Randomized Controlled Trial of a Decision Support Intervention About Cardiopulmonary Resuscitation for Hospitalized Patients Who Have a High Risk of Death

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BACKGROUND: Many seriously ill hospitalized patients have cardiopulmonary resuscitation (CPR) as part of their care plan, but CPR is unlikely to achieve the goals of many seriously ill hospitalized patients.

OBJECTIVE: To determine if a multicomponent decision support intervention changes documented orders for CPR in the medical record, compared to usual care.

DESIGN: Open-label randomized controlled trial.

PATIENTS: Patients on internal medicine and neurology wards at two tertiary care teaching hospitals who had a 1-year mortality greater than 10% as predicted with a validated model and whose care plan included CPR, if needed.

INTERVENTION: Both the control and intervention groups received usual communication about CPR at the discretion of their care team. The intervention group participated in a values clarification exercise and watched a CPR video decision aid.

MAIN MEASURE: The primary outcome was the proportion of patients who had a no-CPR order at 14 days after enrollment.

KEY RESULTS: We recruited 200 patients between October 2017 and October 2018. Mean age was 77 years. There was no difference between the groups in no-CPR orders 14 days after enrollment (17/100 (17%) intervention vs 17/99 (17%) control, risk difference, − 0.2%) (95% confidence interval − 11 to 10%; $p = 0.98$). In addition, there were no differences between groups in decisional conflict summary score or satisfaction with decision-making. Patients in the intervention group had less conflict about understanding treatment options (decisional conflict knowledge subscale score mean (SD), 17.5 (26.5) intervention arm vs 40.4 (38.1) control; scale range 0–100 with lower scores reflecting less conflict).

CONCLUSIONS: Among seriously ill hospitalized patients who had CPR as part of their care plan, this decision support intervention did not increase the likelihood of no-CPR orders compared to usual care.

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INTRODUCTION

For hospitalized patients who have serious illness, CPR is rarely successful. Only 10% of people who have serious illnesses and receive CPR in the hospital leave the hospital alive and less than half of those are functional enough to return home and live independently.[1–4] Many older hospitalized patients with serious illness want care that focuses on quality of life in a home-like environment without the use of machines or aggressive interventions and yet many of these patients have an order in the medical record to administer CPR in the event of a cardiac arrest.[5,6] The discordance between preferences and orders regarding CPR occurs because physicians do not often ask patients about their values and preferences, patients are not clear about the harms and benefits of CPR, and patients have difficulty prioritizing conflicting values.[7–9] Decision support is needed to help patients make decisions about CPR that are consistent with their values.

Decision aids are intended to share information and encourage deliberative decision-making. CPR video decision aids have been shown to improve patients' knowledge and result in different decisions about receiving CPR in hospital.[10] However, there are no publicly available CPR video decision aids

that have been shown to result in different documented decisions' about CPR and no trial has tested a video decision aid among patients with low probability of surviving CPR who have CPR as part of their care plan. Therefore, we conducted a randomized controlled trial of a decision support intervention (DSI) that includes a values clarification exercise and a CPR video decision aid for seriously ill, hospitalized patients who had CPR as part of their care plan. We hypothesized that patients who used the DSI would be more likely to make a decision not to have CPR in the event of a cardiac arrest and consequently would be more likely to have a no-CPR order in their medical record.

METHODS

Design Overview

This was a parallel arm, open-label randomized controlled trial with 1:1 allocation to intervention and control groups. The study was approved by the Ottawa Health Sciences Network Research Ethics Board. The trial is registered at clinicaltrials.gov (NCT03287895). The approved protocol can be found in Supplement 1.

