

Early Intervention in Planning End-of-Life Care With Ambulatory Geriatric Patients

Results of a Pilot Trial

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Background: A large discrepancy exists between the wishes of dying patients and their actual end-of-life care. However, retrospective clinical experience suggests that early advance care planning (ACP) can markedly reduce this discrepancy. This article describes a randomized trial to evaluate the short-term clinical utility of early ACP. We also assessed the feasibility of performing a larger prospective study to document long-term outcomes.

Methods: Ambulatory geriatric patients (N=61) were randomized to either a control group, which received only a Massachusetts Health Care Proxy form to complete, or an intervention group, in which each patient and health care agent discussed ACP with a trained nurse facilitator. The benefits and burdens of life-sustaining treatments were discussed, and patient goals and preferences for these treatments were documented.

Results: Two-month follow-up revealed that the intervention achieved higher congruence between agents and patients in their understanding of patients' end-of-life care preferences, with 76% (19/25) in complete agreement vs 55% (12/22) of the controls (effect size [ES] = -0.43). There was also a greater increase in patient knowledge about ACP in the intervention group (ES=0.22). Intervention patients became less willing to undergo life-sustaining treatments for a new serious medical problem (ES=-0.25), more willing to undergo such treatments for an incurable progressive disease (ES=0.24), and less willing to tolerate poor health states (ES=-0.78). Practical insights were gained about how to conduct a larger study more effectively.

Conclusion: A facilitated discussion about end-of-life care between patients and their health care agents helps define and document the patient's wishes for both patient and agent.

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LIFE SUPPORT measures were never intended to prolong the dying process of patients with incurable conditions. Unfortunately, that outcome is now common. Many conflicts arise in medical decision making at the end of life. To address this problem, a concerted effort has been made to promote the use of advance directives. Despite these efforts, the overall prevalence of advance directive documents remains 15% to 20%.¹⁻³ Even when completed, advance directives often are not readily available to physicians or completely understood by loved ones. Frequently they are vague and incomplete. Without clear documentation of the patient's wishes, the legal and ethical constraints on health care institutions often force them to use aggressive life support measures to keep patients alive, although these measures are not what most patients and their families

want.⁴ There is a wide gap between current practice and the wishes for end-of-life care expressed by patients, family members, and caregivers alike.⁵

Research on interventions aimed at increasing awareness and use of advance directives has generally been disappointing. Perhaps the best-known failure is the \$28 million Robert Wood Johnson Foundation project titled SUPPORT (Study to Understand Prognoses and Preferences for Outcomes and Risks of Treatment).⁶ Focused on seriously ill patients who were hospitalized and had only a 50% probability of long-term survival, this comprehensive observational and intervention study documented a disturbing prevalence of potentially preventable adverse or negative end-of-life experiences for patients and no impact of a nurse-delivered advance care planning (ACP) intervention. The dramatic failure of the SUPPORT intervention has been attributed to not confronting the lack of com-

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PARTICIPANTS AND METHODS

PARTICIPANTS

Ambulatory geriatric participants for this pilot study were recruited from the patient practices of 2 geriatricians (L.L. and Sarah McGee, MD, MPH) and from an independent living facility. Eligibility criteria included being 65 years or older with a chronic or life-threatening disease or being 75 years or older, speaking English, and being mentally competent at the last visit with the health care provider.

PROCEDURE

Patients were sent letters signed by their primary care physician, a description of the study, and a request for their participation. In addition, residents of an independent living facility were informed about the study via flyers left in their mailboxes and an informal presentation by one of us and a nurse practitioner (C.E.S. and P.T.). People who were interested signed up to learn more about the study. These potential participants were then called by a study representative (J.E. and J.Y.), and the study procedures were explained. Interested participants were invited to an intake interview, at which time patients were screened for dementia using the Mini-Mental State Examination²⁷ and a criterion score of 23 or higher. The intake interview took place at either the University of Massachusetts Medical School or the participant's home. During the intake interview, written informed consent was obtained, and a quality-of-life questionnaire packet was completed. The packet was completed by the patient as a paper-and-pencil questionnaire at the beginning of the pilot trial, but we later adopted a semistructured interview because of feedback from several participants that visual problems made filling out a questionnaire burdensome.

