# Supplementary Online Content

Epstein RM, Duberstein PR, Fenton JJ, et al. Effect of a patient-centered communication intervention on oncologist-patient communication, quality of life, and health care utilization in advanced cancer: the VOICE randomized clinical trial. *JAMA Oncol*. Published online September 9, 2016. doi:10.1001/jamaoncol.2016.4373

**eTable 1.** Patient and physician characteristics (no statistically significant differences between intervention and control for Pre-Randomization or Cluster RCT)
**eTable 2.** Physician and patient-caregiver interventions
**eTable 3.** Health care utilization in the final 30 days of life
**eTable 4.** Raw scores for each of the component communication measures
**eFigure 1**. VOICE STUDY Cluster RCT Physician/Patient CONSORT Flow Diagram
**eFigure 2.** Quality of Life, Intervention vs Control: Terminal Decline Model
**eFigure 3.** Health care utilization in the final 30 days of life
**eFigure 4.** Raw scores for each of the component communication measures
**eReferences**

This supplementary material has been provided by the authors to give readers additional information about their work.

© 2016 American Medical Association. All rights reserved.

**Downloaded From: by a Purdue University User on 02/19/2018**

# A Cluster Randomized Trial of a Patient-Centered Communication Intervention in Advanced Cancer: The Values and Options in Cancer Care (VOICE) Study

**R.M. Epstein et al.**

**August 20, 2016**

## ONLINE APPENDIX / SUPPLEMENTAL MATERIALS

**eTables 1 – 4**

**eFigures 1 – 4**

**eReferences**

© 2016 American Medical Association. All rights reserved.



Downloaded From: by a Purdue University User on 02/19/2018

**eTable 1: Patient and physician characteristics (no statistically significant differences between intervention and control for Pre-Randomization or Cluster RCT)**

| | Pre-Randomization (n=118) | | Cluster RCT (N=265) | |
|---|---|---|---|---|
| | Intervention | Control | Intervention | Control |
| | N/Mean (SD/%) | N/Mean (SD/%) | N/Mean (SD/%) | N/Mean (SD/%) |
| **Total** | 58 | 60 | 130 | 135 |
| **Patient age** | 63.5 (SD=12.8) | 59.9 (SD=11.6) | 64.2 (SD=11.7) | 64.5 (SD=11) |
| **Race** | | | | |
| **Non-white** | 5 (9%) | 6 (10%) | 14 (11 %) | 16 (12 %) |
| **White** | 53 (91%) | 54 (90%) | 116 (89 %) | 119 (88 %) |
| **Site** | | | | |
| **Sacramento, CA** | 21 (36%) | 21 (35%) | 46 (35 %) | 48 (36 %) |
| **Western NY** | 37 (64%) | 39 (65%) | 84 (65 %) | 87 (64 %) |
| **Patient education** | | | | |
| **HS or less** | 20 (34%) | 17 (28%) | 41 (32 %) | 32 (24 %) |
| **Some college or more** | 38 (66%) | 43 (72%) | 89 (68 %) | 103 (76 %) |
| **Aggressive cancer**** | | | | |
| **Aggressive** | 28 (48) | 28 (47%) | 59 (45 %) | 74 (55 %) |
| **Less aggressive** | 30 (52%) | 32 (53%) | 71 (55 %) | 61 (45 %) |
| **Gender** | | | | |
| **Male** | 25 (43%) | 28 (47%) | 54 (42 %) | 65 (48 %) |
| **Female** | 33 (57%) | 32 (53%) | 76 (58 %) | 70 (52 %) |
| **Income** | | | | |
| **Missing** | 3 (5%) | 6 (10%) | 17 (13 %) | 19 (14 %) |
| **$20,000 or less** | 12 (21%) | 9 (15%) | 21 (16 %) | 29 (21 %) |
| **$20,001 to $50,000** | 17 (29%) | 19 (32%) | 40 (31 %) | 33 (24 %) |
| **$50,001 to $100,000** | 18 (31%) | 19 (32%) | 37 (28 %) | 37 (27 %) |
| **Over $100,000** | 8 (14%) | 7 (12%) | 15 (12 %) | 17 (13 %) |
| **Marital status** | | | | |
| **Missing** | 0 (0%) | 2 (3%) | 0 (0 %) | 0 (0 %) |
| **Committed/Married** | 33 (57%) | 41 (68%) | 86 (66 %) | 90 (67 %) |
| **Divorced/Separated** | 10 (17%) | 9 (15%) | 20 (15 %) | 30 (22 %) |
| **Never married** | 5 (9%) | 4 (7%) | 13 (10 %) | 4 (3 %) |
| **Widowed** | 10 (17%) | 4 (7%) | 11 (8 %) | 11 (8 %) |
| **Patient insurance** | | | | |
| **Private** | 30 (52%) | 28 (47%) | 50 (38 %) | 43 (32 %) |
| **Medicare** | 26 (45%) | 25 (42%) | 67 (52 %) | 80 (59 %) |
| **Medicaid/Medi-Cal** | 2 (3%) | 5 (8%) | 12 (9 %) | 10 (7 %) |
| **Other** | 0 (0%) | 2 (3%) | 1 (1 %) | 2 (1 %) |
| **Patient religion** | | | | |
| **Christian** | 43 (74%) | 40 (67%) | 99 (76 %) | 92 (68 %) |

