June 1, 2018-March 31, 2019

Intervention Dates (projected): July 2-August 10, 2018

1. **Funding**

JPAL HCDI Pilot Grant: $49,739

1. **Institutional Review Board (IRB): Identify details about IRB approval (date of approval, identity, and address of IRB).**

Date of Approval: 6/1/2018-5/31/2018

IRB of Record: Providence Health and Services (Oregon), IRB00003922 and IRB00001196

Location: Portland, OR

Study ID: STUDY2018000241

1. **Hypotheses/research questions: Describe the specific hypothesis or hypotheses that will be tested in the study.**
	1. Research Question (A1): What is the impact of in-person facilitation of advance directive (AD) completion conducted at primary care clinics (Intervention A) on whether a patient aged 65+ completes and uploads an AD to their electronic medical record (EMR), for patients who do not have an uploaded, complete AD at the beginning of the study?
	2. Research Question (A2): What is the association between Intervention A and decisions documented in the Advance Directive?
	3. Research Question (B1): What is the impact of electronic provision of information (video and brochures from ACP Decisions) about end-of-life decision making (Intervention B) on whether a patient aged 65+ completes and uploads an AD to their electronic medical record (EMR), for patients who do not have an uploaded, complete AD at the beginning of the study?
	4. Research Question (B2): What is the association between Intervention B and decisions documented in the Advance Directive?
	5. Research Question (B3): What characteristics predict treatment effect of Intervention B?
	6. Research Question (B4): What is estimated savings in hassle costs due to Intervention B?
2. **Outcomes: Define your study’s primary outcome(s) as completely as possible, including how and when they will be assessed. Do the same for any secondary outcomes.**

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| **ID** | **Outcome(s) Description** | **Type** | **Measurement Variable** | **Method of Aggregation** | **Time Point** |
| 1 | Uploads Advance Directive to EMR | Primary | Whether patient w/o advance directive at beginning of study uploads one by the end | Binary (proportion) | 4 weeks after intervention outreach  |
| 2a | Fraction Total Patients Uploaded Advance Directive to EMR (clinic level) | Primary | Fraction of Patients in Clinic with AD uploaded to EMR | Fraction | 4 weeks after intervention outreach (measured monthly) |
| 2b | Fraction Total Patients Completing healthcare proxy selection field (clinic level) | Primary | Fraction of Patients in Clinic with completed healthcare proxy selection field in EPIC | Fraction | 4 weeks after intervention outreach (measured monthly) |
| 3a | Completes Surrogate Selection | Secondary | Whether patient has completed healthcare proxy selection field in EPIC | Binary (proportion) | 4 weeks after intervention outreach  |
| 3b | Completes Surrogate Selection | Secondary | Whether patient w/o advance directive at beginning of study uploads one with completed surrogate selection (Oregon AD section B) | Binary (proportion) | 4 weeks after intervention outreach  |
| 4 | Completes Care Preferences | Secondary | Whether patient w/o advance directive at beginning of study uploads one with completed care preferences section (Oregon AD section C) | Binary (proportion) | 4 weeks after intervention outreach |
| 5 | Preference for Life Support  | Secondary | Conditional on Completed AD, Oregon AD section C: Indicator=1 if (# boxes checked in items 1-4 equal to "I want any other life support that may apply" is 1 or more), Otherwise 0 | Binary (proportion) | 4 weeks after intervention outreach |
| 6 | Preference for Tube Feeding | Secondary | Conditional on Completed AD, Oregon AD section C: Indicator=1 if (# boxes checked in items 1-4 equal to "I want to receive tube feeding" is 1 or more), Otherwise 0 | Binary (proportion) | 4 weeks after intervention outreach |
| 7 | Dis-Preference for Life Support  | Secondary | Conditional on Completed AD, Oregon AD section C: Indicator=1 if (box 5 checked or # boxes checked in items 1-4 equal to "I want NO life support" is 4), Otherwise 0 | Binary (proportion) | 4 weeks after intervention outreach |
| 8 | Dis-Preference for Tube Feeding | Secondary | Conditional on Completed AD, Oregon AD section C: Indicator=1 if (box 5 checked or # boxes checked in items 1-4 equal to "I do NOT want tube feeding" is 4), Otherwise 0 | Binary (proportion) | 4 weeks after intervention outreach |
| 9 | Fraction of new ADs with Preference for Life Support (clinic level) | Secondary | Outcome 5 aggregated to clinic level by fraction of new ADs per month | Fraction | 4 weeks after intervention outreach (measured monthly) |
| 10 | Fraction of new ADs with Preference for Tube Feeding (clinic level) | Secondary | Outcome 6 aggregated to clinic level by fraction of new ADs per month | Fraction | 4 weeks after intervention outreach (measured monthly) |
| 11 | Fraction of new ADs with Dis-Preference for Life Support (clinic level) | Secondary | Outcome 7 aggregated to clinic level by fraction of new ADs per month | Fraction | 4 weeks after intervention outreach (measured monthly) |
| 12 | Fraction of new ADs with Dis-Preference for Tube Feeding (clinic level) | Secondary | Outcome 8 aggregated to clinic level by fraction of new ADs per month | Fraction | 4 weeks after intervention outreach (measured monthly) |

1. **Sample size and statistical power: State your study’s sample size and provide details on statistical power calculations.**

Power Analysis below is in reference to Research Question B1, Outcome 1. Research Questions A will be answered using non-experimental methods (synthetic control) and remaining Research Questions B2-B4 are in reference to secondary outcomes.

