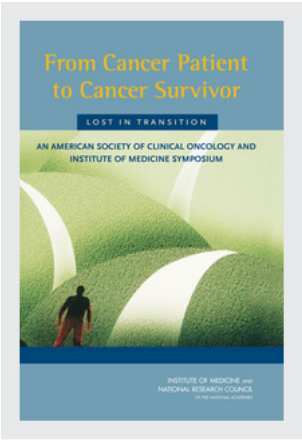

From Cancer Patient to Cancer Survivor: Lost in Transition: An American Society of Clinical Oncology and Institute of Medicine Symposium

DETAILS

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From Cancer Patient to Cancer Survivor

LOST IN TRANSITION

AN AMERICAN SOCIETY OF CLINICAL ONCOLOGY AND INSTITUTE OF MEDICINE SYMPOSIUM

Maria Hewitt and Patricia A. Ganz
Editors

INSTITUTE OF MEDICINE *AND*
NATIONAL RESEARCH COUNCIL
OF THE NATIONAL ACADEMIES

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"Knowing is not enough; we must apply.
Willing is not enough; we must do."
—Goethe

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Contents

Abstract

In this report, the American Society of Clinical Oncology (ASCO) and the Institute of Medicine (IOM) present a one-day symposium that was held at the IOM to further disseminate the conclusions and recommendations of the joint IOM and National Research Council report, *From Cancer Patient to Cancer Survivor: Lost in Transition*. The symposium was introduced by Dr. Sandra Horning, President of ASCO; and Dr. Fitzhugh Mullan, IOM member and one of the founders of the National Coalition for Cancer Survivorship (NCCS). At a plenary session in the morning, four invited experts from academia, the National Quality Forum, and the NCCS gave presentations on: (1) meeting the needs of cancer survivors with an overview of the IOM report's recommendations; (2) implementing the cancer survivorship care plan and coordinating care; (3) developing guidelines, instituting quality improvement, and strengthening professional education programs; and (4) addressing research gaps. In the afternoon, the following six breakout sessions were held where invited speakers gave presentations and moderators engaged the audience in discussion: (1) implementing the cancer survivorship care plan and coordinating care, moderated by Dr. Sheldon Greenfield, University of California, Irvine; (2) building bridges between oncology and primary care providers, moderated by Dr. Steven Woolf, Virginia Commonwealth University; (3) developing and testing models of survivorship care, moderated by Dr. Patricia Ganz, University of California, Los Angeles; (4) developing guidelines, instituting quality improvement, and strengthening professional education programs, moderated by Dr. John Ayanian, Harvard Medical School; (5) making better use of psychosocial and community support services; addressing

employment and insurance issues, moderated by Ms. Ellen Stovall, NCCS; and (6) investing in survivorship research, moderated by Dr. Patricia Ganz, University of California, Los Angeles. Dr. Fitzhugh Mullan provided reflections at lunch over the morning's presentations and discussions. A wrap-up session at the end of the day summarized the issues raised during the breakout sessions.

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Introduction

This report of the proceedings of a symposium held in conjunction with the release of the IOM report, *From Cancer Patient to Cancer Survivor: Lost in Transition*, represents an effort on the part of the American Society of Clinical Oncology (ASCO), the National Coalition for Cancer Survivorship (NCCS), and the Institute of Medicine (IOM) to further disseminate the findings and recommendations of the IOM report and to take the next step toward implementation of those recommendations. The symposium and this report serve as important vehicles to raise awareness, fill gaps that have existed in cancer patients' long-term care, and chart a course for quality care for cancer survivors and their families. More than 100 stakeholders in the cancer community, including survivors, advocates, healthcare providers, government officials, insurers and payers, and researchers participated in the symposium.

This report culminates a series of work at the IOM focused on cancer survivorship. The idea to embark on a major study of cancer survivorship within the National Academies originated with the National Cancer Policy Board (NCPB). The NCPB was established in 1997 in the IOM and the National Research Council's Division of Earth and Life Studies at the request of the National Cancer Institute (NCI), the National Institutes of Health, and the President's Cancer Panel. The NCPB identified emerging policy issues in the nation's effort to combat cancer, and prepared reports that address those issues, including a series of reports on topics ranging from cancer prevention to end-of-life care.

The Board's first major report, *Ensuring Quality Cancer Care* (IOM, 1999), recommended strategies to promote evidenced-based, comprehen-

sive, compassionate, and coordinated care throughout the cancer care trajectory, but its focus was on primary treatment and it did not directly address the quality of care for cancer survivors. However, it noted that such issues needed attention. This report, then, is part of a Board initiative to address quality concerns for cancer survivors with an emphasis on what happens following the primary treatment of cancer. The Board report, *Improving Palliative Care for Cancer* (IOM, 2001), addressed the need for quality care at the end of life for those who die from cancer.

The NCPB decided to separate its exploration of cancer survivorship into three reports. The first report examined childhood cancer survivorship (IOM, 2003a). Some policy issues are common to both children and adults who have survived cancer (e.g., insurance and employment concerns); however, unique features of pediatric treatment and healthcare delivery systems led to the decision to pursue childhood and adult cancer survivorship issues independently. The second report addressed one particular aspect of survivorship, focusing on psychosocial needs of survivors, using female breast cancer as the best studied example (IOM, 2004). The third report, *From Cancer Patient to Cancer Survivor: Lost in Transition,* is intended as a comprehensive look at the current status and future requirements of the large and growing cohort of adult survivors. The symposium reported here seeks to describe and disseminate the content and recommendations of this last report. Furthermore, this sequence has not yet come to an end. A follow-up workshop is being planned to review next steps to implementing survivorship care planning.

The committee's report and this symposium report focuses on adult survivors of cancer during the phase of care that follows primary treatment. In its deliberations, the committee has adopted the definition of cancer survivor used by the NCI's Office of Cancer Survivorship, "An individual is considered a cancer survivor from the time of diagnosis, through the balance of his or her life. Family members, friends, and caregivers are also impacted by the survivorship experience and are therefore included in this definition" (NCI, 2004). In applying this definition, however, the committee decided to focus its attention on a relatively neglected phase of the cancer care trajectory, the period following first diagnosis and treatment and prior to the development of a recurrence of the initial cancer or death. The committee identified several areas of concern for individuals during this monitoring/surveillance period, for example, the lack of clear evidence on recommended follow-up care and the unique psychosocial needs of cancer survivors following treatment, a time when frequent contact with cancer care providers often abruptly ceases. This particular phase of care has been relatively unexamined. The committee also addressed the needs of those individuals with cancer living with disease on an intermittent or chronic basis. Given prior work of the IOM on palliative care (IOM, 2001)

and care at the end of life (IOM, 1997, 2003b), the committee decided to exclude these broad areas from their consideration for the purposes of this report.

ASCO's co-sponsorship of this symposium is significant. ASCO is the leading professional organization representing physicians of all oncology subspecialties who care for people with cancer. ASCO's more than 20,000 members from the United States and abroad set the standard for patient care worldwide and advocate for more effective cancer treatments, increased funding for clinical and translational research, and, ultimately, cures for the many different types of cancer that strike an estimated 11 million people worldwide each year.

In addition to co-hosting the symposium, ASCO has undertaken a range of other activities to move the IOM recommendations forward under the direction of ASCO's Survivorship Task Force, formed in December 2004 and co-chaired by Drs. Horning and Ganz. ASCO's newly convened Survivorship Expert Panel is developing new evidence-based guidelines on the long-term medical care of adult cancer survivors. The overall purpose of the guidelines is to provide health professionals with the knowledge and expertise to decrease morbidity and to improve quality of life for adult survivors of cancer. The panel will draft guidelines in the following areas: cardiovascular disease; hormone replacement therapy; osteoporosis; sexual dysfunction; second malignancies; neurocognitive dysfunction; and psychosocial distress. In response to the IOM's call for public/private partnerships to monitor and improve the care that survivors receive, ASCO and NCCS are co-chairing the new Cancer Quality Alliance, a forum for diverse stakeholders in the cancer community who will work to improve the quality of the cancer care delivery system. Through this partnership, ASCO, NCCS, and the other members will work to establish integrated treatment systems to ensure all people with cancer receive the best care possible. ASCO also will provide educational opportunities to healthcare providers on survivorship through sessions in a new "Patient and Survivor Care" track at its annual meeting in June 2006. One session in this expanded track will focus on how to write a "Survivorship Care Plan," which will highlight the IOM recommendations for outlining a follow-up care plan. Topics addressed in other sessions will include developing cancer survivorship programs; minimizing long-term consequences of breast cancer therapy; nutrition issues for survivors; and survivorship issues in genitourinary malignancies, among other sessions.

The one-day symposium reported here was designed by members of ASCO's Survivorship Task Force, members of the IOM's committee and staff, and the leadership of the NCCS. The morning of the symposium featured an overview plenary session introduced by ASCO President, Sandra Horning and IOM member Fitzhugh Mullan, with presentations from IOM

committee members who highlighted the report's main findings and recommendations. This was followed by a series of six breakout sessions to allow for short focused presentations and discussions on the implementation of the report's recommendations. A brief wrap-up session at the end of the day allowed rapporteurs of the group discussions to summarize the information and recommendations presented during those sessions. The agenda identifying the speakers and their affiliations can be found in Appendix A. The speakers in each breakout session were assembled from different governmental, academic, and private-sector organizations to provide a wide range of perspectives. The participants in discussions, questions, and answers are also reported.