© 2016 American Medical Association. All rights reserved.

Downloaded From: by a Purdue University User on 02/19/2018

| | | | | |
|---|---|---|---|---|
| **Other** | 7 (12%) | 5 (8%) | 14 (11 %) | 9 (7 %) |
| **Non-Religious** | 8 (14%) | 15 (25%) | 17 (13 %) | 34 (25 %) |
| **Have enrolled caregiver?** | | | | |
| **No** | 17 (29%) | 19 (32%) | 29 (22 %) | 42 (31 %) |
| **Yes** | 41 (71%) | 41 (68%) | 101 (78 %) | 93 (69 %) |
| **Physician age** | | | 43.9 (SD=10.3) | 45.3 (SD=9.8) |
| **Physician gender** | | | | |
| **Male** | | | 12 (63 %) | 15 (79 %) |
| **Female** | | | 7 (37 %) | 4 (21 %) |
| **>50% of patients with breast cancer** | | | | |
| **No** | | | 16 (84 %) | 15 (79 %) |
| **Yes** | | | 3 (16 %) | 4 (21 %) |
| **Physician Race** | | | | |
| **Asian** | | | 8 (42 %) | 8 (42 %) |
| **White** | | | 7 (37 %) | 10 (53 %) |
| **Other** | | | 4 (21 %) | 1 (5 %) |

***** Only 7 (4 white, 3 non-white) reported as Latino in the RCT sample, and only 1 (white) reported as Latino in the Pre-RCT sample.

****"** Aggressive" cancers were determined prospectively in consultation with two oncologists, and include lung, GI cancers (except colon), and GU cancers (except prostate). In contrast, less aggressive cancers included breast, prostate and colon.

© 2016 American Medical Association. All rights reserved.

Downloaded From: by a Purdue University User on 02/19/2018

**eTable 2. Physician and patient-caregiver interventions***

| *VOICE Physician Standardized Patient Intervention* | | *VOICE Patient-Caregiver Coaching Intervention* | |
|---|---|---|---|
| Before session #1, shortly after randomization | Standardized patient-instructor (SPI) couple contacts the physician's office to arrange logistics for two in-person sessions.<br><br>Physician reviews a mock medical chart for "patient" with stage IV cancer. | In-person coaching (60 minutes, occurring the same day or within a few days prior to an oncologist visit) | Coach (a trained registered nurse or social worker) gives each patient and caregiver a Question Prompt List (QPL) – the ***My Cancer Care*** booklet developed and piloted for this intervention.[24]<br><br>The booklet suggests questions previously piloted with patients about diagnosis, prognosis, treatment options, symptom management, transitions in care, self-care, and family needs.[76-79] It also lists items that "you would want your doctor to know about you" such as "I hate being dependent on others, " "I can deal with the truth about my condition," "I would rather not discuss how much longer I have left," and "When the time comes, I'd prefer to die at home."<br><br>Coach guides patient and caregiver through the booklet and asks to them to identify up to three key questions they'd like to ask the oncologist in the upcoming office visit.<br><br>Coach offers support to help the patient formulate and ask questions, request clarification, express desire to participate in discussions about their care and prepare for the future. |
| Session #1 (60 minutes) | 15- minute Educational DVD demonstrating 4 key evidence-based communication behaviors in advanced cancer<br><br>15-20 minute mock office visit with standardized patients portraying a "patient" with stage 4 colon cancer and his "wife"<br><br>Focused learner-centered feedback to oncologist on the 4 key skills.**<br><br>Oncologist and SPIs come to agreement on 1-2 of the four skills to work on during the upcoming month.<br><br>Oncologist receives a copy of the DVD to review, a pocket-sized card with key communication skills listed and copies of the patient *My Cancer Care* booklet.<br><br>Wrap up and planning. | | |
| Between Sessions 1 and 2 | SPIs prepare and send written feedback to the oncologist about the mock office visit.<br><br>Research assistant audio-records office visits of two real patients from the oncologist's practice.<br><br>SPIs listen to and provide written feedback on actual | At the oncologist visit | Patient (and caregiver) bring the ***My Cancer Care*** booklet with them to the office visit and use as a guide for discussion with the oncologist |

