

ORIGINAL ARTICLE

A Randomized Trial of Shared Decision-Making in Code Status Discussions

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Abstract

BACKGROUND The effect of a shared decision-making approach on patients' code status decisions remains unknown. We compared an approach for shared decision-making with usual care to evaluate the effect on patients' code status preferences and quality of decision-making.

METHODS In a pragmatic cluster-randomized controlled trial conducted in six teaching hospitals in Switzerland, we randomly assigned residents to conduct code status discussions based on either an approach incorporating didactic teaching, observation, and feedback and a shared decision-making checklist with a decision aid, or usual care. The primary end point was patients choosing a do-not-resuscitate (DNR) code status in the event of a cardiac arrest. The key secondary end point was patients' decisional uncertainty, measured by the Decisional Conflict Scale (range 0 to 100, with lower scores indicating lower decisional uncertainty).

RESULTS A total of 206 residents caring for 2663 medical patients were included in the trial. Compared with patients in the usual care group, patients in the intervention group had a significantly higher frequency of choosing DNR as their code status (685/1370 (50.0%) vs. 481/1293 (37.2%); adjusted risk ratio, 1.37 (95% confidence interval, 1.25 to 1.50); $P < 0.001$). The intervention was associated with lower decisional uncertainty (Decisional Conflict Scale score, 14.4 ± 15.3 vs. 21.8 ± 20.2 points; adjusted difference, -7.06 (95% confidence interval, -9.43 to -4.68)).

CONCLUSIONS An approach for shared decision-making that included the discussion of expected outcomes had a significant influence on the code status of medical patients, with a higher preference for DNR code status, and was associated with less uncertainty around the decision. (Funded by the Swiss National Science Foundation and the Swiss Society of General Internal Medicine; ClinicalTrials.gov number, [NCT03872154](https://clinicaltrials.gov/ct2/show/study/NCT03872154).)

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Introduction

Patients with in-hospital cardiac arrests have a poor prognosis, with a survival to hospital discharge of less than 20%,¹⁻³ and 40% of survivors experience substantial neurologic deficits.⁴ The unpredictability of cardiac arrest underscores the importance of understanding a patient's preferences about advanced life support efforts, even before the full clinical picture of the patient's disease has been elucidated. One key component of advance care planning is discussing and documenting patients' individual preferences regarding resuscitation procedures in the case of a cardiac or respiratory arrest upon hospital admission.^{5,6} While active involvement of patients in critical medical decisions related to end-of-life care is generally recommended,⁷⁻¹⁰ studies have shown that discussions about resuscitation measures often lead to misconceptions of cardiopulmonary resuscitation (CPR) and expected outcomes.¹¹⁻¹⁸ Patients often overestimate the probability of survival with good neurologic outcome in the case of a cardiac arrest, which may lead to patients choosing a "full code" status despite poor prognosis.¹⁸ While specific communication interventions have been shown to influence code status decisions in end-of-life and critical care settings,¹⁹⁻²¹ there is insufficient evidence regarding whether specific communication interventions improve the quality of code status discussions and thereby influence the decisions of patients in the inpatient medical setting.

Shared decision-making has become the standard for choosing treatments based on both scientific evidence and the person's preferences, beliefs, and values when several treatment options are available. The goal of shared decision-making is to provide patients with the best available evidence while considering their perceptions and preferences.²² Through this process, the informed patient is empowered to weigh the different treatment options and actively influence medical decisions. Shared decision-making leads to higher satisfaction rates, better understanding, and increased self-responsibility of patients.²³ We hypothesized that an approach that includes didactic teaching, observation, and feedback and a checklist and decision aid for shared decision-making would improve the quality of code status discussions, provide more realistic expectations about possibilities of resuscitation measures, and influence patients' decisions regarding do-not-resuscitate (DNR) code status, while increasing patient comfort, knowledge, and satisfaction across different quality dimensions.

Methods

TRIAL SETTING

In this pragmatic, multicenter cluster-randomized controlled trial, we randomly assigned residents to conduct code status discussions based on either this shared decision-making-centered approach or usual care. The trial was conducted in the general medical divisions of six Swiss teaching hospitals (University Hospital Basel, Cantonal Hospital Aarau, Cantonal Hospital Baselland, University Hospital Bern, Cantonal Hospital Lucerne, and St. Claraspital Basel) between June 2019 and April 2023. The trial was approved by the local ethics committees (Northwestern and Central Switzerland Ethics Committee and Ethics Committee Bern, EKNZ 2019-00078). At each hospital, the heads of the departments of medicine provided consent to permit residents to be included in the trial. All residents willingly participated and consented to be included in the trial. A member of the trial team obtained written informed consent from patients after the code status discussion, usually when administering the follow-up questionnaires. For patients admitted overnight, medical residents conducted the code status conversations the next day during regular working hours, and the trial team subsequently obtained informed consent from 1954 patients for the patient interview following the code status discussion. The trial was designed by C.B., S.B., and S.H., and the initial draft of the article was written by C.B., S.G., and S.H., with critical revisions from all authors. No agreement required confidentiality of the data. The trial was registered on ClinicalTrials.gov on March 13, 2019, before trial initiation ([NCT03872154](https://clinicaltrials.gov/ct2/show/study/NCT03872154)).

TRIAL POPULATION, DESIGN, AND RANDOM ASSIGNMENT

Resident physicians caring for patients newly admitted to medical wards were randomly assigned to either the intervention group, which included didactic teaching in shared decision-making, a code status communication checklist, a decision aid, observation, feedback, and coaching (intervention group), or a general training in patient-centered communication (usual care group). Details about the intervention in both groups are presented within the Supplementary Appendix in the Content of Usual Care Workshop section.