All the presentations and discussions were edited for easier reading and to add graphic material in the form of figures from PowerPoint presentations used during each speaker's presentation. This dissemination report contains only what was said and displayed at the symposium. It is, therefore, a less formal forum than a committee or IOM report. Much interesting information, analysis, and provocative ideas and suggestions can emerge during such an event from the experts, officials, and opinion leaders assembled. The ASCO and IOM hope that this record of the day will provide continuing food for thought and ideas for actions in support of cancer survivorship in the years to come.

Maria Hewitt
and
Patricia A. Ganz

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Plenary Session

INTRODUCTIONS TO THE SYMPOSIUM AND FOR REPRESENTATIVES OF THE AMERICAN SOCIETY OF CLINICAL ONCOLOGY AND THE INSTITUTE OF MEDICINE

Ellen Stovall, Vice Chair, Committee on Cancer Survivorship: Improving Care and Quality of Life; and President and CEO, National Coalition for Cancer Survivorship

Good morning. My name is Ellen Stovall, and I am a 34-year cancer survivor. I am president of the National Coalition for Cancer Survivorship (NCCS) and one of the editors of this wonderful report that we are here today to celebrate. I want to begin by thanking the American Society of Clinical Oncology (ASCO) for sponsoring this wonderful symposium today.[1] We would not be here today without the efforts of many of the people here today. Looking at you all fills me with great joy and a sense of extraordinary accomplishment. So, thank you.

I want to introduce our first two speakers today, Dr. Sandra Horning and Dr. Fitzhugh Mullan. Both of them are cancer survivors. Dr. Sandra Horning is Professor of Medicine, Oncology and Blood and Marrow Transplantation, at Stanford University. She is also the president of the American Society of Clinical Oncology, and a great friend to all of us in the community. Dr. Fitzhugh Mullan is a dear friend, and the architect of our 20-year-

[1]The symposium agenda can be found in Appendix A.

old survivorship movement and the founder of the NCCS. He is the Murdock Head and Professor of Medicine and Health Policy and Professor of Pediatrics at George Washington University. I am delighted to introduce them both here to you today.

INTRODUCTORY REMARKS

Sandra Horning, President, American Society of Clinical Oncology

Thank you. It is a distinct pleasure for me to be here as ASCO president, and as a cancer survivor, to introduce today's symposium. As you know, the purpose of the symposium is to convene the stakeholders, you, who are committed to the care and the quality of life of cancer survivors, so that we can discuss the findings of this report, present the challenges that are outlined, and develop action plans to realize the recommendations.

ASCO is clearly committed to cancer survivorship, and we have made a lot of progress in the last year.[2] First of all, an expert panel was convened by my predecessor, David Johnson, also a cancer survivor. This ASCO Survivorship Task Force is co-chaired by Patricia Ganz and myself. Members of the task force participated in the planning of today's symposium. Our charge was to fully integrate survivorship into the activities throughout ASCO and all of its committees. We are also currently discussing partnerships with primary care societies in joint educational activities.

Survivorship is one of three major themes for the 2005-2006 ASCO year. It is very prominent in our member communications and is displayed prominently in our logo. And there will be concentrated sessions on survivorship and visibility of these issues at the 2006 annual meeting.

Some of our accomplishments in the areas of education and science include providing a permanent home for survivorship in our patient and survivor care track. This means that we have, and will continue to recruit, individuals with an interest and expertise in survivorship to populate both of our committees.

Our educational sessions at the 2006 meeting will include among others, Dr. Ganz talking about the development of a survivorship care plan and Dr. Lois Travis (NCI) talking about assessment of the risks of secondary cancers. We feel that having this permanent home in our scientific programs will help us to attract and promote survivorship research on a permanent basis. We have also begun to integrate survivorship into the core curriculum for oncology fellows.

[2]For more information on ASCO's survivorship activities, see its November 7, 2005, press release in Appendix B.

ASCO members are working as we speak on guidelines that relate to cancer survivorship. These include the areas of fertility preservation; hormone replacement therapy; bone health; cardiovascular late effects; neurocognitive and psychosocial issues; as well as second cancers.

In the area of communications ASCO sponsored a Meet the Expert media event in December of the past year, and held a press conference in May that was dedicated to cancer survivorship and the research presented at the 2005 annual meeting of the society. The coverage, both press and national broadcast media, on survivorship research presented at our last annual meeting was extensive.

And our award-winning peoplelivingwithcancer.org web site has featured survivorship stories. There will be ongoing chats with survivorship experts. And we have shared content with the Lance Armstrong Foundation.

Cancer survivors, as we all know, number 10 million and are growing strong. My professional interest in lymphoma and Hodgkin's disease results in my seeing a lot of cancer survivors. My mother is a cancer survivor. I am a cancer survivor. I am clearly in great support of the work that all of you have done over these many years, culminating in this comprehensive report and call to action. Cancer survivors need to be found, and their needs must be met. I know you look forward, as I do, to a very productive day. Thank you for your attention.

INTRODUCTORY REMARKS

Fitzhugh Mullan, Member, Institute of Medicine

Thank you, Sandra, and thank you, Ellen. It is a pleasure to be here. Survivors say that at the opening of meetings with a particular verve. It is really good to be here. I am a 30-year survivor of a primary mediastinal seminoma. I am also an IOM member, and I would like to extend a welcome from the IOM. It is a wonderful place, both intellectually, institutionally, and architecturally. The IOM has served the nation fabulously well in its ability to take issues, mediate them, broker them, raise them to new levels of evidence-based visibility, and put them on the national stage. And that this is being done with survivorship by dint of this committee and this report I think is just fabulous.

My own reading of the report, which I was fortunate to have the opportunity to do before today, *From Cancer Patient to Cancer Survivor,* is that it is a monumental piece of work, both for the science and the public policy that it brings to the fore, and for the fact that it takes issues that many of us have been grappling with for many years in happily lessening obscurity, but obscurity to begin with, and puts them between two hard

covers and out into the public policy stream in a far more potent way than has ever happened before. So, it is terrific.

My story was that one day in 1975, I took my own chest x-ray, because I had been having some funny feelings, and put the x-ray up on the viewing screen, and I didn't know what it was, but I knew what I saw didn't belong there. It was big and it was ugly, and it led to a return to Washington, treatment at the National Naval Medical Center, radiation, chemotherapy, surgery, and a pretty hellacious course of events over the next couple of years.

I was fixated then on the question of would I live, as everyone is, and when would I know that I would live, when would I be cured? And it was that intellectual and spiritual struggle that sort of brought to my attention the fact that while I wasn't dead, happily yet, I wasn't alive in the way I had been before, at least not at that point, whether it was in the ICU tubed up, or back at home sort of struggling along 30 pounds down, with radiation burns and an uncertain future.

I was surviving, and although the survivorship concept was with us, it was used in the context of Holocaust survivors and airline crash survivors, but not to refer to this purgatory or this period of time following the diagnosis of cancer. The term "survivorship" was used, but not in the cancer lexicon.

As I cast about for help or guidance or counsel, there was little in that regard. I found many people who were struggling with this both personally as survivors, and professionally as oncologists, oncology nurses, physicians, social workers, and counselors. Although the idea began to percolate in my mind, and certainly others understood it, it was then a fairly amorphous phenomenon. And in the 1985 paper, "The Seasons of Survival," I wrote about it (Mullan, 1985). I went back and re-read it just this week, and just to quote a couple of things: "Despite the success on the treatment front, we have done very little in a concerted and well-planned fashion to investigate and address the problems of survivors. It is as if we had invented sophisticated techniques to save people from drowning, but once they had been pulled from the water, we leave them on the dock to cough and splutter on their own in the belief that we have done all that we can." And then later on, "Survivorship should be studied as a phenomenon in itself, rather than as a byproduct or afterthought of basic research on cancer treatment." And I really am delighted that the work of this committee, and the work in this report, has raised those concerns to a new level and given them a new poignancy. And this isn't to say that in between 1985 and 2005, there hasn't been a great deal of accomplishment in this area, but today's report is really a high-water mark for that.

Now, it is a victory, and it is terrific that it is here. You could argue it has been a long time coming. Certainly, the survivors in the world, or the

survivors in the room might say, yes, but couldn't we have gotten here quicker? And one could sketch out a phenomenon or scenario where that might have happened.

I do think particularly speaking to the research community, but also to the clinical community, we tend to focus particularly as researchers or clinicians on victories. You want to win. You want cures. One wants cures, and certainly patients do, too. But the world view, the environment, intellectual, clinical view that is thereby created is one of victors. And we celebrate victors. Lance Armstrong has perhaps done a better job than anyone in doing that, and that is good. But there is the reality that many of the victories in cancer are encumbered by ongoing issues: uncertainty as to outcome; compromises as a result of therapies; psychosocial issues; *et cetera*, that we know well and are well documented in the report. Developing and supporting clinicians, research scientists, and support system personnel who really see as their mission in life a very rigorous set of activities, whether they are clinical or investigative with survivors, is really a change in the paradigm, or it is an addition to the paradigm, and happily that is coming. But I do think the natural proclivity to look for victory is both to be respected, and also to be looked askance at, or to be at least challenged. You've got to remember it isn't just a question of pulling them out of the water. But you get them on the dock. Are they going to stay on the dock? And are they going to have a reasonably civil time on the dock, or is it going to be hellacious while everybody turns their back on them and goes back to pulling somebody else out of the water? Without pushing the metaphor too far, I think that this is really a mission.

I would like to credit the NCCS, and Ellen in particular, for keeping survivorship on the agenda. And if it has taken arguably 20 years from the birth of the NCCS to today's report, which really puts this, as I say, in the national pantheon of topical issues, both medically and socially, it has been a hard forced march, and Ellen has been at the front of the column for most of that time, leading to this effort. So, I think it is a real salute to her and to all the organizations in cancer care, including ASCO, but the NCCS has been on message week in, week out over those two decades.