Setting and Participants

Participants were recruited at the General Hospital and the Civic Hospital in Ottawa, Canada, two affiliated academic tertiary-care teaching hospitals. All patients admitted to internal medicine or neurology wards had a 1-year risk of death calculated by an automated, validated risk prediction model running on hospital databases.[11] Patients were eligible if they were older than 55 years old, had a 1-year risk of death greater than 10%, and had an order in their medical record for CPR in the event of cardiac arrest, or no documented order regarding CPR in their medical record. Research assistants recruited patients in their hospital rooms. Internal medicine and neurology wards were selected because of high risk of death and longer median length of stay in these populations making CPR discussions more relevant. In our jurisdiction, patients must verbally consent to any order regarding CPR during the hospital admission. In cases where the eligible patient did not have capacity to make medical decisions for themselves, their healthcare proxy (HCP) was eligible for participation.

Randomization

Participants were randomized using a centralized automated computer-generated sequence to intervention or control groups using randomly permuted block sizes of 2, 4, or 6 for allocation concealment.

Intervention

The DSI was administered by trained research assistants in the patient's hospital room. The first component consisted of two values clarification exercises that helped patients prioritize health goals (Supplement 2). The first exercise presents the patient with 2 values at opposite ends of a linear scale and asks them to select the point on the scale that represents the relative importance of the values. For example, the first scale is labeled with "how well you live" at one end of the scale and "how long you live" at the other. The second values clarification exercise uses a methodology called "best-worst scaling" to establish the relative importance of four values. To prioritize the values, the user is asked sequentially to select which value is most important and least important from sets of 3 of the 4 values. The four values are as follows: maintain independence, quality of life/well-being, live as long as possible, avoid machines to keep me alive.

The second component of the DSI was a video decision aid about CPR viewed immediately after the values clarification exercises.[12] The video is 7 min long, fulfills 7/7 criteria of International Patient Decision Aids Standards to be considered a decision aid, and has been shown to be acceptable and increase patient knowledge.[13–15] The decision aid presents the harms and benefits of CPR for people who have serious chronic disease, similar to those in this trial.

Participants then received a "Dear Doctor Letter" that summarized their responses to each part of the intervention and their response to the question about CPR. Patients were instructed to give the letter to their doctor in hospital to discuss what is important to them and their wishes regarding CPR.

Patients randomized to usual care were told to ask their physician in hospital if they had questions about CPR. Usual care at the participating hospital includes a hospital policy that patients should have an order to administer or withhold CPR within 48 h of admission. There is no structure to enforce the policy and all aspects of the communication are at the discretion of the physicians.

Outcomes

The primary outcome was the difference in no-CPR orders between groups at the time of death, discharge, or 14 days after enrollment, whichever came first. Secondary outcomes were as follows: patient stated preferences for CPR immediately after the intervention, decisional conflict, satisfaction with decision-making, health care proxy's decision-making self-efficacy, quality of documentation about goals for future medical care, and concordance between values and stated preference for CPR.

Outcome Measures

Orders for CPR were abstracted from patient charts by a blinded outcome assessor. To assess the quality of patient's decisions, we used the decisional conflict scale (DCS) a measure of uncertainty in decision-making and factors that contribute to uncertainty.[16] The DCS is scaled 0–100 with lower scores meaning less decisional conflict. For satisfaction in decision-making, we used the decision-making domain of the CANHELP survey.[17] The CANHELP survey, scaled from 0 to 100, measures satisfaction with end-of-life care and has