© 2016 American Medical Association. All rights reserved.

Downloaded From: by a Purdue University User on 02/19/2018

| | | | |
|---|---|---|---|
| | patient visits. | | |
| Session #2 (45-60 minutes), approximately 1 month later, after 1-2 study patients have completed patient coaching | Review of prior session and feedback.<br><br>15-20 minute mock office visit with the SPIs. The "patient's" cancer has progressed further despite treatment.<br><br>Feedback on the 1-2 key skills identified at the end of Session #1, with opportunity for discussion of the other skills if the oncologist wishes to do so. | Follow-up phone calls (3-45 minutes each, timed to anticipate oncologist visits) | Over the next three months, the coach makes three follow-up telephone calls to the patient and caregiver to check in, provide further reinforcement, strategize with about how to address the patient's concerns if necessary and to identify new questions, at the patient's discretion.<br><br>Calls are timed to coincide with upcoming oncologist visits.<br><br>Coach sends a summary and thank you letter to the patient. |

*Copies of the SPI and coach training manuals, fidelity instruments, the CD-ROM and materials distributed to patients, caregivers and physicians are available from the authors.

** Feedback was structured to match the four goals of the intervention, and to invite reflection and skill-building and to meet each individual learner's needs. For each skill, the SPI first named the skill, asked the physician his/her intention (e.g. to transmit information, build rapport, etc.) then asked for brief self-critique followed by brief critique of the SPIs focusing on salient elements. For example, if an oncologist inquired whether the patient wished to know her prognosis, then kept talking and did not leave a silence, the SPIs might comment on the lack of space for a response as a barrier to communication. The physician would then be given the opportunity to "replay the tape" and practice doing the interview differently. The same principles were applied to SPI feedback from the live patient interviews that were audio-recorded.

© 2016 American Medical Association. All rights reserved.

Downloaded From: by a Purdue University User on 02/19/2018

**eTable 3: Health care utilization in the final 30 days of life***

| | Intervention | Criteria | Scoring | Total score |
|---|---|---|---|---|
| Aggressive treatment in the last 30 days of life | Chemotherapy | ***Initiation or continuation of*** IV or oral chemotherapy, excluding hormonal therapy | • within 14 days of death (2 points)<br>• 15-30 days before death (1 point)<br>• not at all (zero points) | Sum of the points for all three indicators (0–6 points) |
| | Potentially burdensome interventions | ***Initiation of*** CPR, mechanical ventilation, tracheostomy, G-tube or J-tube placement, dialysis | • within 14 days of death (2 points)<br>• 15-30 days before death (1 point)<br>• not at all (zero points) | |
| | Emergency department or hospital admission | Admission to Emergency Department or any unit in hospital except a palliative/hospice unit | • more than two (2 points)<br>• two (1 point) one or<br>• none (zero points) | |
| Hospice utilization | Admission to a certified hospice organization. | Location of care can be home, comfort care home, skilled nursing facility and/or hospital. Exclusions: Non-hospice comfort care, palliative care and enhanced care. | Use/no use of hospice in last 30 days before death | Yes/no |
| | | | Hospice days from date of enrollment in hospice until death (truncated at 30 days) | 0 – 30 Days |

*Reliability was assessed through review of ten charts from each site and re-abstraction of 10 additional charts by trained 4th-year medical students, which revealed few inconsistencies which were all resolved by the PIs in favor of the original abstractions. Concerns about ambiguous or missing data were resolved by consensus of the investigators.

© 2016 American Medical Association. All rights reserved.