A couple of words about *Lost in Transition,* the report. I think that subtitle is great. I will remember it as *Lost in Transition* more easily than, *From Cancer Patient to Cancer Survivor*. Three recommendations I think stand out, and given a couple of moments at the podium, I just want to take the opportunity to hit those home.

The survivorship care plan concept, an individualized roadmap for each survivor, ought to be part of what we do clinically, and what people into survivorship encounter. It is terribly important. Just to pause for a moment, the late Peter Jennings, as we know, had a difficult and rapid downhill course with lung cancer. And you probably noted, that on the day

he announced his cancer, he said, "I am a survivor." Actually, the quote in *The Washington Post* was, "I'm told I'm a survivor," which meant he had to learn that this is a concept. But that that concept had gotten that far I think is a credit again to people in this room, both the clinical and the patient community that have pushed this idea, and gotten it to the newsmakers of America, even though they take a little instructing at that moment. And his survivorship was short, but the concept was there, and I think that is important. And while I don't know the intimate details of it, I suspect it was useful to him. But the notion that Peter Jennings and every one of us ought to have a survivorship care plan I think is just a terrific idea.

Survivorship research is a "gimme" in IOM reports—they always say there should be more research, and once again, we have said that. I think that is true, underline, exclamation point. The issues of long-term outcomes, of secondary effects of second tumors, which Dr. Horning has been particularly involved in personally herself, really need to be high on the agenda of cancer research. And I say that as a customer of cancer research and cancer care. I have not recently examined the figures, although I did at one point, and the amount we spent on what would be characterized as survivorship research was a pittance compared to what we spent trying to move ahead on more cures and more heroic rescues. It is good work, but we also have to look at the survivorship side.

And finally, what is not a gimme in all reports, although the IOM happily has had a number concerning it, is the issue of universal health insurance coverage. I could not leave this podium without hitting that home. There was a figure in the report stating that 11 percent of adult cancer survivors under age 65 do not have insurance. Nationally, 15 percent of the population does not have health insurance. And if you exclude the Medicare-eligible population, who virtually all have insurance, it is almost 18 percent of the population under 65 that are uninsured. I do not understand why cancer patients have a higher rate of insurance. But whether it is 11 percent or 18 percent, it is a bunch of folks. If it is the 18 percent, it is almost 1 in 5, and this presents a problem beyond being diagnosed with cancer. Being diagnosed with cancer now in an environment rich in interventions, rich in therapies, and even rich in a word I do not always use, cures or at least extended survivorship, and yet lacking the ticket to get into that care, that is a huge problem.

I had the opportunity in one of my other lives as a journalist to interview Senator Connie Mack when he was still in the Senate. Senator Mack, as you perhaps know, is a survivor himself, and has multiple family members who had cancer, and was a real champion in the Senate for cancer funding, cancer research, cancer support. He also was a fairly outspoken opponent of healthcare reform, expanded coverage in various ways. And I put that question to him. I said, on the one hand you have been terribly

articulate and very effective in generating support for cancer therapies and for new treatments, and for getting people saved. And yet, we have this orifice, this huge, gaping hole in our national tapestry of care called the uninsured, which lots of cancer patients fall into. And yet, you are not seemingly exercised about that. As a survivor and the champion of survivorship, doesn't that strike you as something that ought to be at the top of the agenda. And he answered in a fulsome way. He said, "Well, I hear what you are saying. But I am concerned that if we go to more governmental interventions in the field of healthcare coverage, it will discourage innovation. That if we get involved, it will mean more regulation, and the very productive research sector and the drug industry and so forth in America will be discouraged and will not continue to be as productive as they have been." And essentially, you could boil that down to saying that a move towards equity will kill off enterprise. I think he would agree that is essentially his argument. And that is a holdable position. That is an arguable case. I happen to think it is wrong, and I also happen to think that it is a formula for continued unfairness, and continued suffering. And certainly, from the perspective of cancer patients, that is a real issue.

Cancer patients whatever their views are—right, left, or center; Democrat or Republican—when they get diagnosed and do not have health insurance coverage, have a huge problem. And we have a huge problem as spokespeople for them and for that area. So, universal coverage, and you can color it or brand it whichever way you like, has got to be front and center on the agenda of survivorship in cancer, and I am delighted that it is in the report; one more good point in a great report. Thank you.

A SHORT VIDEO PRODUCED TO ACCOMPANY THE IOM REPORT AND ILLUSTRATE ITS FINDINGS AND RECOMMENDATIONS WAS SHOWN (IOM, 2006a)

INTRODUCTION TO THE PLENARY SESSION SPEAKERS

Sheldon Greenfield, Director, Center for Health Policy Research, University of California, Irvine

I am Shelly Greenfield, co-chair with Ellen Stovall of the IOM committee that issued the survivorship report. I am a primary care internist. There were four of us with a primary care focus on the committee amongst the people with various backgrounds, a testimony to the wisdom of the IOM in the recognition that survivorship is a truly integrative process, for which coordination of the various aspects of care is important. Before introducing

the panel, I want to thank the members of this committee and its staff. I have had the privilege and honor of being associated with many IOM committees over the past 10 years, and I will say that I have been on no committee or participated in no committee in which the members have been as diligent and as emotionally engaged as this committee.

I am not going to introduce the speakers this morning. You know them. I might ask them to say for outsiders, a word or two about themselves. Ellen has already introduced herself. So, we will just ask them to come forward. We will ask each of them to try to confine their comments to 15 to 20 minutes. We will have a few questions afterwards, and hopefully there will be a little bit of time after everybody has spoken for more general questions.

MEETING THE NEEDS OF CANCER SURVIVORS—RECOMMENDATIONS FROM THE IOM

Ellen Stovall, President and CEO,
National Coalition for Cancer Survivorship

Thank you, Shelly. I would like to begin with a brief history. Almost everyone in this room knows about some of the landmark events that informed this report. But to let you know how this all got started, it began with changing the language of the words "victim" and "patient" to the word "survivor" in 1985, when Fitzhugh Mullan wrote his landmark article in the *New England Journal of Medicine* (Mullan, 1985). The term "survivorship" existed nowhere in the medical literature in 1986 when the NCCS was founded. It was a term of art only. You couldn't find any references to it in any journal articles. Today, thankfully, it is a term of science.

In 1989, Natalie Davis Spingarn, one of the early founders of the NCCS, crafted the Cancer Survivor Bill of Rights, which laid forth many of the principles that are embodied in this report, including the survivorship care plan. The NCCS's *Imperatives for Quality Care,* published in 1995, we very proudly note led to the establishment of the Office of Cancer Survivorship at the NCI in 1996. We wanted a division, we got an office. And in 2003, the Centers for Disease Control and the Lance Armstrong Foundation brought many of us in the community together to create a national action plan on cancer survivorship, taking cancer survivorship into the public health arena (CDC and LAF, 2004). In 2003-2004, the President's Cancer Panel did a series of reports on cancer survivorship that have continued to inform us (President's Cancer Panel, 2004a; President's Cancer Panel, 2004b).

The IOM's survivorship report's origin can be traced to 1999, when the National Cancer Policy Board at the Institute of Medicine issued its report,

Ensuring Quality Cancer Care (IOM, 1999). Among the report's many findings was that "for many types of cancer, answers to basic questions are not yet available, for example, how frequently patients should be evaluated following their primary cancer therapy, what tests should be included in the follow-up regimen, and who should provide follow-up care."

The 1999 quality report spawned several other reports: a 2003 report, *Childhood Cancer Survivorship: Improving Care and Quality of Life* (IOM, 2003), which my friend and colleague Susan Weiner and Maria Hewitt shepherded through the IOM; a 2004 workshop report, *Meeting the Psychosocial Needs of Women with Breast Cancer* (IOM, 2004), and the report that we are now seeing here today.

The IOM committee that Shelly referred to is an outstanding group of wonderful colleagues and now friends. I am going to ask them just to stand briefly and be acknowledged by all of you. Those that are here today, if you would just stand so people can see you.

The committee started out by identifying who we are calling cancer survivors; about 3 percent of the population in this country and 15 percent of those 65 and older are survivors. Our report concluded that they are often lost to follow-up by oncology and primary care physicians. They are lost to follow-up through our healthcare systems, and they are grossly understudied by the research community. Successes in treating cancer and the aging of the population will bring us more and more cancer survivors as the years go forward.

The charge to the committee was to raise awareness of the consequences of cancer, to define quality care and outline strategies to achieve it, and to recommend policies to improve care and quality of life. The 17-member committee was referred to earlier. It included oncology and primary care physicians, people in urban and rural practice in this country, and people devoted to clinical and health policy research. We met three times over the gestation period, as I call it, to birth this baby, and we heard from lots and lots of outside experts, as the IOM process is exquisitely formulated to do, bringing forth the best and the brightest people in any one specific area of science.

The committee at its outset decided to accept the NCCS and the NCI definitions of a cancer survivor. Accordingly, an individual diagnosed with cancer is a survivor from the moment of diagnosis and for the remainder of his or her life. For purposes of this report we chose to focus on those we felt were most neglected, who fall off the cliff, and who are lost to follow-up, and that is those who have completed their primary treatment and are not being treated for a recurrence of their cancer (or a relapse) and are not receiving end-of-life care.

In its findings, the committee concluded that the negative consequences of cancer and its treatment are substantial and underappreciated. And al-

though the population is heterogeneous with some experiencing few late effects of their cancer, many, many more suffer permanent and disabling symptoms that impair their normal functioning even when their initial primary cancer treatment has been excellent.