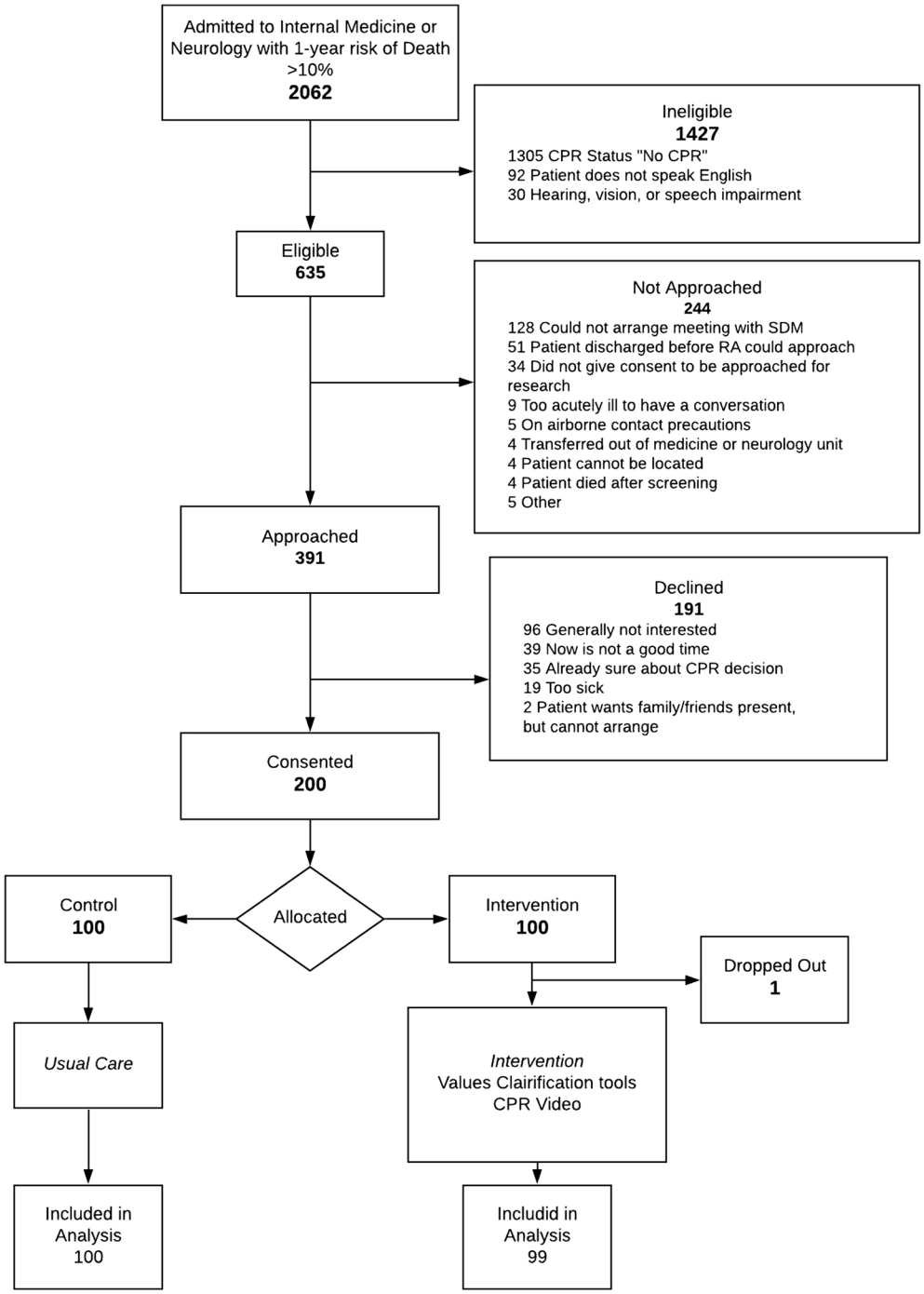

Figure 1 Consort flow diagram. CPR, cardiopulmonary resuscitation; SDM, substitute decision maker.

been shown to be valid and internally consistent. We used the HCP Self Efficacy scale (range from 1 to 4) to measure HCP self-efficacy to make decisions on behalf of the patient.[18] All surveys were completed immediately after the intervention for the intervention group and at enrollment for the control group. After completing the intervention, patients were read the following script: "Whether you choose to have CPR or not, treatment is still focused on helping you live as well as you can for as long as you can. You will always receive treatment to help you with symptoms and care for your needs. Given your current health condition, at this point in time, what would you want if your heart were to stop beating?

1) Use machines and all possible measures including Cardiopulmonary Resuscitation (CPR) with a focus on keeping me alive at all costs.
2) Allow a natural death with no artificial prolongation of life and no CPR.
3) I am unsure."