Downloaded From: by a Purdue University User on 02/19/2018

**eTable 4. Raw scores for each of the component communication measures**

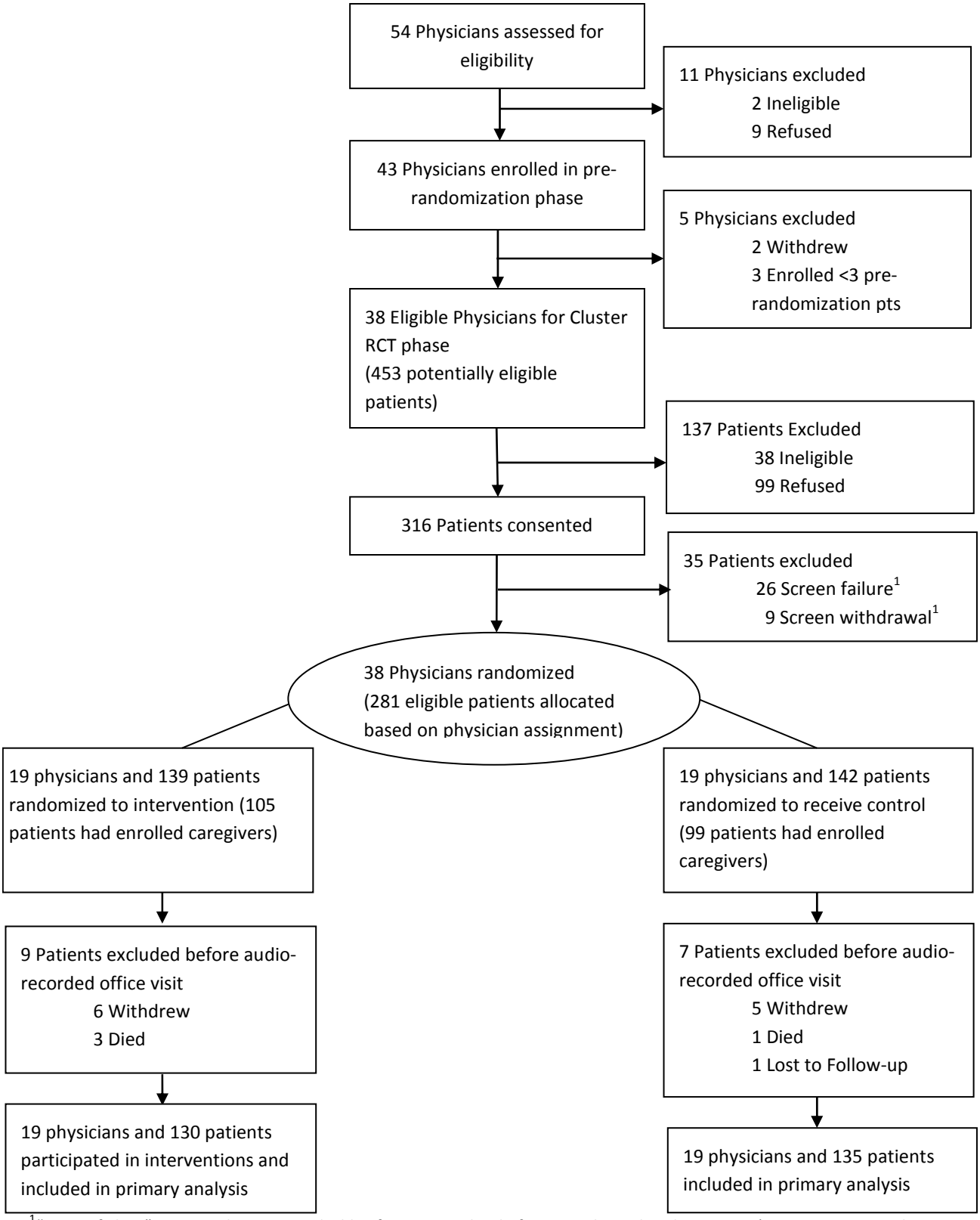
| | Pre-randomization* | | | | | Cluster RCT* | | | | | Difference in difference (Cluster RCT minus Pre-randomization) | | |
|---|---|---|---|---|---|---|---|---|---|---|---|---|---|
| | Intervention (58) | | Control (60) | | Difference intervention minus control | Intervention (130) | | Control (135) | | Difference intervention minus control | | | |
| | Mean (std) | Range | Mean (std) | Range | Mean | Mean (std) | Range | Mean (std) | Range | Mean | unadjusted Mean difference | * adjusted mean difference (95% CI) | p-value |
| Mean of 4 z-scored key Aim 1a components | -0.1 (0.5) | 2 | 0.1 (0.6) | 2.4 | -0.2 | 0.2 (0.8) | 5.7 | 0 (0.7) | 4.1 | 0.2 | 0.4 | 0.34 (0.06, 0.62) | 0.017 |
| ENGAGING outcome measure(APPC)** | 12.2 (9.7) | 45 | 14.4 (12) | 0 - 54 | -2.2 | 16.6 (12.7) | 67 | 13.1 (11.4) | 55 | 3.5 | 5.7 | 5.75 (0.72,10.77) | 0.025 |
| RESPONDING outcome measure(VERONA) | 0.8 (1.4) | 7 | 0.9 (1.7) | 0 - 11 | -0.1 | 1 (1.7) | 11 | 0.5 (1) | 7 | 0.5 | 0.6 | 0.51 (-0.1, 1.12) | 0.102 |
| INFORMING outcome measure (PTCC)** trimmed at 4 | 3.1 (3.6) | 13 | 4.2 (5.1) | 0 - 21 | -1.1 | 4.3 (3.8) | 14 | 4 (4.1) | 19.2 | 0.3 | 1.4 | 1.39 (-0.3, 3.08) | 0.107 |
| FRAMING outcome measure (PTCC)** | 0 (0.1) | 1 | 0.1 (0.2) | 0 - 1 | -0.1 | 0 (0.3) | 3 | 0.1 (0.3) | 2 | -0.1 | 0 | 0.03 (-008, 0.14) | 0.591 |