Psychological distress, sexual dysfunction, infertility, impaired organ function, cosmetic changes, and limitation in mobility, communication, and cognition are among the many problems faced by cancer survivors. And the survivors' health, as we all know, is forever altered. And the good news out of this report is there is an awful lot that we can do to ameliorate these conditions.

We also found that survivors may be very unaware of their risk. The public lacks an awareness of cancer's effects and assumes that survivors have a plan for their follow-up. Shelly was telling us the other night that when he discusses the report's findings with people, they just can not believe that survivors would not be told what to expect or what to do following their diagnosis, but it is, in fact, the case. And so, opportunities to intervene when these consequences occur may often be missed. We have not tested models of survivorship care that are out there. And we know that the whole system of cancer care, not just this phase, suffers from an absence of coordination.

The committee made ten recommendations. Simply and most importantly, we recommended that awareness of the needs of cancer survivors be raised; that cancer survivorship be established as a distinct phase of cancer care; and that responsible parties act to ensure the delivery of appropriate survivorship care. Awareness needs to be raised for both healthcare providers and for the general public. It is common now for cancer patients to finish their treatment unaware of their risks. They are therefore, ill prepared to manage their future health needs. Oncologists exhibit wide variation in their follow-up practices, and primary care providers often lack up-to-date knowledge on survivorship.

To overcome the problem, the committee recommended that all patients completing primary treatment be provided with a survivorship care plan, and Patti Ganz is going to go into much more detail in the next presentation, so I will not elaborate on that. Survivorship care planning is not a new recommendation. It has been called for by the President's Cancer Panel (PCP, 2004b), the Centers for Disease Control and Prevention, the Lance Armstrong Foundation's Action Plan on Survivorship (CDC and LAF, 2004), the NCCS's Imperatives for Quality Cancer Care (NCCS, 1996), and many, many other groups.

The committee's third recommendation calls for the development and use of clinical practice guidelines. Some guidelines are available for certain aspects of survivorship care, but most are incomplete and not based on solid evidence. Cancer survivors represent a very large at-risk population, and without evidence-based clinical practice guidelines and quality-of-care

indicators healthcare providers will continue to vary widely in their practices. More than 60 percent of cancer survivors are aged 65 and older, so the Centers for Medicare & Medicaid Services, the administrators of the Medicare Program, have a stake in the development of clinical practice guidelines and quality-of-care measures. Because cancer is a complex disease and its management involves the expertise of many specialists often practicing in different settings, cancer illustrates well the quality chasm that exists within the U.S. healthcare system overall, and the need for health insurance reforms and innovations in healthcare delivery.

Several models that are promising for delivering survivorship care are emerging, including collaborative shared care models that formally link oncology specialists with primary care providers, nurse-led models, and specialized survivorship clinics. Our fifth recommendation calls for demonstration programs to test these potential models for survivorship care.

The report's sixth recommendation calls for congressional support for the Centers for Disease Control and Prevention and states to develop, implement, and evaluate comprehensive cancer control plans that include consideration of survivorship care.

Recommendation number seven calls for the NCI, professional associations, and voluntary organizations to expand and coordinate their efforts to provide educational opportunities to healthcare providers to equip them to address the health and quality-of-life issues facing cancer survivors. Few oncology and primary care professionals have formal education and training regarding cancer survivorship. With the growing ranks of cancer survivors at 10 million strong today, it is likely that additional health personnel will be needed, particularly nurses with advanced oncology training. To insure access to psychosocial services, continuing education opportunities are needed for social workers and other mental health providers. In addition, efforts are need to maintain social services in cancer programs.

Most cancer patients who worked before their diagnosis continue to work, but they often require some kind of accommodation. As many as 1 in 5 of us who worked at the time of diagnosis have cancer-related limitations in ability to work one to five years later. Half of those with limitations are unable to work at all. All survivors are at risk of experiencing subtle, although not necessarily blatant, employment discrimination. Federal laws enacted in the 1990s have offered cancer survivors some protections from discrimination such as firing or denial of benefits because of cancer. Our eighth recommendation calls for employers, legal advocates, healthcare providers, and others to act to minimize adverse effects of cancer on employment while supporting cancer survivors with short-term and long-term limitations in their ability to work.

Recommendation nine calls on federal and state policymakers to act to ensure that all cancer survivors have access to adequate and affordable

health insurance. Furthermore, insurers and payers of health care should recognize survivorship care as a distinct part of cancer care, and design benefits, payment policies, and reimbursement mechanisms to facilitate coverage for evidence-based aspects of care. The health insurance issues facing cancer survivors today bring into sharp focus the gaps and limitations of health insurance throughout our country. All Americans are at risk of becoming a cancer survivor and finding themselves without access to adequate and affordable health insurance. Cancer survivors, like other Americans with serious chronic health conditions, face significant barriers to coverage because of their health status. In particular, access to individual health insurance may be denied to residents in many states. Cancer survivors may also face surcharge premiums for coverage, because of their cancer history. The improvements in the care of cancer survivors envisioned by the committee cannot be achieved without health insurance that is accessible, adequate, and affordable.

Our last recommendation concludes that a greater investment in research is needed to learn more about cancer's late effects and their management. Cancer treatments are constantly evolving and, consequently, what is known about today's cancer survivors may not be relevant to future patients.

I want to conclude by quoting from an article that was in the *Annals of Internal Medicine* four years ago (McKinley, 2000):

> After my last radiation treatment for cancer, I lay on a cold, steel table, hairless, half-dressed, and astonished by the tears streaming down my face. I thought I would feel happy about finally reaching the end of treatment, but instead I was sobbing. At the time I wasn't sure what emotions I was feeling. Looking back, I think I cried, because this body had so bravely made it through 18 months of surgery, chemotherapy, and radiation. Ironically, I also cried, because I would not be coming back to that familiar table where I had been comforted and encouraged. Instead of joyous, I felt lonely, abandoned, and terrified. This was the rocky beginning of cancer survivorship for me. I'm done according to the medical profession, but I don't feel done. I think we survivors are never truly done. We just move from the quantifiable, treatable disease to the immeasurable uncertainty of survivorship. Being in the midst of active treatment means being seen regularly by a nurse or a doctor, being truly cared for. As I got up off that radiation table for the last time and walked away, I found myself alone with a cancer ghost who would not let me forget where I had been, or allow me to freely choose where I might be going. We cancer survivors are a million strong, and our ranks will grow as improved treatments extend our lives, but because the struggle with uncertainty after treatment is completed is usually a silent battle waged outside of the doctor's office, most physicians don't think or talk about it. In my life as a primary care doctor before cancer, I certainly did not. Now I believe that we physicians need to talk with our cancer survivors about

the unique struggles of survivorship. Oncologists need to focus on preparing us cancer patients for survivorship. That is, they must address the loss experienced by survivors when active treatment is over, and they are sent away from a very intense environment. They must help survivors understand the impact of fear and uncertainty on their lives, and what might help us to reduce those stresses."

Dr. Greenfield: Are there questions that we might entertain at this time?

Bob Weiss: I am representing the National Lymphedema Network. In the definition of cancer survivor, do you include the patients who have been diagnosed and treated for ductal carcinoma *in situ* (DCIS) and lobular carcinoma *in situ* (LCIS). I know that they are not included in the cancer statistics of cancer diagnoses.

Dr. Ganz: DCIS and LCIS are included in cancer registries. DCIS is stage 0 breast cancer. Women who are treated for DCIS may experience late effects and would be considered a survivor of early stage breast cancer.

IMPLEMENTING THE CANCER SURVIVORSHIP CARE PLAN AND COORDINATING CARE

Patricia Ganz, Director, UCLA Division of Cancer Control, Jonsson Comprehensive Cancer Center

My name is Patti Ganz. I am a medical oncologist. Actually, I am very pleased to be here as well, because I was one of the founding members of the National Coalition for Cancer Survivorship. When Fitz Mullan invited me to go to that small meeting in Albuquerque, I did not know it would lead to this. So, it is really exciting to be here today.

I am going to be talking about the cancer survivorship plan. First, I am going to give you my perspective as an oncologist, reflecting on how things have changed, and why it is important, and why we are where we are now; and some of the complexities and challenges of treatment. I am also going to discuss some of the strategies that we can use, and then specifically how the survivorship care plan can serve as a model of coordinated patient-centered quality of care. Finally, I will review recommendations for implementation. I will be highlighting my experience with breast cancer in my remarks, but most of the themes that emerge are applicable to other cancers.

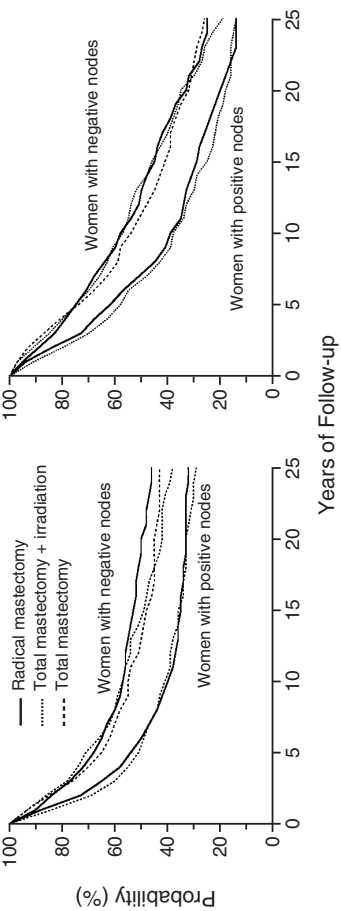
So, first of all, I am going to talk about breast cancer treatment from a historical perspective. In 1971, I was doing my surgical rotation in medical school and, incredible as it may seem, a woman with a lump in her breast was anesthetized, and had to sign a consent to either a mastectomy or a

biopsy, and would awake with bandages, not knowing whether she had her breast or not. And indeed, she was actually in the setting where I was trained, consenting for the randomized trial, the National Surgical Adjuvant Breast and Bowel Project (NSABP) B-4 trial, so she didn't even know if she was going to have a modified radical mastectomy or a Halsted radical mastectomy. Again, it is really shocking to think that this is the way we managed breast cancer at that point in time.