Participants were then randomized using blinded envelopes. If randomized to standard care, participants were given a Massachusetts Health Care Proxy form to take home and complete. If randomized to the *Respecting Choices* intervention, participants were given 2 pamphlets that briefly describe ACP and include questions that prompt patients to consider what factors affect their personal goals for end-of-life care. The pamphlets also include vignettes about situations in which ACP would be beneficial. Patients were encouraged to read the materials, to think about whom they might appoint as a health care agent, and to discuss the materials with family members or their health care agent. The facilitator subsequently contacted the patient to schedule a facilitated discussion with the patient and his or her health care agent.

At least 1 meeting was then held with the facilitator, the patient, and the patient's health care agent (if identified). In the *Respecting Choices* intervention, this interview focused on enhancing patients' understanding of ACP and encouraged them to reflect on their goals for end-of-life care, to communicate with their loved ones about their wishes,

and to develop a written plan to document those wishes.²⁸ Such a plan included choosing an appropriate agent and specifying decisions regarding likely scenarios given the patient's health status. Open-ended questions encouraged patients to raise any issues that are personally important to them. Facilitators frequently repeated and discussed patients' statements to be sure that their meaning was clearly understood. Facilitators were trained to administer the structured interview so that all topics were addressed, but additional information was also tailored to patients' or agents' needs. The intervention typically consisted of a 1-hour session, but additional sessions were offered to patients as necessary to meet individual needs. The content of the session(s) was recorded on a checklist to ensure that all desired components of the discussion were included (see **Figure 1** for an example of a checklist for progressive chronic disease).

Facilitators began each interview by assessing the patient's motivation to engage in ACP. They elicited information regarding previous experiences with health care decision making and level of understanding about ACP. Facilitators assessed patients' perception of their health status and their understanding of how their condition was likely to progress. Patients who expressed uncertainty about the course of their illness were encouraged to address questions to their health care providers. Facilitators next clarified patients' preferences, asking specific questions about personal goals, including religious and cultural beliefs. They explained specific treatment options relevant to the individual patient's health status. The facilitators discussed life support treatments that might be applicable to the individual patient (eg, cardiopulmonary resuscitation, mechanical ventilation, artificial nutrition and hydration, antibiotic drugs, pain medication, and hospitalization). They described the benefits and burdens of each treatment and encouraged patients to weigh benefits and burdens from their own perspective. The facilitator then determined specific preferences for comfort care, such as pain and symptom control, emotional support, and counseling needs, including financial, legal, psychological, and spiritual needs. This discussion also directed patients to identify specific activities and experiences that contribute to, or detract from, quality of life. Finally, the facilitator assisted the patient in completing a written Statement of Personal Values for end-of-life care. This statement was appended to the Massachusetts Health Care Proxy document. (Although an advance directive is not legally binding in Massachusetts, a Statement of Personal Values can be of great assistance to both physicians and health care agents when difficult decisions regarding end-of-life care must be made later.) Copies of these documents were then given to the patient, the health care agent, and the referring physician and placed in the study file.

MEASURES

To evaluate the effectiveness of the program, outcomes data were collected twice from patients (at baseline and 2 months

munication between patients and physicians (ie, a nurse implemented the intervention), not ensuring that patients' wishes were documented in readily accessible places (eg, the medical record), attempting to intervene at a sub-optimal time (ie, a time of medical crisis) for promoting good communication about patients' wishes,⁷ and not ad-

ressing the cultural resistance to discussing end-of-life care that is common to patients and physicians.⁸⁻¹¹

Only a few published studies¹²⁻¹⁶ of ACP have yielded heartening results. The most striking benefit was documented in a retrospective study of 540 decedents from La Crosse, Wis.¹² This study compared the prevalence of

later) and once from the designated health care agent (2 months after baseline).

The patient packet contained questionnaires to assess knowledge, treatment preferences, and response shifts in values, conceptualizations, and internal standards of quality of life. The Knowledge Questionnaire was adapted from a form used in the La Crosse training manual to test facilitators' and patients' knowledge of advance directives. The original form listed only misconceptions about advance directives, but we modified the questionnaire to include some items that were true and some that were false. The test assesses understanding of the meaning, legality, and ramifications of advance directives. This 9-item questionnaire had an α reliability coefficient of .78, and scores at baseline ranged from 0 to 9 (mean \pm SD, 6.1 \pm 2.3).

