# Efficacy of Communication Skills Training for Giving Bad News and Discussing Transitions to Palliative Care

Anthony L. Back, MD; Robert M. Arnold, MD; Walter F. Baile, MD; Kelly A. Fryer-Edwards, PhD; Stewart C. Alexander, PhD; Gwyn E. Barley, PhD; Ted A. Gooley, PhD; James A. Tulsky, MD

**Background:** Few studies have assessed the efficacy of communication skills training for postgraduate physician trainees at the level of behaviors. We designed a residential communication skills workshop (Oncotalk) for medical oncology fellows. The intervention design built on existing successful models by teaching specific communication tasks linked to the patient's trajectory of illness. This study evaluated the efficacy of Oncotalk in changing observable communication behaviors.

**Methods:** Oncotalk was a 4-day residential workshop emphasizing skills practice in small groups. This preintervention and postintervention cohort study involved 115 medical oncology fellows from 62 different institutions during a 3-year study. The primary outcomes were observable participant communication skills measured during standardized patient encounters before and after the workshop in giving bad news and discussing transitions to palliative care. The standardized patient encounters were audiorecorded and assessed by blinded coders using a validated coding system. Before-after comparisons were made using each participant as his or her own control.

**Results:** Compared with preworkshop standardized patient encounters, postworkshop encounters showed that participants acquired a mean of 5.4 bad news skills (P<.001) and a mean of 4.4 transitions skills (P<.001). Most changes in individual skills were substantial; for example, in the bad news encounter, 16% of participants used the word "cancer" when giving bad news before the workshop, and 54% used it after the workshop (P<.001). Also in the bad news encounter, blinded coders were able to identify whether a standardized patient encounter occurred before or after the workshop in 91% of the audiorecordings.

**Conclusion:** Oncotalk represents a successful teaching model for improving communication skills for post-graduate medical trainees.

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ATIENTS WITH LIFE-THREATening illnesses need physicians with excellent communication skills, yet what they encounter in their physician's office is often suboptimal.<sup>1-8</sup> The communication skills required in these settings go beyond basic interviewing taught in medical school; complex biomedical issues must be integrated with patientcentered values. Thus, the Accreditation Council for Graduate Medical Education now requires competency in communication skills for residents and fellows.9 However, educators face significant challenges in addressing this competency. The communication content must be integrated with biomedical content, and the teaching should include skills practice, which few faculty have been trained to facilitate. Few rigorously evaluated studies of communication skills training have addressed postgraduate trainees.<sup>10-22</sup>

Author Affiliations are listed at the end of this article.

We designed an experiential curriculum for oncology fellows involving 5 pa-

tients with cancer seen at critical incidents along the illness trajectory, using step-by-step approaches or cognitive road maps for specific communication tasks (such as giving bad news) and skills practice with simulated patients. The resulting workshop, called Oncotalk, also incorporated features of other successful programs.<sup>11,13,23</sup> To evaluate Oncotalk, we used a system of content-based coding of audiorecordings of encounters with standardized patients because self-assessment often does not correlate with objective measures.<sup>24</sup> Herein we report the primary outcome of this evaluation, learner acquisition of communication skills, for the 2 different tasks of delivering bad news and discussing transitions to palliative care.

### **METHODS**

# SETTING AND INTERVENTION

Oncotalk was a 4-day residential workshop conducted for 20 fellows per workshop biannu-

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Table 1. Communication Skills Curriculum Based on Illness Trajectory

Session No.	Content Focus	Skills Practice With Simulated Patient
1	Developing a relationship Dealing with uncertainty	47-year-old woman with breast cancer who underwent lumpectomy, chemotherapy, and radiation 1 y ago, seen for routine surveillance, notes some back pain
2	Giving bad news	1 wk later, bone scan ordered at the last visit shows multiple metastases; computed tomogram shows liver metastases
3	Discussing transition to palliative care	3 y later, now has undergone multiple chemotherapy regimens, with disease progression on therapy
4	Discussing do-not-resuscitate orders	2 mo later, at home with hospice care, told nurse she "wants everything"

ally. Oncology fellows were recruited by sending brochures and e-mails to fellowship directors listed by the American Society for Clinical Oncology.<sup>25</sup> Participant selection was based on interest in communication as expressed in a brief personal statement, potential as an educator, and research in communication.