The NSABP B-4 trial was a randomized trial that compared the Halsted radical mastectomy to the less invasive modified radical mastectomy. The Halstead procedure involved removal of all of the pectoral muscles, an axillary dissection that often included the excision of as many as 30 lymph nodes, and left women with substantial morbidity in terms of arm function and edema. The modified radical mastectomy does not remove the pectoral muscles and fewer lymph nodes are excised. Figure 2-1 shows disease-free survival and overall survival rates through 25 years of follow-up from the NSABP B-4 trial for women with node-negative and node-positive disease. For women with breast cancer, the Halsted radical mastectomy proved to be no better than the modified radical mastectomy.

In the 1970s then, there was a growing recognition that breast cancer was a systemic disease, and we recognized then that local treatment of the breast really did not affect mortality, but rather women died because there was distant disease that had escaped before, in fact, the cancer was found. And this was especially critical for women if they had tumor in the lymph nodes. During this period, early trials of adjuvant chemotherapy, which at that time was being given for as long as two years after primary treatment, were initiated, particularly in women with node-positive disease to see if we could do anything to improve the recurrence rate and survival.

In the 1980s there was increasing consumer involvement as in all health care, but particularly in breast cancer. There happily was elimination of the one-step procedure and adoption of a two-step procedure, so that if a woman presented with a lump in her breast, she would first have a biopsy done as an outpatient, and then could go ahead and prepare herself for the fact that she had cancer and needed to have a mastectomy. There was mounting clinical evidence by two large trials, one done in Europe and one done in the United States, that breast-conserving surgery (lumpectomy and radiation therapy) was equivalent to mastectomy, and lo and behold, there began a revolution in the primary treatment of breast cancer. And with this, there was increasing patient involvement in surgical decision-making. That is, if these two treatments are equivalent, would you rather spare your breast, or would you rather have a mastectomy? This was perhaps not a great choice, but clearly one women could opt for. Fortunately, today we don't present women with that difficult choice. We just tell them they are candidates for breast-conserving surgery.



No. at Risk						
Negative nodes						
Radical mastectomy	362	174	47	362	218	59
Total mastectomy + irradiation	352	181	41	352	216	56
Total mastectomy	365	170	50	365	209	59
Positive nodes						
Radical mastectomy	292	99	23	292	120	27
Total mastectomy + irradiation	294	93	28	294	115	32

FIGURE 2-1 Results of NSABP B-4 clinical trial.
SOURCE: Fisher et al., 2002. Copyright © 2002 Massachusetts Medical Society. All rights reserved.

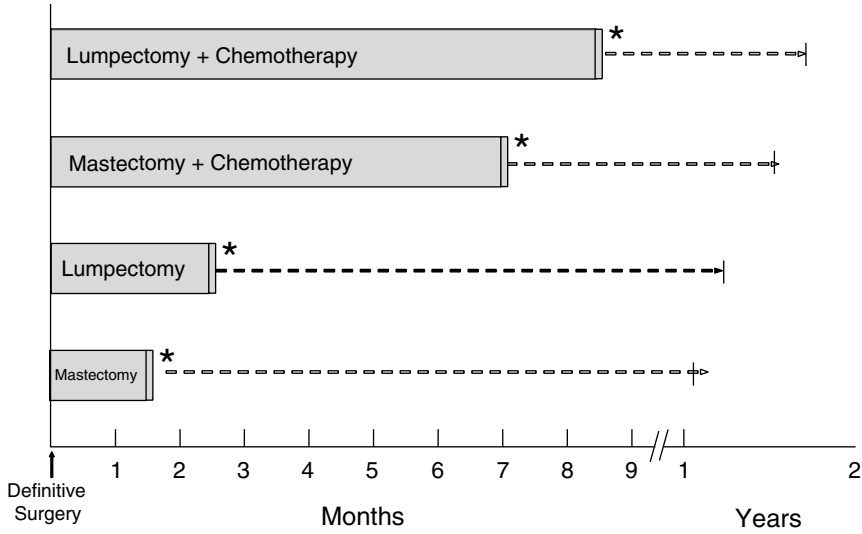


FIGURE 2-2 Current breast cancer primary treatment patterns. Adapted from Ganz et al., 2004, with permission, Oxford University Press.

Three important National Institutes of Health (NIH) consensus conferences have focused on breast cancer. In 1985, there was a consensus conference that concluded that adjuvant therapy with chemotherapy should be given to all pre-menopausal women with node-positive disease. In 1990, a consensus conference focused on the primary treatment of breast cancer, that is, the issue of mastectomy versus breast-conserving surgery. This conference recommended that all women be offered breast-conserving treatment if possible, and that the option of adjuvant therapy be discussed. In 2000, a consensus conference focused on adjuvant chemotherapy and recommended that all women with tumors that were greater than a centimeter in size should receive chemotherapy, and if the tumor contained hormone receptors, women should receive endocrine therapy. This focus on small tumors is notable. The tumors that I first saw when I was a medical student were usually 3, 4, and 5 centimeters in size. Now, with mammographically detected cancers they are often less than a centimeter in size.

Figure 2-2 comes from a study that we recently completed and illustrates how extensive the treatment for breast cancer is. If a woman just has a mastectomy, she may complete her primary treatment in about a month or so in terms of recovering. If she has a lumpectomy with radiation and no chemotherapy, she might be finished with her primary treatment at about

TABLE 2-1 Five-Year Relative Survival (Percent) during Three Time Periods, by Cancer Site

Site	Relative Survival* (%) during Three Time Periods by Cancer Site		
	1974-1976	1983-1985	1992-1999
All sites	50	52	63
Breast (female)	**75**	**78**	**87**
Colon and rectum	50	57	62
Leukemia	34	41	46
Lung & bronchus	12	14	15
Melanoma	80	85	**90**
Non-Hodgkin's lymphoma	47	54	56
Ovary	37	41	53
Pancreas	3	3	4
Prostate	67	75	**98**
Urinary bladder	73	78	**82**

*Five-year relative survival rates based on follow-up of patients through 2000.
SOURCE: Surveillance, Epidemiology, and End Results Program, 1975-2000, Division of Cancer Control and Population Sciences, National Cancer Institute, 2003.

three months. With mastectomy and chemotherapy it can go out to eight months. And with lumpectomy and chemotherapy, treatment may extend way beyond nine months because radiation therapy is delayed until after chemotherapy is completed. So, again, this is a very long and complex road that a woman with breast cancer, who has an excellent survival, has to face in terms of the primary treatment of her disease.

Table 2-1 shows statistics that document improvement in survival from the 1970s to the 1990s. Five-year relative survival for all cancer sites has improved from 50 percent when I was doing my training as a medical student and early oncologist to 63 percent by the 1990s. But look at breast cancer, 5-year relative survival has increased from 75 to 87 percent over this period. Improvements have also been made for other cancers including melanoma, prostate cancer, and bladder cancer. These are phenomenal data in terms of survivorship.

Figure 2-3 shows trends in use of screening mammography and adjuvant therapy published in a recent article from the *New England Journal of Medicine,* again just to show you how things have changed. In 1985, very few women were getting their mammograms, and now we have women getting mammograms regularly which contributes to improvements observed in breast cancer survival rates. Figure 2-3 also shows data on the use

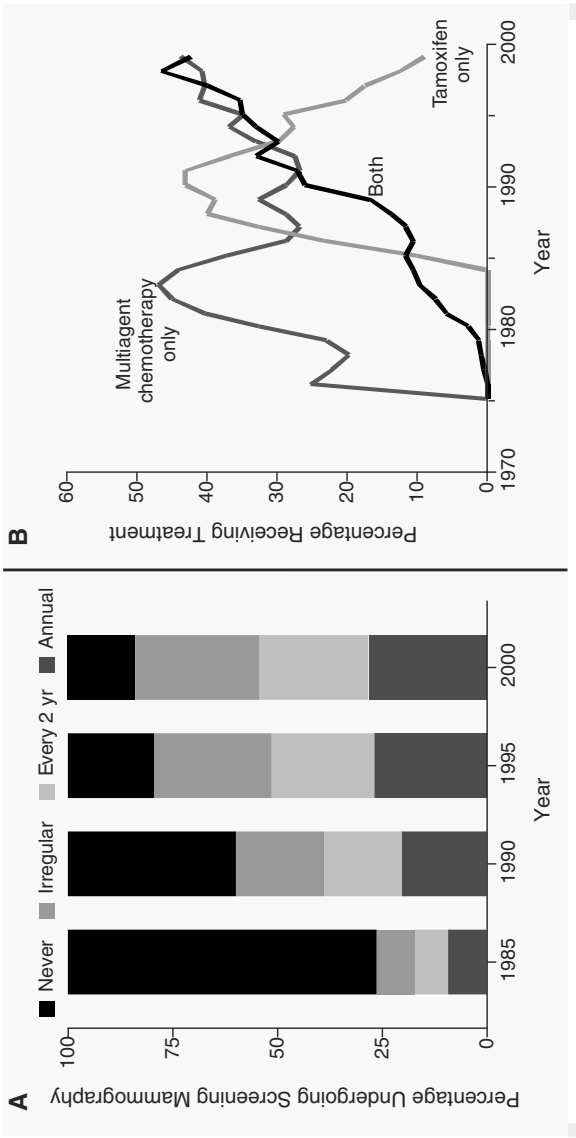


FIGURE 2-3 Changes in the pattern of use of screening mammography among women 40 to 79 years of age (Panel A) and in the use of adjuvant therapy among women 50 to 69 years of age with node-positive stage II or IIIA breast cancer (Panel B).
SOURCE: Berry et al., 2005. Copyright © 2005 Massachusetts Medical Society. All rights reserved.

of adjuvant chemotherapy, and endocrine therapy, indicating the dissemination of both of these modalities, again leading to vast improvements in survival, but adding complexity.