Our implementing partner has indicated that a change as small as a 5 percentage points increase in advance directive completion would be of clinical and policy relevance. We will have power to detect a 2.4 percentage point increase in advance directive uploads resulting from the electronic information provision treatment. This assumes that in the randomly selected group of individuals that do not receive the videos, 5% of patients without an advance directive will upload one during the study period of 4 weeks. It assumes a two-sided test with alpha=0.5, and power of 80%. Our study population is two clinics of roughly 2000 patients each, in which roughly 19% already have an advance directive. Patients will be randomized to receive the intervention at the individual level.



1. **Data sources: Describe the source(s) of data in detail.**

We will collect survey data from participants who respond to the survey using the REDCap (Research Electronic Data Capture) electronic data capture tool hosted by PSJH. We will distribute the survey via email to a randomly selected 80% of patients meeting the inclusion criteria in the two selected clinics. The survey will be open to participation for two weeks and will be distributed directly prior to the implementation of the interventions. An initial email message will be sent to all eligible patients and then three follow-up messages will be sent at twice weekly intervals to patients who have not yet agreed or declined to complete the survey. A copy of the survey can be found in Appendix B.

We will also obtain the following information from electronic medical records directly prior to the implementation of the interventions for all patients meeting the study inclusion criteria:

* Patient Demographics: Age, sex, race, ethnicity, marital status, preferred language, zip code, latitude and longitude for primary home address, religion, employer, contact preference, MyChart activation status
* Insurance: Patient insurer, Medicare/Medicaid dual eligible
* Clinical Information:
	+ Most recent active problem list diagnoses
	+ Most recent medication list
	+ Most recent medical and surgical history
	+ Most recent height and weight or BMI
	+ Most recent depression screening results
	+ Most recent labs and vital signs
	+ Number of primary care and any other outpatient visits to PSJH or affiliate sites, two years prior to study start date
	+ Number of inpatient days at PSJH or affiliate sites, two years prior to study start dat
	+ PCP and PCP specialty
	+ ACP documentation: A downloaded copy of any ACP documentation in the patients EMR, including date of upload

We will also obtain the following information from PSJH administrative records for each study clinic:

* Clinic information
	+ Clinic Name
	+ Clinic location
	+ Number of PCPs at clinic
	+ License type, specialty, and panel size for each PCP
1. **Intervention/policy: Describe the intervention or policy being tested, in as much detail as is feasible.**

After the survey completion date, we will proceed with the interventions: (1) a series of Advance Directive Drives at one of the two selected clinics (Clinic A) and (2) a distribution of a link to an ACP Decisions video via email to a randomly selected 50% of patients with an active MyChart account who meet the inclusion criteria in the two selected clinics (Clinic A and Clinic B). All patients in the two clinics with an activated MyChart account will be contacted with an email message and patients without an activated MyChart account will be contacted by paper letter as described in **Table 1**.

**Table 1. Intervention distribution across patient groups**

|  |  |  |
| --- | --- | --- |
| Patient group | Intervention Description | % of patients in patient group |
| Clinic A – AD Drive | Clinic B – No AD Drive |
| MyChart activated | MyChart not activated | MyChart activated | MyChart not activated |
| No intervention | A reminder to complete AD | 0% | 0% | 50% | 100% |
| Advance Directive Drive alone | A reminder to complete AD and a reminder to attend the AD drive | 50% | 100% | 0% | 0% |
| ACP Decisions video only | A reminder to complete AD with a link to the ACP Decisions video | 0% | 0% | 50% | 0% |
| Advance Directive Drive and ACP Decisions video | A reminder to complete AD with a reminder to attend the AD drive and a link to the ACP Decisions video | 50% | 0% | 0% | 0% |
| TOTAL, ALL GROUPS |  | 100% | 100% | 100% | 100% |

*AD Drive Intervention*

Clinic A will host a series of three AD drives, where patients can ask questions about ACP, have a notary or appropriate witness validate the AD, and receive assistance in adding the AD to their EMR. The drives will be held in an open-house style (no appointment needed) on three different days. Patients at these clinics will receive an email message with information about the drives and a reminder to complete and upload an AD. Patients without activated MyChart accounts will receive a mailed paper letter version of the message. The AD drive will be open to everyone going through the selected clinic, but only patients meeting study inclusion/exclusion criteria will receive the communication intervention. Patients at Clinic B will only receive a reminder to complete an AD.