The Oncotalk curriculum emphasized skill practice. Except for short overviews, the retreat was taught in small groups of 5 participants and 1 faculty facilitator. The curriculum was organized around 5 simulated patients (with breast cancer, prostate cancer, lymphoma, lung cancer, and melanoma) who appear each day at a different point in their illness trajectory (**Table 1**). Learning activities included overviews, skills practice sessions, and reflective discussions.<sup>19,26-28</sup> We taught cognitive road maps for common communication tasks, including giving bad news and discussing transitions to palliative care.<sup>26</sup> These road maps are based on empirical studies of patient preferences.<sup>4,5,29-33</sup> We emphasized attending to the patient agenda, recognizing empathic opportunities,<sup>34</sup> and responding verbally.<sup>26</sup>

The simulated patients used for teaching were professional actors trained for at least 6 hours by the investigators using a detailed character script, with an additional hour of refresher training given immediately before each retreat.

To develop a consistent teaching approach, one of us (K.A.F.-E.) coordinated faculty development; she observed each facilitator, provided individual feedback, videorecorded or audiorecorded skills practice sessions, and produced a DVD to identify best teaching practices.<sup>35,36</sup>

### MEASUREMENTS

Participants completed preretreat questionnaires that included demographic information and other data not reported herein.

Participant communication skills were evaluated with 2 preretreat standardized patient (SP) encounters at the beginning of the retreat and 2 postretreat encounters 4 days later. These SP encounters for evaluation used actors different from the simulated patients used for teaching during the week. The SP encounter for giving bad news required the participant to discuss the results of a computed tomogram showing disease recurrence to a patient previously thought to be in remission. The SP encounter for discussing transition to palliative care required the participant to develop and discuss a care plan for a patient whose cancer had progressed despite use of available evidence-based palliative chemotherapy. Each participant saw 1 bad news and 1 transition SP before and after the retreat, for a total of 4 SP encounters per participant (each limited to 20 minutes). To avoid a training effect, 4 different SP characters were developed so that no learner would see the same character before and after the workshop. The SPs were presented in random order.

The SPs were recruited and trained by the Center for Advancing Professional Excellence at the University of Colorado at Denver. Each of 4 SP characters had a standardized script and videotape used for training. The SPs received 6 hours of initial training and 2 hours of refresher training every year. The SP training included review of the case as a group, self-study by the SPs to memorize the case, and then portrayal of the case by each SP with feedback until their performance was rated as consistent. The SPs were blinded to the retreat curriculum.

We developed a content-based coding scheme consisting of observable behaviors for each step in giving bad news and transitions to palliative care that could be recognized by coders with adequate interrater reliability. For giving bad news, the codes followed the stepwise approach with the acronym SPIKES, as defined by Baile et al.<sup>37</sup> The 6 steps in SPIKES include (1) preparing the setting; (2) assessing the patient's perception; (3) making an invitation to disclose the news; (4) sharing the knowledge about the news; (5) responding to the patient's emotion; and (6) summarizing the plan. We identified codes for each step except the first (which involves finding a quiet place to talk and verifying the information). Table 1 shows examples of dialogue that met the definition of the codes for each step. The codes were chosen because they represent a best communication practice.<sup>29,30,32</sup> One of the codes, however, requires further explanation. One code measuring how participants responded to emotion (step 5) was based on a required SP behavior. After hearing the bad news, the SP was trained to react by becoming upset but not saying anything for 20 seconds, after which the SP would look at the participant as if ready to talk. Ideally, a participant would not address the SP until the SP looked up. We measured whether the participant could remain silent for at least 10 seconds as an indicator that the participant was attending to the patient's emotion to some degree.