Now, what is happening in the 21st century? After the 2000 NIH consensus conference, there was a very short period of time where we agreed on what to do. But here we are, and now women are getting endocrine therapy for at least 10 years and maybe more. There will be clinical trials testing this. Adjuvant trastuzumab (Herceptin®) was recently shown to have a phenomenal benefit in terms of the adjuvant therapy for women whose tumors over-express human epidermal growth factor receptor 2 (HER2), and treatment with this particular agent is intravenously given for a year, and there are some studies looking at two years of therapy. Again, I want to tell you that the story of breast cancer and the success in terms of survivorship is really replicated for many other cancers. This is just one tumor history and story.

So, what are the challenges that this particular anecdote brings to mind? Well, cancer treatment is, if nothing else, very complex. It is multimodal. There are many individuals involved in the care, and it is usually a surgeon, a radiotherapist, and a medical oncologist. There may be multiple consultations prior to going on to an experimental protocol. It is very, very complicated. It is toxic, and there is no doubt about that. That is why we have to look at the safety, as well as the benefit issues in terms of our treatment. And it is very expensive. And this is again, high out on the radar screen for the Centers for Medicare & Medicaid Services (CMS) and other funders of insurance. And finally, it is often poorly coordinated. Even though I have shown you that there have been tremendous advances in dissemination of what we know, often individuals are even lost during this primary treatment; it is not just lost in transition.

Cancer treatment usually occurs in isolation from primary healthcare delivery. If you can imagine yourself as a patient going through one of these scenarios in terms of treatment, it is pretty hard to get up the energy to go visit your primary care doctor to have a chat. And unless you have a lot of other co-morbid conditions that have to be managed simultaneously along with your cancer, you are probably not going to check in with your primary doctor, who may have diagnosed your cancer, until many months or even a year or more later. So, there is a natural isolation, because of the complexity of treatment.

There are other challenges in survivorship care. There has been limited systematic study of the late effects of cancer therapy, and this is documented very well in our report. Follow-up care plans have been ad hoc, with a limited focus on surveillance for recurrence. And that is really what the oncologist's primary interest is. "Now that I have gotten you through this treatment, I want to make sure that you do not have a recurrence," and

that is again all of what we learn in our training in terms of how we follow patients on clinical trials, the emphasis being on detecting a recurrence. There is little emphasis placed on health promotion and disease prevention. And again, this is really the issue. When can we make that transition? When is the person considered out of the woods in terms of recovering from the toxicity of therapy, so that we can say, "Well, you need to lose weight and you need to go out and exercise" and put this high on the radar screen? Another important survivorship issue with quality-of-life implications is infertility. Women have commonly been told, "Dear, you should just be happy to be alive." I don't think that is acceptable today. If we expect somebody to live a normal life span after their primary treatment, we need to address the issue of infertility, and this goes for both men and women.

So, why does cancer care present such a challenge? And again, just to summarize, an average of three specialists are involved per patient. Consequently, if you want to do chart reviews, you have to get all these charts to thoroughly evaluate quality. Treatments may occur across time and space and not be confined to the same institution. In a place like Los Angeles, where I work, very few patients get radiotherapy at my facility. They go to a place closer to their home. There is limited communication among the treating physicians, and there are multiple medical records.

Proposed strategies to address these challenges, even in the primary treatment of cancer, include an integrated electronic medical record. People are using patient navigators. Many savvy cancer centers have facilitators for the patients to help them get through this maze. And people like Laura Esserman have looked at a consultation planning session. Shelly Greenfield and his wife Sherry Kaplan did this a long time ago, where they prompted patients about what to do in terms of going into their visits with their doctors. But none of these strategies is actually widely available, even for patients receiving active treatment. And so, it is not surprising that they fall through the cracks when treatment ends.

So, why do we need this survivorship care plan now? I think it is critical that we summarize and communicate what transpired during the cancer experience. Certainly, the patient who may be stressed by that process and going through it may understand in the beginning about what they are going to be getting, but they have no idea often what exact drugs they got, what their side effects are, what the doses were, and so forth. We need to somehow summarize this information for them, and for the physicians who are going to be caring for them in the future, and for the medical record, so that there is one place in the record we can find it. The survivorship care plan is also needed to describe any known and potential late effects of cancer treatments, with the expected time course. There is a paucity of information on some late effects, but we do have information on some, and what we do know needs to be adequately communicated. We also need to

BOX 2-1
Attributes of Quality Care,
IOM Committee on Quality of Health Care in America

- Care based on continuous healing relationships
- Customization based on patient needs and values
- The patient as the source of control
- Shared knowledge and the free flow of information
- Evidence-based decision-making
- Safety as a system property
- The need for transparency
- Anticipation of needs
- Continuous decrease in waste
- Cooperation among clinicians

SOURCE: (IOM, 2001).

communicate to the survivor and other healthcare providers what has been done, and again importantly, what needs to be done in the future, again, to the best of our abilities at that point in time. The survivorship care plan is also needed to promote a healthy lifestyle to prevent recurrence and reduce the risk of other co-morbid conditions. Wendy Demark-Wahnefried, Julia Rowland, and others just wrote a wonderful article in the *Journal of Clinical Oncology* talking about the missed opportunities for prevention and healthy lifestyle promotion in survivors (Demark-Wahnefried et al., 2005). Cancer survivors are at risk not only because of their exposures, but because they get other co-morbid conditions due to aging. There is never a time to miss the opportunity to provide consultation.

The optimal delivery of survivorship care, as Ellen has already alluded to, flows from recommendations from other IOM reports focused on quality of care, in particular, *Crossing the Quality Chasm* (IOM, 2001). The attributes of a system delivering quality care are listed in Box 2-1. I think the issues of shared knowledge and free flow of information, the need for transparency, and the anticipation of needs are really important. Vital also is cooperation among clinicians, again, because of the fragmentation of our system.

Committee member Rodger Winn eloquently pointed out in our discussions that most oncologists do not realize that there is a distinct group of people within the cancer care trajectory that are in need of survivorship care. This survivorship care phase of the cancer care trajectory is repre-

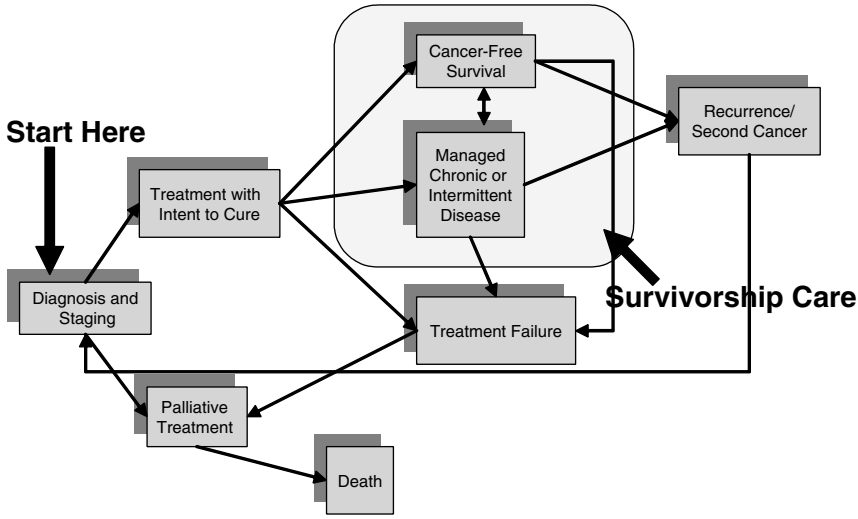


FIGURE 2-4 Survivorship care as a part of the cancer care trajectory.
SOURCE: IOM, 2006b.

sented in Figure 2-4 as the large shaded box. In the figure, everybody comes into the treatment system upon diagnosis. Some patients may be candidates only for palliative treatment at the beginning, but the majority of patients we see are treated, often with an attempt to cure. And the very large number of individuals wind up in this shaded space where, again, we have little information about how care should be managed, and no communication about the transition into this phase. So, this is what we are acknowledging in this report, this phase of the cancer care trajectory, which patients may, in fact, inhabit for a very long time, completely disease-free, or go back and forth, or be maintained very well with long-term therapy.

The other point that I would like to make is that the survivorship care plan is really a place to start in ensuring quality cancer care. We have paid a lot of lip service to this, and again, if we want to start somewhere, it may be somewhat simpler to address the quality of survivorship care than to address the quality of primary treatment for each of the different cancers. We can focus on quality during this transitional phase by establishing a care plan and it will be applicable for the vast majority of individuals treated for cancer.

The key elements of the survivorship care plan are outlined in Box 2-2. The care plan should communicate to the patient clearly: their diagnosis; the stage of the disease; the initial treatment plan; whether they actually got what had been planned for them, or whether excessive toxicity limited the

BOX 2-2
Key Elements Included in the Survivorship Care Plan

- Specific tissue diagnosis and stage
- Initial treatment plan and dates of treatment
- Toxicities during treatment
- Expected short- and long-term effects of treatment
- Late toxicity monitoring needed
- Surveillance for recurrence or second cancer
- Who will take responsibility for survivorship care
- Psychosocial and vocational needs
- Recommended preventive behaviors/interventions

SOURCE: (IOM, 2006b).

ability to deliver what was planned; and toxicities experienced during treatment. Patients, for example, sometimes receive blood transfusions during treatment which can pose risks for hepatitis and other infections that can have long-term health consequences. Other key elements of the survivorship care plan include the expected short- and long-term toxicities or late effects expected from the treatments and the kind of surveillance and monitoring needed both for these late effects, as well as for recurrence or second cancers.