Random assignment was done with the use of an interactive web-response system based on a list generated by a

computer randomization scheme using block randomization with variable block sizes of 4 to 6 (secuTrial). All residents were asked to conduct a systematic code status discussion with 10 to 15 consecutive adult patients admitted to the general medical ward during a trial period of 3 weeks. Patients were eligible regardless of their primary diagnosis, except for cognitive impairment (e.g., dementia, delirium), severe mental health issues, or severe hearing impairment. Most residents spoke German, English, and/or French. Patients who spoke other languages were excluded if no interpreter was available, as these language barriers rendered meaningful code status discussions impractical. Patients were also excluded if they had previously been included in the trial or if a resuscitation attempt was deemed futile, defined by a Good Outcome Following Attempted Resuscitation (GO-FAR) score of 14 points or more (indicating a chance of survival with minimal neurologic disability <1.7%^{24,25}) or by the Clinical Frailty Scale score of 7 or more points (indicating severe frailty with debilitating chronic conditions).²⁶ The GO-FAR score is a prognostic score that ranges from -15 to 76 points and provides an estimate of survival probability with a good neurologic outcome following in-hospital cardiac arrest, with higher scores indicating a lower likelihood of survival. We excluded patients with a GO-FAR score of 14 points or more because the aim of our trial was to assess the effect of a shared decision-making approach on code status decisions. Shared decision-making is most appropriate in situations of equipoise, where different treatment options are reasonable. However, in patients with a GO-FAR score of 14 points or more, we did not consider there to be equipoise, as the likelihood of a meaningful recovery is exceedingly low. A recent meta-analysis including five external validation cohorts showed this score has good statistical discrimination (concordance statistic of 0.78).²⁷ The Clinical Frailty Scale is a 9-point tool used to assess a patient's level of frailty, ranging from 1 (very fit) to 9 (terminally ill), based on their physical fitness, dependence, and chronic health conditions.²⁶

To reduce the risk of bias, patients and resident physicians were not provided with specific details about the intervention and main end point before random assignment; instead, they were informed that the trial aimed to compare two different communication strategies and were asked for their participation.

TRIAL FLOW AND DESCRIPTION OF INTERVENTION

Residents allocated to the intervention group participated in a 1-hour communication workshop directed by research team members who are all active in the field of academic teaching of medical communication skills. During this

workshop, residents received detailed teaching regarding shared decision-making and information on prognostic factors and outcomes of resuscitation attempts in hospitalized patients. They were trained to use a checklist and a decision aid (an English translation of the checklist used in the trial is shown in Figure S2 within the Protocol available at evidence.nejm.org) depicting a patient undergoing CPR and a mechanically ventilated patient in an intensive care unit, and reporting a graph visualizing the realistic outcomes of CPR. The decision aids were based on previously published data and partially adapted from other decision aids registered in the Ottawa decision aid inventory.^{28,29} We developed the checklist based on research and guidelines for shared decision-making.³⁰ To create the checklist, we grouped aspects of shared decision-making into five categories, from which we generated the acronym "CLEAR" (clinician-patient engagement; learn and inform; explore patient preferences; assess and document; and review advance directives). A more comprehensive explanation is provided in the Supplementary Appendix in the Development of a Communication Checklist section. We initially tested the checklist for clarity of content within the research team and later tested it for clarity of content and minimizing risk of discomfort with 25 patients and 15 physicians. During the workshops, residents were asked to have a code status conversation with a simulated patient using the checklist and the decision aid. Subsequently, the workshop instructor provided critical feedback on how to facilitate the use of the checklist and decision aids.

In the participating hospitals, the treating residents on the ward usually conduct code status discussions upon hospital admission. To ensure fidelity to the intervention, the workshop instructor accompanied the resident for at least three code status discussions in the intervention group. Each time, residents received feedback on their discussions and, if needed, specific training components were rehearsed briefly.

To mitigate bias, residents randomly assigned to the usual care group attended a different communication workshop of the same duration. This workshop provided information about the significance of code status discussions and included general communication skills, such as structuring information and responding to emotions. However, it did not cover shared decision-making, and no checklist or decision aids were provided.

PATIENT INVOLVEMENT IN TRIAL DESIGN

A total of 25 patients hospitalized in the medical wards of University Hospital Basel, as well as 15 clinicians (physicians

and nurses) with experience in internal medicine, end-of-life care, and emergency or intensive care medicine, were involved as our advisory group in the design of the trial and intervention, as well as the review of the trial protocol according to patient and public involvement strategies.³¹ To design the trial, this advisory group helped us to define and prioritize outcomes. The advisory group also gave input on the intervention, particularly regarding the decision aid. Additionally, the decision aid and checklist were further adapted based on input from additional clinical experts.

DATA COLLECTION

Data collection occurred at baseline before the code status discussion, within 24 hours of the code status discussion, and 30 days after hospital discharge. Baseline data included patients' sociodemographic characteristics, comorbidities, and medical conditions leading to hospitalization. By reviewing the electronic medical record at each trial site, we calculated patients' Charlson Comorbidity Index score,³² as an indicator of comorbidity, and National Early Warning Score 2.³³ The National Early Warning Score 2 is a physiological score for the early detection of a patient's clinical deterioration that ranges from 0 to 20, with higher scores indicating a greater risk of clinical deterioration and the need for more intensive monitoring or intervention. After the code status discussion, a blinded research team member interviewed patients to assess secondary end points.

OUTCOME MEASURES

The primary outcome was the frequency of DNR code status as documented in the electronic medical record the same day of the code status discussions. DNR refers to patients deciding that CPR, mechanical ventilation, and intensive care interventions should not be administered in the event of cardiac arrest. We separately asked patients whether mechanical ventilation and intensive care interventions should be administered in the event of clinical deterioration not involving cardiac arrest (e.g., in cases of respiratory failure or sepsis).

Secondary end points related to different categories, including decisional quality and cognition (e.g., patients' accuracy of risk perception and knowledge); attributes of the decision-making process (e.g., Decisional Conflict Scale score); process- and system-level outcomes (e.g., the 9-Item Shared Decision-Making Questionnaire [SDM-Q-9], patient and physician satisfaction with care and process); and emotion-associated outcomes (e.g., quality of life measures, patients' concerns and fears) (Supplementary Appendix, in the Definition of Outcomes Assessed during the Trial section).

The key secondary end point was patients' decisional conflict and comfort regarding the final code status, assessed through the German translation of the Decisional Conflict Scale.³⁴ This validated questionnaire measures patients' uncertainty in choosing between treatment options and modifiable factors associated with this uncertainty, as well as perceived effective decision-making. The DCS ranges from 0 (no decisional conflict) to 100 (highest decisional conflict), with a score of 25 or more indicating relevant decisional conflict.^{35,36} We also assessed patients' involvement in decision-making through a validated German translation of the SDM-Q-9, range 0–100, with higher scores indicating greater involvement in shared decision-making).³⁷ To measure patients' general knowledge about resuscitation and prognosis, we used a questionnaire validated in prior research studies (score range 0–6, with higher scores indicating greater knowledge).^{38,39} We assessed patients' perceived quality of care and communication using a visual analog scale ranging from 0 to 10. We also assessed physicians-reported outcomes such as satisfaction. Thirty days after hospital discharge, we reviewed patients' medical records to assess additional outcomes (Supplementary Appendix, Table S3).