For transitions to palliative care, the codes followed a stepwise approach that we developed.<sup>26</sup> **Table 2** shows examples of dialogue that met the definition of the codes for each step. The 6 steps included (1) assessing patient understanding of the situation; (2) eliciting "big-picture" goals or values; (3) asking about worries, fears, and concerns; (4) responding to patient emotion; (5) proposing a care plan that addresses goals, values, and concerns; and (6) checking for patient understanding. We measured participant skills for step 4 by having the SP routinely ask the questions "How much time do I have?" and "Isn't there anything more you can do?" For both required cues, we measured whether participants included an empathic statement in their response, and for the "anything more" required cue, we measured empathic and "I wish" statements<sup>38</sup> in the response.

Finally, in the bad news and transitions SP encounters, we also measured participant use of verbal empathic expressions based on the acronym NURSE, which we previously modified<sup>26</sup> from Smith<sup>39</sup>: (1) *n*aming emotions; (2) expressing *un*derstanding; (3) showing respect or praise for a patient's behavior; (4) articulating support for the patient; and (5) *exploring* 

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Step	Participant Behavior Code	Example of Dialogue Coded Positively		
Setting	Not assessed			
Perception	Assesses the patient's perception of the situation	"Have you been told anything about your test by anyone else?"		
Invitation	Requests the patient's permission to proceed	"Are you ready to talk about the CT results now?"		
Knowledge	Uses the word <i>cancer</i> when giving the bad news	"The CT shows that the cancer has returned."		
Emotion	Waits at least 10 s after giving bad news	Silence for 10 s while the patient is still too upset to talk		
Makes an empathic statement as the first response to the patient after bad news	"It looks like this is not what you expected."			
Asks for the patient's emotional reaction explicitly at some point after the bad news	"How are you doing with all this?"			
Summary	Summarizes the follow-up plan	"So the next step will be for us to meet tomorrow to talk about the chemo in more detail."		

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Abbreviation: CT, computed tomography.

the patient's emotional state. These verbal empathy codes were used to score participant dialogue that occurred at any point in the SP encounter and were required to be statements separate from the codes used for the stepwise approaches for bad news and transitions (ie, a single participant statement could not be coded for both a bad news step and an empathic expression).

The preretreat and postretreat SP encounters were recorded using digital audiorecorders, and the audiofiles were transferred into a software package designed for Web-based, audio-content coding.<sup>40</sup> The coders were trained for 40 hours using a manual with detailed definitions. Coders, blinded to whether an audiofile was made before or after the retreat, assessed audiofiles in random order. To assess reliability, a random sample of 10% of the audiofiles was coded twice by different coders. Only codes with a  $\kappa$  statistic greater than 0.60 (good to excellent agreement) were included in the final analysis<sup>41</sup> (Table 2 and **Table 3**). The  $\kappa$  statistics for the codes used in the bad news encounter ranged from 0.73 to 1.00; in the transitions encounter, they ranged from 0.72 to 1.00.

All study activities were approved by the institutional review boards of the University of Washington and Duke University.

## HYPOTHESES AND ANALYSIS PLAN

We hypothesized that, after the workshop, participants would demonstrate increased numbers of communication skills. The

#### Table 3. Content-Based Codes for Transitions to Palliative Care

Step	Participant Behavior Code	Example of Dialogue Coded Positively
Assess perception	Assesses the patient's perception of the situation	"Tell me what your understanding is at this point."
Discuss big picture	Elicits the patient's values or goals	"What is most important to you now?"
Ask about worries	Asks about worries, fears, or concerns	"Do you have any particular concerns?"
Respond to emotional content of difficult questions	Responds to the question "How much time do I have?" including an empathic response	"Is there anything in the future you are thinking about specifically?"
	Responds to the question "Isn't there anything more you can do?" including an empathic response	"There are many things we can do to help."
Propose care plan Checks for understanding	Not assessed Checks that the patient has understood the conversation	"Tell me what you are taking away from our talk."

proportion of subjects who possessed a skill at their preretreat session was compared using the McNemar test with the proportion who possessed the skill at their postretreat session. This comparison was made for each behavior assessed. We also estimated the probability that a participant who did not demonstrate a skill in the preworkshop encounter would demonstrate that skill in the postworkshop encounter as a simple ratio (number of participants with a negative pretest and positive posttest result/number of participants with a negative pretest and positive or negative posttest result). We estimated 95% confidence intervals using standard techniques. We used 1-sample *t* tests to test the null hypothesis that participants would acquire zero skills.