Treatment preferences were assessed using a modified version of the Emanuel and Emanuel²⁹ Medical Directive. This form asks patients to consider 4 hypothetical situations: coma, incurable progressive disease, end-stage terminal illness, and a new serious medical problem (eg, stroke). It then asks patients to indicate their goals for treatment (ie, to prolong life or comfort care only) and their preferences for 6 specific treatments (ie, cardiopulmonary resuscitation, mechanical ventilation, artificial nutrition and hydration, antibiotic drugs, pain medications, and hospitalization for treatments to prolong life, such as the intensive care unit). This measure was used to assess patient-agent congruence (ie, the primary outcome) and response shifts in values (ie, the secondary outcome).

Response shifts in patient conceptualizations of quality of life were measured using the Beliefs and Values Questionnaire.³⁰ This 18-item questionnaire asks patients to consider various disabilities that are not uncommon at the end of life and asks them to rate on a 4-point scale how strongly they feel that life would or would not be worth living with this condition.

Three visual analog scale items assessed self-reported pain, anxiety, and alertness. These items were given in a 10-point Likert scale format and were also adapted to a "then-test" format in follow-up questionnaires to assess response shifts in internal standards over time. The then-test asks respondents at the posttest evaluation to give a renewed judgment about their level of functioning on a target construct at baseline.^{31,32} It is subsequently compared with the baseline score to estimate changes in internal standards of the target construct,²⁰ in this case quality of life.

The health care agent questionnaire packet contained (1) the same Knowledge Questionnaire as the patient completes, (2) an adaptation of the Medical Directive questionnaire to query their understanding of the wishes of the patient for whom they are a health care agent, and (3) the Agent Comfort Questionnaire (available on request from C.E.S.), a new measure we devised to assess the agent's level of comfort with the responsibility of making health care decisions for the patient. This 6-item measure had an α reliability coefficient of .70, and scores ranged from 8 to 24 (mean \pm SD, 12.7 \pm 2.7).

STATISTICAL ANALYSIS

All analyses were performed by intention to treat,³³ as is standard in clinical trials research. Two of the 3 participants who refused to participate in the *Respecting Choices* intervention after randomization provided follow-up data for analysis, and 1 of their health care agents provided data for analysis.

Owing to the small sample sizes of this pilot trial, we did not have sufficient statistical power to document even a large effect. We thus report results in terms of effect size (ES) using the formula of Cohen³⁴: $(\mu_1 - \mu_2)/\sigma$. This approach summarizes the clinical importance of the detected changes by estimating the magnitude of change over time in units of standard deviations. An ES of 0.20 to 0.40 is considered small, 0.41 to 0.79 is considered medium, and 0.80 or greater is considered large. Because the focus of this trial was to determine the clinical effectiveness of the *Respecting Choices* intervention (ie, Does the intervention seem to result in a clinically significant change?), we computed a clinical ES by dividing the mean change score by the average SD of the baseline and posttest measurements. These statistics are not only useful summaries of the magnitude of the detected change but can also be useful for planning subsequent trials that build on this pilot work because power calculations rely on a "best guess" of the magnitude of change anticipated.

The primary outcome in the pilot trial was the congruence between patient and health care agent in reporting patient goals of treatment in the 4 hypothetical health state scenarios. To evaluate this outcome, an index of congruence was created by summing the absolute difference between patient and agent on the global preference indicator for each hypothetical health state, in which respondents indicated whether the patient's goal of treatment was "to prolong life, treat everything" or "comfort care only." The mean congruence index in the 2 groups was compared initially using a *t* test. Paired *t* tests were used to compare change over time in the 2 randomization groups regarding change in patients' and agents' knowledge about ACP and agents' reported comfort with their role as a health care agent. Results of these *t* tests were summarized in terms of ES.

Response shift in patients' values were investigated by examining changes during follow-up in patients' treatment preferences for each of the 4 hypothetical end-of-life scenarios. A within-subject congruence score was estimated for each participant and compared among intervention groups. Response shifts in patients' quality-of-life conceptualization were determined using a *t* test comparing a within-subject congruence score on the Beliefs and Values Questionnaire. Response shifts in internal standards were assessed using within-group *t* tests on the difference scores of the visual analog scale items for pain, anxiety, and alertness. The difference in then-test values and baseline values (ie, then-test minus baseline) estimated changes in internal standards.