STATISTICAL ANALYSIS AND POWER CALCULATION

Based on a previous study in a similar patient population,⁴⁰ we estimated that 30% of patients in the usual care group would have a DNR code status. We calculated that including at least 174 residents (cluster) and 2610 patients (i.e., 15 patients per resident) would provide 80% power with an alpha of 0.05 and an intercluster correlation of 0.5 to detect a 50% increase in the frequency of DNR (i.e., from 30% to 45%).

The primary efficacy analysis was performed in the intention-to-treat population. The cumulative incidence of trial outcomes was compared at the individual level with the use of a binomial regression model with robust sandwich standard errors to account for grouping within clusters. We defined a generalized linear model with a binomial distribution and a log link function to estimate the risk ratio as a measure of effect. The analyses were adjusted for the baseline variables of patient age, sex, principal admission diagnosis, and trial center as outlined in the trial protocol. We performed additional prespecified sensitivity analyses to assess the consistency of effects by additionally adjusting for comorbidities (Charlson Comorbidity Index). We found an intraclass correlation of 0.054 (95% confidence interval [CI], 0.034 to 0.085). We conducted all statistical analyses using Stata 15.0 (Stata, College Station, TX, USA). We did not specify a plan to adjust for multiple comparisons for the evaluation of secondary outcomes; CIs are not adjusted for

multiplicity and should not be used in place of hypothesis testing. There were no missing data for the primary outcome and main model covariates (missing data for other outcomes and covariates are reported in detail within the Supplementary Appendix in Tables S2, S3, and S4).

Results

TRIAL FLOW AND BASELINE CHARACTERISTICS

Of the 220 eligible residents, 214 agreed to participate and were randomly assigned to one of the two trial arms. There were 8 post-random assignment exclusions, resulting in 106 residents in the intervention group and 100 residents in the usual care group. Residents cared for a total of 3379 eligible patients. After exclusion of 716 patients, the final population consisted of 1370 patients in the intervention group and 1293 patients in the usual care group (Fig. 1).

Patients had a mean age of 68 years, 45% were female, and most patients had multiple comorbidities with a mean Charlson Comorbidity Index score of 4.7 points. Principal admission diagnoses included ischemic heart disease (8.4%), heart failure (8.8%), infectious disease (12.3%), and cancer (15.1%). Randomization arms were well balanced regarding admission diagnoses, comorbidities, and other clinical parameters. Baseline characteristics are shown in Table 1 and Table S1.

PRIMARY OUTCOME: FREQUENCY OF DO-NOT-RESUSCITATE CODE STATUS

There was a significantly higher frequency of DNR code status in case of cardiac arrest in patients randomly assigned to the intervention group compared with the usual care group (685/1370 [50.0%] vs. 481/1293 [37.2%]; adjusted risk ratio, 1.37; 95% CI, 1.25 to 1.50; $P < 0.001$) (Table 2 and Fig. S1). The intervention was also associated with a lower preference for mechanical ventilation in case of clinical deterioration (812/1236 [65.7%] vs. 868/1206 [72.0%]; adjusted risk ratio, 0.91; 95% CI, 0.86 to 0.96) and intensive care unit admission (1070/1352 [79.1%] vs. 1048/1271 [82.5%]; adjusted risk ratio, 0.96; 95% CI, 0.92 to 0.99) compared with patients in the usual care group.

SECONDARY OUTCOMES

Patient-Reported Outcomes

Of the 2663 included patients, 1954 patients consented to further interviews and assessments (Fig. 1). The intervention was associated with less uncertainty with the code

status decision, with lower mean scores on the Decisional Conflict Scale compared with the usual care group (14.4 ± 15.3 vs. 21.8 ± 20.2 ; adjusted difference, -7.1 ; 95% CI, -9.4 to -4.7) (Fig. S1). The intervention was also associated with better knowledge of resuscitation measures, assessed in a structured questionnaire, compared with usual care (4.0 ± 1.5 vs. 3.2 ± 1.5 points; adjusted difference, 0.77 ; 95% CI, 0.59 to 0.94) (Fig. S1), and more involvement in the shared decision-making process, assessed in the SDM-Q-9 questionnaire (76.6 ± 22.0 vs. 58.6 ± 26.9 ; adjusted difference, 17.2 ; 95% CI, 13.7 to 20.8).

The intervention was associated with higher perceived quality of the explanation of resuscitation measures on a visual analog scale (7.7 ± 3.0 vs. 5.3 ± 4.1 ; adjusted difference, 2.3 ; 95% CI, 1.8 to 2.8), whereas anxiety measures were similar between groups (Table 2). On the visual analog scale, the reported perception of being put under pressure from a scale of 0 to 10 (with higher scores indicating more pressure) was 0.7 (standard deviation [SD] 1.9) in the intervention group compared with 0.4 (SD 1.5) in the standard care group (adjusted difference, 0.31 ; 95% CI, 0.13 to 0.48) (Table 2).

Physician-Associated Outcomes

There were no apparent differences in physician-reported outcomes, particularly regarding overall satisfaction with resuscitation discussions as assessed on a visual analog scale (7.7 ± 1.9 vs. 7.6 ± 1.9 ; adjusted difference, 0.05 ; 95% CI, -0.2 to 0.3). Physicians in the intervention group reported having spent more time with patients for code status discussions (Table 2).

Outcomes at 30-Day Follow-Up

Based on a chart review at 30 days, there was still a higher frequency of DNR code status in patients randomly assigned to the intervention group compared with the usual care group (658/1370 [48.0%] vs. 474/1293 [36.7%]; adjusted risk ratio, 1.26 ; 95% CI, 1.14 to 1.38) (Table 2). Further outcomes, including the average length of hospital stay, the frequency of intensive care unit admissions after the resuscitation discussion, the frequency of hospital readmissions after the initial discharge, and the frequency of patients dying within 30 days of hospital discharge, were similar between randomization arms (Table 2).