We report patient responses to the values clarification question about the trade-off between "I want doctors to do everything

Table 1 Clinical Characteristics and Demographics of Participants

	Control $n = 100$	Intervention $n = 99$	Total $n = 199$
Age, mean (SD)	78 (9)	76 (10)	77 (10)
Sex, *n* (%)			
Male	61 (61.0)	59 (59.6)	120 (60.3)
Female	39 (39.0)	40 (40.4)	79 (39.7)
Mean probability of death within 1 year*, mean percentage (SD)	25.8 (18.1)	24.2 (14.1)	25.0 (16.2)
CPR status at enrolment, *n* (%)			
No order regarding CPR	15 (15.0)	16 (16.2)	31 (15.6)
Order to receive CPR	85 (85.0)	83 (83.8)	168 (84.4)
Self-assessed clinical frailty scale, *n* (%)			
Very fit	2 (2.0)	4 (4.0)	6 (3.0)
Well	13 (13.0)	13 (13.1)	26 (13.1)
Managing well	31 (31.0)	30 (30.3)	61 (30.7)
Vulnerable	19 (19.0)	17 (17.2)	36 (18.1)
Mildly frail	18 (18.0)	17 (17.2)	35 (17.6)
Moderately frail	11 (11.0)	11 (11.1)	22 (11.1)
Severely frail	5 (5.0)	6 (6.1)	11 (5.5)
Very severely frail	1 (1.0)	1 (1.0)	2 (1.0)
Marital status, *n* (%)			
Married/living as married	57 (57.0)	47 (47.5)	104 (52.3)
Widowed	21 (21.0)	29 (29.3)	50 (25.1)
Divorced/separated	12 (12.0)	12 (12.1)	24 (12.1)
Never married	10 (10.0)	11 (11.1)	21 (10.6)
Education level, *n* (%)			
Less than high school	25 (25.0)	18 (18.2)	43 (21.6)
High school	16 (16.0)	18 (18.2)	34 (17.1)
College and/or some university	25 (25.0)	24 (24.2)	49 (24.6)
Undergraduate degree	18 (18.0)	21 (21.2)	39 (19.6)
Graduate or professional degree	13 (13.0)	18 (18.2)	31 (15.6)
Missing	3 (3.0)	0 (0.0)	3 (1.5)
Race, *n* (%)			
Caucasian/White	85 (85.0)	82 (82.8)	167 (83.9)
East Indian	3 (3.0)	3 (3.0)	6 (3.0)
African/Black North American	1 (1.0)	3 (3.0)	4 (2.0)
Asian/Pacific Islander	0 (0.0)	1 (1.0)	1 (0.5)
First Nations/Inuit/Metis/Aboriginal	1 (1.0)	2 (2.0)	3 (1.5)
Other	10 (10.0)	8 (8.1)	18 (9.0)
Health care information needs‡, *n* (%)			
A lot	66 (66.0)	72 (72.7)	138 (69.3)
Some	30 (30.0)	22 (22.2)	52 (26.1)
Just a little	2 (2.0)	4 (4.0)	6 (3.0)
None	1 (1.0)	1 (1.0)	2 (1.0)
Missing	1 (1.0)	0 (0.0)	1 (0.5)
Language spoken daily, *n* (%)			
English	87 (87.0)	85 (85.9)	172 (86.4)
French	6 (6.0)	8 (8.1)	14 (7.0)
Other	7 (7.0)	6 (6.1)	13 (6.5)
Patient perceived quality of life§, *n* (%)			
Excellent	8 (8.0)	23 (23.2)	31 (15.6)
Very Good	32 (32.0)	27 (27.3)	59 (29.6)
Good	28 (28.0)	21 (21.2)	49 (24.6)
Fair	20 (20.0)	17 (17.2)	37 (18.6)
Poor	12 (12.0)	11 (11.1)	23 (11.6)
ED visits in past year, mean (SD)	3.4 (2.8)	3.0 (2.4)	3.2 (2.6)
Hospital admissions in past year, mean (SD)	1.9 (1.3)	2.2 (1.5)	2.1 (1.4)
Days in hospital in past year, mean (SD)	18.6 (19.7)	22.6 (22.8)	20.5 (21.3)
Elixhauser Comorbidity Score, mean (SD)	11.5 (8.6)	11.6 (8.5)	11.5 (8.5)
Patient was represented by their Health Care Proxy *n* (%)	16 (16)	18 (18)	34 (17)