#### RESULTS

## PARTICIPANT CHARACTERISTICS

One hundred fifteen fellows participated in the 6 retreats held from April 2002 through October 2004 (**Table 4**), representing 42% of eligible fellowship programs.

# GIVING BAD NEWS

From the 115 participants, we obtained 106 evaluable pairs of preretreat and postretreat audiofiles for the bad news encounter. Nine participants were missing a preretreat or a postretreat audiofile because of late arrival (n=4), early departure (n=2), operator error (n=2), or equipment failure (n=1). In each pair of bad news encounters (preretreat and postretreat), we measured 14 separate skills. The percentage of fellows demonstrating specific skills before or after the retreat is shown in **Table 5**.

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Characteristic	Finding
Sex	
Male	59 (51)
Female	56 (49)
Year in fellowship	
First	23 (20)
Second	59 (51)
Third	32 (28)
Did not answer	1 (1)
Ethnicity	
White	62 (54)
Asian/Pacific Islander	20 (17)
East Indian/Pakistani	19 (17)
Hispanic/Latino	5 (4)
African American	4 (3)
Mixed ethnicity	2 (2)
Other/did not answer	3 (3)
Personal experience with death	
No	25 (22)
Yes	90 (78)
Age, median (range), y	33 (29-56
No. of deaths of patients cared for in	20 (0-300

\*Data are presented as number (percentage) of participants unless otherwise indicated.

In the SPIKES cognitive map, we directly tested 5 of the 6 recommended steps. We were unable to test step 1 of the SPIKES map (setting), which involves finding a quiet room and verifying the bad news, because of the experimental setting. In postretreat encounters, participants demonstrated statistically significant skill acquisition for steps 2 (perception; P <.001), 3 (invitation; P <.001), 4 (knowledge; P <.001), and 5 (emotion; P <.001). For step 6 (summary), skill acquisition was not statistically significant (P =.35).

In the bad news encounters, we also measured participant use of 5 empathic verbal behaviors. In postretreat encounters, participants demonstrated statistically significant skill acquisition for the empathic skills of naming (P<.001), respecting (P<.001), supporting (P<.001), and exploring (P<.001). For understanding, no significant change was demonstrated (P=.25) (Table 5).

Because a subset of participants demonstrated skills during the preretreat encounters, we measured the percentage of participants who had not demonstrated a skill before the retreat who went on to demonstrate the skill after the retreat (**Figure 1**). For the SPIKES skills, 38% to 73% of participants who did not demonstrate a skill before the retreat went on to demonstrate the skill after the retreat.

We measured 3 additional skills using required cues performed by the SPs. In the first required cue, after hearing the bad news, the SPs reacted nonverbally for 20 seconds and the coders noted whether the participant was able to remain silent for at least 10 seconds. Before the retreat, 55% of participants did not remain silent for 10 seconds; after the retreat, about two thirds of these participants were able to remain silent for at least 10 seconds after giving the bad news. In the second required cue, the SP was required to say, "Doctor, I'm really scared" at some point after hearing the bad news. Before the retreat, 15% of participants did not respond with an empathic statement to this cue; after the retreat, all of these participants responded with an empathic statement.