and adherence to advance directives before and after a concerted 2-year intervention called *Respecting Choices* (Gundersen Lutheran Medical Foundation, La Crosse, Wis). The intervention included community-based educational outreach efforts and a facilitated discussion between patient and health care agent. The La Crosse educational out-

reach efforts were aimed at changing the reluctance in our culture to discuss death or dying, including medical decision making at the end of life. The efforts included educational and promotional materials (eg, posters, brochures, handouts) that were placed in hospital clinics and physicians' offices, as well as presentations at civic and church

| Patient ID Number: _____ | | | |
|--|--------------------------|--------------------------|----------|
| Name of Facilitator: _____ | | Date: ____ / ____ / ____ | |
| Checklist | Did | Not Do | Comments |
| 1. Assess the motivation of the person you are assisting. | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| 2. Allow patients to tell why they are seeking assistance and to describe experiences they have had. | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| 3. Explore and clarify person's statements. | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| 4. Provide information on advance care planning. | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| 5. Begin advance care planning slowly. Remind the patient that these discussions need to occur over time. | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| 6. Provide at least one scenario on how this person's disease is likely to progress and what treatments he or she is likely to face in the future. | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| 7. Offer the option of time-limited trials of life-sustaining treatment. | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| 8. Develop a plan of action for further discussion, if desired. | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| <input type="checkbox"/> Provide written information | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| <input type="checkbox"/> Encourage discussion with and inclusion of the rest of the family | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| <input type="checkbox"/> Assist in choosing a surrogate | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| <input type="checkbox"/> Make referrals as needed | <input type="checkbox"/> | <input type="checkbox"/> | _____ |
| <input type="checkbox"/> Schedule return visits | <input type="checkbox"/> | <input type="checkbox"/> | _____ |

Figure 1. *Respecting Choices* checklist for the advance care planning interview for adults with incurable, progressive disease. From Gunderson Lutheran Medical Foundation, copyright 2000.²³

groups and frequent media exposure (eg, radio, television, newspaper) related to the importance of ACP. It emphasized coalition building between health care, legal, civic, and religious organizations.

The facilitated discussion intervention was typically led by a nonphysician health care professional (eg, medical ethicist, nurse, social worker, pastoral counselor, or highly selected volunteer). It aimed at helping patients and their loved ones to discuss the patient's wishes for end-of-life care, explained the benefits and burdens of medical treatments at the end of life, and focused on clearly defining and documenting the patient's wishes so as to be readily available later for the patient's health care agent and attending physician.

Similar to other communities, only 15% of adults in the general population of La Crosse had advance directives before the intervention. In contrast, after the intervention, 85% of all patients who died during a 1-year study had written advance directives.¹² Furthermore, 96% of these documents were readily available in the decedent's medical record, and in 98% of cases, the patient's wishes were followed.¹² The La Crosse program has since been recognized as a "best practice" by the National Coalition on Health Care and the Institute for Health Care Improvement.

The success of the La Crosse study has not previously been documented in a prospective randomized trial, but the retrospective clinical experience strongly suggests that the program has had a markedly positive effect

on end-of-life care.¹² The *Respecting Choices* intervention promotes early intervention in ACP rather than waiting until a medical crisis; provides training to facilitators in ACP and gives structure to their interviews with patients and agents; specifically encourages patients to discuss their wishes for medical care at the end of life with their loved ones and their physicians; and documents such wishes in the medical records of area hospitals.

Interpretation of the excellent results obtained in the La Crosse study is somewhat difficult because it was not a randomized trial and it relied on a historical control to assess the impact of the intervention. The program has several components, and their relative contributions are unclear. For example, it is unclear to what extent the good results are owing to the community educational outreach and to what extent they are owing to the facilitated interview.

A basic tenet of the La Crosse intervention is that ACP should be revisited periodically to ascertain any changes in patients' values over time with regard to what constitutes an acceptable quality of life. However, some patient desires are relatively consistent. Most people want their treatment preferences known. They conceive of a "good death" experience as including good symptom management, good personal care, a sense of trust in their health care professionals, the ability to make practical preparations for end of life, the ability to complete personally important life tasks, and being treated as a "whole person."^{17,18} Other desires may change with time and progression of disease. When people experience health state changes, they often change their perceptions of what constitutes an acceptable quality of life.^{19,20} For example, patients may become more tolerant of pain or disability than they had previously imagined would be acceptable to them. These "response shifts" occur as part of human adaptation.²¹ Response shift phenomena have significant implications for treatment outcomes research²²⁻²⁴ and medical decision making.²⁵ Accordingly, advance directives created when patients were relatively healthy may no longer be valid when they are approaching death.²⁶ This shifting of values has significant ramifications for end-of-life care planning and for ensuring that patients' current wishes are clear to their health care agents. The present study thus sought to document and investigate response shifts in patient values and to examine whether facilitating a clearer understanding of the benefits and burdens of treatment leads to changes in or clarification of patients' values and concepts regarding what constitutes an acceptable quality of life.