**HOMR-now! Score11*
‡Patients were asked, "Thinking about your wishes for medical care in the future when you are seriously ill, which of the following options best describes how much information you would like to receive to help you make the best decision about the kinds of medical treatments that would be right for you?"
§Patients were asked, "In general, how would you rate your overall quality of life?"

possible, including use of machines, to keep me alive for as long as possible" and "I would want a peaceful death without being attached to machines" because responses to this question are expected to correlate with responses to the question about CPR preferences.

We assessed the frequency and quality of documented conversations about CPR and goals for future medical care using a standardized chart abstraction tool that contained 17 components in 4 domains.[19] Abstraction of the primary outcome and quality of documented conversations was done by a blinded outcome assessor who reviewed the chart.

Patient and Admission Characteristics

Marital status, place of residence, education, race, information needs, language, and quality of life were collected by self-report before randomization. Participants self-assessed their

Table 2 Secondary Outcomes

	Control $n = 100$	Intervention $n = 99$	p
Patients' stated preferences for CPR immediately after the intervention or after enrolment for the control group n (%)			
CPR	63 (63)	58 (59)	0.14
No CPR	21 (21)	17 (17)	
Unsure	15 (15)	19 (19)	
Missing	1 (1)	5 (5)	
Decisional conflict mean (SD)—lower scores indicate less decisional conflict. Each item is normalized on a scale from 0 to 100			
Decisional Conflict Scale Summary Score	22.0 (22.4)	18.6 (18.9)	0.26
Q1—Know what matters most	10.4 (17.1)	8.6 (15.9)	0.46
Q2—Know enough about options	40.4 (38.1)	17.5 (26.5)	< 0.001
Q3—Enough support from family	11.9 (26.3)	21.8 (37.1)	0.04
Q4—Enough support and information from doctor	28.0 (37.2)	30.4 (37.0)	0.66
Q5—Sure about best choice for you	19.2 (32.9)	14.8 (26.1)	0.30
CANHELP, mean (SD) normalized on a scale 0–100			
CANHELP summary score	67.5 (24.7)	67.7 (20.7)	0.94
Q1—Satisfaction with information about future care	64.3 (33.0)	64.4 (31.6)	0.99
Q2—Satisfaction with conversations about CPR in hospital	65.2 (31.1)	70.3 (26.6)	0.22
Q3—Satisfaction with information about end stage of illness	63.0 (31.2)	64.8 (28.5)	0.69
Q4—Satisfaction with decision-making role	76.8 (24.0)	70.7 (26.4)	0.10
HCP self-efficacy, mean (SD) (range 1–4) higher scores more efficacy	n = 16 3.5 (0.4)	n = 18 3.4 (1.0)	0.70
Documented goals of care conversations, n (%)			
0	83 (83.8)	88 (88.9)	0.31
1	6 (6.1)	5 (5.1)	
2	3 (3.0)	4 (4.0)	
3	5 (5.1)	1 (1.0)	
4 +	2 (2.0)	1 (1.0)	
Documentation that life-sustaining treatments were discussed, n (%)	9 (9.1)	6 (6.1)	0.59

frailty using a validated tool.[20] We collected age, sex, risk of death within 1 year, comorbidities, and information on prior healthcare encounters from our institutional data warehouse.

