ONLINE FIRST

Improving the Science and Politics of Quality Improvement

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QUALITY AND SAFETY ARE CRITICAL ISSUES FOR health care systems around the world and have appropriately been highlighted in ongoing efforts to reform and improve health care. Care of critically ill patients is a domain in which issues of quality and safety take on monumental importance because of the severity of illness and the complexity of providing high-quality critical care.

In this issue of *JAMA*, Scales and colleagues[1] report the results of an important study designed to evaluate the effectiveness of quality improvement efforts in community-based critical care units in Ontario. The authors use a multifaceted "knowledge transfer" intervention including education, dissemination of algorithms, and audit and feedback, transferred through an interactive telecommunication strategy. The goal of the intervention was to increase adherence to 6 quality measures that have been documented to improve patient outcomes: prevention of ventilator-associated pneumonia (VAP), prophylaxis for deep venous thrombosis (DVT), daily spontaneous breathing trials, prevention of catheter-related bloodstream infections, early enteral feeding, and prevention of decubitus ulcers. Although debate remains about some of the evidence supporting these measures, there is general consensus that appropriate implementation of each measure can decrease risk of harm for critically ill patients.

Numerous studies have investigated the value and implementation of these quality measures, but the study by Scales and colleagues has several notable features. First, the design and implementation reflect state-of-the art methods for a study evaluating quality improvement and advancing the state of science. Second, the study design, knowledge transfer intervention, and analyses are extremely complex but appropriate to the complex phenomenon under study. Third, the results were positive, documenting significant improvement in quality, although benefits were modest. Fourth, this study—with its state-of-the-art, complex methods—was funded by the Ontario health care delivery system rather than a research funding agency, which has important policy implications for improving health care in North America and beyond. Each of these 4 points warrants further discussion.

Many studies have been designed to improve health care quality, but relatively few are randomized trials. Although much can be learned from nonrandomized and nonexperimental studies, the authors' use of a randomized design with an appropriate control group improves their ability to control for bias and greatly enhances the ability to draw causal inferences. An observational study with historical controls would be unable to exclude temporal change as an explanation for the findings. These authors also addressed the problems that result from having the control group receive no intervention by using the same knowledge transfer intervention targeting different quality measures in pairs. Each intensive care unit was randomly assigned to simultaneously be the experimental group receiving the knowledge transfer intervention for one quality measure (eg, VAP prevention) and the control group receiving no knowledge transfer intervention for the other measure of the pair (eg, DVT prophylaxis). Additional innovative methods included a "decay-monitoring period" demonstrating that the improvements persist and qualitative interviews with participants to explore mechanisms of action and facilitators of success.

Another feature of this study is its complexity. Rather than using the standard scientific method of changing one variable and examining its effect, the authors designed a multifaceted knowledge transfer intervention. Yet this complexity is not only appropriate; it is essential. Years of research suggest that multifaceted interventions are needed to change clinician behavior and transfer knowledge of best practices into the complicated health care system.[2-4] The cluster randomized design is appropriate for an intervention targeting the hospital, yet requires complex statistical approaches to account for clustering by center, can significantly reduce effective sample sizes (if intracluster correlations are high), and substantially reduces effectiveness of randomization, thereby increasing risk of randomization imbal-

See also p 363.

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ances. Cluster randomized trials are complex to design, conduct, analyze, and interpret. The primary outcome in this study—a summary ratio of odds ratios—is also complicated yet appropriate for the primary research question: does this multifaceted knowledge transfer intervention improve quality across a series of measures?

The answer to the primary research question is yes, the intervention improved quality—yet the improvement was relatively modest. There was significant improvement in adherence to quality measures in the intervention sites compared with the control sites across all quality measures, but improvement in individual measures was less clear. Improvements were seen in only 2 of 6 measures, semirecumbent positioning to prevent VAP and precautions to prevent catheter-related bloodstream infections. Only the latter measure improved significantly compared with the control group. The findings were limited by relatively high adherence to some quality measures at baseline—a good problem to have, but one that makes it difficult to demonstrate an intervention effect. Furthermore, this study only examined changes in process measures assessing delivery of health care and did not demonstrate or examine differences in patient outcomes. Nonetheless, the focus on improvement in overall quality and on process measures was reasonable. Despite having more than 9000 intensive care unit admissions, this trial did not have the necessary sample size to find differences in patient outcomes. Such a trial would have been prohibitively large and expensive; requiring patient-level outcomes in every such study would slow progress.

Perhaps most interesting about this study is that this high-quality cluster randomized trial was funded not by a research funding agency but by an organization that funds delivery of health care. To make significant steps toward improving the quality of health care and controlling the rate of increase in health care costs, this is an important model for the future. In the United States, the Affordable Health Care for America Act calls for demonstration projects that document effective methods to improve quality and control costs. Using these demonstration projects to make significant advances will require the same type of rigorous, high-quality research used by Scales and colleagues. The use of health care reimbursement to encourage and enforce quality is a reality of the US health care system today and in the future, but these quality measures must be selected and implemented based on rigorous science, and the implementation must be demonstrated to be effective without unintended consequences that lower quality in other ways or other areas of health care.[5]

Despite efforts to develop rigorous quality measures and demonstration projects, there are a number of examples of significant problems and unintended consequences.[5-8] High-quality science in quality improvement is needed to minimize such problems. One way to promote high-quality science in this area is for research funding agencies to continue to fund projects that advance the science of quality improvement and knowledge transfer. Another is to ensure that agencies responsible for developing and implementing quality measures and demonstration projects are working in collaboration with the scientists and clinicians in the relevant fields. One example of this collaboration is the Critical Care Societies Collaborative (CCSC), which includes 4 of the largest scientific and professional critical care societies: the American Association of Critical-Care Nurses, the American College of Chest Physicians, the American Thoracic Society, and the Society of Critical Care Medicine.[9] Working in collaboration, the CCSC joined forces with the Department of Health and Human Services (DHHS) to design and implement quality improvement initiatives. The DHHS cannot work with each individual professional society, but large collaboratives like the CCSC offer an opportunity to bring together scientists, clinicians, and policy makers to develop and implement quality measures and reimbursement programs that improve quality and control costs.

Debate about the future of health care continues to rage and yet all parties agree about the importance of finding ways to maintain and improve quality while also controlling costs. The study by Scales and colleagues provides a good example to help in this quest.

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Insurers Test New Cancer Pay Systems

By **REED ABELSON**

Several large health insurers, including UnitedHealthcare and Aetna, are focusing on one of the country's most costly diseases: cancer.

The insurers have begun tightening oversight of the care provided to patients with many different types of cancer, hoping to lower expenses by experimenting with new ways to pay specialists.

UnitedHealthcare plans to announce on Wednesday a one-year project with five oncology practices, offering doctors an additional fee. The new fee is meant to encourage doctors to follow standard treatments rather than opting too often for individualized and unproven courses of therapy, which can include the most expensive drug combinations. By proposing a different type of payment structure, companies hope to lower doctors' dependence on a system that generates substantial sums for cancer specialists who routinely favor top-of-the line treatments.

Regional insurers in some states, including California, Washington and Pennsylvania, are negotiating similar limits with doctors and their clinics. WellPoint, another large insurer, is developing a way of paying oncologists to coordinate and manage patient care.

By almost any measure, cancer treatments can be exorbitantly expensive. Cancer care in the United States costs almost $100 billion a year, and medical bills for the average patient on chemotherapy can top $100,000 a year.

With the new health care law, everyone is under pressure to find ways to save money. Many specialists favor the most aggressive care even if there is little to no evidence the patient will benefit, because both doctors and patients have every incentive to spare no expense. Patients and their families often demand one last treatment. And oncologists can reap tremendous profits, sometimes earning more than half of their income on the difference between what they pay for chemotherapy drugs and what they charge the insurers for the patient's treatment plan.

Dr. Lee Newcomer, the oncologist who is heading the UnitedHealthcare program, said that yearly double-digit increases in the cost of cancer care had forced insurers to confront the issue. “Oncology, or cancer care, has been a bit of a sacred cow,” he said.

With life and death questions at stake, insurers and supporters are quick to promote the new measures as a way to extract cost savings and also as a way to ensure that terminally ill patients are not subjected to unnecessary, often exhausting treatments that provide no hope.

Still, detractors worry that these changes could represent a first step toward denying patients additional treatments or the latest chemotherapy regimen based solely on the cost. In other words, they argue that even if oncologists still decide what course of treatment a patient should receive, as these new plans allow, the new effort could be viewed as a move toward rationing care at the end of life.

“We do not want to get into the realm where they are restricting treatments when they are clearly indicated,” said Dr. David Eagle, an oncologist who is the president of the Community Oncology Alliance, a nonprofit lobbying group for community oncologists, who generally practice outside of an academic medical center.

“In my view, the insurance companies have the ultimate conflict of interest,” Dr. Eagle said. But many cancer specialists acknowledge that the current payment system is unsustainable. “It has all the potential to bankrupt the system,” said Dr. Michael Neuss, an oncologist in private practice in Cincinnati. He described the existing payment plans as “our dirty little secret.”

“A lot of us want to get out of selling drugs,” he said.

Companies are also springing up to develop treatment guidelines and serve as intermediaries between oncologists and health plans. US Oncology, a network of affiliated cancer doctors, teamed up with Aetna in May to develop a program to persuade doctors to follow treatment guidelines.

Another company, P4 Healthcare, is working with Highmark, a Pennsylvania insurer, and others. Cardinal Health, the large health care services company, bought P4 in July.

“There’s a lot of money to be made and saved,” said Dr. Peter Bach, a health policy analyst and physician at Memorial Sloan-Kettering Cancer Center in New York, who also served as a consultant to the federal Medicare program.

For example, doctors could choose less expensive therapies. When an oncologist considers different treatments, “it’s hard not to look at price differentials,” Dr. Bach said. In treating one type of lung cancer, for example, doctors can select from as many as eight treatments that are generally considered appropriate. Their costs under the Medicare program range from about $1,300 to $7,000 a month.

Dr. Marcus Neubauer, a doctor near Kansas City, Kan., whose practice is affiliated with US Oncology and one of the five involved in the UnitedHealthcare experiment, pointed to the effect of rising costs when people are required to pay a large amount of their overall medical bills. “It’s not just a payer problem; it’s a patient problem, too,” he said.

Some insurers say there may be savings if doctors just follow standard treatments, rather than a variety of alternative regimens, for patients with the same type of cancer. “In medical oncology, there is tremendous variability in the way care is delivered,” said Dr. Lonny Reisman, Aetna’s chief medical officer.

Aetna and US Oncology recently compared what happens when doctors treating certain lung cancer patients followed guidelines with what happens when the doctors did not. According to the analysis, treatment costs over a 12-month period were 35 percent lower when doctors adhered to standards, with no effect on patients.

Aetna is now working with about 250 doctors in Texas and says it plans to expand the program next year to include even more cancer specialists in its network. In California, Blue Shield joined with Hill Physicians Medical Group to treat a group of state workers in Sacramento. Local oncologists are being rewarded for saving money, but Hill has made sure the doctors are still getting paid even if the patients’ care becomes very expensive.

Joseph P. Newhouse, a health policy professor at Harvard who has studied how the Medicare payment system affects doctors’ choice of treatments, suggested that some payment options might give doctors an incentive to stop treatments if they lose money or make too much by not actively treating patients. “Wherever you set” the incentives, he said, “you’re going to make errors.”

In the UnitedHealthcare program, for example, oncologists still get a fee even if the patient is not getting chemotherapy. To make sure no one is stinting on care, the oncologists involved review one another’s treatment decisions and results. The doctors involved in the program say there is no danger that they will fail to treat patients who would benefit from another round of chemotherapy.

“These are patients we know by name,” said Dr. Bruce Gould, an oncologist outside Atlanta who is one of the participants. “As medical oncologists, our goal is to take care of these patients and keep them living as long as possible.”

Specialists do worry that the complexity of caring for cancer patients may make any hard-and-fast rules about treatments difficult. Dr. Neuss offered an example involving two drugs, with the cheaper one requiring patients to undergo a much longer treatment than the more expensive choice. “What’s the patient’s time worth in that equation?” he asked.

Dr. Newcomer of UnitedHealthcare acknowledged that some trade-offs were not clear cut but could be judged on factors like the difference in cost between the drugs — is it a few hundred dollars or a few thousand? “I think that’s a perfectly legitimate debate,” he said.