The primary purpose of the present work was to evaluate the importance of the facilitated interview portion of the La Crosse intervention in a prospective randomized trial conducted in a different part of the country and studying a different patient mix. This work is a pilot study to test the hypothesis that the facilitated interview used in the La Crosse intervention is effective in improving short-term outcomes associated with end-of-life care. Specifically, we studied outcomes such as (1) patient-agent congruence as to patient wishes for end-of-life care, (2) patient knowledge about the legal and practical aspects of ACP, and (3) the agent's comfort with his or her role. A secondary objective of the present work was to examine whether the La Crosse intervention affected patient preferences by educating the patient about

the benefits and burdens of end-of-life care. In addition, we determined the feasibility of performing a large randomized clinical trial of the La Crosse intervention to document long-term outcomes.

RESULTS

RECRUITMENT RESPONSE RATE

Of 337 patients who received letters, 61 (18%) agreed to participate in the trial. Of 11 elderly residents of an independent living facility who indicated interest in the study after the informational meeting, 5 (45%) were enrolled in the study and randomized. The most prevalent reasons for refusing to participate included already having a health care agent, lack of interest in the topic, and not having transportation.

Five patients dropped out of the study after the intake interview, leaving a total of 61 (92% of those randomized) with complete baseline and follow-up data. Of the 61 enrolled patients, 31 were randomized to the *Respecting Choices* intervention group and 30 to the standard care control group (ie, simply being given a statutory Massachusetts Health Care Proxy form to fill out). Five patients who did not have a designated health care agent at the beginning of the study did not subsequently identify a health care agent. One of these patients received the *Respecting Choices* intervention. Ninety-five percent of the health care agents provided complete data.

DESCRIPTIVE STATISTICS OF PILOT TRIAL PARTICIPANTS

Of the 61 randomized participants, 51 were women and 10 were men. The mean age was 80 years (range, 65-92 years). The study sample was predominantly white, and most had at least some college education. About 85% of the participants were Christian, and more than half of the participants indicated that spiritual practice was important to their well-being. The 2 study arms were comparable on all of the sociodemographic variables examined (**Table 1**).

IMPACT OF THE INTERVENTION

Patients and health care agents in the *Respecting Choices* intervention demonstrated greater congruence in reporting the patient's goals for treatments at the end of life than did those in the control group, with 76% of the *Respecting Choices* group in complete agreement vs 55% of the control group (ES of difference in overall congruence index=0.43) (**Figure 2**). *Respecting Choices* participants also demonstrated a greater increase in knowledge about ACP (ES=0.22), and their health care agents demonstrated a greater degree of comfort with their potential responsibility than did those in the control group (ES=0.31) (**Table 2**).

RESPONSE SHIFT EFFECTS

Comparing the results of preintervention and postintervention assessments, participants in the *Respecting Choices* intervention became less willing to undergo life-sustaining