Discussion

In this cluster-randomized trial involving medical inpatients from six hospitals in Switzerland, the use of a shared

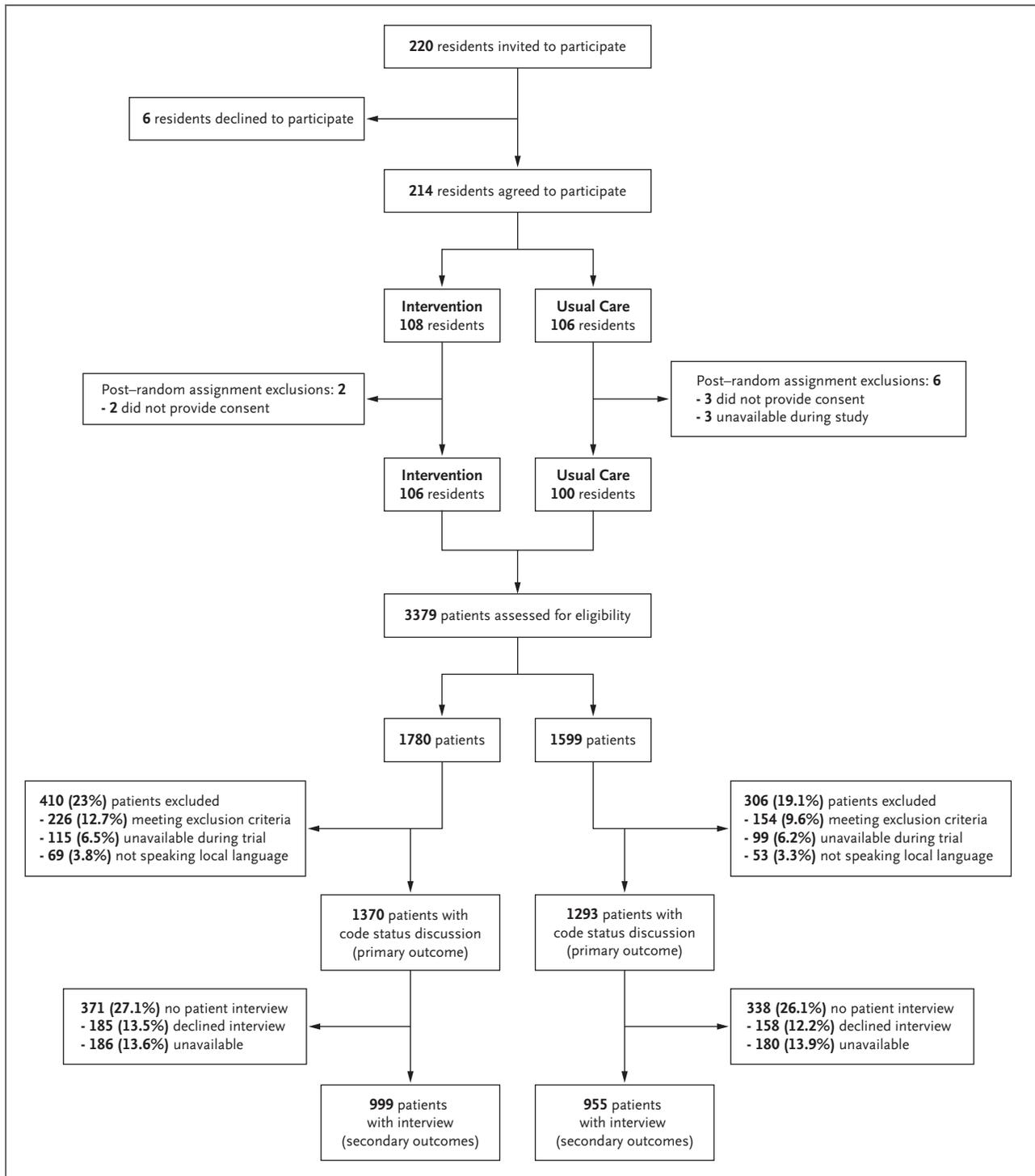


Figure 1. Flowchart of the Cluster-Randomized Trial.

decision-making approach that incorporated a decision-making checklist and a decision aid with information about prognosis, as compared with usual care, had strong effects on patients' decisions regarding code status. Overall,

patients were more likely to choose a DNR code status in the intervention arm compared with the standard care arm. The intervention was also associated with greater certainty among patients about their decision.

Table 1. Baseline Characteristics of Trial Participants.*

Characteristic	Intervention Group	Usual Care Group
Patients (n)	1370	1293
Age (years), mean (SD)	68.1 (15.8)	67.9 (16.0)
Female sex, n (%)	600 (43.8%)	598 (46.2%)
Marital status, n (%)		
Single	178 (13.1%)	179 (14.0%)
Married/in a relationship	807 (59.3%)	714 (55.7%)
Divorced	169 (12.4%)	158 (12.3%)
Widowed	206 (15.1%)	231 (18.0%)
Has children (Yes), n (%)	970 (72.2%)	925 (72.8%)
Country of citizenship, n (%)		
Switzerland	1083 (79.1%)	1028 (79.5%)
Germany	69 (5.0%)	85 (6.6%)
Italy	63 (4.6%)	52 (4.0%)
Other	155 (11.3%)	128 (9.9%)
Religious affiliation, n (%)		
No religious affiliation	387 (28.5%)	355 (27.8%)
Protestant	442 (32.5%)	443 (34.7%)
Catholic	412 (30.3%)	375 (29.4%)
Muslim	55 (4.1%)	39 (3.1%)
Employment status, n (%)		
Working/vocational training	311 (22.7%)	296 (22.9%)
Unemployed	31 (2.3%)	34 (2.6%)
Retired/disability pension	987 (72.1%)	918 (71.1%)
Principal diagnosis on admission		
Ischemic heart disease, n (%)	124 (9.1%)	100 (7.7%)
Heart failure, n (%)	116 (8.5%)	118 (9.1%)
Other cardiac disease, n (%)	131 (9.6%)	107 (8.3%)
Cancer, n (%)	213 (15.5%)	190 (14.7%)
Infectious disease, n (%)	165 (12.0%)	163 (12.6%)
Respiratory disease, n (%)	71 (5.2%)	76 (5.9%)
Gastrointestinal disease, n (%)	150 (10.9%)	128 (9.9%)
Metabolic disease, n (%)	62 (4.5%)	68 (5.3%)
Neurologic disease, n (%)	95 (6.9%)	77 (6.0%)
Other, n (%)†	243 (17.7%)	266 (20.6%)
Comorbidity		
Charlson Comorbidity Index Score, mean (SD)	4.7 (2.8)	4.7 (2.8)
Clinical value		
NEWS 2, mean (SD)	2.0 (2.1)	1.9 (2.0)
GO-FAR Score, mean (SD)	-1.9 (6.1)	-2.0 (6.2)
Clinical Frailty Scale Score, mean (SD)‡	3.6 (1.2)	3.6 (1.2)
Resident physicians (n)	106	100
Age (years), mean (SD)	30.6 (3.0)	31.0 (3.5)
Female sex, n (%)	54 (50.9%)	55 (55.0%)
Primary language, n (%)		
German	91 (86.7%)	74 (74.0%)
Not German	14 (13.3%)	26 (26.0%)
Work experience (years), mean (SD)	3.4 (1.9)	3.7 (2.1)

* GO-FAR denotes Good Outcome Following Attempted Resuscitation (ranges from -15 to 76 points, with higher scores indicating a lower likelihood of survival with a good neurologic outcome following in-hospital cardiac arrest); NEWS, National Early Warning Score (ranges from 0 to 20 with higher scores indicating greater risk for clinical deterioration); and SD, standard deviation.