Statistical Analysis

The sample size calculation was based on a previous CPR video decision aid study.[21] A sample size of 200 patients had 80% power to detect a 15% absolute difference in orders for CPR (primary outcome) between groups with an alpha of 0.05. The primary analysis was the risk difference between groups. As a secondary analysis, we performed logistic regression to determine the odds ratio (OR) of the primary outcome in intervention group compared to the control group adjusted for the CPR order at the time of enrollment (either order for CPR or no order regarding CPR). We used a chi-square test to test consistency with the null hypothesis for the primary outcome, and for other categorical variables. We used Fisher's Exact test for categorical variables with cells containing fewer than five observations. For ordinal scales (DCS, CANHELP, and HCP self-efficacy), we used the Wilcoxon signed-rank test. Analysis was done by a statistician who was blinded to allocation. We used complete case analysis for missing outcome data.

RESULTS

Study Population

Recruitment lasted from October 20, 2017, until October 22, 2018. We screened 2061 patients for eligibility, 631 were eligible, 391 were approached, and 200 were enrolled (Fig. 1). A total of 34 participants were HCPs participating on behalf of the patient. The mean age of the patients was 77 years old and 60.3% were male (Table 1). The mean probability of death within 1 year was 25%. At the time of enrollment, 168/199 (84%) of patients had an order in the medical record for CPR in the event of cardiac arrest while the other 31/199 (16%) had no orders regarding CPR. The mean length of stay in hospital at the time of enrollment was 3.4 days. The mean time between enrollment and discharge was 10.4 days.

Outcomes

When patients were asked about their preference regarding CPR immediately after the intervention, 17/100 (17.0%) patients in the intervention group and 21/99 (21%) in the control group stated they would not want CPR ($p = 0.76$) (Table 2).

Fourteen days after the intervention, 17/100 (17.0%) patients in the intervention group and 17/99 (17.2%) patients in the control group had a no-CPR order (risk difference, − 0.2%; 95% confidence interval [CI] − 10 to 11%; $p = 0.98$). Among those who had an order for CPR at enrollment, the proportion of patients who had a no-CPR order was 1.6% higher in the intervention group at 14 days (14.5% vs 12.9%, difference 1.6% [95% CI − 8.9–11.9%] $p = 0.77$). Among those without a CPR order at enrollment, the proportion with a no-CPR order was 8.8% lower in the intervention group at 14 days (31.3% vs 40.0%, risk difference − 8.8% [95% CI − 24.9–42.4%] $p = 0.61$). In regression analysis adjusted for the presence of a

CPR order at enrollment, the OR for a no-CPR order for patients in the intervention group at 14 days was 0.99 (95% CI 0.46–2.12).

Decisional conflict (lower scores are better) was 18.6/100 in the intervention group and 22.2/100 in the control group ($p = 0.26$) (Table 2). For the DCS item on knowledge of options, the mean score (lower scores are better) in the intervention group was 17.5/100 versus 40.4/100 ($p < 0.001$) in the control group. For the item on clarity of values, the mean score in the intervention group was 8.6/100 versus 10.4/100 ($p = 0.46$) in the control group. In the control and intervention, 83/100 and 88/99 respectively had no documented goals of care discussion from enrollment to discharge.

All patients, 13/13 (100%), who said *no* to CPR, when asked immediately after the intervention, also preferred a peaceful death without the use machines more than staying alive as long as possible. However, 21/49 (43%) of those who said *yes* to CPR also wanted a peaceful death without the use of machines.

DISCUSSION

We tested a values clarification exercise and a CPR video decision aid in hospitalized patients who were at high risk of death and whose care plan included CPR, if necessary. We found no difference between groups in no-CPR orders at 14 days after the intervention. There was no difference in DCS summary score, but patients in the intervention group felt they had better knowledge about CPR.