Clinician Integrity and Limits to Patient Autonomy

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A 28-year-old man with chronic granulomatous disease developed worsening respiratory status in the setting of chronic bacterial and fungal infections. The attending physician recommended transfer to the intensive care unit (ICU), but the patient declined. The patient understood that the nurses in the ICU have expertise in caring for patients with poor respiratory function. He also understood that he faced an increased risk of dying if he remained on the medical ward. At the same time, the patient was familiar with the nurses on the medical ward and felt comfortable there. Unsure of whether it was appropriate for clinicians to agree to provide less than optimal care for a critically ill patient, the clinicians on the medical ward requested a bioethics consultation. This article reviews the ethical issues that arise when patients ask clinicians to provide less than optimal care. Although it is well established that clinicians ought to respect patient autonomy, that obligation conflicted, in the present case, with the clinicians' sense of professional integrity. Future research on this vital but underexplored topic is needed to determine the extent to which clinicians' professional integrity places limits on the types of patient requests to which they should agree.

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RESPECT FOR PATIENT AUTONOMY plays a central role in modern clinical ethics,[1] and clinicians today are trained to provide care based on patients' preferences and requests.[2-4] However, patients occasionally request treatments that their clinicians think are inappropriate. In these cases, respect for patient autonomy can conflict with clinicians' professional integrity, forcing clinicians to decide to what extent their professional integrity places limits on the types of care they should agree to provide.

This dilemma arises because the physicians and nurses who provide medical care have rights and obligations of their own.[5] Patient autonomy can conflict with clinician autonomy and, in such a clash of values, it is not obvious which should prevail. Guidance is thus needed to help clinicians determine to what extent their professional integrity places limits on the types of care they should agree to provide.

BACKGROUND

Cases in which clinicians' personal values might conflict with the provision of patient care have received a good deal of attention.[6,7] For example, there has been significant discussion regarding whether pharmacists and physicians may refuse to be involved in providing emergency contraceptives based on their personal values.[8-10] This discussion concerns potential conflicts between clinicians' personal integrity and patient autonomy. There has been significantly less discussion about potential conflicts between clinicians' professional integrity and patient autonomy. How should clinicians approach cases in which the values, rights, and obligations that attend to being a clinician might conflict with respect for patient autonomy?

Potential conflicts between clinicians' professional integrity and respect for patient autonomy frequently arise in the context of cardiopulmonary resuscitation (CPR).[11] Several years ago, our hospital ethics committee was presented with the case of a patient with advanced cancer who clearly had just days to live. The physicians recommended a do not resuscitate (DNR) order, but the patient refused. He recognized that he was unlikely to live very long and that he had bony metastases, which made chest compressions much

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more likely to harm than to help him. However, the patient still wanted CPR because as he saw it he wanted to fight to the very end.

Several members of the ethics committee argued that CPR should be provided to the patient in the event of cardiac arrest. Clinicians, they said, should respect patients' preferences regarding end-of-life care. If the patient understands the risks and very low potential benefits and still wants to receive CPR, clinicians should agree to provide it.

Other ethics committee members were uncomfortable with agreeing to the patient's request, pointing out that chest compressions would not provide any benefit to the patient. Moreover, given the cancer in the patient's chest, there was a real chance that the clinicians performing the resuscitation would break the patient's ribs and possibly hasten or precipitate his death. This case was not just a matter of respecting patient autonomy, they argued. It is inappropriate for clinicians to provide certain types of care, even when patients request them.

Cases such as this might be evaluated in terms of futility.[12] Futility claims are straightforward—clinicians have no obligation to provide care that has no chance of success. In practice, however, it is rare for a patient to request a treatment that has absolutely no chance of benefit. Usually, there is a small chance of at least a little benefit. At the same time, the fact that there is some chance of benefit does not necessarily imply that clinicians must provide the requested treatment. When patients request a particular treatment, clinicians must consider whether it is appropriate for them to provide it.

This challenge introduces the clinician as an agent in the patient's care, thereby raising the possibility that clinician integrity—claims about the types of things that individuals as clinicians should and should not do—might place limits on the kinds of treatment they ought to provide. The case discussed below raises another variation on this theme. Rather than requesting a therapy with essentially no chance of success, the patient requested a therapy that in the clinicians' minds was suboptimal. This case is therefore not resolvable by reference to futility analysis. It raises instead the need for guidance on when professional integrity might limit the kinds of care clinicians should provide their patients.

CASE PRESENTATION

A 28-year-old man was diagnosed as a young child with chronic granulomatous disease, an inherited disorder of phagocytic cells that resulted in an inability to produce bactericidal superoxide anions, leading to recurrent and persistent infections. The patient, who had spent several years of his life in the hospital receiving treatment for bacterial and fungal infections, was well known to the hospital staff and had a good relationship with them. In early 2009, the patient was admitted to the hospital to prepare for a genetically modified stem cell transplant. At the time of admission, he was receiving intravenous caspofungin acetate and posaconazole to treat paecilimyces fungus, and piperacillin and tazobactam to treat chryseobacterium. For chronic pain episodes, he received narcotic analgesics.

After being in the hospital for 2 weeks, the patient was transferred to the intensive care unit (ICU) due to increasing respiratory distress. It was his fourth admission to the ICU during his life. This ICU admission involved intubation, tracheostomy, and placement of a percutaneous endoscopic gastrostomy tube. The 52-day ICU stay was very difficult for the patient. He was severely ill and underwent numerous invasive procedures. During this time, he told his physicians that he missed the nurses on the medical floor and did not feel comfortable with the ICU staff.

A Possible DNR Order

Once the patient's condition improved, he was transferred back to the medical floor. At that time, the primary team initiated discussions with the patient regarding a possible DNR order. The primary team felt that CPR would not be appropriate. They stressed to the patient that a DNR order applied only to CPR and would not limit or restrict the use of any other interventions. The patient objected to a DNR order and said that he wanted all available treatment, including CPR.

Despite the team's aggressive treatment, the patient's condition continued to worsen. After being hospitalized for 3 months, the patient developed a new severe infection and deteriorating respiratory status. He was given granulocyte transfusions 3 times a week and occasional transfusions of packed red blood cells. He developed chest wall abscesses. Gancyclovir and foscarnet intravenously were administered for treatment of cytomegalovirus infection. The primary team began discussions with the patient regarding possible transfer back to the ICU. The team explained that the ICU had experts in the kinds of care that the patient would require and that certain types of care, including intubation, could not be provided on the medical floor.

Although the patient recognized that he faced increased risks if he continued to receive treatment on the medical floor, he felt comfortable there. His stay in the ICU had been very difficult and he did not want to return. Although the patient wanted all possible care, he was willing to accept some increased risks, and some limits on his care, so that he could remain on the medical floor and continue to receive treatment there. The patient's family preferred that he be transferred to the ICU. However, they agreed that the ultimate decision was the patient's to make. They supported him in his desire to remain on the medical floor.

The physicians and nurses wanted to respect the patient's preferences. However, they also recognized that they would not be able to give optimum care if the patient remained on the medical floor. They were concerned that agreeing to the patient's request might lead to their being responsible for a poor outcome that could have been avoided if the patient were transferred to the ICU.

To discuss this concern, the staff requested a bioethics consultation.

Bioethics Consultation

The bioethics consultants met with the patient and determined that he was competent to make decisions. This assessment was consistent with previous evaluations by a consulting psychiatrist who had found the patient's mood to be appropriate to his situation and not experiencing any psychiatric disorder, including depression or anxiety. The patient clearly understood his condition, including the high likelihood that his health would further deteriorate and that he would require care best provided in the ICU. However, he was willing to accept the increased risks of remaining on the medical floor because he felt that it was his home away from home. The ICU was not a place to which he wanted to return, especially given the difficulties with his previous stay there.

The patient would not agree to preemptive ICU admission, but accepted that in the event of a full cardiopulmonary arrest he would be transferred to the ICU. Based on the primary team's concern that the patient equated a DNR order with their giving up on him, the bioethics consultants emphasized that a DNR order was limited to CPR and was consistent with the team providing other types of care, including aggressive treatments the patient might need. The patient indicated that he understood the nature of a DNR order, but still wanted to receive full resuscitative efforts in the event he needed them. He wanted all possible treatments that could be provided outside of the ICU, including CPR.

The bioethics consultants presented several options for transferring the patient to the ICU, including having a nurse from the medical floor with whom the patient was familiar provide care in the ICU. Although the patient wanted all treatments that had a chance of helping him and keeping him alive, he also wanted to remain on the medical floor and would not agree to be transferred to the ICU. If that preference meant that he would not receive certain treatments, he was willing to accept those risks. The bioethics consultants wondered how best to balance respect for the patient's preference to remain on the medical floor with the clinicians' concern that they were being asked to provide less than optimal care to a critically ill patient.

COMMENT

The first issue this case raises is whether it is acceptable to try to persuade patients to pursue optimal care. Clinicians should always encourage patients to seek care that promotes the individual patient's medical interests. It might be thought that this approach fails to respect patient autonomy. By this view, once the patient stated his preference to remain on the medical floor, the clinicians should not have engaged in any further discussion about his reasons, his understanding, or the wisdom of his decision. Such discussions could have been seen as an inappropriate abrogation of the patient's autonomy.

This view regards autonomy as so fragile that it can be undermined by the slightest hint of a contrary view or questioning. This view of what it means to respect autonomy is mistaken and is inconsistent with both classic philosophic conceptions of autonomy and with medical ethics.[13,14] Mill, an ardent defender of individual liberty and autonomy, argued that liberty is only achieved by the free exchange of ideas and in trying to persuade one another of the superiority of one view of the world over another.[15] Autonomy is not achieved by being protected from disagreements and contrary views. In the present case, the clinicians showed respect for the patient as a competent adult by engaging him in dialogue and debate, and encouraging him to accept transfer to the ICU.

The more difficult question is how to proceed when efforts at discussion and persuasion fail. Clinicians should not go beyond encouraging competent patients to forcing or coercing them; doing so would be going too far. At some point, clinicians need to accept that at this time at least the patient's request represents the considered preferences of a competent adult. This conclusion highlights the central question of this case: When should clinicians agree to patient requests that involve the clinicians in providing less than optimal care?

There always are limits for good reasons on the types and extent of care that physicians and nurses provide. Some of these limits derive from the multiple missions of the hospital and multiple patients who are in a hospital at any given time. Hospitals need to be organized in a way that makes sense as a system. Limitations on clinical care are determined by many factors and parties—by state licensing laws, the US Food and Drug Administration, hospital administrators, insurance companies, quality improvement programs, institutional review boards, and other entities and organizations.

Although some degree of pluralism is beneficial, clinicians are not always obligated to grant their patients' wishes (eg, a patient who prefers giving birth in the hallway rather than in a delivery room). Repeatedly deciding which treatments would be provided where, and which exceptions would be allowed when, inevitably would take time and energy away from the hospital's primary mission. Efficiency, fairness, and cost-effectiveness are good reasons to place limits on the extent to which clinicians accept patient requests.

This case highlights an important feature of patient autonomy as it developed in bioethics, clinical practice, and health law. Clinicians respect patient autonomy, but nonetheless constrain the range of choices over which patients may exercise autonomy.[16,17] Patients may choose among the options within the proffered range, but they cannot go beyond it. In this way, patient autonomy has boundaries and limits.

The patient's right to forgo treatment is stronger than the right to receive a particular treatment. Competent patients can refuse most treatments, no matter how potentially beneficial they might be. Patients do not have the same authority to demand treatments, in part, because treatment usually requires the participation of a clinician. Thus, the clinician's own moral agency is engaged. Some treatments are not appropriate for clinicians to provide, even when competent patients request them. Clinicians have rights and interests too, some of which derive from their status as medical professionals.

To consider the aspect of clinician integrity most central to the present case, clinicians can refuse to agree with patient requests that involve treatments outside their range of expertise. Expertise is not dichotomous; some clinicians have more expertise than others at caring for patients with certain diseases. For example, many internists provide care for conditions like asthma for which others may have more expertise. However, clinicians may refuse to provide care if they do not feel they have the necessary expertise. In addition, in some cases, the clinician's professional obligations suggest that he or she should refuse to provide the requested care. If a patient asks a general practitioner to perform a complex surgical procedure, the clinician should decline to do so, even if the patient understands that the physician is not a surgeon and even if the patient states clearly that he or she will not hold the clinician responsible for any adverse outcomes that might result from the operation. The clinician should decline to perform the procedure because clinicians have a beneficence-based obligation to do what is best for the patient that must be balanced with an autonomy-based obligation to do what the patient requests. Assuming a more skilled surgical practitioner is available, the clinician who declines to perform the surgical procedure is not interfering with the patient's autonomous right to treatment, only with the patient's choice of practitioner.