For the third required cue in the bad news encounters, the SP was required to ask "Is there any hope for a cure?" after hearing the bad news. Of the participants who did not respond with an empathic statement before the retreat, 38% did so after the retreat. For example, in the preretreat encounter, participant 410 responded to the cue "Is there any hope for a cure?" by saying "Umm . . . it's possible that this [cancer] might take your life." After the retreat, this same participant responded with "I don't think so—I wish that were not the case." Of the participants whose preretreat response to the cue "Is there any hope for a cure?" was an immediate offering of anticancer therapy, 68% were able to make a different response after the retreat. For example, before the retreat, participant 502 responded by saying to the patient with new liver metastases from colon cancer, "Definitely. I'm talking about at least a 60% or higher chance of cure" and went on to discuss "new therapies." After the retreat, the same participant responded by saying "I'm afraid not. I really wish there was."

Overall, in the postretreat bad news encounters, learners demonstrated acquisition of a median of 6 new skills (mean, 5.4; P<.001). Remarkably, for 91% of the bad news audiorecordings, blinded coders were able to identify whether the recorded encounter was before or after the workshop.

### TRANSITIONS TO PALLIATIVE CARE

From the 115 participants, we obtained 100 evaluable pairs of preretreat and postretreat audiofiles for the transition to palliative care encounter. Fifteen participants were missing a preretreat or postretreat audiofile because of late arrival (n=4), early departure (n=2), operator error (n=5), or equipment failure (n=4). In each pair of transitions encounters, we measured 16 separate skills. The percentage of fellows demonstrating specific skills before and after the retreat is shown in **Table 6**.

In the transitions cognitive map, we directly measured 5 of the 6 recommended steps and we also measured whether participants avoided a common pitfall. In postretreat encounters, participants demonstrated statistically significant skill acquisition for steps 1 (assessing understanding; P=.02), 2 (discussing the big picture; P<.001), 3 (asking about worries, fears, and concerns; P=.004), and 4 (responding to emotion; P=.02to P<.001). We were unable to directly measure whether participants demonstrated skill acquisition for step 5 (proposing a care plan) because we could not devise a code with adequate reliability. For step 6 (checking understanding), skill acquisition was not statistically significant (P=.25).

In the transitions encounters, we also measured participant use of specific empathic verbal statements. In the postretreat encounters, participants demonstrated statistically significant skill acquisition for the empathic skills of naming (P<.001), understanding (P=.01), respect-

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		% of Fellows With Skill		
Coding Scheme	Participant Behavior Code	Before Retreat	After Retreat	<i>P</i> Value
SPIKES				
Setting	Not assessed			
Perception	Assesses the patient's perception of the situation	25	59	<.001
Invitation	Requests the patient's permission to proceed before giving news	5	42	<.001
Knowledge	Uses the specific word <i>cancer</i> when giving bad news	16	54	<.001
Emotion	Waits at least 10 s after giving bad news	45	73	<.001
	Makes an empathic statement as the first response after giving bad news	52	81	<.001
	Asks for the patient's emotional reaction to the bad news	17	38	<.001
Summary	Summarizes the follow-up plan	57	51	.35
Empathic verbal skills (NURSE)				
Naming	Names an emotion that the patient seems to be experiencing but has not explicitly articulated at any point	39	71	<.00
Understanding	Expresses understanding or appreciation of a patient emotion	97	100	.25
Respecting	Expresses respect or praise about how the patient is handling the situation	6	41	<.00
Supporting	Makes a statement of support or nonabandonment	54	70	.007
Exploring	Explores the patient's emotional state at any point	59	83	<.00



Figure 1. Skill acquisition for giving bad news. Codes are listed in the same order as in Table 2 (first 7 measured codes). Dark bars indicate the percentage of participants acquiring a skill, as defined in the "Measurements" subsection of the "Methods" section. Light bars indicate 95% confidence intervals.

ing (P<.001), supporting (P=.02), and exploring (P<.001) (Table 6).

The percentage of participants who had not demonstrated a skill before the retreat and went on to do so after the retreat is shown in **Figure 2**. For the transitions map skills, 30% to 86% of participants who had not demonstrated a skill before the retreat did so after the retreat.