† The most common diagnoses categorized as “other” include rheumatoid conditions (4.6%), psychiatric conditions (2.2%), non-malignant blood disorders (e.g., anemia) (1.8%), and peripheral arterial occlusive disease (1.4%).

‡ Clinical Frailty Scale ranges from 1 (very fit) to 9 (terminally ill), based on patient’s physical fitness.

Table 2. Primary and Secondary End Points.			
End Point	Intervention Group (n=1370)	Usual Care Group (n=1293)	Adjusted Risk Ratio or Difference (95% CI)*
Primary end point			
Documented DNR code status in case of cardiac arrest, n (%)	685 (50.0%)	481 (37.2%)	1.37 (1.25, 1.50)†
Documented preference for mechanical ventilation in case of clinical deterioration, n (%)	812 (65.7%)	868 (72.0%)	0.91 (0.86, 0.96)
Documented preference for ICU admission in case of clinical deterioration, n (%)	1070 (79.1%)	1048 (82.5%)	0.96 (0.92, 0.99)
Key secondary end point			
Decisional conflict scale (0–100), mean (SD)	14.4 (15.3)	21.8 (20.2)	−7.06 (−9.43, −4.68)
Decisional conflict (≥25 points), n (%)	187 (21.3%)	304 (36.7%)	0.65 (0.54, 0.78)
Additional secondary end points			
Patient's general knowledge about resuscitation (0–6), mean (SD)	4.0 (1.5)	3.2 (1.5)	0.77 (0.59, 0.94)
Patient's involvement in decision-making (SDM-Q-9) (0–100), mean (SD)	76.6 (22.0)	58.6 (26.9)	17.21 (13.66, 20.77)
Patient's concerns and fears			
Disturbance caused by the discussion (VAS 0–10), mean (SD)	1.8 (2.8)	1.6 (2.6)	0.26 (−0.03, 0.55)
Fear of experiencing an actual cardiac arrest (VAS 0–10), mean (SD)	0.6 (1.8)	0.7 (1.8)	−0.08 (−0.28, 0.13)
Fear of experiencing life-threatening disease (VAS 0–10), mean (SD)	0.7 (2.0)	0.7 (1.9)	0.06 (−0.14, 0.27)
Perception of being put under pressure during discussion (VAS 0–10), mean (SD)	0.7 (1.9)	0.4 (1.5)	0.31 (0.13, 0.48)
Patient's satisfaction and perceived quality of code status discussion			
Perceived transparency of the discussion (VAS 0–10), mean (SD)	8.9 (1.8)	8.5 (2.1)	0.38 (0.16, 0.6)
Perceived quality of the explanation of options regarding resuscitation (VAS 0–10), mean (SD)	7.7 (3.0)	5.3 (4.1)	2.3 (1.78, 2.81)
Patient's quality of life (EQ-5D-3L), mean (SD)	0.8 (0.3)	0.8 (0.3)	0.01 (−0.02, 0.04)
30-day outcomes			
Documented DNR code status in case of cardiac arrest at day 30, n (%)	658 (48.0%)	474 (36.7%)	1.26 (1.14, 1.38)
Length of hospital stay (days), mean (SD)	8.5 (9.3)	8.1 (8.2)	0.64 (−0.17, 1.45)
ICU admission after code status discussion, n (%)	46 (3.4%)	45 (3.5%)	0.94 (0.75, 1.18)
Readmission to hospital after discharge, n (%)	215 (15.7%)	243 (18.8%)	0.88 (0.74, 1.05)
All-cause mortality within 30 Days, n (%)	41 (3.0%)	56 (4.3%)	0.86 (0.71, 1.04)
In-hospital resuscitation attempts, n (%)	7 (0.5%)	3 (0.2%)	0.4 (0.1, 1.57)
Code status violation (resuscitation attempt despite DNR code status), n (%)	1 (0.1%)	1 (0.1%)	0.95 (0.06, 15.16)
Physician's perception of code status discussion			
Physician's overall satisfaction with code status discussion (VAS 0–10), mean (SD)	7.7 (1.9)	7.6 (1.9)	0.05 (−0.22, 0.31)
Physician's satisfaction with time management for code status discussions (VAS 0–10), mean (SD)	7.5 (2.1)	7.9 (1.9)	−0.44 (−0.79, −0.1)
Would you be surprised if the patient died within the next 12 months?, n (%)	770 (61.1%)	695 (57.8%)	1.00 (0.91, 1.11)

* Adjusted for cluster, principal diagnosis, age, sex, and study center. Confidence intervals have not been adjusted for multiple comparisons and should not be used in place of hypothesis testing. CI denotes confidence interval; DNR, do not resuscitate; EQ-5D-3L, 3-Level European Quality of Life 5 Dimensions index (values range from −0.205 to 1, with higher scores indicating better quality of life); ICU, intensive care unit; SD, standard deviation; SDM-Q-9, 9-item Shared Decision-Making Questionnaire; and VAS, visual analog scale (range 0–10, with lower levels of patient's concerns and fears).

† P<0.01.

Advanced care planning aims to align medical care with patients' goals and values to ultimately improve clinical outcomes.⁵ However, it is difficult for most patients to make an informed medical decision far in advance of a clinical deterioration that necessitates decision-making.^{18,41-43} Several trials of advanced care planning interventions have not demonstrated clinical benefit for patients in terms of increased goal-concordant care, reduced hospitalizations, or improved satisfaction by simply having an advance care planning document in place.⁴⁴⁻⁴⁶ Current advanced care planning models often do not focus on the actual process by which patients comprehend their prognosis, express their priorities, and then iteratively express their preferences for medical care. Therefore, informing patients about the different treatment options in the event of a cardiac arrest, especially among older adults and patients with multiple comorbidities, is considered an essential component of high-quality medical care.⁴⁷⁻⁴⁹ In routine clinical practice, code status discussions are often low quality, lacking clear and individualized information on CPR outcomes and failing to integrate patients' values and goals.⁵⁰ While our trial found that this shared decision-making intervention influenced the decisions of patients regarding their code status, the trial was not powered to show differences in clinical outcomes and CPR attempts.