The question in this case is whether keeping the patient on the medical floor is more like a general practitioner treating uncomplicated asthma, or more like a general practitioner performing a complex surgical procedure. The answer is not completely straightforward and depends in part on the patient's severity of illness. The more severe the illness, the greater the chance that providing less than optimal care may lead to the clinician contributing to a bad outcome that could have been avoided had the clinician not agreed to the patient's request.

The issue of whether the clinicians should agree to the patient's request to remain on the medical floor raises several questions. Should the hospital administration force clinicians to provide care for the patient on the medical floor? The answer to that is surely "no." The more important question is if clinicians are willing to provide the care, should they be permitted to do so? The answer to that is "yes." Such a decision by a clinician involves providing therapy that is beyond the expertise of the clinician, but is not a therapy for which another, more skilled, practitioner could easily be found. Instead, it is an idiosyncratic intervention that is to be provided primarily because it is consistent with the patient's value system. All clinicians would not feel comfortable providing such care, but some might and they should be permitted to do so.

If the clinicians were unwilling to provide the requested care, they would have other options. They could try to find other clinicians in the hospital who would provide the care the patient requested or they could try to transfer the patient to another hospital. In the present case, the clinicians agreed to provide the care, recognizing that even less than optimal care might do some good. If clinicians choose such a course of action, they should clearly document the rationale for the unorthodox care. Such documentation should include the details of the discussion with the patient, the grounds for finding that the patient had decisional capacity, and the clinician's recommendations and concerns regarding the patient's choice of treatment.

OUTCOME OF THE CASE

The primary team and the patient agreed that he would remain on the medical floor based on a clear understanding of the limitations that doing so placed on the care he could receive and the extent to which he would face greater risks. The patient also wanted to receive CPR with an agreement that he would be transferred to the ICU in the event of a cardiopulmonary arrest. On this basis, a care plan was developed to make the patient as safe as possible. The patient was placed in a room close to the nurses' station, and his family stayed in the room with him. The ICU team was informed that the patient was at high risk for needing to be intubated in the very near future. With this plan in place, the patient remained on the medical floor while his clinical status continued to decline. Three days later, he agreed to a DNR order, accepting that the team would do everything else it could to help him. However, the next morning, the patient died due to respiratory arrest.

CONCLUSIONS

Respect for patient autonomy is important, but has limits. Some limits are the result of institutional considerations, like efficiency and fairness. Clinician integrity also places limits on the kinds of patient requests that clinicians should accept. This is especially true when the patient asks the clinician to provide unusual care, as opposed to the patient refusing treatment or asking to be left alone. Future research is needed to help define this concept and its implications, including the nature of clinicians' professional integrity and the extent to which it places limits on the types of care clinicians should agree to provide. In the meantime, physicians and other members of the health care team will have to use sound judgment to determine how to proceed in individual cases.

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Study concept and design: Lantos, Matlock, Wendler.
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> Of work comes knowledge, of knowledge comes fruitful work; of the union of knowledge and work comes the development of intelligence.
>
> —Vinoba Bhave (1895-1982)

Mind Matters in Cancer Survival

David Spiegel, MD

MODERN MEDICINE HAS FOCUSED SO INTENTLY ON fighting disease that it has overlooked a natural ally in the battle—the patient's personal mental management of the stresses associated with cancer. Even at the end of life, helping patients face death, make informed decisions, mobilize social support, and control pain is not only humane but also may be medically more effective than simply continuing aggressive anticancer treatment. For example, in a randomized clinical trial of palliative care for non–small cell lung cancer,[1] patients who received an average of 4 visits that focused on choices about resuscitation preferences, pain control, and quality of life lived longer than those who received standard anticancer care (median survival, 11.65 vs 8.9 months; $P = .02$). This apparently counterintuitive finding suggests that emotional support is not only psychologically beneficial but also medically efficacious. Moreover, the palliative care intervention also improved the quality of life by reducing depression.[1]

How could confronting death at the end of life lead to living longer? There is increasing evidence that social support affects survival.[2,3] Social isolation is associated with increases in all-cause mortality risk to the same degree as smoking or high cholesterol levels.[4] Individuals tend to die after rather than before their birthdays and major holidays, suggesting some ability to postpone death for a short period to reach a meaningful goal.[5] Conversely, depression is an independent predictor of shorter cancer survival.[6] Death is inevitable but is modifiable by psychosocial factors, even at the end of life. However, early support groups for patients with cancer in the 1970s led to concerns that watching others die of the same disease would be demoralizing and might even hasten death. On the contrary, women with advanced breast cancer benefitted from serious discussions about death and dying and showed no signs of depression or panic.[2] Indeed, initial studies, now confirmed by many others, indicate that facing death and discussing it openly reduces distress and pain.[2,3,7,8]

Importance of a Supportive Setting

Studies of social support and survival suggest that facing death in a supportive setting helps patients with cancer live longer. An early clinical trial demonstrated that women with metastatic breast cancer randomized to a year of weekly group therapy lived 18 months longer than control patients.[2] The finding was not attributable to differences in initial disease severity or subsequent chemotherapy and radiotherapy. A replication study completed a decade later showed no overall effect of a similar group therapy intervention on breast cancer survival,[8] although there was a significant effect on a certain tumor subtype. Specifically, the group therapy–induced survival advantage was confined to those with estrogen receptor–negative breast cancer. Why the difference? Major advances in hormonal therapies and chemotherapies have improved overall survival for women with metastatic breast cancer in the interim. Notably, women with estrogen receptor–negative tumors benefit little from newer treatments that block estrogen receptors (selective estrogen receptor modulators) or inhibit the production of estrogen (aromatase inhibitors). Thus, it was those patients with the poorest prognosis, exempt from the benefits of improved hormonal treatment, who continued to show an increase in longevity in response to group therapy.

Accumulating data buttress the conclusion that in the absence of other more targeted and effective treatments, supportive care makes a difference to longevity. The findings are consistent in a variety of cancers with the poorest prognosis, including malignant melanoma, non–small cell lung cancer, leukemia, and gastrointestinal tract cancers: intensive emotional support extends survival. The variability in results stems primarily from studies of breast cancer. A recent randomized trial of group therapy for women with early-stage breast cancer found significantly reduced rates of relapse and longer survival.[3] However, 6 other studies, 4 of which involved patients with breast cancer, observed no survival benefit for those who received psychotherapy. Notably, 3 of those 4 studies showed no psychological benefit of the intervention, making any possible survival advantage of the treatment unlikely. In the fourth study involving metastatic breast cancer, patients in the treatment group were significantly more depressed than those in the control group at baseline,[7] which would give the treatment group

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a poorer medical prognosis from the outset.[6] Importantly for breast and other cancers, when aggressive antitumor treatments are less effective, supportive approaches appear to become more useful.

Host Resistance Factors

How could living better at the end of life help cancer patients live longer? While a large portion of the variance in any disease outcome is accounted for by the specific local pathophysiology of that disease, some variability must also be explained by "host resistance" factors, including response to the stress of the illness. Such factors include the endocrine, immune, and autonomic nervous systems. Activation of the hypothalamic-pituitary-adrenal axis (HPA) is an adaptive response to acute stress, but over time, cumulative stress can lead to adverse physiological consequences, including abnormalities of glucose metabolism, hippocampal damage, accumulation of abdominal fat, and depression.[9] Women with metastatic breast cancer have flatter than normal diurnal cortisol patterns, and the degree of loss of daily variation in cortisol predicts earlier mortality with breast cancer.[10] Such HPA dysregulation is also associated with disruption of sleep and other circadian rhythms.[10] Abnormal cortisol patterns, in turn, can affect expression of oncogenes such as *BRCA1* and retard apoptosis of malignantly transformed cells. Abnormal levels of cortisol also may stimulate tumor proliferation via differential gluconeogenesis in normal and tumor tissue as well as activation of hormone receptors that promote tumor growth.

Chronic stress is known to suppress and dysregulate immune function, as has been shown extensively in animals and for which there is an increasing body of evidence in humans. The HPA hyperactivity associated with depression is associated with elevated levels of cytokines that affect the brain and trigger sickness behavior that overlaps with the symptoms of depression. HPA dysregulation also can enhance proinflammation, and tumor cells co-opt certain mediators of inflammation such as nuclear factor-*k*B, growth-promoting cytokines, and angiogenic factors to promote tumor progression and metastasis. Also, exposure to elevated levels of norepinephrine triggers release of vascular endothelial growth factor, which facilitates metastatic tumor growth. Therefore, the stress of advancing cancer is associated with endocrine, immune, and autonomic nervous system dysfunction that has consequences for host resistance to cancer progression.

In conclusion, it is plausible that interventions providing emotional and social support at the end of life have a positive influence on physiological stress-response systems that affect survival. A welcome additional effect is that these interventions also improve quality of life. Treating the patient with the disease, not just the disease within the patient, contributes to overall medical outcome. It is not simply mind over matter—but mind matters.

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ORIGINAL ARTICLE

Early Palliative Care for Patients with Metastatic Non–Small-Cell Lung Cancer

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ABSTRACT

BACKGROUND

Patients with metastatic non–small-cell lung cancer have a substantial symptom burden and may receive aggressive care at the end of life. We examined the effect of introducing palliative care early after diagnosis on patient-reported outcomes and end-of-life care among ambulatory patients with newly diagnosed disease.

METHODS

We randomly assigned patients with newly diagnosed metastatic non–small-cell lung cancer to receive either early palliative care integrated with standard oncologic care or standard oncologic care alone. Quality of life and mood were assessed at baseline and at 12 weeks with the use of the Functional Assessment of Cancer Therapy–Lung (FACT-L) scale and the Hospital Anxiety and Depression Scale, respectively. The primary outcome was the change in the quality of life at 12 weeks. Data on end-of-life care were collected from electronic medical records.

RESULTS

Of the 151 patients who underwent randomization, 27 died by 12 weeks and 107 (86% of the remaining patients) completed assessments. Patients assigned to early palliative care had a better quality of life than did patients assigned to standard care (mean score on the FACT-L scale [in which scores range from 0 to 136, with higher scores indicating better quality of life], 98.0 vs. 91.5; P=0.03). In addition, fewer patients in the palliative care group than in the standard care group had depressive symptoms (16% vs. 38%, P=0.01). Despite the fact that fewer patients in the early palliative care group than in the standard care group received aggressive end-of-life care (33% vs. 54%, P=0.05), median survival was longer among patients receiving early palliative care (11.6 months vs. 8.9 months, P=0.02).

CONCLUSIONS

Among patients with metastatic non–small-cell lung cancer, early palliative care led to significant improvements in both quality of life and mood. As compared with patients receiving standard care, patients receiving early palliative care had less aggressive care at the end of life but longer survival. (Funded by an American Society of Clinical Oncology Career Development Award and philanthropic gifts; ClinicalTrials.gov number, NCT01038271.)

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THE QUALITY OF CARE AND THE USE OF medical services for seriously ill patients are key elements in the ongoing debate over reform of the U.S. health care system.[1] Oncologic care is central to this debate, largely because anticancer treatments are often intensive and costly.[2] Comprehensive oncologic services for patients with metastatic disease would ideally improve the patients' quality of life and facilitate the efficient allocation of medical resources. Palliative care, with its focus on management of symptoms, psychosocial support, and assistance with decision making, has the potential to improve the quality of care and reduce the use of medical services.[3,4] However, palliative care has traditionally been delivered late in the course of disease to patients who are hospitalized in specialized inpatient units or as a consultative service for patients with uncontrolled symptoms.[5,6] Previous studies have suggested that late referrals to palliative care are inadequate to alter the quality and delivery of care provided to patients with cancer.[7,8] To have a meaningful effect on patients' quality of life and end-of-life care, palliative care services must be provided earlier in the course of the disease.

Metastatic non–small-cell lung cancer, the leading cause of death from cancer worldwide,[9] is a debilitating disease that results in a high burden of symptoms and poor quality of life; the estimated prognosis after the diagnosis has been established is less than 1 year.[10-12] We previously found that introducing palliative care shortly after diagnosis was feasible and acceptable among outpatients with metastatic non–small-cell lung cancer.[13] The goal of the current study was to examine the effect of early palliative care integrated with standard oncologic care on patient-reported outcomes, the use of health services, and the quality of end-of-life care among patients with metastatic non–small-cell lung cancer. We hypothesized that patients who received early palliative care in the ambulatory care setting, as compared with patients who received standard oncologic care, would have a better quality of life, lower rates of depressive symptoms, and less aggressive end-of-life care.