* Each of the means and ranges refers to the number of codable statements made by patients (APPC) or physicians (VERONA and PTCC).
** Adjusted for site, breast cancer doctor, patient age, gender, race, education and aggressive cancer.

© 2016 American Medical Association. All rights reserved.

Downloaded From: by a Purdue University User on 02/19/2018

## eFigure 1: VOICE STUDY Cluster RCT Physician/Patient CONSORT Flow Diagram



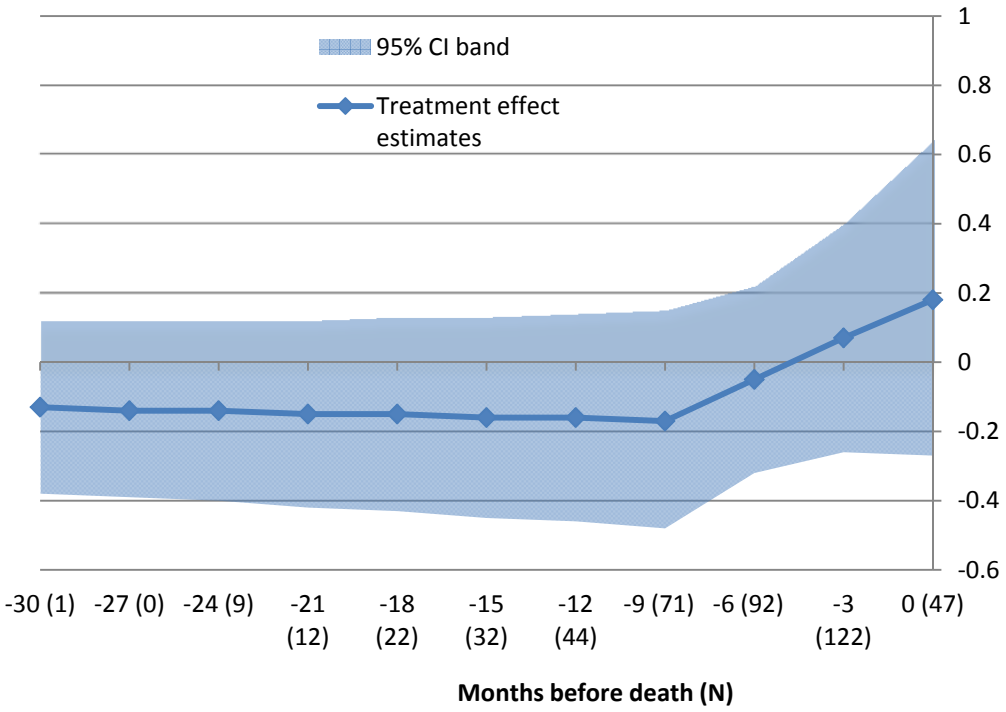

[1]"Screen failure" = patient becomes ineligible after consent but before completing baseline survey (e.g. patient enters hospice care) and "Screen withdrawal"= consented but withdrew prior to completing baseline.