A recent survey suggested that overestimating favorable neurologic outcomes after cardiac arrest was a key predictor for patients preferring to be resuscitated in case of cardiac or pulmonary arrest.¹⁸ The data suggested that better informing patients about expected outcomes of CPR within the framework of a shared decision-making approach may have an impact on this decision. The present trial demonstrated that training resident physicians and providing patients with structured information, including a checklist and decision aid about the prognosis and potential side effects of CPR, including neurologic deficits, led to significantly higher preferences for DNR code status. Importantly, the increase in DNR preference was paralleled with associated improvements in quality measures regarding the decision-making process and certainty with the decision.

Discussing resuscitation measures with patients upon hospital admission is challenging and may lead to anxiety and uncertainty among patients. For this reason, physicians may not address this topic properly.⁵¹ Our results showed the opposite — the intervention was not associated with patient reports of higher levels of fear due to the discussion and was associated with lower decisional conflict. Checklist-guided shared decision-making including the provision of easy-to-understand information on CPR outcomes thus appears to have facilitated a more informed and

confident decision-making process, aligning with the overarching goal of promoting patient autonomy and ensuring that individuals are active participants in decisions about their care. This is in line with other clinical situations where decision aids were shown to improve patients' and physicians' knowledge about the expected disease outcomes⁵² and different practice guidelines calling for a collaborative approach when making clinical decisions.^{17,53} Importantly, the intervention did lead to a slightly higher frequency of patients reporting feeling pressured.

Strengths of our trial include the pragmatic, cluster-randomized, multicenter design and the inclusion of 30-day follow-up data, which enhance both its generalizability and internal validity. Also, we included patients and physicians in the planning of the intervention based on the principles of public and patient involvement.

Our trial also has several limitations. First, it was conducted within the specific setting of six Swiss teaching hospitals and included only hospitalized medical patients, which limits the generalizability of our findings to other health care settings (e.g., nonteaching hospitals). This distinction is important because influencing the behavior of attending physicians with educational or training interventions alone may be more challenging. Most patients were White, and we did not collect specific data on race or ethnicity. Also, we did not collect detailed data on the content of conversations in the usual care and intervention arms, which limits our ability to determine the specific mechanisms by which the intervention influenced outcomes. Importantly, our trial was not powered to detect differences in clinical outcomes.

Because less than 1% of patients experienced an in-hospital cardiac arrest in our sample, a much larger trial would be needed to understand the effects of our intervention on clinical outcomes. Due to practical considerations and to ensure feasibility, we did not include other outcome measures, such as a measure of decision regret, and used only a single-item visual analog scale to assess emotional outcomes related to anxiety rather than employing a validated tool with established psychometric properties. A further limitation is a possible Hawthorne effect, as fidelity monitoring involved observing 20 to 33% of residents' code status discussions, which may have influenced behavior and contributed to the observed outcomes.

Conclusion

An approach to code status discussion among hospitalized medical patients, as compared with usual care, increased

the preference for DNR code status, and was associated with reduced uncertainty with the decision and improvements in different measures of satisfaction and knowledge. Future trials are needed to determine if similar results are observed in nonteaching hospitals, other countries, and other inpatient populations beyond general medicine.

Disclosures

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References

- Perkins GD, Cooke MW. Variability in cardiac arrest survival: the NHS Ambulance Service Quality Indicators. *Emerg Med J* 2012;29:3-5. DOI: [10.1136/emered-2011-200758](https://doi.org/10.1136/emered-2011-200758).
- Meaney PA, Nadkarni VM, Kern KB, Indik JH, Halperin HR, Berg RA. Rhythms and outcomes of adult in-hospital cardiac arrest. *Crit Care Med* 2010;38:101-108. DOI: [10.1097/CCM.0b013e3181b43282](https://doi.org/10.1097/CCM.0b013e3181b43282).
- Virani SS, Alonso A, Aparicio HJ, et al. Heart disease and stroke statistics-2021 update: a report from the American Heart Association. *Circulation* 2021;143:e254-e743. DOI: [10.1161/CIR.0000000000000950](https://doi.org/10.1161/CIR.0000000000000950).
- Girotra S, Chan PS. Trends in survival after in-hospital cardiac arrest. *N Engl J Med* 2013;368:680-681. DOI: [10.1056/NEJMc1215155](https://doi.org/10.1056/NEJMc1215155).
- Jackson VA, Emanuel L. Navigating and communicating about serious illness and end of life. *N Engl J Med* 2024;390:63-69. DOI: [10.1056/NEJMcp2304436](https://doi.org/10.1056/NEJMcp2304436).
- Overdyk FJ, Dowling O, Marino J, et al. Association of opioids and sedatives with increased risk of in-hospital cardiopulmonary arrest from an administrative database. *PLoS One* 2016;11:e0150214. DOI: [10.1371/journal.pone.0150214](https://doi.org/10.1371/journal.pone.0150214).
- Back AL, Anderson WG, Bunch L, et al. Communication about cancer near the end of life. *Cancer* 2008;113:1897-1910. DOI: [10.1002/cncr.23653](https://doi.org/10.1002/cncr.23653).
- Lo B, McLeod GA, Saika G. Patient attitudes to discussing life-sustaining treatment. *Arch Intern Med* 1986;146:1613-1615. DOI: [10.1001/archinte.1986.00360200193031](https://doi.org/10.1001/archinte.1986.00360200193031).
- Nicolasora N, Pannala R, Mountantonakis S, et al. If asked, hospitalized patients will choose whether to receive life-sustaining therapies. *J Hosp Med* 2006;1:161-167. DOI: [10.1002/jhm.78](https://doi.org/10.1002/jhm.78).
- Elkin EB, Kim SH, Casper ES, Kissane DW, Schrag D. Desire for information and involvement in treatment decisions: elderly cancer patients' preferences and their physicians' perceptions. *J Clin Oncol* 2007;25:5275-5280. DOI: [10.1200/JCO.2007.11.1922](https://doi.org/10.1200/JCO.2007.11.1922).
- Tulsky JA, Chesney MA, Lo B. How do medical residents discuss resuscitation with patients? *J Gen Intern Med* 1995;10:436-442. DOI: [10.1007/BF02599915](https://doi.org/10.1007/BF02599915).
- Einstein DJ, Einstein KL, Mathew P. Dying for advice: code status discussions between resident physicians and patients with advanced cancer — a national survey. *J Palliat Med* 2015;18:535-541. DOI: [10.1089/jpm.2014.0373](https://doi.org/10.1089/jpm.2014.0373).
- Anderson WG, Chase R, Pantilat SZ, Tulsky JA, Auerbach AD. Code status discussions between attending hospitalist physicians and medical patients at hospital admission. *J Gen Intern Med* 2011;26:359-366. DOI: [10.1007/s11606-010-1568-6](https://doi.org/10.1007/s11606-010-1568-6).
- Marco CA, Larkin GL. Cardiopulmonary resuscitation: knowledge and opinions among the U.S. general public. State of the science-fiction. *Resuscitation* 2008;79:490-498. DOI: [10.1016/j.resuscitation.2008.07.013](https://doi.org/10.1016/j.resuscitation.2008.07.013).
- Diem SJ, Lantos JD, Tulsky JA. Cardiopulmonary resuscitation on television. Miracles and misinformation. *N Engl J Med* 1996;334:1578-1582. DOI: [10.1056/NEJM199606133342406](https://doi.org/10.1056/NEJM199606133342406).
- Rocker G, Cook D, Sjøkvist P, et al. Clinician predictions of intensive care unit mortality. *Crit Care Med* 2004;32:1149-1154. DOI: [10.1097/01.ccm.0000126402.51524.52](https://doi.org/10.1097/01.ccm.0000126402.51524.52).
- Curtis JR, Vincent JL. Ethics and end-of-life care for adults in the intensive care unit. *Lancet* 2010;376:1347-1353. DOI: [10.1016/S0140-6736\(10\)60143-2](https://doi.org/10.1016/S0140-6736(10)60143-2).
- Gross S, Amacher SA, Rochowski A, et al. "Do-not-resuscitate" preferences of the general Swiss population: results from a