METHODS

STUDY DESIGN

From June 7, 2006, to July 15, 2009, we enrolled ambulatory patients with newly diagnosed metastatic non–small-cell lung cancer in a nonblinded, randomized, controlled trial of early palliative care integrated with standard oncologic care, as compared with standard oncologic care alone. The study was performed at Massachusetts General Hospital in Boston. Eligible patients were enrolled within 8 weeks after diagnosis and were randomly assigned to one of the two groups in a 1:1 ratio without stratification. Patients who were assigned to early palliative care met with a member of the palliative care team, which consisted of board-certified palliative care physicians and advanced-practice nurses, within 3 weeks after enrollment and at least monthly thereafter in the outpatient setting until death. Additional visits with the palliative care service were scheduled at the discretion of the patient, oncologist, or palliative care provider.

General guidelines for the palliative care visits in the ambulatory setting were adapted from the National Consensus Project for Quality Palliative Care and were included in the study protocol.[14] Using a template in the electronic medical record, palliative care clinicians documented the care they provided according to these guidelines (see Table 1 in the Supplementary Appendix, available with the full text of this article at NEJM.org). Specific attention was paid to assessing physical and psychosocial symptoms, establishing goals of care, assisting with decision making regarding treatment, and coordinating care on the basis of the individual needs of the patient.[14,15] Patients who were randomly assigned to standard care were not scheduled to meet with the palliative care service unless a meeting was requested by the patient, the family, or the oncologist; those who were referred to the service did not cross over to the palliative care group or follow the specified palliative care protocol. All the participants continued to receive routine oncologic care throughout the study period. Before enrollment in the study was initiated, the protocol was approved by the Dana Farber/Partners CancerCare institutional review board. All participants provided written informed consent. The protocol, including the statistical analysis plan, is available at NEJM.org. All the authors attest that the study was performed in accordance with the protocol and the statistical analysis plan.

PATIENTS

Patients who presented to the outpatient thoracic oncology clinic were invited by their medical oncologists to enroll in the study; all the medical oncologists in the clinic agreed to approach, recruit, and obtain consent from their patients. Physicians were encouraged, but not required, to offer participation to all eligible patients; no additional screening or recruitment measures were used. Patients were eligible to participate if they had pathologically confirmed metastatic non–small-cell lung cancer diagnosed within the previous 8 weeks and an Eastern Cooperative Oncology Group (ECOG) performance status of 0, 1, or 2 (with 0 indicating that the patient is asymptomatic, 1 that the patient is symptomatic but fully ambulatory, and 2 that the patient is symptomatic and in bed <50% of the day)[16] and were able to read and respond to questions in English. Patients who were already receiving care from the palliative care service were not eligible for participation in the study.

PATIENT-REPORTED MEASURES

Health-related quality of life was measured with the use of the Functional Assessment of Cancer Therapy–Lung (FACT-L) scale, which assesses multiple dimensions of the quality of life (physical, functional, emotional, and social well-being) during the previous week.[17] In addition, the lung-cancer subscale (LCS) of the FACT-L scale evaluates seven symptoms specific to lung cancer. The primary outcome of the study was the change from baseline to 12 weeks in the score on the Trial Outcome Index (TOI), which is the sum of the scores on the LCS and the physical well-being and functional well-being subscales of the FACT-L scale.

Mood was assessed with the use of both the Hospital Anxiety and Depression Scale (HADS) and the Patient Health Questionnaire 9 (PHQ-9).[18,19] The 14-item HADS, which consists of two subscales, screens for symptoms of anxiety and depression in the previous week. Subscale scores range from 0, indicating no distress, to 21, indicating maximum distress; a score higher than 7 on either HADS subscale is considered to be clinically significant. The PHQ-9 is a nine-item measure that evaluates symptoms of major depressive disorder according to the criteria of the fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV). A major depressive syndrome was diagnosed if a patient reported at least five of the nine symptoms of depression on the PHQ-9, with one of the five symptoms being either anhedonia or depressed mood. Symptoms had to be present for more than half the time, except for the symptom of suicidal thoughts, which was included in the diagnosis if it was present at any time.

MEASURES OF HEALTH CARE USE

Data were collected from the electronic medical record on the use of health services and end-of-life care, including anticancer therapy, medication prescriptions, referral to hospice, hospital admissions, emergency department visits, and the date and location of death. Patients were classified as having received aggressive care if they met any of the following three criteria: chemotherapy within 14 days before death, no hospice care, or admission to hospice 3 days or less before death.[20-22] Finally, we assessed whether patients' resuscitation preferences were documented in the outpatient electronic medical record.[23]

DATA COLLECTION

Participants completed baseline questionnaires before randomization. Follow-up assessments of quality of life and mood were performed at 12 weeks (or at an outpatient clinic visit within 3 weeks before or after that time point). Participants who had no scheduled clinic visits within this period received the questionnaires by mail. When responses on questionnaires were incomplete, research staff documented the reasons for which the participant did not give a full response.

STATISTICAL ANALYSIS

Data obtained through December 1, 2009, were included in the analyses. The primary outcome was the change in the score on the TOI from baseline to 12 weeks. We estimated that with 120 patients, the study would have 80% power to detect a significant between-group difference in the change in the TOI score from baseline to 12 weeks, with a medium effect size of 0.5 SD.[24] The protocol was amended in August 2008 to allow for the enrollment of an additional 30 participants in order to compensate for the loss of any patients to follow-up.

Statistical analyses were performed with the use of SPSS software, version 16.0 (SPSS). Descriptive statistics were used to estimate the frequencies, means, and standard deviations of the study variables. Differences between study groups in baseline characteristics and clinical outcomes were assessed with the use of two-sided Fisher's exact tests and chi-square tests for categorical variables and independent-samples Student's t-tests for continuous variables. Multivariate linear regression analyses, adjusted for baseline scores, were used to examine the effect of early palliative care on quality-of-life outcomes. For intention-to-treat analyses, we used the conservative method of carrying baseline values forward to account for all missing patient-reported outcome data, including data that were missing owing to death. Survival time was calculated from the date of enrollment to the date of death with the use of the Kaplan–Meier method. Data from patients who were alive at the last follow-up (December 1, 2009) were censored on that date. A Cox proportional-hazards model was used to assess the effect of early palliative care on survival, with adjustment for demographic characteristics and baseline ECOG performance status.

RESULTS

BASELINE CHARACTERISTICS OF THE PATIENTS

A total of 151 patients were enrolled in the study (see the figure in the Supplementary Appendix). The percentage of patients enrolled was similar for each of the thoracic oncologists in the clinic.

Table 1. Baseline Characteristics of the Study Participants.*

Variable	Standard Care (N=74)	Early Palliative Care (N=77)	P Value†
Age — yr	64.87±9.41	64.98±9.73	0.94
Female sex — no. (%)	36 (49)	42 (55)	0.52
Race — no. (%)‡			0.06§
White	70 (95)	77 (100)	
Black	3 (4)	0	
Asian	1 (1)	0	
Hispanic or Latino ethnic group‡	1 (1)	1 (1)	1.00
Marital status — no. (%)			1.00
Married	45 (61)	48 (62)	
Single	9 (12)	9 (12)	
Divorced or separated	12 (16)	12 (16)	
Widowed	8 (11)	8 (10)	
ECOG performance status — no. (%)¶			0.24
0	30 (41)	26 (34)	
1	35 (47)	46 (60)	
2	9 (12)	5 (6)	
Presence of brain metastases — no. (%)	19 (26)	24 (31)	0.48
Initial anticancer therapy — no. (%)			0.87‖
Platinum-based combination chemotherapy	35 (47)	35 (45)	
Single agent	3 (4)	9 (12)	
Oral EGFR tyrosine kinase inhibitor	6 (8)	6 (8)	
Radiotherapy	26 (35)	27 (35)	
Chemoradiotherapy	3 (4)	0	
No chemotherapy	1 (1)	0	
Receipt of initial chemotherapy as part of a clinical trial — no. (%)	20 (27)	16 (21)	0.45
Never smoked or smoked ≤10 packs/yr — no./total no. (%)	16/73 (22)	18/76 (24)	0.85
Assessment of mood symptoms — no./total no. (%)			
HADS**			
Anxiety subscale	24/72 (33)	28/77 (36)	0.73
Depression subscale	18/72 (25)	17/77 (22)	0.70
PHQ-9 major depressive syndrome††	12/72 (17)	9/76 (12)	0.48

Table 1. (Continued.)

Variable	Standard Care (N=74)	Early Palliative Care (N=77)	P Value†
Scores on quality-of-life measures‡‡			
FACT-L scale	91.7±16.7	93.6±16.5	0.50
Lung-cancer subscale	18.7±4.4	20.1±4.4	
Trial Outcome Index	55.3±13.1	56.2±13.4	

* Plus–minus values are means ±SD. Percentages may not total 100 because of rounding. ECOG denotes Eastern Cooperative Oncology Group, EFGR epidermal growth factor receptor, FACT-L Functional Assessment of Cancer Therapy–Lung, HADS Hospital Anxiety and Depression Scale, and PHQ-9 Patient Health Questionnaire 9.

† P values were calculated with the use of two-sided chi-square and Fisher's exact tests for categorical variables and the independent-samples Student's t-tests for continuous variables.

‡ Race or ethnic group was self-reported.

§ The P value is for the between-group comparison of the proportions of patients who were white and those who were members of a minority group (black and Asian), calculated with the use of Fisher's exact test.

¶ An ECOG performance status of 0 indicates that the patient is asymptomatic, 1 that the patient is symptomatic but fully ambulatory, and 2 that the patient is symptomatic and in bed less than 50% of the day.

‖ The P value is for the between-group comparison of the proportion of patients receiving platinum-based combination chemotherapy and the proportion receiving other treatments, calculated with the use of Fisher's exact test.

** The HADS consists of two subscales, one for symptoms of anxiety and one for symptoms of depression. Subscale scores range from 0, indicating no distress, to 21, indicating maximum distress; a score higher than 7 indicates clinically meaningful anxiety or depression.

†† The PHQ-9 is a nine-item measure that evaluates symptoms of major depressive disorder according to the criteria of the fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV). A major depressive syndrome was diagnosed if a patient reported at least five of the nine symptoms of depression on the PHQ-9, with one of the five symptoms being either anhedonia or depressed mood. Symptoms had to be present for more than half the time, except for the symptom of suicidal thoughts, which was included in the diagnosis if it was present at any time.

‡‡ The quality of life was assessed with the use of three measures: the FACT-L scale, on which scores range from 0 to 136, with higher scores indicating a better quality of life; the lung-cancer subscale of the FACT-L scale, on which scores range from 0 to 28, with higher scores indicating fewer symptoms; and the Trial Outcome Index, which is the sum of the scores on the lung-cancer, physical well-being, and functional well-being subscales of the FACT-L scale (scores range from 0 to 84, with higher scores indicating a better quality of life).

No significant differences in demographic characteristics or overall survival were seen between the study participants and eligible patients who were not enrolled in the study. The baseline characteristics were well matched between the two study groups (Table 1). Known prognostic factors, including age, sex, ECOG performance status, presence or absence of brain metastases, smoking status, and initial anticancer therapy, were also balanced between the study groups. Although genetic testing was not routinely performed, the proportions of patients with mutations in the epidermal growth factor gene (*EGFR*) were similar between the study groups among the patients who underwent testing (9% in the palliative care group and 12% in the standard-treatment group, P=0.76). No significant between-group differences were seen in baseline quality of life or mood symptoms.

PALLIATIVE-CARE VISITS

All the patients assigned to early palliative care, except for one patient who died within 2 weeks after enrollment, had at least one visit with the palliative care service by the 12th week. The average number of visits in the palliative care group was 4 (range, 0 to 8). Ten patients who received standard care (14%) had a palliative care consultation in the first 12 weeks of the study, primarily to address the management of symptoms, with seven patients having one visit and three having two visits.