Table 1. Sociodemographic Characteristics of 61 Study Patients*

| Characteristic | <i>Respecting Choices</i> ²⁸ | | P Value |
|---|---|---------------------------------|---------|
| | Interview (n = 31) | Nondirective Interview (n = 30) | |
| Age, mean ± SD, y | 79.88 ± 7.47 | 80.83 ± 4.82 | .55 |
| Mini-Mental State Examination score, mean ± SD | 28.2 ± 1.65 | 27.9 ± 1.80 | .50 |
| Sex | | | |
| M | 3 (10) | 7 (23) | .15 |
| F | 28 (90) | 23 (77) | |
| Race or ethnicity | | | |
| White | 30 (97) | 27 (90) | .51 |
| Other | 1 (3) | 2 (7) | |
| Marital status | | | |
| Married | 14 (45) | 10 (33) | .34 |
| Not married | 17 (55) | 20 (67) | |
| Education | | | |
| Grades 1-8 | 0 | 2 (7) | .93 |
| Grades 9-11 | 0 | 1 (3) | |
| High school graduate | 11 (36) | 5 (17) | |
| Some college | 7 (23) | 8 (27) | |
| Junior college (2 y) | 1 (3) | 5 (17) | |
| College degree (4 y) | 6 (19) | 5 (17) | |
| Advanced degree | 5 (16) | 4 (13) | |
| Religion | | | |
| Catholic | 13 (42) | 10 (33) | .70 |
| Other Christian | 11 (35) | 15 (50) | |
| Jewish | 3 (10) | 2 (7) | |
| Other | 1 (3) | 2 (7) | |
| Spiritual practices add to your sense of well-being | | | |
| A great deal | 16 (52) | 21 (70) | .34 |
| Somewhat | 11 (35) | 4 (13) | |
| A little | 1 (3) | 3 (10) | |
| Not at all | 2 (6) | 2 (7) | |

*Data are given as number (percentage) except where indicated otherwise. Rounding of percentages to whole numbers yielded a sum greater than 100 in some cases. Some groups do not sum to total sample because of missing data.

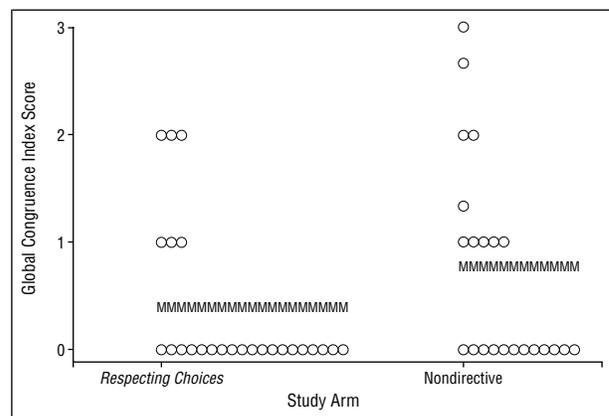


Figure 2. Patients and health care agents in the *Respecting Choices*²⁸ intervention group demonstrated greater congruence in reporting the patient's goals for treatments at the end of life compared with controls receiving nondirective standard care (effect size = -0.43). Ms represent the mean of the distribution, and open circles represent the distribution.

treatments for a new serious medical problem (ES = -0.25) and more willing to undergo such treatments for an incurable progressive disease (ES = 0.24), suggesting a response

Table 2. Effect Sizes of Trial Outcomes*

| Variable | Respecting Choices ²⁸ Interview | Nondirective Interview | Effect Size |
|--|--|------------------------|-------------|
| Patient-agent congruence score (Global Congruence Index (E subject-proxy)), mean (SD) | 0.37 (0.70) | 0.73 (0.96) | -0.43 |
| Global Congruence Index score of zero, No./Total No. (%) | 19/25 (76) | 12/22 (55) | 0.23 |
| Knowledge score, mean (SD) | | | |
| Baseline | 5.9 (2.4) | 6.2 (2.3) | 0.22 |
| Follow-up | 7.4 (1.4) | 7.1 (2.5) | |
| Change, follow-up – baseline | 1.5 (2.5) | 0.9 (2.9) | |
| Health care agent comfort score, mean (SD) | 13.05 (3.21) | 12.25 (1.94) | 0.31 |
| Treatment preference change (ie, response shift in values), mean (SD) | | | |
| Coma | -0.29 (2.84) | -0.88 (4.89) | 0.15 |
| Incurable progressive disease | 0.10 (3.57) | -0.81 (4.01) | 0.24 |
| End-stage terminal illness | -0.12 (3.63) | -0.23 (3.32) | 0.03 |
| New serious medical problem | -1.74 (5.61) | -0.52 (4.24) | -0.25 |
| Beliefs and Values Questionnaire score (ie, response shift in quality of life conceptualization) | | | |
| Baseline, mean | 52.80 | 48.43 | -0.78 |
| Follow-up, mean | 48.62 | 48.53 | |
| Change, follow-up – baseline, mean (SD) | -4.18 (6.6) | 0.09 (4.4) | |

*These clinical effect sizes represent the magnitude of change during follow-up in units of SDs, where an effect size of 0.20-0.40 is considered small, 0.41-0.79 is considered medium, and ≥ 0.80 is considered large.

shift in values (Table 2). The intervention group also became less willing to tolerate poor health states (ES=0.78), suggesting a response shift in conceptualization of quality of life (Table 2). There were no small, medium, or large ESs for comparisons of change during follow-up on the visual analog scale items for pain, anxiety, or alertness, and there were no significant then-test minus baseline differences on these items, suggesting that participants in both arms did not make response shifts in internal standards (data not shown). Thus, patients did not seem to recalibrate their standards for quality-of-life outcomes but rather to reflect on and define their own values after having a better understanding of benefits and burdens of end-of-life care. This in turn led to different wishes with respect to potential end-of-life medical decision making.