In contrast to our study, El-Jawahri et al. found that patients who viewed a CPR video decision aid were less likely to prefer CPR.[21] We used a different video that was longer than the one used by El-jawahri et al., 7 min compared to 3 min, but we cannot compare the content because their video is not in the public domain. Patients in our study all had a 1-year risk of death greater than 10% but in the El-jawahri et al. study patients had an expected survival of less than 1 year, meaning they likely had worse prognosis than those in our study and CPR was even less beneficial. This may be one reason for our different result. Another difference between the studies is that in most patients in our study (84%) already had an order for CPR in the medical record based on some discussion with a physician whereas in the El-jawahri et al. study only 40% of patients reported having a conversation about CPR since admission. It is plausible that patients who are naïve to discussions or decisions about CPR in hospital are sensitive to the effect of a CPR decision aid whereas patients who have already engaged in a discussion are unlikely to change their minds. Of all the patients with an elevated risk of death during our screening process, more than half already had a no-CPR order and so were not eligible for our study suggesting we selected a unique population who wanted CPR despite low probability of benefit.

Our intervention did not change patient's confidence in knowing what was right for them, which was high in both groups, or their stated preferences immediately after viewing the video and so it is not surprising that it did not change orders in the medical record. Even though there were no changes in documented or stated preferences for CPR, we might have expected the "dear doctor" letter to activate patients to engage in goals of care discussions, but there was no difference between groups in documented discussions about goals of care suggesting that the intervention was insufficient to trigger patient-physician discussions. Interventions to encourage discussions about future medical care need to activate both physicians and patients and then facilitate a conversation with a tool as others have shown.[22–26] Simply asking the patient to use the letter as a conversation starter is not enough in this setting.

Overall decisional conflict was quite low in both groups.[16] Specifically, patients in both groups felt they were "sure of the best choice for them" even though control group participants did not know very much about the options. Decisions around CPR may be best understood through fuzzy trace theory with gist understandings such as "CPR keeps me alive" and prone framing effects, exemplified by different responses when questions about resuscitation are asked using "do not resuscitate" versus "allow natural death".[27–30]

Default options have been shown to influence decisions about resuscitation; deciding against the default is less common than sticking with the default.[31] Perhaps future studies should select a default for each patient based on the probability of benefit to that patients. In practice, this is often what happens.[32]

Patients in the intervention group who said "no" to CPR all prioritized a peaceful death without machines above living as long as possible but patients who said "yes" to CPR were divided, with some prioritizing a peaceful death and others prioritizing living as long as possible. The apparent discordance between values and treatment preferences among patients who said "yes" to CPR suggests that patients cannot reliably connect their values to medical treatment options. More sophisticated tools that make this process more transparent, such as used in PlanWellGuide.com, may increase values-concordant decision-making.[9,33] Alternatively, when a decision requires tradeoffs between deeply held values, decision coaching may be useful, especially for those who have discordant values and treatment preferences.[34]

Our study has a number of strengths. We used a pragmatic design that engaged patients in a brief interaction in their hospital rooms. We used randomization and assessed a real-world outcome of documented preferences for CPR.

Our study has several limitations. We could not blind participants which may have resulted in bias. Our results may not be generalizable to centers with different demographics. Another limitation is that we do not know how patients interpreted the question about CPR preferences. Patients may be unwilling to express a preference not to receive

CPR if they perceived that saying "no" to CPR means less medical treatment; pilot testing the question with cognitive interviewing before trial initiation would have been useful. While the question of CPR is a binary decision, it is embedded in a plan of care that has many possible levels of intervention based on patient goals. Interventions that focus on goals of care instead of specific decisions like CPR are probably more useful in creating a coherent values concordant care plan.[35,36]

CONCLUSIONS

Among seriously ill hospitalized patients who had CPR as part of their care plan, a values clarification exercise coupled with a CPR video decision aid did not change orders for CPR but did improve knowledge about CPR. Seriously ill hospitalized patients in both groups in our trial had low decisional conflict suggesting that they were confident in their decisions despite the low probability of success. Further research can explore how patients with serious illness make decisions under uncertainty and how to help patients process conflicting desires to live as long as possible and also have a peaceful death. Future efforts must empower patients and activate clinicians to trigger goals of care discussions.

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