QUALITY-OF-LIFE AND MOOD OUTCOMES

A comparison of measures of quality of life at 12 weeks showed that the patients assigned to early palliative care had significantly higher scores than did those assigned to standard care, for the total FACT-L scale, the LCS, and the TOI, with effect sizes in the medium range (Table 2). Patients in the palliative care group had a 2.3-point increase in mean TOI score from baseline to 12 weeks, as compared with a 2.3-point decrease in the standard care group (P=0.04) (Fig. 1). With the use of linear regression to control for baseline quality-of-life values, the group assignment significantly predicted scores at 12 weeks on the total FACT-L scale (adjusted difference in mean

Table 2. Bivariate Analyses of Quality-of-Life Outcomes at 12 Weeks.*

Variable	Standard Care (N=47)	Early Palliative Care (N=60)	Difference between Early Care and Standard Care (95% CI)	P Value†	Effect Size‡
FACT-L score	91.5±15.8	98.0±15.1	6.5 (0.5–12.4)	0.03	0.42
LCS score	19.3±4.2	21.0±3.9	1.7 (0.1–3.2)	0.04	0.41
TOI score	53.0±11.5	59.0±11.6	6.0 (1.5–10.4)	0.009	0.52

* Plus–minus values are means ±SD. Quality of life was assessed with the use of three scales: the Functional Assessment of Cancer Therapy–Lung (FACT-L) scale, on which scores range from 0 to 136, with higher scores indicating better quality of life; the lung-cancer subscale (LCS) of the FACT-L scale, on which scores range from 0 to 28, with higher scores indicating fewer symptoms; and the Trial Outcome Index (TOI), which is the sum of the scores on the LCS and the physical well-being and functional well-being subscales of the FACT-L scale (scores range from 0 to 84, with higher scores indicating better quality of life).

† The P value was calculated with the use of two-sided Student's t-tests for independent samples.

‡ The effect size was determined with the use of Cohen's d statistic, which is a measure of the difference between two means (in this case, the mean in the group assigned to early palliative care group minus the mean in the group assigned to standard care) divided by a standard deviation for the pooled data. According to the conventional classification, an effect size of 0.20 is small, 0.50 moderate, and 0.80 large.

[±SE] scores, 5.4±2.4; 95% confidence interval [CI], 0.7 to 10.0; P=0.03) and the TOI (adjusted difference in mean scores, 5.2±1.8; 95% CI, 1.6 to 8.9; P=0.005), but not on the LCS (adjusted difference in mean scores, 1.0±0.6; 95% CI, −0.2 to 2.3; P=0.12). In addition, the percentage of patients with depression at 12 weeks, as measured by the HADS and PHQ-9, was significantly lower in the palliative care group than in the standard care group, although the proportions of patients receiving new prescriptions for antidepressant drugs were similar in the two groups (approximately 18% in both groups, P=1.00) (Fig. 2). The percentage of patients with elevated scores for symptoms of anxiety did not differ significantly between the groups.

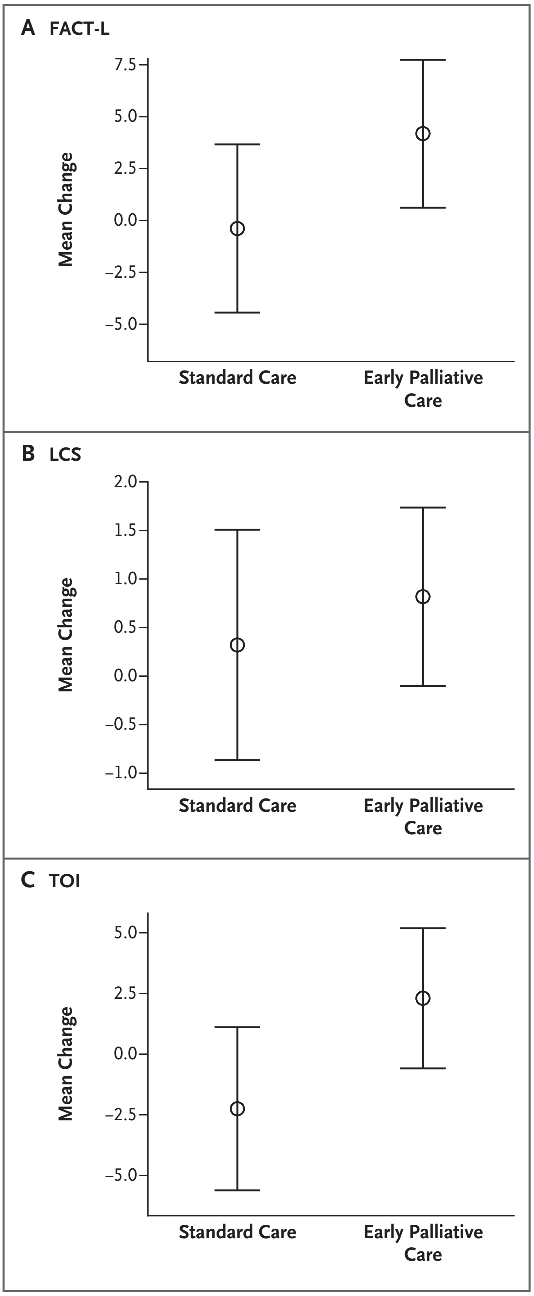
The figure in the Supplementary Appendix includes an explanation of missing data according to study group. There was no significant association between missing data on patient-reported outcomes at 12 weeks and any baseline characteristic (although there was a trend toward a significant association between missing data and assigned treatment [P=0.07]). When we carried the baseline scores of the participants forward for the missing data on patient-reported outcomes, all primary treatment effects were replicated with respect to quality of life (P=0.04 for the 12-week FACT-L score, P=0.01 for the 12-week LCS score, P=0.04 for the 12-week TOI score, and P=0.04 for the mean change from baseline to 12 weeks in the TOI score) and mood (P=0.04 for the comparison of patients with elevated scores on the HADS depression subscale, and P=0.02 for the comparison of patients with symptoms of major depression on the PHQ-9).

END-OF-LIFE CARE

At the time of the analysis of end-of-life care, 105 participants (70%) had died; the median duration of follow-up among participants who died was 5.7 months. Within this subsample, a greater percentage of patients in the group assigned to standard care than in the group assigned to early palliative care received aggressive end-of-life care (54% [30 of 56 patients] vs. 33% [16 of 49 patients], P=0.05). In addition, fewer patients in the standard care group than in the palliative care group had resuscitation preferences documented in the outpatient electronic medical record (28% [11 of 39 patients who had preferences documented during the course of the study] vs. 53% [18 of 34 patients], P=0.05). The study did not have adequate power to examine specific indicators of aggressive care at the end of life. However, analyses of various measures of utilization, such as rates of hospitalization and emergency department visits (Table 2 in the Supplementary Appendix), as well as the duration of hospice care (median duration, 11 days in the palliative care group vs. 4 days in the standard care group; P=0.09 with the use of the Wilcoxon rank-sum test), suggested an improvement in the quality of care with early palliative care. Despite receiving less aggressive end-of-life care, patients in the palliative care group had significantly longer survival than those in the standard care group (median survival, 11.6 vs. 8.9 months; P=0.02) (Fig. 3).

Figure 1. Mean Change in Quality-of-Life Scores from Baseline to 12 Weeks in the Two Study Groups.

Quality of life was assessed with the use of the Functional Assessment of Cancer Therapy–Lung (FACT-L) scale, on which scores range from 0 to 136, with higher scores indicating a better quality of life; the lung-cancer subscale (LCS) of the FACT-L scale, on which scores range from 0 to 28, with higher scores indicating fewer symptoms; and the Trial Outcome Index (TOI), which is the sum of the scores on the LCS and the physical well-being and functional well-being subscales of the FACT-L scale (scores range from 0 to 84, with higher scores indicating a better quality of life). With study group as the independent variable, two-sided independent-samples Student's t-tests showed a trend toward a significant between-group difference in the mean (±SD) change in scores from baseline to week 12 on the FACT-L scale (−0.4±13.8 in the standard care group vs. 4.2±13.8 in the palliative care group; difference between groups, 4.6; 95% confidence interval [CI], −0.8 to 9.9; P=0.09) (Panel A), no significant between-group difference in the mean change in scores on the LCS (0.3±4.0 and 0.8±3.6 in the two groups, respectively; difference between groups, 0.5; 95% CI, −1.0 to 2.0; P=0.50) (Panel B), and a significant between-group difference in the mean change in scores on the TOI (−2.3±11.4 vs. 2.3±11.2; difference between groups, 4.6; 95% CI, 0.2 to 8.9; P=0.04) (Panel C). Data are from the 47 patients in the standard care group and the 60 patients in the palliative care group who completed the 12-week assessments. I bars indicate 95% confidence intervals.



DISCUSSION

This study shows the effect of palliative care when it is provided throughout the continuum of care for advanced lung cancer. Early integration of palliative care with standard oncologic care in patients with metastatic non–small-cell lung cancer resulted in survival that was prolonged by approximately 2 months and clinically meaningful improvements in quality of life and mood. Moreover, this care model resulted in greater documentation of resuscitation preferences in the outpatient electronic medical record, as well as less aggressive care at the end of life. Less aggressive end-of-life care did not adversely affect survival. Rather, patients receiving early palliative care, as compared with those receiving standard care alone, had improved survival. Previous data have shown that a lower quality of life and depressed mood are associated with shorter survival among patients with metastatic non–small-cell lung cancer.[25-27] We hypothesize that improvements in both of these outcomes among patients assigned to early palliative care may account for the observed survival benefit. In addition, the integration of palliative care with standard oncologic care may facilitate the optimal and appropriate administration of anticancer therapy, especially during the final months of life. With earlier referral to a hospice program, patients may receive care that results in better management of symptoms, leading to stabilization of their condition and prolonged survival. These hypotheses require further study.

Improving quality of life and mood in patients

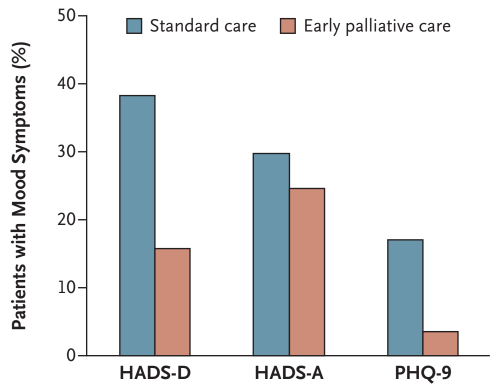


Figure 2. **Twelve-Week Outcomes of Assessments of Mood.**

Depressive symptoms were assessed with the use of the Hospital Anxiety and Depression Scale (HADS), which consists of two subscales, one for symptoms of anxiety (HADS-A) and one for symptoms of depression (HADS-D) (subscale scores range from 0, indicating no distress, to 21, indicating maximum distress; a score higher than 7 on either HADS subscale is considered to be clinically significant) and with the use of the Patient Health Questionnaire 9 (PHQ-9). The PHQ-9 is a nine-item measure that evaluates symptoms of major depressive disorder according to the criteria of the fourth edition of the *Diagnostic and Statistical Manual of Mental Disorders* (DSM-IV). A major depressive syndrome was diagnosed if a patient reported at least five of the nine symptoms of depression on the PHQ-9, with one of the five symptoms being either anhedonia or depressed mood. Symptoms had to be present for more than half the time, except for the symptom of suicidal thoughts, which was included in the diagnosis if it was present at any time. The percentages of patients with mood symptoms, assessed on the basis of each of these measures, in the group assigned to standard treatment and the group assigned to early palliative care, respectively, are as follows: HADS-D, 38% (18 of 47 patients) versus 16% (9 of 57), $P=0.01$; HADS-A, 30% (14 of 47 patients) and 25% (14 of 57), respectively; $P=0.66$; and PHQ-9, 17% (8 of 47 patients) versus 4% (2 of 57); $P=0.04$. The analyses were performed with the use of a two-sided Fisher's exact test.

with metastatic non–small-cell lung cancer is a formidable challenge, given the progressive nature of the illness.[28] The improvement we observed in the quality of life among patients assigned to early palliative care, as indicated by a mean change in the TOI score by 12 weeks that was approximately 5 points higher in the palliative care group than in the standard care group, is similar to the improvement in the quality of life that has been observed among patients who have a response to cisplatin-based chemotherapy.[29] Most studies show that there is a deterioration in the quality of life over time, which is consistent with the results in the standard care group in our study.[30-32] Despite similar cancer therapies in our two study groups, the patients assigned to early palliative care had an improved quality of life, as compared with those receiving standard care. Rates of depression also differed significantly between the groups, with approximately half as many patients in the palliative care group as in the standard care group reporting clinically significant depressive symptoms on the HADS, and this effect was not due to a between-group difference in the use of antidepressant agents.

