

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,

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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.

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

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

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| 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. |

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 resources³²⁻³⁴ 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).

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

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.

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.

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AUTHOR CONTRIBUTIONS

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