Critical to this plan is designating who will take responsibility for what aspects of follow-up care. In sitting down with the patient and presenting the plan, the oncologist can say, "Well, I'll take care of your follow-up mammograms, but your primary care doctor needs to take care of your hypertension, your diabetes, checking your cholesterol, and making sure that you get your bone density studies done. And we'll talk frequently about the results and how they may be related to the treatment that you received." Also important is attending to psychosocial and vocational needs, as highlighted in our video. Interventions are also needed to prevent additional sequela that may occur, and the common problems that people have in our society because of obesity and lifestyle risk factors.

So, how should we use this in practice? I am thinking about this written care plan as a document that would facilitate communication at the end of treatment visits. It would enable me to sit down with the patient and go over the key elements in a systematic way, very much the way I do initially with patients when I have their initial pathology report, and I discuss the randomized trials that are available to discern what type of treatment is

best for them. It is kind of a bookend to that initial consultation. The survivorship care plan is a formalized way to coordinate follow-up care, and to really define who will take charge, and what follow-up care is needed. Critically, it is a form of communication for all involved with the patient's care, those who have been involved in the past, and those who need to be involved in the future. The care plan also tells a story about what went on. And again, as I have told you by my anecdote about breast cancer, it is pretty complicated. Often the primary care physician is not along for the ride, and has to pick up the pieces afterwards.

What do we need to do to implement this survivorship care plan? First, I think we need to have widespread acceptance of cancer as a chronic disease. And unlike other chronic diseases, which may actually accelerate and get worse over time, we have this up-front intensive therapy and then diminished treatment activity. So, again, cancer care doesn't strictly follow the usual chronic model, say of a disease like diabetes or asthma. Secondly, we need to provide adequate reimbursement for this evaluation and management time that will be required both to prepare the plan for that consultation, and to effectively communicate it to patients and those providers who are involved in their care. Thirdly, we need to expand the evidence base of knowledge regarding late effects. And of course this needs to be through systematic research. And more importantly, we need to find the health professionals out there who are willing to focus on this topic. Lastly, we need to train physicians starting at the medical school level, but going through post-graduate education and also for practitioners in practice about how they can in fact work together to ensure high-quality care for cancer survivors.

Figure 2-5 illustrates where a cancer survivorship care plan might fit in a chronic care model, where we have a proactive, prepared practice team, and we have an informed, activated patient. And again, I can think of nothing better than the survivorship care plan to be interdigitated in this interaction. We have the rest of the healthcare system in the external part, but we are talking about patient-centered care, survivorship-centered care, and again, this type of document can greatly facilitate this activity.

Some of the facts you have already heard. Importantly, there are now more than 10 million cancer survivors, representing about 3.5 percent of the U.S. population. That is really what the imperative is for us. Who are the stakeholders? And how can they be influenced to promote the survivorship care plan? Figure 2-6 is a busy diagram, and I hope I haven't missed identifying stakeholders. To ensure better outcomes for chronic conditions including cancer, we have to influence the policy environment through the public, advocates, and employers, and through important community links through organizations such as the Centers for Disease Control and Prevention (CDC), the Lance Armstrong Foundation (LAF), the American Cancer

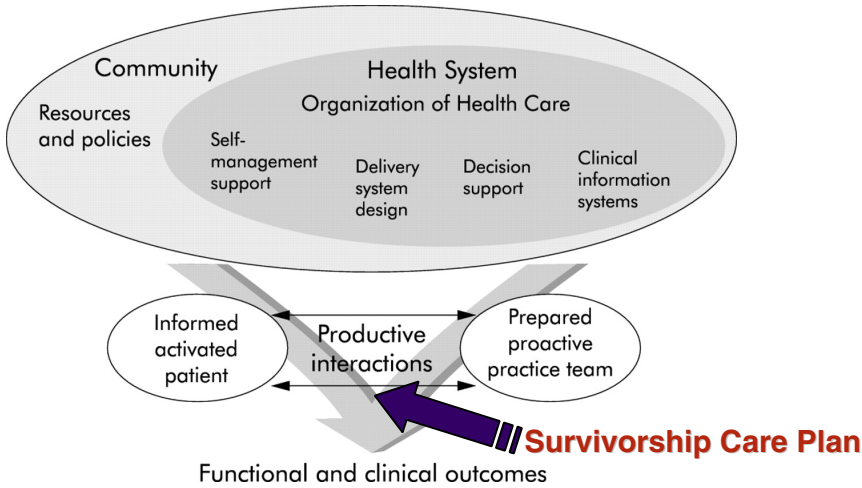


FIGURE 2-5 Where does the survivorship care plan fit into the chronic care model?
SOURCE: Adapted from Epping-Jordan et al., 2004.

Society (ACS), ASCO, and associations representing primary care providers. Coordinated efforts are needed to raise community awareness, encourage better outcomes, and mobilize and integrate resources. In terms of healthcare organizations, we have the employers playing a big role as a major source of health insurance. But clearly CMS, the Department of Veterans Affairs (VA), even the provider organizations that deliver the care need to encourage and provide the environment in which the chronic care management for cancer survivors can become a reality.

So, some final thoughts. I think we are really at a critical juncture in time here. Again, many of us bemoan the fact that we have a huge federal deficit, that there are very few resources now for research in the way we have had them over the past decade. But sometimes we can work more creatively and efficiently under these kinds of constraints. There may be opportunities for us to find and save money, decrease waste, and increase coordination of care by doing something as simple as implementing the cancer survivorship plan. Cancer care is high on the agenda because it is a major component of the healthcare budget and our drugs are very beneficial, but it is also very expensive. The majority of cancer patients are Medicare beneficiaries, and with rapid expansion of this group over the next several decades because of the aging of the baby boom population, cancer survivorship should become a high priority on the policy agenda for

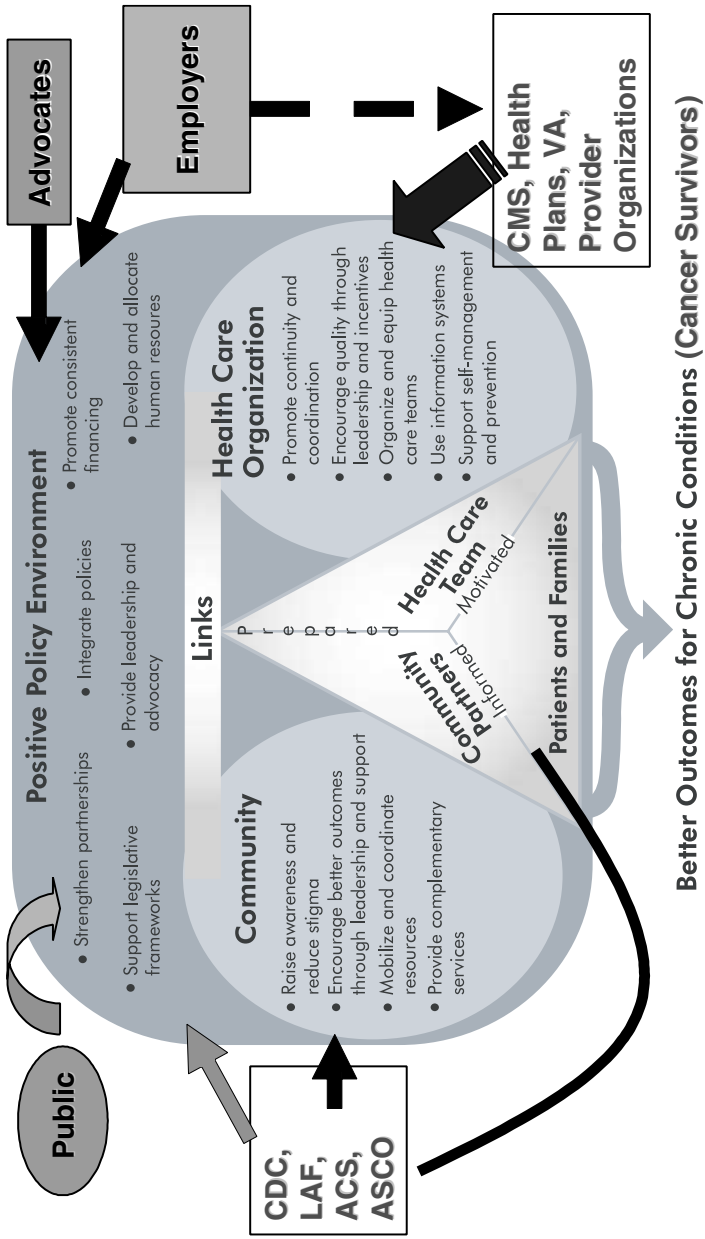


FIGURE 2-6 Cancer survivorship stakeholders.
SOURCE: Adapted from Epping-Jordan et al., 2004.

CMS. I believe it is time to use cancer survivorship as a model for quality chronic disease management, and the survivorship care plan is a place to start.

Dr. Greenfield: Are there any questions?