To date, evidence supporting a benefit of palliative care is sparse, with most studies having notable methodologic weaknesses, especially with respect to quality-of-life outcomes.[8] One study with sufficient power to examine quality-of-life outcomes showed that among patients receiving radiation therapy, a multidisciplinary intervention focused on education, behavioral modification, and coping style resulted in improvements in the quality of life.[33] A recent study showed that Project ENABLE (Educate, Nurture, Advise, Before Life Ends), a telephone-based, psychoeducational program for patients with advanced cancer, significantly improved both quality of life and mood.[34] However, the percentage of patients who completed the study assessments was somewhat low, and the study did not use a traditional palliative care model.

Our study also showed that early outpatient palliative care for patients with advanced cancer can alter the use of health care services, including care at the end of life. Other studies of outpatient palliative care have failed either to investigate these outcomes or to show an effect on the use of resources.[5,34,35] In our trial, significantly more patients in the group assigned to early palliative care than in the standard care group had resuscitation preferences documented in the outpatient electronic medical record, an essential step in clarifying and ensuring respect for patients' wishes about their care at the end of life.[36] Early introduction of palliative care also led to less aggressive end-of-life care, including reduced chemotherapy and longer hospice care. Given the trends toward aggressive and costly care near the end of life among patients with cancer, timely introduction of palliative care may serve to mitigate unnecessary and burdensome personal and societal costs.[20,37]

Our study has several advantages over previous studies, in which investigators have often relied on referrals to palliative care instead of using a recruitment approach designed to obtain a representative sample.[5,35] Because all patients with a new diagnosis of metastatic non–small-cell lung cancer were eligible for enrollment in our study, we extended the generalizability of our findings. Another strength of our trial was the low rate of loss to follow-up and the high percentage of participants who completed the study assessments. In addition, the dropout rate by week 12 was less than 1%, further supporting the feasibility and acceptability of early palliative care. Finally, the trial was adequately powered to detect changes in both quality of life and mood, and we prospectively collected data on end-of-life care.

Several limitations of the study deserve mention. It was performed at a single, tertiary care site with a specialized group of thoracic oncology providers and palliative care clinicians, thereby limiting generalization of the results to other care settings or patients with other types of cancer. In addition, because the sample lacked diversity with respect to race and ethnic group, we were unable to assess the effect of these important factors on study outcomes. Although we used a randomized, controlled design, both the patients and the clinicians were aware of the study assignments. To account for possible influences of care that are not specific to the palliative care provided, follow-up investigations should include a control group that receives a similar amount of attention. In addition, we did not deny palliative care consultations to participants receiving standard care, and a small minority of patients in the standard care group was seen by the palliative care team. The data from these patients were analyzed with the data from their assigned study group (standard care), a factor that may have diluted our findings. Finally, carrying the last observation forward for all missing data in the intention-to-treat analyses is a conservative approach; therefore, the actual treatment effect of early palliative care may be greater than we report.

Early integration of palliative care for patients with metastatic non–small-cell lung cancer is a clinically meaningful and feasible care model that has effects on survival and quality of life that are similar to the effects of first-line chemotherapy in such patients.[28,38,39] As compared with the study participants who received standard care, those who were assigned to early palliative care had improved mood, more frequent documentation of resuscitation preferences, and less aggressive end-of-life care. Although our findings must be replicated in a variety of care settings and cancer populations, the results nonetheless offer great promise for alleviating distress in patients with metastatic disease and addressing critical concerns regarding the use of health care services at the end of life.

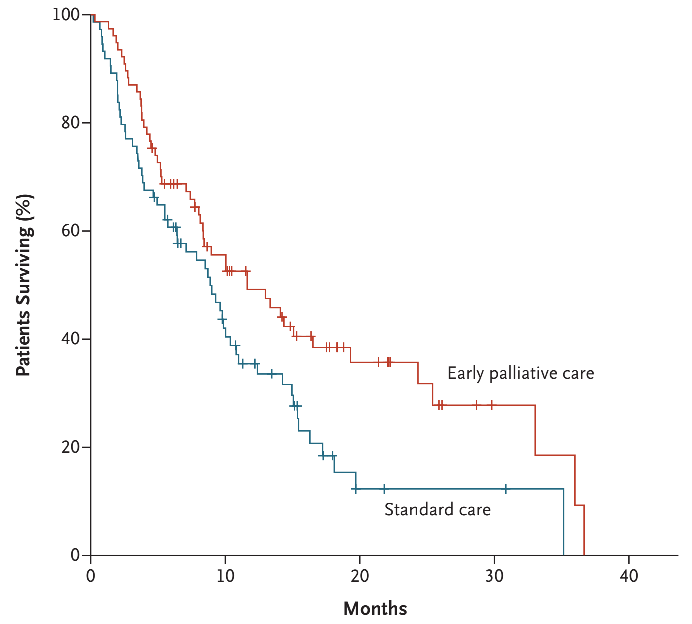


Figure 3. Kaplan–Meier Estimates of Survival According to Study Group.
Survival was calculated from the time of enrollment to the time of death, if it occurred during the study period, or to the time of censoring of data on December 1, 2009. Median estimates of survival were as follows: 9.8 months (95% confidence interval [CI], 7.9 to 11.7) in the entire sample (151 patients), 11.6 months (95% CI, 6.4 to 16.9) in the group assigned to early palliative care (77 patients), and 8.9 months (95% CI, 6.3 to 11.4) in the standard care group (74 patients) ($P=0.02$ with the use of the log-rank test). After adjustment for age, sex, and baseline Eastern Cooperative Oncology Group performance status, the group assignment remained a significant predictor of survival (hazard ratio for death in the standard care group, 1.70; 95% CI, 1.14 to 2.54; $P=0.01$). Tick marks indicate censoring of data.

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Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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EDITORIAL

Palliative Care — A Shifting Paradigm

Amy S. Kelley, M.D., M.S.H.S., and Diane E. Meier, M.D.

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Article

Palliative care focuses on relieving suffering and achieving the best possible quality of life for patients and their family caregivers. It involves the assessment and treatment of symptoms; support for decision making and assistance in matching treatments to informed patient and family goals; practical aid for patients and their family caregivers; mobilization of community resources to ensure a secure and safe living environment; and collaborative and seamless models of care across a range of care settings (i.e., hospital, home, nursing home, and hospice). Palliative care is provided both within the Medicare hospice benefit (hospice palliative care) and outside it (nonhospice palliative care). Nonhospice palliative care is offered simultaneously with life-prolonging and curative therapies for persons living with serious, complex, and life-threatening illness. Hospice palliative care becomes appropriate when curative treatments are no longer beneficial, when the burdens of these treatments exceed their benefits, or when patients are entering the last weeks to months of life.[1]

Comprehensive palliative care services integrate the expertise of a team of providers from different disciplines to address the complex needs of seriously ill patients and their families. Members of a palliative care team typically include professionals from medicine, nursing, and social work, with additional support from chaplaincy and professionals in nutrition, rehabilitation, pharmacy, and other professional disciplines, as needed. These programs are now available at more than 80% of large U.S. hospitals (those with more than 300 beds), where most Americans receive their care during complex and advanced illness.[2]

Despite the increasing availability of palliative care services in U.S. hospitals and the body of evidence showing the great distress to patients caused by symptoms of the illness,[3] the burdens on family caregivers,[4] and the overuse of costly, ineffective therapies during advanced chronic illness,[5] the use of palliative care services by physicians for their patients remains low. Physicians tend to perceive palliative care as the alternative to life-prolonging or curative care — what we do when there is nothing more that we can do — rather than as a simultaneously delivered adjunct to disease-focused treatment.[6]

In this issue of the *Journal,* Temel and colleagues challenge this prevailing notion of palliative care by presenting the results of a randomized, controlled trial of early palliative care in addition to standard oncologic care for patients with newly diagnosed metastatic non–small-cell lung cancer.[7] A total of 151 subjects were recruited and enrolled in the study at a single academic thoracic oncology practice. Health-related quality of life and mood were measured at baseline and at 12 weeks. In addition to standard oncologic care, patients in the intervention group met with a palliative care clinician at the time of enrollment and at least monthly thereafter. As compared with the standard care group, the intervention group had better quality of life, lower rates of depression, and a 2.7-month survival benefit.

The results of this study show that palliative care is appropriate and potentially beneficial when it is introduced at the time of diagnosis of a serious or life-limiting illness — at the same time as all other appropriate and beneficial medical therapies are initiated. The fact that palliative care improved quality-of-life outcomes is consistent with the results of other studies of both nonhospice and hospice palliative care. The substantial survival advantage observed, though it is supported by other recent studies,[8,9] requires replication.

The specific components of the study's palliative care intervention remain unspecified and hence may not be easily reproducible in other practice settings. For example, the salutary effect of additional time with and attention from health care providers and physicians, as opposed to a specific benefit derived from palliative care itself, was not assessed and is a limitation of the study. The reasons for the 2.7-month survival benefit in the palliative care group — a benefit that is equivalent to that achieved with a response to standard chemotherapy regimens — are unknown but may result from effective treatment of depression, improved management of symptoms, or a reduction in the need for hospitalization. The current study was not designed to address these important questions. Despite these limitations, Temel and colleagues are to be commended for overcoming many of the challenges and barriers to conducting a randomized trial of a palliative care intervention.

Future studies of palliative care must begin to test and identify the actual components of palliative care that are provided and received. Such methodologic rigor is necessary to establish the evidence for best practice. Studies of other disease populations beyond patients with cancer and in other settings (e.g., long-term care) are also necessary to identify the ways in which palliative care can be appropriately delivered in diverse patient populations and settings. Finally, although studies have shown that palliative care programs reduce hospital expenditures,[10] additional studies examining the effect of palliative care on overall health care costs need to be undertaken.

The study by Temel et al. represents an important step in confirming the beneficial outcomes of a simultaneous care model that provides both palliative care and disease-specific therapies beginning at the time of diagnosis. This study is an example of research that shifts a long-held paradigm that has limited access to palliative care to patients who were predictably and clearly dying. The new approach recognizes that life-threatening illness, whether it can be cured or controlled, carries with it significant burdens of suffering for patients and their families and that this suffering can be effectively addressed by modern palliative care teams. Perhaps unsurprisingly, reducing patients' misery may help them live longer. We now have both the means and the knowledge to make palliative care an essential and routine component of evidence-based, high-quality care for the management of serious illness.

Disclosure forms provided by the authors are available with the full text of this article at NEJM.org.

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ASCO SPECIAL ARTICLE

American Society of Clinical Oncology Statement: Toward Individualized Care for Patients With Advanced Cancer

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ABSTRACT

Patients with advanced incurable cancer face complex physical, psychological, social, and spiritual consequences of disease and its treatment. Care for these patients should include an individualized assessment of the patient's needs, goals, and preferences throughout the course of illness. Consideration of disease-directed therapy, symptom management, and attention to quality of life are important aspects of quality cancer care. However, emerging evidence suggests that, too often, realistic conversations about prognosis, the potential benefits and limitations of disease-directed therapy, and the potential role of palliative care, either in conjunction with or as an alternative to disease-directed therapy, occur late in the course of illness or not at all. This article addresses the American Society of Clinical Oncology's (ASCO's) vision for improved communication with and decision making for patients with advanced cancer. This statement advocates an individualized approach to discussing and providing disease-directed and supportive care options for patients with advanced cancer throughout the continuum of care. Building on ASCO's prior statements on end-of-life care (1998) and palliative care (2009), this article reviews the evidence for improved patient care in advanced cancer when patients' individual goals and preferences for care are discussed. It outlines the goals for individualized care, barriers that currently limit realization of this vision, and possible strategies to overcome these barriers that can improve care consistent with the goals of our patients and evidence-based medical practice.

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INTRODUCTION

Personalized cancer care describes our aspiration to base treatment on the unique biologic features of a patient's disease. However, in the context of advanced cancer, defined as incurable disease, there is a need to more broadly consider how we can best "personalize" or tailor care to the diverse physical, psychological, social, and spiritual consequences of cancer for the individual patient. Such an approach requires stepping back from the paradigm of applying one line of therapy after the other and focusing primarily on disease-directed interventions. Instead, we need to move toward developing a treatment plan that is consistent with evidence-based options (including disease-directed and palliative care) and the patient's informed preferences for how we pursue and balance these options throughout the course of illness.