FEASIBILITY

Our experience suggests that performing a larger randomized trial is feasible and desirable for statistical validation of the *Respecting Choices* intervention. All of the participants in this pilot trial completed the *Respecting Choices* interview in one session that lasted 1 to 2 hours. We also believe that specific steps can be taken to improve the design of the trial reported herein and that this would enhance the results obtained. By modifying study procedures over the course of the pilot trial, we increased enrollment and reduced the risk of attrition. One significant modification included offering interviews in the patient's home. Once we moved data collection from the medical school to the patient's home, half of the patients who initially refused to participate because of transportation problems enrolled in the study. For a larger trial to recruit participants easily, it will be important to conduct interviews in the home. A second significant modification involved contacting patients' health care agents in person regarding the need for follow-up participation rather than relying on the patient to inform the agent of his or her participation. We were able to increase the agents' response

rates from 33% to 95% when we made personal contact with the agents.

COMMENT

We conclude that the *Respecting Choices* intervention seems to have a beneficial effect on patient-agent congruence in understanding the patient's goals for end-of-life care. This intervention also improves the patient's knowledge about ACP and the agent's level of comfort with the role of health care agent. Furthermore, it seems that the *Respecting Choices* intervention led to appropriate changes in patient desires for specific treatments based on their own values of quality of life and on a better understanding of the burdens and benefits associated with these medical decisions. It led to specific changes in preferences for life-sustaining treatments in some hypothetical health state scenarios. These changes may reflect response shifts in values and clearer concepts of quality of life. These values and concepts became clarified as patients were given the opportunity to reflect on their personal priorities and to discuss them at length with their health care agent, usually the family member closest to them. They sometimes modified their wishes as they became more knowledgeable about the true benefits and burdens of life-sustaining treatments based on their own current and likely future health states.

There was a notable discrepancy in intervention participants' preferences for life-sustaining treatments: there was increasing conservatism regarding life-sustaining treatments for a new serious medical problem, but patients became less conservative in their preferences for life-sustaining treatments in the context of a progressive chronic disease. Increasing conservatism has been documented in health care providers, compared with laypeople, and has been postulated to reflect a better understanding of the true advantages and disadvantages of such treatments by health care professionals.³⁵ This explanation could account for the greater reluctance of intervention patients to undergo life-

sustaining treatment for a new serious medical problem. However, the greater acceptance of life-sustaining treatment for a progressive chronic disease suggests that a better understanding of the benefits and burdens of treatments does not always lead to more conservative treatment preferences. This discrepancy in the intervention patients' treatment preferences between new and chronic disease may reflect how rational principles of weighing the benefits and burdens of treatments may have less impact in situations that are emotionally salient. Research on cognitive-experiential self theory and other dual-mode processing theories suggests that rational and experiential modes of decision making operate in tandem.³⁶ The situational context determines which system prevails. The same rational principles can operate in 2 different situations, but the decisions reached may be different if one situation is more emotionally meaningful than the other. In the present study, patients were perhaps more experienced with a chronic progressive disease situation. They may have already suffered a good deal to sustain life but found life still to be worth living. They might accordingly have been less willing to forego life-sustaining treatments for a more familiar situation. With a new disease, on the other hand, a patient would simply be choosing between the benefits and burdens of treatments emphasizing the rational rather than the emotional mode of processing. It may thus have been easier to apply their new knowledge to the new problem. On a purely rational basis, dealing with a hypothetical (and therefore less emotionally salient) situation, their decision did not favor life-sustaining treatment.