- national survey. *Resusc Plus* 2023;14:100383. DOI: [10.1016/j.resplu.2023.100383](https://doi.org/10.1016/j.resplu.2023.100383).
19. Becker C, Lecheler L, Hochstrasser S, et al. Association of communication interventions to discuss code status with patient decisions for do-not-resuscitate orders: a systematic review and meta-analysis. *JAMA Netw Open* 2019;2:e195033. DOI: [10.1001/jamanetworkopen.2019.5033](https://doi.org/10.1001/jamanetworkopen.2019.5033).
 20. Andereck WS, McGaughey JW, Schneiderman LJ, Jonsen AR. Seeking to reduce nonbeneficial treatment in the ICU: an exploratory trial of proactive ethics intervention*. *Crit Care Med* 2014;42:824-830. DOI: [10.1097/CCM.0000000000000034](https://doi.org/10.1097/CCM.0000000000000034).
 21. Schneiderman LJ, Gilmer T, Teetzel HD. Impact of ethics consultations in the intensive care setting: a randomized, controlled trial. *Crit Care Med* 2000;28:3920-3924. DOI: [10.1097/00003246-200012000-00033](https://doi.org/10.1097/00003246-200012000-00033).
 22. Oshima Lee E, Emanuel EJ. Shared decision making to improve care and reduce costs. *N Engl J Med* 2013;368:6-8. DOI: [10.1056/NEJMp1209500](https://doi.org/10.1056/NEJMp1209500).
 23. Hess EP, Hollander JE, Schaffer JT, et al. Shared decision making in patients with low risk chest pain: prospective randomized pragmatic trial. *BMJ* 2016;355:i6165. DOI: [10.1136/bmj.i6165](https://doi.org/10.1136/bmj.i6165).
 24. Schneiderman LJ, Jecker NS, Jonsen AR. Medical futility: its meaning and ethical implications. *Ann Intern Med* 1990;112:949-954. DOI: [10.7326/0003-4819-112-12-949](https://doi.org/10.7326/0003-4819-112-12-949).
 25. Ebell MH, Jang W, Shen Y, Geocadin RG. Get With the Guidelines-Resuscitation I. Development and validation of the Good Outcome Following Attempted Resuscitation (GO-FAR) score to predict neurologically intact survival after in-hospital cardiopulmonary resuscitation. *JAMA Intern Med* 2013;173:1872-1878. DOI: [10.1001/jamainternmed.2013.10037](https://doi.org/10.1001/jamainternmed.2013.10037).
 26. Rockwood K, Song X, MacKnight C, et al. A global clinical measure of fitness and frailty in elderly people. *CMAJ* 2005;173:489-495. DOI: [10.1503/cmaj.050051](https://doi.org/10.1503/cmaj.050051).
 27. Amacher SA, Blatter R, Briel M, et al. Predicting neurological outcome in adult patients with cardiac arrest: systematic review and meta-analysis of prediction model performance. *Crit Care* 2022;26:382. DOI: [10.1186/s13054-022-04263-y](https://doi.org/10.1186/s13054-022-04263-y).
 28. Frank C, Pichora D, Suurd J, Heyland D. Development and use of a decision aid for communication with hospitalized patients about cardiopulmonary resuscitation preference. *Patient Educ Couns* 2010;79:130-133. DOI: [10.1016/j.pec.2009.08.002](https://doi.org/10.1016/j.pec.2009.08.002).
 29. Heyland DK, Frank C. Cardio-pulmonary resuscitation (CPR): a decision aid for patients and their families. Canadian Researchers at the End of Life Network (CARENET). 2015 (<https://www.thecarenet.ca/docs/ACPCPRTool.pdf>).
 30. Elwyn G, Frosch D, Thomson R, et al. Shared decision making: a model for clinical practice. *J Gen Intern Med* 2012;27:1361-1367. DOI: [10.1007/s11606-012-2077-6](https://doi.org/10.1007/s11606-012-2077-6).
 31. National Institute for Health and Care Research. Briefing notes for researchers — public involvement in NHS, health and social care research. April 5, 2021 (<https://www.nihr.ac.uk/briefing-notes-researchers-public-involvement-nhs-health-and-social-care-research>).
 32. Charlson ME, Pompei P, Ales KL, MacKenzie CR. A new method of classifying prognostic comorbidity in longitudinal studies: development and validation. *J Chronic Dis* 1987;40:373-383. DOI: [10.1016/0021-9681\(87\)90171-8](https://doi.org/10.1016/0021-9681(87)90171-8).
 33. Smith GB, Prytherch DR, Meredith P, Schmidt PE, Featherstone PI. The ability of the National Early Warning Score (NEWS) to discriminate patients at risk of early cardiac arrest, unanticipated intensive care unit admission, and death. *Resuscitation* 2013;84:465-470. DOI: [10.1016/j.resuscitation.2012.12.016](https://doi.org/10.1016/j.resuscitation.2012.12.016).
 34. O'Connor AM. Validation of a decisional conflict scale. *Med Decis Making* 1995;15:25-30. DOI: [10.1177/0272989X9501500105](https://doi.org/10.1177/0272989X9501500105).
 35. Lorenzo AJ, Braga LH, Zlateska B, et al. Analysis of decisional conflict among parents who consent to hypospadias repair: single institution prospective study of 100 couples. *J Urol* 2012;188:571-575. DOI: [10.1016/j.juro.2012.04.022](https://doi.org/10.1016/j.juro.2012.04.022).
 36. Hong P, Gorodzinsky AY, Taylor BA, Chorney JM. Parental decision making in pediatric otoplasty: the role of shared decision making in parental decisional conflict and decisional regret. *Laryngoscope* 2016;126:S5-S13. DOI: [10.1002/lary.26071](https://doi.org/10.1002/lary.26071).
 37. Kriston L, Scholl I, Holzel L, Simon D, Loh A, Harter M. The 9-item Shared Decision Making Questionnaire (SDM-Q-9). Development and psychometric properties in a primary care sample. *Patient Educ Couns* 2010;80:94-99. DOI: [10.1016/j.pec.2009.09.034](https://doi.org/10.1016/j.pec.2009.09.034).
 38. Volandes AE, Brandeis GH, Davis AD, et al. A randomized controlled trial of a goals-of-care video for elderly patients admitted to skilled nursing facilities. *J Palliat Med* 2012;15:805-811. DOI: [10.1089/jpm.2011.0505](https://doi.org/10.1089/jpm.2011.0505).
 39. El-Jawahri A, Podgurski LM, Eichler AF, et al. Use of video to facilitate end-of-life discussions with patients with cancer: a randomized controlled trial. *J Clin Oncol* 2010;28:305-310. DOI: [10.1200/JCO.2009.24.7502](https://doi.org/10.1200/JCO.2009.24.7502).
 40. Becker C, Manzelli A, Marti A, et al. Association of medical futility with do-not-resuscitate (DNR) code status in hospitalised patients. *J Med Ethics* 2021 January 29 (Epub ahead of print). DOI: [10.1136/medethics-2020-106977](https://doi.org/10.1136/medethics-2020-106977).
 41. Hickman SE, Torke AM, Sachs GA, et al. Factors associated with concordance between POLST orders and current treatment preferences. *J Am Geriatr Soc* 2021;69:1865-1876. DOI: [10.1111/jgs.17095](https://doi.org/10.1111/jgs.17095).
 42. McMahan RD, Tellez I, Sudore RL. Deconstructing the complexities of advance care planning outcomes: what do we know and where do we go? A scoping review. *J Am Geriatr Soc* 2021;69:234-244. DOI: [10.1111/jgs.16801](https://doi.org/10.1111/jgs.16801).
 43. Sudore RL, Walling AM, Gibbs L, Rahimi M, Wenger NS, Team UCHCPS. Implementation challenges for a multisite advance care planning pragmatic trial: lessons learned. *J Pain Symptom Manage* 2023;66:e265-e273. DOI: [10.1016/j.jpainsymman.2023.04.022](https://doi.org/10.1016/j.jpainsymman.2023.04.022).