In 1998 the American Society of Clinical Oncology (ASCO) published a special article, "Cancer Care During the Last Phase of Life," that outlined aspirations, challenges, and an agenda for research and policy innovations that could ensure quality cancer care throughout the course of a patient's illness.[1] Some progress has been made in the ensuing 12 years in terms of widespread development of hospital-based palliative care programs and community-based hospice organizations, improved education of oncologists and other multidisciplinary care providers regarding the delivery and importance of palliative care, and a growth in the quantity and quality of research in this field.[2] Although widespread availability and awareness of quality palliative care services have improved options for patients with advanced cancer, the transition from a focus on disease-directed treatment to an emphasis on palliative care all too often occurs within days of the end of life. Conversations regarding prognosis, likely outcomes from available interventions, and alternatives or complementary interventions to disease-directed therapy, aimed at establishing the goals of care in the setting of a terminal illness, happen late in the course of treatment or not at all, despite our collective agreement that this is a critically important component of high-quality patient care.[3,4]

There is a need to change the paradigm for advanced cancer care to include an earlier and more thorough assessment of patients' options, goals, and preferences, and to tailor the care that we deliver to these individual needs throughout the continuum of care. Below, we outline the goals for individualized care, barriers that currently limit realization of this vision, and strategies that may overcome these barriers and can improve care consistent with the wishes of our patients and evidence-based medical practice.

GOALS OF INDIVIDUALIZED CARE FOR PATIENTS WITH ADVANCED CANCER

Several core issues (summarized in Table 1) should be addressed with all patients with advanced cancer.

Can We Treat the Cancer?

Whether we can intervene and improve the quality of life or survival of our patients with advanced cancer through cancer-directed therapy should always be a primary consideration. Although cancer-directed therapy in this context is virtually always palliative in some sense, prognosis for advanced cancer varies substantially on the basis of the type of cancer, effectiveness of therapy, and the patient's overall condition and comorbidities. A critical aspect of quality cancer care is to evaluate and explain the available therapeutic options to our patients, including both potential benefits and risks of therapy.

The current landscape of therapy for advanced cancer is rapidly evolving, and for several cancers, there are now interventions such as imatinib mesylate for chronic myelogenous leukemia or gastrointestinal stromal tumor and trastuzumab in human epidermal growth factor receptor 2 (HER2) –positive breast cancer that can dramatically alter the course of illness.[5,6] In other settings, we have multiple lines of effective interventions, including an increasing array of novel targeted therapies that can improve outcomes with little additional toxicity.[6-11] However, despite many advances, the fact remains that in the vast majority of cases, these interventions control disease by months, rather than years, and efficacy measured in terms of disease response or time-to-progression does not always translate into improvement in patient quality of life or survival. Further, in many settings, including late lines of therapy for most cancers, we simply have no options with clear evidence of benefit, yet all interventions have some chance of toxicity and detriment to quality of life. Given these limitations of current therapy, treating the cancer should be viewed as an option for discussion rather than a given.[12]

As a guiding principle, anticancer therapy should be considered only when it has a reasonable chance of working and providing meaningful clinical benefit. For patients with markedly poor performance status or lack of response to two prior chemotherapies, guidelines in most settings suggest stopping further cancer-directed therapy.[13-15] Although some patients and clinicians may wish to consider interventions with a low probability of success, this decision and its consequences (including the potential to cause harm and/or to distract from a focus on comfort-based measures) should be explicitly discussed and recognized. Interventions with insufficient evidence of efficacy or unknown toxicity may at times be requested by patients, but in keeping with the standards of evidence-based medicine, should typically not be considered outside the highly regulated context of a clinical trial.[16,17] Although our goal should be to provide care consistent with our patients' preferences whenever possible, oncologists should feel no obligation to provide an intervention that clinical evidence and the clinician's best judgment suggest will provide no meaningful benefit to the patient and may cause harm.

Table 1. Key Elements of Individualized Care for Patients With Advanced Cancer

1. Patients should be well informed about their prognosis and treatment options, ensuring that they have opportunities to make their preferences and concerns regarding treatment and supportive care known.
2. Anticancer therapy should be discussed and offered when evidence supports a reasonable chance of providing meaningful clinical benefit.
3. Options to prioritize and enhance patients' quality of life should be discussed at the time advanced cancer is diagnosed and throughout the course of illness along with development of a treatment plan that includes goals of therapy.
4. Conversations about anticancer interventions should include information on likelihood of response, the nature of response, and the adverse effects and risks of any therapy. Direct costs to the patient in terms of time, toxicity, loss of alternatives, or financial impacts that can be anticipated should also be discussed to allow patients to make informed choices.
5. Whenever possible, patients with advanced cancer should be given the opportunity to participate in clinical trials or other forms of research that may improve their outcomes or improve the care of future patients.
6. When disease-directed options are exhausted, patients should be encouraged to transition to symptom-directed palliative care alone with the goal of minimizing physical and emotional suffering and ensuring that patients with advanced cancer are given the opportunity to die with dignity and peace of mind.

How Can We Maximize Quality of Life?

Care intended to enhance patients' quality of life should be a priority throughout the disease trajectory of advanced cancer. This can at times be consistent with a concurrent focus on disease-directed treatments but should in all cases be an explicit part of patient assessment and management. The potential impact of cancer-directed therapy on quality of life should be discussed with symptom-directed palliative care alone presented as an alternative, particularly for interventions that may yield disease response or slow progression but do not prolong survival. Evidence suggests that when such conversations occur, patients frequently request a focus on palliation of symptoms rather than a focus on disease control.[18]

The recent evidence from a randomized trial—that early involvement of a palliative care team, in conjunction with regular oncologic care, can improve both quality of life and survival compared with standard oncologic care alone in patients with advanced lung cancer—highlights the importance of assessing the need and desire for such care in all patients with advanced cancer.[19] In contrast, analysis of current patterns of care suggest that despite the widespread availability of palliative care services and hospice, patients are increasingly receiving chemotherapy within the last 2 weeks of life, requiring more frequent visits to the hospital and emergency department in the last month of life, and are often referred to hospice care in the last days of life as a means of managing death, rather than as a tool for palliation of symptoms in the later months of advanced disease.[20] A substantial portion of this care may result from our failure to have regular discussions about prognosis, quality of life, and treatment goals with our patients. When these discussions are held, patients are more likely to understand their prognosis, more likely to seek hospice care, and less likely to receive futile therapy in the intensive care unit immediately before death.[18,21-23] Importantly, there is no increase in anxiety or distress reported as a result of telling patients the truth about their illness.[24]

Some patients will wish to pursue any possible anticancer intervention, even in the last weeks of life, but such treatment should be the result of an informed choice, rather than a consequence of failure to realistically address prognosis or the limitations of current treatments. Patients who want to die at home or in hospice receiving maximal symptom control rather than potentially toxic therapy should have this option. Further, when patients have no reasonable therapeutic options remaining, they should be encouraged to transition to active palliative care to maximize their quality of life. In the setting of incurable cancer, in addition to considerations of chemotherapy and other cancer-directed interventions, it should be our goal to minimize physical and emotional suffering and to ensure that all patients are given the opportunity to die with dignity and peace of mind.

Consideration of Clinical Trials

In addition to the considerations already mentioned, individualized advanced cancer care should include an assessment of the patient's interest in participation in clinical research that may help others or, in some cases, offer potential for direct personal benefit.

At present, $<$ 3% of adult patients with cancer participate in clinical trials.[25] This represents a significant failure to learn from most of our patients. For many patients, clinical trials represent a means to gain access to promising new interventions when standard therapy has little to offer and to do so in a highly regulated setting that offers a chance to contribute to improvement in outcomes for future patients. Detailed studies of trial accrual at single institutions suggest that the generally low rates of trial participation often reflect failure to consider clinical trials, trial ineligibility, or lack of trial availability appropriate for a given patient.[26-28] Although there are substantial barriers to increasing the participation of patients with cancer in clinical trials, particularly in heavily pretreated advanced cancer, patient willingness to participate when offered the opportunity to do so may approach 50%.[26] Given the paucity of trials for heavily pretreated patients in many settings, however, patients should be encouraged to consider trials in early lines of therapy rather than holding out trials as a potentially unrealistic last resort.

Candid Conversations Are Key

Central to all of these goals is the need for realistic conversations about options and alternatives that should occur throughout the course of the patient's illness. Such conversations may currently occur in $<$ 40% of patients with advanced cancer.[18,22] All patients are owed comprehensive information about their prognosis and treatment options, with the amount of detail tailored to the individual patient.[29,30] All patients must have a regular opportunity to make their preferences about how to live their final weeks and months clear to their oncologist. Given that the default care plan in the absence of these conversations is often further systemic therapy, there is a need to regularly and specifically address the question of whether further anticancer-directed therapy is consistent with the patient's wishes and the current clinical picture. Only through these discussions do we have the opportunity to match patients' goals with the actual care delivered.[18]

When cancer-directed therapy is considered, the patient must be told the likelihood of response, the nature of response (ie, symptom improvement, shrinking tumors, slowing progression, improving survival), and the toxicities to which they will be exposed. Provision of both pessimistic information (the chance of no response) and optimistic information (chance of response) leads to better understanding and informed decision making than presentation of an optimistic picture alone.[21] The direct financial impact of treatment decisions and costs in terms of time, toxicity, and alternatives that will be precluded by a given treatment decision should also be addressed.[31] There are several published articles and resources[32-34] offering practical strategies for incorporating these discussions into routine clinical practice.

BARRIERS TO ACHIEVING INDIVIDUALIZED CARE FOR PATIENTS WITH ADVANCED CANCER

We need to be realistic about the barriers to achieving comprehensive goals of care for advanced cancer.

Awareness of the Importance of the Issue

Oncologists need to be aware of the importance of this issue, be willing to discuss these issues with their patients, and be trained to facilitate and provide such care for patients with advanced cancer. Initiating conversations about a poor prognosis or the possibility of forgoing any cancer-directed therapy is inherently difficult and can seem like giving up or admitting failure to patients, families, and other clinicians. Oncologists may not feel comfortable or prepared to engage in such conversations with their patients and their patients' families.[35] Reserving such conversations for late in the course of a patient's illness, as opposed to developing an open dialogue about the choices and options facing patients early in the course of routine care for advanced cancer may heighten this problem. Programs to improve oncologist communication skills have expanded, but incorporating those skills into training programs and continuing medical education is mixed.[36] There is also little attention given during training to issues such as how to provide optimal supportive care in the community practice setting, which diminishes the ability of even well-trained physicians to translate this vision of care into reality.

Guidelines for Discontinuing Cancer-Directed Therapies

Although there are clear guidelines for when to stop disease-directed therapy in some settings,[34] clinicians may be unaware of the guidelines or uncertain whether they apply to a given patient. In many cases, there is some degree of uncertainty surrounding immediate prognosis and the potential for benefit or toxicity from a standard intervention, even if the statistical likelihood of response is low. In addition, the likelihood of direct personal benefit from any experimental intervention being considered is, by definition, unknown.

Systemic Barriers to Individualized Care of Patients With Advanced Cancer

One potential barrier to this vision of individualized care is time. There are multiple aspects of quality cancer care that must be addressed in a follow-up visit, and engaging in a discussion of prognosis, options, and the patient's goals and preferences requires substantially more time than is commonly allotted for the standard follow-up visit.

In addition, the current reimbursement system strongly favors intervention over prolonged discussion. There is a misalignment of incentives in the current health care system that inadvertently encourages administration of cancer-directed treatment at the end of life rather than the time-consuming, emotionally challenging discussions that emphasize candor, comfort, family, and quality of life. Current reimbursement policies also reinforce a potentially false choice between focusing on maximal supportive care through involvement of hospice services and active therapy or participation in a clinical trial.

Barriers to Consideration of Research Participation

For those patients with late-stage cancer who have exhausted all evidence-based treatment options, multiple barriers impede participation in research. Strict eligibility requirements may serve legitimate scientific goals, but they deprive some patients of the opportunity to participate in research and deprive society of the opportunity to learn from a broader range of patients. In addition, the reimbursement and regulatory framework for oncology interventions favors development of early lines of therapy when patients are more likely to respond to a novel intervention and in which the market share will be bigger for approved drugs. Finally, there are relatively few trials of supportive care interventions that might improve our ability to address symptoms and improve quality of life for patients with advanced cancer.

HOW DO WE GET THERE FROM HERE?