The *Respecting Choices* intervention seems to have a beneficial effect on short-term outcomes with respect to patients' wishes being understood by their health care agents. Thus, it should help ensure that any ultimate decision by the health care agent will be more consistent with the patient's wishes. The intervention also helps to clarify the patients' wishes in their own minds and in their agents' minds. This clarification seems to be based on thoughtful reflection and better understanding of the issues involved. The effects noted in this study were all moderate in magnitude and lacked compelling statistical validity owing to the small size of the study population. Although we believe that actual end-of-life care will be more consistent with the patients' wishes for many of the study participants, it was impossible to document this in a small study with only a 2-month follow-up. There were no deaths among our study participants.

We were surprised to find as high as 55% "absolute congruence" between patient and health care agent in the control group. We wondered if the necessary constraints of our research study—and especially the need for informed consent—may have constituted an inadvertent form of intervention. To recruit patients for the study required explanation of its importance. To obtain informed consent required a more detailed discussion of the importance of patient/family dialogue about end-of-life decision making, including the potential need for a facilitator. When randomized to the control group, patients may have believed that they had missed out on a potentially important benefit. They may have had a greater sense of the need for patient/family dialogue. This may have increased their desire to have a thorough discussion with their health care

agent. If so, the benefits of the intervention we documented might have been more striking compared with a more typical (ie, nonresearch study) patient group.

The feasibility of implementing this trial in a larger population was assessed by investigating the recruitment response rate and the follow-up response rate and by identifying any procedures that might be modified to improve the results of the larger trial. Our experience thus far suggests that performing a large randomized trial is feasible and that specific steps can be taken that will enhance its results. During the pilot trial, we modified our mode of data collection from paper-and-pencil self-reporting conducted primarily at research offices in the medical school setting by the patients to semistructured interviews performed by facilitators in the home. We also modified the intake and randomization procedures so that they were conducted by impartial research staff rather than trained *Respecting Choices* facilitators who had an emotional commitment to the facilitated discussion intervention. These changes enhanced the patient response rate in the pilot trial and also led to an improved study design for a larger trial. In addition, these changes are also likely to have added random error to our measured outcomes, reducing our statistical power for the pilot trial analyses. This situation provides further justification for relying on clinical ES analyses rather than inferential statistics (ie, reliance on *P* values) for the outcomes evaluation of the pilot trial.

Findings from the pilot trial also convinced us of the need to implement a communitywide intervention to change the cultural norms about ACP. Despite the apparent simplicity of the La Crosse intervention, our experience has been that its implementation is complex. There are significant barriers to promoting advance directives despite addressing deficits in information and access.¹⁵ Increasing public awareness of the need for ACP would assist in recruiting patients into an advance directive initiative. Many patients and families are reluctant to discuss such issues. There needs to be encouragement of such discussions on the part of patients and families by civic and religious groups and the medical profession. Furthermore, there seemed to be a general misunderstanding among potential participants that simply designating a health care agent constitutes adequate ACP. People need to understand that the agent must be thoroughly informed about the patient's wishes. Discussing end-of-life care touches on many sensitive matters, including medical, psychosocial, spiritual and religious, and socioeconomic issues. These sensitive and often difficult discussions between patient and health care agent usually do not happen if left to chance. Also, patients and agents often lack the specific information needed to make truly well-informed decisions. Although many physicians make an effort to provide such information, often the time required and the complexity of the issues makes it unrealistic to expect the physician to facilitate a thorough discussion between patients and their health care agents. Having a trained nonphysician facilitator, usually a nurse or social worker with considerable experience in end-of-life care, helps ensure that an adequate dialogue occurs between patients and their health care agents or family members. It would also be worthwhile to implement the La Crosse intervention in community settings with significant numbers of elderly

people, such as independent living facilities. Successfully influencing the end-of-life experience for an entire community entails recognizing and anticipating such complexities and developing culturally sensitive approaches for outreach, recruitment, and intervention.

Implementation of procedural improvements identified during this study would enhance results, but it is still advisable that a subsequent trial be powered to detect a moderate ES (ie, at least 62 patients per study arm). It would also be desirable to carry out long-term follow-up so that the ultimate impact of the intervention on actual end-of-life experience can be documented. We conclude that performing a randomized trial comparing the *Respecting Choices* intervention is feasible and that procedural modifications identified in this trial would enhance its results. Pending further study, this preliminary randomized trial confirms the benefit of a facilitated discussion of ACP, as first described in a retrospective clinical study from La Crosse, Wis.¹²

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Intervention flowchart available from the authors.

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