Two additional skills were measured using required cues performed by the SPs. In the first transitions required cue, after hearing that palliative chemotherapy is no longer working, the SP asked, "Isn't there anything more you can do?" Of the 92% of participants did not include an empathic or an "I wish" statement in their response to this cue, approximately one third used one of these responses after the retreat. For example, participant 112 responded before the retreat by saying "You've been on quite a few chemotherapies, haven't you—3 or 4?" After the retreat, this participant responded with: "There are more things we can do, yes. This has been a roller-coaster ride for you, hasn't it?" For the second required transitions cue, the SP asked, "How much time do I have?" Before the retreat, 90% of the participants did not include an empathic statement or an exploratory question (eg, "Is there something specific you are thinking about in the future?") in their response to this cue. After the retreat, 78% were able to use at least one of those responses (Figure 2), and 44% provided a direct answer to the patient's question.

Overall, in the postretreat transitions encounters, learners demonstrated acquisition of a median of 4 new skills

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		% of Fellows With Skill		
Coding Scheme	Participant Behavior Code	Before Retreat	After Retreat	<i>P</i> Value
6-Step approach				
Assess patient understanding of situation	Assesses understanding	23	39	.02
Discuss big picture	Elicits values or personal goals	20	63	<.00
Ask about worries, fears, and concerns	Elicits concerns	31	49	.004
Respond to emotion	Empathic response to "How much time?"	7	31	<.00
	Empathic response or "I wish" to "Isn't there anything more you can do?"	8	31	<.00
Propose care plan	Not assessed			
Avoid pitfall	Does not offer more chemotherapy	61	79	<.00
Check for understanding	Checks for understanding	8	13	.25
Empathic verbal skills (NURSE)				
Naming	Names an emotion that the patient seems to be experiencing but has not explicitly articulated at any point	27	60	<.00
Understanding	Expresses understanding or appreciation of a patient's emotion	82	94	.01
Respecting	Expresses respect or praise about how the patient is handling his or her situation	13	52	<.00
Supporting	Makes a statement of support or nonabandonment	57	73	.02
Exploring	Explores the patient's emotional state at any point	28	75	<.00



Figure 2. Skill acquisition for discussing transitions to palliative care. Codes are listed in the same order as in Table 3 (first 7 measured codes). Dark bars indicate the percentage of participants acquiring a skill, as defined in the "Measurements" subsection of the "Methods" section. Light bars indicate 95% confidence intervals.

(mean, 4.4; P < .001). For 70% of the transitions audiorecordings, blinded coders were able identify whether the recorded encounter occurred before or after the workshop.

# COMMENT

This study demonstrates the efficacy of a teaching model for communication skills designed for postgraduate trainees. Oncotalk participants demonstrated substantial numbers of new communication skills in the postretreat SP encounters. For bad news, participants began with a median of 8 skills and acquired a median of 6 new skills. This degree of behavior change produces a quality of patient centeredness that was easily recognized by the coders, the SPs, and the participants themselves. One of our participants, on her first day back home in her clinic, had a patient say appreciatively, "No one has ever talked to me like this." Another participant wrote, "I feel less flustered and my words are less tangled; I can focus on the person across from me and find out what they need from me in that moment."<sup>42</sup>

How do our results compare with those of other interventions that rigorously measured behavior change? In the randomized study by Fallowfield et al,<sup>11</sup> which videotaped oncologists with real patients and used a different coding method, oncologists before the workshop responded appropriately to 43% of patients' emotional cues (similar to our empathy expressions), compared with 57% of cues after the workshop. (In that study, improvement per oncologist was not reported.) In Oncotalk, by comparison, 39% of participants used an empathic naming statement before the workshop, compared with 71% after the workshop. In the Oncotalk analysis, each participant received a score for using each type of empathic statement only once because we believe that broadening the repertoire of available skills is more important than repeatedly performing the same skill. Comparing Oncotalk with studies involving 28 pediatric residents,<sup>43</sup> 20 internists,<sup>12</sup> and 69 internists<sup>44</sup> also suggests that Oncotalk is more efficacious for acquiring skills than these other interventions.