© 2016 American Medical Association. All rights reserved.



Downloaded From: by a Purdue University User on 02/19/2018

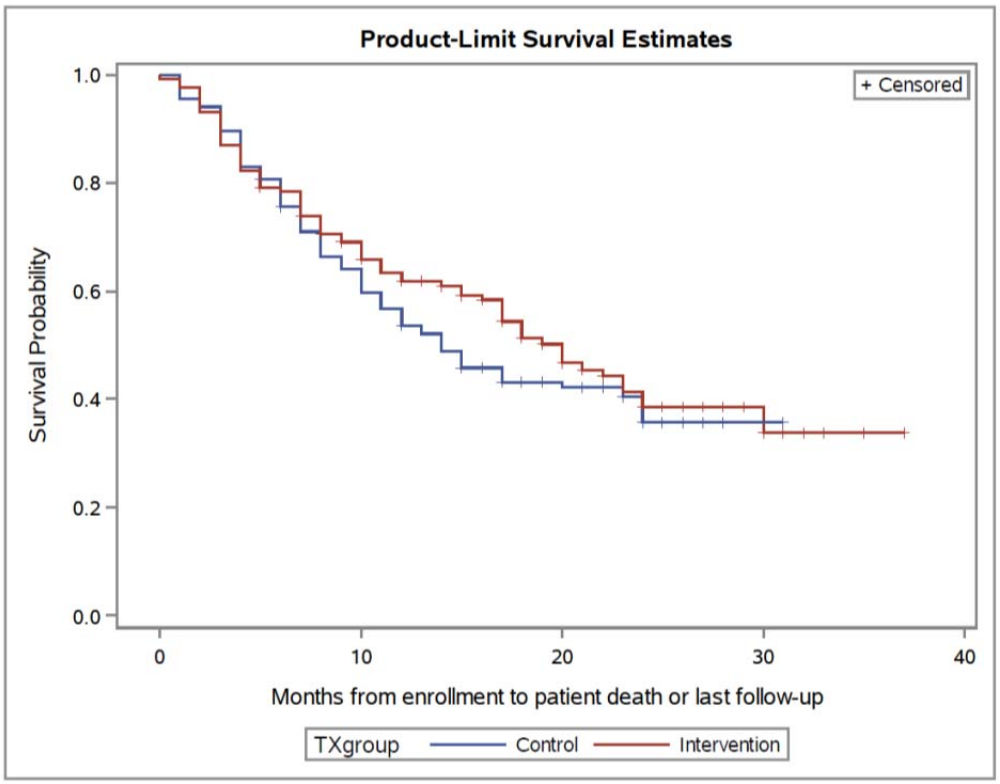
**eFigure 2: Quality of Life, Intervention vs Control: Terminal Decline Model**




© 2016 American Medical Association. All rights reserved.