There are several steps that individuals and organizations in the oncology community can take to help fulfill this vision for advanced cancer care (Table 2).

Table 2. ASCO Recommendations for Achieving Individualized Care for Patients With Advanced Cancer

Provider initiatives
Increase education and awareness among oncology care providers about the importance of establishing an individualized treatment plan for patients and their families.
Increase interdisciplinary collaboration around care for patients with advanced cancer.
Include the patient's primary care provider in development of an individualized treatment plan and improve communication between all care providers.
Improve training in communication skills for discussing prognosis and care options for patients with advanced cancer.
Develop clinic resources to facilitate delivery of palliative care in addition to delivery of chemotherapy and other cancer-directed therapies.
Incorporate quality palliative care in American Board of Internal Medicine oncology training and certification.
Incorporate clinical palliative care experience into oncology fellowship training programs.
For oncologists already in practice, incorporate individualized care for advanced cancer into MOC modules, QOPIs, and ASCO tumor boards.
Patient/family awareness and education
Empower patients to initiate realistic discussions of care options by providing more detailed information on prognosis, outcomes from standard interventions, and palliative care on clinic and patient-oriented Web sites such as the National Cancer Institute's cancer.gov and ASCO's cancer.net.
Insurance reimbursement reform
Provide direct reimbursement for advanced cancer care planning to support the time and effort required to effectively provide individualized care.
Expand and support pilot programs to explore the potential for providing maximal supportive care with hospice or comparable palliative care while allowing for direct cancer interventions in advanced cancer.
Research priorities
Increase support for research aimed at understanding and overcoming barriers to communication between oncologists and patients regarding goals of care for advanced cancer and end-of-life preferences.
Increase support for correlative science research designed to determine which patients may optimally benefit from novel interventions and to understand and overcome mechanisms of resistance.
Increase support for palliative care research that seeks to maximize quality of life and improve outcomes for patients with advanced cancer.

Abbreviations: ASCO, American Society of Clinical Oncology; MOC, maintenance of certification; QOPIs, Quality Oncology Practice Initiatives.

Emphasize Individualized Care in Education, Training, and Quality Improvement Programs

Oncology care providers must recognize the importance of establishing an individualized treatment plan for our patients and their families and the consequences of failure in this area. Willingness to initiate potentially difficult conversations with patients and families about prognosis, outcomes, options, and end-of-life preferences must be matched with competency to do so in a way that is tailored to the patient's preferences for information and involvement in decision making, and with competency to establish a practice model that supports interdisciplinary collaboration around care for patients with advanced cancer and delivery of high-quality palliative care.

These skills must be emphasized in oncology training, certification, and continuing medical education. Quality palliative care should be incorporated into American Board of Internal Medicine training and certification, and all oncology fellows should receive training in this area. In addition, we must train oncologists to establish a practice model in which clinic resources comparable to those used to facilitate delivery of chemotherapy are devoted to supporting the care of patients who opt for a focus on symptom management. There is a need to think critically about how to develop, establish, and monitor the quality of such training programs.[37]

For oncologists already in practice, care in this area could be improved through incorporation of individualized care for advanced cancer into Maintenance of Certification modules, Quality Oncology Practice Initiatives, ASCO tumor boards, and through greater focus on these issues within ASCO educational sessions and publications, including *Journal of Clinical Oncology* and *Journal of Oncology Practice*.

Support for Individualized Care

Although the primary incentive for changing the way oncologists approach patients with advanced cancer is to improve the quality of care, there is also a need to recognize the value of these conversations to both our patients and society and the effort such care requires in our reimbursement systems. Currently, our system highly incentivizes delivery of cancer-directed interventions (chemotherapy, targeted therapy, and so on) over conversations that are critical to establishing a patient's goals and preferences and providing individualized care. Efforts to compensate oncologists and others for delivering this important aspect of cancer care were unfortunately politicized in the recent health care reform debates, but these efforts had at their core a critical patient-centered societal interest and should be revisited.[38]

In addition, pilot programs initiated by the insurance industry to explore the potential for providing maximal supportive care with hospice or comparable care while allowing for direct cancer interventions in advanced cancer should be expanded and supported. Programs that use concurrent hospice care and chemotherapy may double the referrals to hospice and reduce end-of-life hospitalizations by more than half.[39]

Empowering Patients

Access to accurate education and prognostic information is important to help patients and their families understand the likely course of illness and plan for the future. Patient-oriented information presented in the National Cancer Institute's cancer.gov, ASCO's cancer.net, and patient advocacy group Web sites could be helpful in empowering patients to initiate realistic discussions of care options by providing more detailed information on prognosis and likely outcomes from standard interventions for common incurable cancers. In addition to discussing potential treatments, disease-specific sites also could advise patients with incurable cancer to discuss advanced medical directives and/or hospice care with their families and physicians.

Need for Further Research in Advanced Cancer Care

Finally, there is a need for further research on the delivery of advanced cancer and end-of-life care. This research is needed to increase the percentage of patients who are having conversations about goals and preferences for care throughout the course of illness, identify specific barriers to such discussions, and develop strategies to overcome these barriers. Clearly, clinical research to develop novel interventions that can improve outcomes is central to the goal of improving care for patients with all stages of cancer. In such research, we must ask not merely does a drug work, but why, and in what patients. Correlative science to address these questions requires investment on the part of clinical researchers, research sponsors, and perhaps most of all, research participants. Such research is essential to identify biomarkers of response and resistance to therapy so that we can truly personalize therapy. There should be greater emphasis on assessing the impact of novel interventions on quality of life and patient-reported outcomes so that patients and clinicians can make more informed decisions about the value of intervention in advanced cancers.[40,41] More research is needed into how best to measure quality of life in this population with a focus on symptoms such as pain and shortness of breath that can be most important among patients with advanced cancer. In addition, there is a need for greater funding of supportive care research that seeks to maximize quality of life and improve outcomes for these patients.

SUMMARY

The vision of individualized care for patients with advanced cancer articulated above will benefit our patients and society through alignment of care with patients' personal goals, ensuring that resources are used in a manner consistent with evidence-based medicine and patient preferences. Central to this vision is the need to initiate what admittedly can be difficult conversations regarding prognosis, preferences, and options with our patients earlier in the course of illness. Data suggesting that patients tend to welcome such conversations and that they frequently change the plan of care should bolster our professional resolve to make this happen in the clinic.[18] This statement is also a call to action to clinical researchers and funding sources to support research into physician- and patient-based barriers to individualized advanced cancer care and to support evaluation of interventions to overcome barriers to this care. Further research into the optimal content of such conversations and how we can best help our patients make informed choices in the face of incurable cancer is also needed.[42] Finally, this is a clarion call for oncologists as individual practitioners, and for our profession in general, to take the lead in curtailing the use of ineffective therapy and ensuring a focus on palliative care and relief of symptoms throughout the course of illness.

AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTERESTFN

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AUTHOR CONTRIBUTIONS

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ASCO Recommends Steps to Improve Doctor-Patient Communication about End-of-Life Cancer Care

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-ASCO Issues New Policy Statement and Patient Guide -

ALEXANDRIA, Va. – The American Society of Clinical Oncology (ASCO) today called on physicians, medical schools, insurers, and others to help improve quality of life for people with advanced cancer. In a **new policy statement**, ASCO recommends steps to ensure that physicians initiate candid discussions about the full range of palliative care and treatment options soon after patients' diagnosis with advanced cancer (defined as incurable disease).

"While improving survival is the oncologist's primary goal, helping individuals live their final days in comfort and dignity is one of the most important responsibilities of our profession," said ASCO President George W. Sledge, Jr., MD. "Patients have a right to make informed choices about their care. Oncologists must lead the way in discussing the full range of curative and palliative therapies to ensure that patients' choices are honored."

Because doctor/patient communication is critical to optimal patient care, ASCO also released a **guide to help patients** with advanced cancer broach difficult conversations about their prognosis, treatment and palliative care options with their physicians. Later this year, ASCO will issue its first clinical guidance to help oncologists initiate these conversations and better integrate palliative therapy into oncology practice.

"Studies show that palliative therapies not only improve patient quality of life, but can even extend life," said Dr. Sledge. "Yet for many with advanced cancer, conversations about palliative and hospice options do not occur until the patients' final weeks or days of life, if they happen at all. This not only hurts patients, but their caregivers as well. ASCO's new patient booklet and upcoming clinical guidance will help patients and physicians broach these topics early in the course of care."

A randomized trial sponsored by The ASCO Cancer Foundation recently found that patients with advanced lung cancer who received both chemotherapy and palliative care immediately after their diagnosis lived almost three months longer than those who received chemotherapy alone. Another study published in the *Journal of Clinical Oncology* showed that caregivers of terminally ill patients who receive palliative therapy suffer less emotional stress. ICU and hospital deaths were associated with more psychiatric illness among bereaved caregivers compared with home hospice deaths.

In addition, a new, preliminary analysis of 5,500 patient records from ASCO's Quality Oncology Practice Initiative (QOPI) – an innovative quality improvement program involving about 600 oncology practices nationwide – indicates that less than half (45%) of cancer patients are enrolled in hospice care before death. Of those enrolled, one-third were enrolled in the last week of life. The analysis also found that a significant number of patients did not receive appropriate management of their pain (one-in-five patients) or shortness of breath (two-in-three patients) in their last two medical visits.

ASCO's policy statement was published today in ASCO's Journal of Clinical Oncology. It outlines essential elements of care for patients with advanced cancer and identifies barriers that currently prevent advance cancer care planning conversations between physicians and patients. The statement enumerates critical steps to ensure that care is individualized to address each patient's needs, goals and preferences throughout the course of their illness.

The key elements identified by ASCO to individualize advanced cancer care include:

- Physicians should initiate candid discussions about prognosis with their patients soon after an advanced cancer diagnosis. Such conversations currently occur with less than 40% of patients with advanced cancer.
- Quality of life should be an explicit priority throughout the course of advanced cancer care. Physicians must help their patients fully understand their prognosis, the potential risks and benefits of available cancer treatments, and quality of life considerations. In cases where active treatment is unlikely to extend survival, palliative care should be discussed as a concurrent or alternate therapy.
- Clinical trial opportunities should be increased. Currently, very few patients with advanced cancer participate in trials due to strict eligibility criteria, a dearth of trials that address quality of life issues, and other barriers. Increasing opportunities for these patients to potentially benefit from trials and to contribute to improving cancer care should be a high priority.

Many barriers currently prevent physicians and patients from engaging in optimal advanced cancer care planning. "Oncologists recognize the importance of palliative therapy and other quality of life measures in advanced cancer, but physician education and training programs historically have provided little guidance in this area," said ASCO CEO Allen S. Lichter, MD. "Although patients are entitled to make informed choices about their palliative care and treatment options, our nation's health care system currently places no value on conversations that can guide these decisions."

To address barriers to advanced cancer care planning, ASCO recommends:

- Emphasize advanced cancer care planning in physician education and training programs

  - Communication skills for discussing prognosis and care options should be emphasized both in oncologists' initial training and in continuing medical education (CME).
  - For oncologists in practice, advanced cancer care planning should be a key part of ongoing quality improvement programs.
  - Palliative care should be incorporated into American Board of Internal Medicine oncology training and certification, and into oncology fellowship programs.

- Provide insurance coverage for advanced cancer care planning discussions. Most public and private insurance plans provide little or no compensation for discussions with patients about palliative care options, despite their demonstrated value. To address these issues, ASCO's statement calls for:
  - Public and private insurers to provide direct reimbursement for advanced cancer care planning discussions.
  - Private insurers to expand pilot programs that maximize palliative care (e.g., hospice) without requiring patients to abandon cancer-focused treatment. (By requiring patients to end their cancer treatment in order to receive palliative care, many plans currently reinforce the false choice between fighting the cancer and maximizing quality of life).

- Increase opportunities for advanced cancer patients to participate in clinical research. ASCO calls for researchers and research sponsors to prioritize studies that:
  - Evaluate strategies to maximize quality of life for patients with advanced cancer.
  - Examine potential ways to improve communication between oncologists and patients to ensure patients' care reflects their individual goals and preferences.
  - Assess which patients with advanced cancer are most likely to benefit from novel treatments, and study how to overcome biological mechanisms that make their cancer resistant to available treatments.

- Increase educational resources for patients with advanced cancer. To help guide patients through difficult yet important doctor-patient discussions, ASCO has a free comprehensive educational booklet for patients with advanced cancer. For more information and copies of the booklet, please visit **Cancer.Net.**

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