Some may comment that Oncotalk is not a controlled study. The main reasons for caution in interpreting uncontrolled phase 2 studies are secular trend and confounding variables. In this case, a control group would have measured whether oncology fellows who did not attend Oncotalk had improved their communication skills spontaneously during a 5-day period, which we think would be exceedingly unlikely given that other controlled studies have clearly shown that communication skills did not improve in the control arms.<sup>11,12,44,45</sup> Furthermore, we cannot identify any possible confounding variables present when subjects were used as their own controls and their skills were evaluated after 5 days. Thus, we believe that this before-after cohort design of adequate size represents an important test of efficacy.

This study has notable strengths. The Oncotalk teaching methods and curricular materials have been published to enable others to replicate this course.<sup>19,26-28,35,36</sup> The participants were diverse in program location, ethnicity, and previous training and represented 42% of the medical oncology or hematology-oncology fellowship programs and 56% of the National Cancer Institute– designated comprehensive cancer centers. The contentbased coding has high face validity for clinicians, directly measures skills taught in the curriculum, and achieved extremely high reliability.

The study also has limitations. First, the evaluation used SPs rather than real patients. Physicians may behave differently in an SP encounter than in real practice.<sup>46</sup> We performed 1 posttest SP evaluation, and conflicting data exist regarding the persistence of skills after a single intervention.<sup>15,47</sup> Thus, the effectiveness of Oncotalk in actual practice remains to be determined. Second, the cognitive maps have not been validated in patient outcome studies (eg, motivational interviewing has been shown to change alcohol use).48 Third, our coding system focused primarily on verbal skills, because the measurement methods are robust and we did not explicitly teach nonverbal techniques.<sup>33</sup> Fourth, we did not specifically test the skills in settings simulating patients from minority, disadvantaged, and low-literacy backgrounds, although we emphasized understanding patient perceptions, which is useful in dealing with cultural difference.<sup>49</sup> Finally, the participants are self-selected, and personal motivation may be important.

The Oncotalk teaching model warrants further study, especially for other subspecialties involving communication about life-threatening illnesses; although the simulated scenarios would differ, many core skills are identical. Future studies should also address nonresidential settings, faculty development,<sup>45</sup> and the effect of the improved skills on patient-level outcomes.

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Author Affiliations: Departments of Medicine (Dr Back) and Medical History and Ethics (Drs Back and Fryer-Edwards), University of Washington, and Clinical Research Division (Drs Back and Gooley), Fred Hutchinson Cancer Research Center, Seattle; Department of Medicine, University of Pittsburgh, Pittsburgh, Pa (Dr Arnold); Department of Behavioral Science, University of Texas M. D. Anderson Cancer Center, Houston (Dr Baile); Department of Medicine (Drs Alexander and Tulsky), Center for Palliative Care (Drs Alexander and Tulsky), and Duke Comprehensive Cancer Center (Dr Tulsky), Duke University and Center for Health Services Research (Drs Alexander and Tulsky), Durham Veterans Affairs Medical Center, Durham, NC; and Department of Family Medicine, University of Colorado at Denver, Aurora (Dr Barley).

**Correspondence:** Anthony L. Back, MD, Department of Medicine/Oncology, University of Washington, 825 Eastlake Ave E, PO Box 19023, Seattle, WA 98109-1023 (tonyback@u.washington.edu).

Author Contributions: Study concept and design: Back, Arnold, Baile, Fryer-Edwards, and Tulsky. Acquisition of data: Back, Baile, and Barley. Analysis and interpretation of data: Back, Arnold, Baile, Alexander, and Tulsky. Drafting of the manuscript: Back, Arnold, Alexander, and Barley. Critical revision of the manuscript for important intellectual content: Back, Arnold, Baile, Fryer-Edwards, Barley, and Tulsky. Statistical analysis: Alexander and Gooley. Obtained funding: Back. Administrative, technical, and material support: Back, Barley, and Tulsky. Study supervision: Back, Alexander, and Tulsky.

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