44. Brinkman-Stoppelenburg A, Rietjens JA, van der Heide A. The effects of advance care planning on end-of-life care: a systematic review. *Palliat Med* 2014;28:1000-1025. DOI: [10.1177/0269216314526272](https://doi.org/10.1177/0269216314526272).
45. Korfage IJ, Carreras G, Arnfeldt Christensen CM, et al. Advance care planning in patients with advanced cancer: a 6-country, cluster-randomised clinical trial. *PLoS Med* 2020;17:e1003422. DOI: [10.1371/journal.pmed.1003422](https://doi.org/10.1371/journal.pmed.1003422).
46. Hoffmann F, Schnakenberg R, Silies K, et al. Effects of advance care planning in care dependent **community**-dwelling older persons (STADPLAN): a cluster-randomised controlled trial. *Palliat Med* 2023;37:1193-1201. DOI: [10.1177/02692163231180322](https://doi.org/10.1177/02692163231180322).
47. Davis RM, Genel M, Howe JP, et al. Good care of the dying patient. *JAMA* 1996;275:474-478. DOI: [10.1001/jama.1996.03530300058041](https://doi.org/10.1001/jama.1996.03530300058041).
48. Lo B, Snyder L. Care at the end of life: guiding practice where there are no easy answers. *Ann Intern Med* 1999;130:772-774. DOI: [10.7326/0003-4819-130-9-199905040-00018](https://doi.org/10.7326/0003-4819-130-9-199905040-00018).
49. Lynn J. Measuring quality of care at the end of life: a statement of principles. *J Am Geriatr Soc* 1997;45:526-527. DOI: [10.1111/j.1532-5415.1997.tb05184.x](https://doi.org/10.1111/j.1532-5415.1997.tb05184.x).
50. Deep KS, Griffith CH, Wilson JF. Communication and decision making about life-sustaining treatment: examining the experiences of resident physicians and seriously-ill hospitalized patients. *J Gen Intern Med* 2008;23:1877-1882. DOI: [10.1007/s11606-008-0779-6](https://doi.org/10.1007/s11606-008-0779-6).
51. Becker C, Kunzli N, Perrig S, et al. Code status discussions in medical inpatients: results of a survey of patients and physicians. *Swiss Med Wkly* 2020;150:w20194. DOI: [10.4414/smw.2020.20194](https://doi.org/10.4414/smw.2020.20194).
52. Hoffrage U, Lindsey S, Hertwig R, Gigerenzer G. Medicine. Communicating statistical information. *Science* 2000;290:2261-2262. DOI: [10.1126/science.290.5500.2261](https://doi.org/10.1126/science.290.5500.2261).
53. Kon AA, Davidson JE, Morrison W, et al. Shared decision making in ICUs: an American college of critical care medicine and American thoracic society policy statement. *Crit Care Med* 2016;44:188-201. DOI: [10.1097/CCM.0000000000001396](https://doi.org/10.1097/CCM.0000000000001396).