*Information Intervention*

Patients at both clinics will be randomly assigned at the individual level to receive electronic access (via a link in an email message) to a video and two informational sheets from ACP Decisions with instructions for watching. The [ACP Decisions](http://www.acpdecisions.org) (<https://www.acpdecisions.org/>) videos provide evidence-based explanations of key topics relevant to ACP and the completion of ADs, available in multiple languages (El-Jawahri et al. 2015). The video to be disseminated is titled “Advance Care Planning for Healthy Adults, All Chapters Reduced Length”, in addition to two informational sheets titled “A Guide to End of Life Choices” and “A Guide to Feeding Tubes”.

1. **RCT-specific considerations: If the study is an RCT, please provide the following:**

Research Question B1 will be answered via randomized evaluation. Other questions will employ different methodologies.

* 1. **Describe the level of randomization and the level at which the outcome data will be collected.**

Randomization and outcomes (1, 3, 4) will be done at the individual level.

* 1. **Describe any further details about the randomization and design.**

Randomization will be stratified by clinic.

* 1. **Describe who, if anyone, will be blinded after random assignment (such as participants, providers, anyone assessing outcomes, or the research team themselves), and how**

Participants will not know whether they are part of a study (waiver of consent).

* 1. **Describe any inclusion or exclusion criteria.**

Inclusion Criteria

As of study start date:

* + Assigned to a PCP at the Providence Medical Group (PMG) – Gresham Clinic or the PMG – Mercantile clinic
	+ Patients 65 and over
	+ Had at least one active encounter type documented in their electronic medical record in the past 24 months

Exclusion Criteria

* + Patients who have an advance directive uploaded to the EMR at the start of the study will not be included in the intervention cohort.
1. **Statistical methods: Describe the statistical methods that are intended to be used:**
	1. Research Questions (A1- Outcomes 2a-b), (A2- Outcomes 9-12): Synthetic Control
		1. A synthetic control will be created for the clinic receiving treatment 1 (Clinic A), from a weighted average of all other clinics in Oregon excluding Clinic B, matched based on clinic size and 6 pre-treatment monthly observations of Outcome. Method will follow Abadie, Diamond and Hainmueller 2010.
		2. Data will be collected 6 months pre-treatment and 2 months post.
		3. Placebo testing will follow the method in Abadie, Diamond and Hainmueller 2010.
		4. For A2, an additional simple comparison will be made of Outcomes 9-12 in clinic A for the treatment period to aggregated rates of the same outcomes 6 months prior to the treatment period.
	2. Research Question (B1- Outcomes 1, 3, 4): Randomized Evaluation
		1. In addition to ITT, will use randomization as an instrument for watching the video (defined as clicking through the link)
		2. Will include a control for Clinic in all specifications (accounts for stratification and effect of intervention 1).
	3. Research Question (B2- Outcomes 4-8): Randomized Evaluation
		1. Limit to clinic A and patients who have newly filled out directives, compare randomized groups
			1. ITT as in (ii)
			2. Control for clinic as in (ii)
		2. An additional simple comparison of Outcomes 5-8 in population of new ADs during intervention period with same outcomes aggregated among ADs added in the 6 months before
	4. Research Question (B3- Outcomes 1,3,4): Machine Learning
		1. We will follow the Honest Causal Tree Method from Athey and Imbens 2015 to identify heterogenous effects of intervention 2.
		2. We will use covariates outlined in section 13 including patient demographics, insurance, clinic information, survey responses, and clinic (A or B). Survey response variables will be divided sensibly into outcomes based on overall response distributions.
	5. Research Question (B4- Outcomes 1,3): Model Estimation, model of surrogate selection
		1. Assume that each individual receives value Bi if their preferred health care decision maker is legally authorized to make proxy medical decisions for them. Bi is unknown and distributed normally in the population. Bi is assumed to be 0 if the preferred proxy is the legal default. This is discounted by $δ^{E\left(y\right)}$ , the agent's exponential discount factor from survey data and age minus life expectancy (computed from reference data based on age and number of chronic conditions).
		2. Each individual has a cost Ci to completing the Advance Directive form, which is assumed to be based entirely on reported number of hours perceived for AD completion (from survey) and wage estimates (from survey). Additionally, depending on treatment status, the cost may be lowered by an unknown value TEi (assumed to be distributed normally), the effect of the treatment in lowering hassle costs (assume for now TEi is independent of Ci, may relax this later).
		3. Thus, an individual selects a proxy decision maker in the present period if

$C\_{i}-I\left(Treat\right)\*TE\_{i}\leq B\_{i}\*δ^{E\left(y\right)}$

* + 1. We will estimate the mean and sd of TEi and Bi using maximum likelihood.
		2. Additional iterations and versions of this model may be considered.
1. **Additional statistical considerations: How will the research team handle the following, if applicable?**
	1. **Missing data-** We don’t anticipate missing data for primary outcomes, but in the case that we have substantial missing outcome data we will check for balance across treatment and control groups before dropping missing observations from analysis. For isolated missing covariates (e.g. not all data is missing), we will impute to the mean and flag missing in a separate variable.
	2. **Attrition-** N/A
	3. **Censoring-** We will replace only medically infeasible values with missing.
	4. **Multiple Comparison Adjustment:** Because we are only studying one primary outcome and expect other outcomes to be highly correlated, we will not make adjustments for multiple comparisons.
	5. **Robustness checks:** TBD