Downloaded From: by a Purdue University User on 02/19/2018

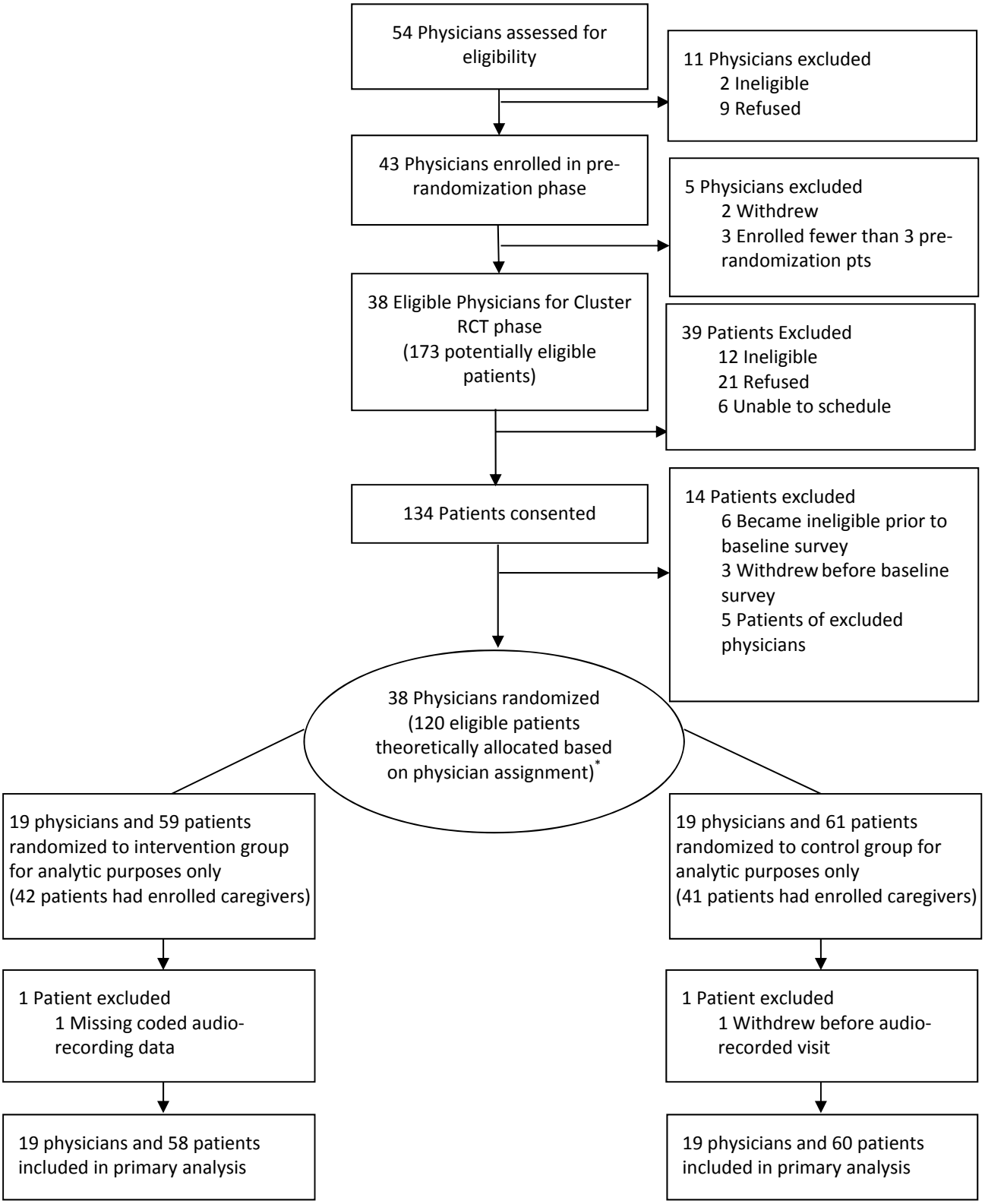
## eFigure 3: Kaplan-Meier Survival Curve: Intervention and Control




© 2016 American Medical Association. All rights reserved.

Downloaded From: by a Purdue University User on 02/19/2018

## eFigure 4: VOICE Study CONSORT Diagram: Pre-randomization Sample




*For analytic purposes, patients were retroactively allocated to intervention or control based on their physician's subsequent assignment.

© 2016 American Medical Association. All rights reserved.

Downloaded From: by a Purdue University User on 02/19/2018

# eReferences

1. Walczak A, Mazer B, Butow PN, et al. A question prompt list for patients with advanced cancer in the final year of life: development and cross-cultural evaluation. Palliat Med. 2013;27(8):779-788. Medline:23630055

2. Oliver JW, Kravitz RL, Kaplan SH, Meyers FJ. Individualized patient education and coaching to improve pain control among cancer outpatients. J Clin Oncol. 2001;19(8):2206-2212. Medline:11304773

3. Brown RF, Butow PN, Dunn SM, Tattersall MH. Promoting patient participation and shortening cancer consultations: a randomised trial. Br J Cancer. 2001;85(9):1273-1279. Medline:11720460

4. Kinnersley P, Edwards A, Hood K, et al. Interventions before consultations for helping patients address their information needs. Cochrane Database Syst Rev. 2007;(3):CD004565. Medline:17636767

5. Clayton JM, Butow PN, Tattersall MH, et al. Randomized controlled trial of a prompt list to help advanced cancer patients and their caregivers to ask questions about prognosis and end-of-life care. J Clin Oncol. 2007;25(6):715-723. Medline:17308275

© 2016 American Medical Association. All rights reserved.

Downloaded From: by a Purdue University User on 02/19/2018