Susan Leigh: I am one of the very proud founding members of NCCS. Patti, thank you so much for your overview of the survivorship care plan. I would like to add that there is one area that we really need to start focusing on, and that is how we prepare people for the potential risks and for the different decisions that have to be made once something happens. In following up on your example for breast cancer, I am a long-term Hodgkin's survivor who then developed breast cancer. My decision-making was very, very different from someone who was initially diagnosed with breast cancer. I know that you want to start taking a look at that particular population, because we are all having to make very different decisions, because we have got different kinds of cancers, and we have different histories with the therapies that we had in the past.

Dr. Ganz: Thank you.

Dr. Greenfield: I am sure to most people in this room, this is like water flows down hill. I don't want to blindside you, but could you give your sense of the resistance against this notion of a survivorship care plan?

Dr. Ganz: I am a sensitive, caring, cancer survivorship doctor. Do I use a survivorship care plan? No. Why? Because nobody has told me that I should do it. I do sit down with patients at the end of treatment, and I do have a systematic discussion about how often I am going to see them, and what kind of problems to expect. I am certainly attending to their menopausal symptoms that they have gotten as a result of my treatments, and I am doing all of those things verbally in my consultations. I am going to follow those patients, and I am not going to abandon them. And I usually have pretty good relationships with the physicians whose patients I see. But I do not send a consult note to their primary care physician at the end of treatment, which is what I do at the beginning. I do not have a structured, written set of materials, which I do when I see a new patient with breast cancer. I have kind of an education sheet that I actually go through. So, while I hate to say we need regulation and external reasons to do this, I think things that would facilitate survivorship care planning include the development of templates, a call to action that this is the expectation, and training medical oncology fellows, surgeons, and others who take care of cancer patients to consider this as an aspect of quality care. So, we have to

start at all these levels. I think it can become a reality, but right now it is just not a routinized part of practice.

DEVELOPING GUIDELINES, INSTITUTING QUALITY IMPROVEMENT, AND STRENGTHENING PROFESSIONAL EDUCATION PROGRAMS

Rodger Winn, Clinical Consultant, National Quality Forum

Good morning. I am a medical oncologist who has worked in both private practice and academic settings and have been an observer of the healthcare system in cancer. I have been involved with the development of clinical practice guidelines and quality measures, so I bring that sort of expertise to this symposium. I am going to address the issues of education, guidelines, and quality measures as we discuss moving ahead and implementing the IOM's recommendations. As Patti Ganz has already mentioned, I advocated to the IOM committee that we view cancer survivorship as a distinct phase of the cancer trajectory with a unique constellation of needs and problems requiring specific interventions. This conceptualization was, in part, inspired by the experience with end-of-life care. Until fairly recently, there was a perception that individuals with a cancer recurrence went from recurrence to death, and that there was nothing in between. And then a group of very bright people said there is something called end-of-life care, which is a distinct phase of care, and which requires its own set of interventions and assessments. It is only when this distinct phase of care became recognized, that the whole field moved forward, and end-of-life care became integrated into practice. I think we have recognized that following primary treatment, there is another "box" called survivorship care. Having said that, the question then is "Once you recognize it, is that all that there is to it?" I would like to suggest that it is not a given that our healthcare professionals will, in fact, be able to deal with this "box." They may not possess the appropriate knowledge and skills to assess and address the unique needs and problems of cancer survivors.

This is probably not a perfect analogy, but one could consider mantle cell lymphoma, which is a lymphoma variant that was widely recognized several years ago once special tests became available. Individuals with mantle cell lymphoma now require colonscopy and aggressive therapy. For the lymphoma doctors, the recognition of this variant did not represent a departure from their practices. There was no change in the paradigm. Once you recognized it, it took some different kinds of interventions, but they moved right into it. The other example that might be more applicable to survivorship is your primary care doctor in the early eighties who suddenly has a pneumonia patient with AIDS. This is no longer a pneumonia patient.

BOX 2-3
Domains of Survivorship Care

- Surveillance for recurrence
- Detection of metachronous tumors
- Management of late effects of disease
- Management of late effects of treatment
- Prevention of secondary tumors
- Genetic evaluations
- Psychological sequelae
- Social/economic consequences
- Legal consequences

This is a totally different "box," if you will. This takes a whole different set of skills and learning to deal with. The question for us here today is where are we with survivorship?

Survivorship care is incredibly comprehensive as reflected in its many domains (Box 2-3). Many of these areas are really outside of the purview of what is called active treatment. How do we gear up to provide this range of services? Can we do it?

Just to illustrate this issue, we can take the management of depression as an example. Table 2-2 provides data from the work of Steve Passik on oncologists' recognition of depression among their patients (Passik et al., 1998). He assessed over 1,000 patients in 12 oncologists' practices for depression using the Zung Self-Rating Depression Scale. He compared these results to oncologists' ratings of their patients' level of depressive symptoms. About 60 percent of the patients had stable or no evidence of disease, so they were in the survivorship phase. While physician ratings of depression were concordant with patient reports of no significant depressive symptoms 79 percent of the time, they were only concordant 33 and 13 percent of the time in the mild-to-moderate and severe ranges, respectively. Nurses assessments really were not very much better. It is not sufficient just to say that depression is part of survivorship care. We really need to increase providers' skills in this area.

The IOM committee identified three areas where recommendations could advance the field—professional education, clinical practice guidelines, and healthcare quality measures. My presentation on these topics may sound like a litany of despair, but I would like to show you where we are now, because that at least shows us where we need to start, and how we can move forward.

TABLE 2-2 Oncologists' Recognition of Depression

	Percent Concordance
Oncologists	
• No depression	79
• Mild-to-moderate depression	33
• Severe depression	13
Nurses	
• Mild to moderate	29
• Severe	14

SOURCE: Passik et al., 1998.

In the area of education, the IOM committee's seventh recommendation calls for the NCI, professional associations, and voluntary organizations to expand and coordinate their efforts to provide educational opportunities to healthcare providers to equip them to address the healthcare and quality-of-life issues facing cancer survivors. I reviewed professional education and training opportunities for physicians including residency and fellowship programs, medical textbooks and journals, and continuing medical education (CME) programs. Committee member Betty Ferrell completed a comparable review for nursing.

So, what about physician training programs? When you look at the curricula developed by the American Academy of Family Physicians (AAFP) and the American Board of Internal Medicine (ABIM), there is really virtually nothing on cancer survivorship. When I looked at the curriculum for clinical oncologists, survivorship content was lacking, but Dr. Horning mentioned this morning that survivorship is being put into the curricula for fellows. Very often, the curricula I reviewed would address certain relevant domains, but survivorship was not covered comprehensively.

How about medical texts? If you are in practice, where do you go to learn about a new subject? One resource is medical textbooks. I reviewed seven family practice and internal medicine textbooks available at the library, and my first observation was that survivorship was not indexed in any of the texts. And I am not sure why this is. There is a lot of emphasis on Hodgkin's disease follow-up and on issues related to genetics, both of which are important. However, half of cancer survivors have a history of breast, prostate, or colorectal cancer and there is virtually nothing on issues directly pertaining to them. I do not know why a focus on these more common cancers is lacking. But even more important, very often the information pertaining to survivorship is purely descriptive. For example, a text might say, "If you have a patient with this, make sure that there are no

sexuality problems." But the text does not then tell you how to assess sexuality problems, nor does it tell you what to do about them. So the text just says it might be there, so it is not really a lot of help.

If you look up survivorship in the index of the latest edition of the oncology text authored by Vincent DeVita and colleagues (DeVita et al., 2004), you find that there are two whole pages listed. When you turn to them, however, it is really only half a column on one page, and half a column on the other page. Having said that, in reality there are two 100-page chapters looking at late effects and follow-up, *et cetera*. So, at least for medical oncologists, there actually is a pretty good resource.

When you go to the specialty oncology texts, the only one that I could find that really gets into survivorship is the Harris text, *Diseases of the Breast* (Harris et al., 2004). This text has six chapters looking at all phases of rehabilitation and convalescence from breast cancer. It is very, very good. We are fortunate to have Frank Johnson here in the audience and represented on our committee. He has written a book, *Cancer Patient Follow-Up,* that includes a very good review and discussion of follow-up strategies, mostly concentrating on surveillance (Johnson and Virgo, 1997). Berger's textbook, *Principles and Practice of Palliative Care and Supportive Oncology*, has a chapter on survivorship authored by Noreen Aziz who works in the NCI's Office of Cancer Survivorship (Aziz, 2002). The remaining texts that I reviewed included very fragmentary sections related to survivorship. The classic example of difficulties in coverage of survivorship in specialty oncology textbooks comes from urology. I pulled out a couple of urology texts to see what they cover. Given that urologists specializing in oncology see so many prostate cancer survivors, I looked up impotence, thinking that it would definitely be covered. Well, it was buried under social work. Penile implants are discussed under social work! I guess it is a social disease, but I am not quite sure how someone interested in this area would ever find the relevant text.

I also reviewed coverage of survivorship in primary care and oncology journals. In the primary care journals, there was a focus on breast and colon cancer with a heavy emphasis on genetics and menopause. There was not much coverage of long-term effects, and really no articles that told providers how to monitor individuals with a history of cancer. It became clear from this review, that primary care providers need a cancer survivorship care plan because there are few readily available resources for them. The survivorship-related content I found in internal medicine journals was very narrowly focused original research with limited generalizability. There was very little on how to monitor patients following their primary treatment.

In terms of the oncology journals I reviewed, the *Journal of Clinical Oncology* covers a broad range of survivor-related studies. Most articles reflect focused primary research, but the findings and discussions are most

often generalizable to the broad survivor population. Probably the best single journal source for information on cancer patient follow-up, if I had to identify one right now, would be two Seminars in Oncology issues published in 2003, *Post-treatment Surveillance for Potentially Curable Malignancies* and *Late Effects of Treatment* and *Survivorship Issues in Early-Stage Breast Carcinoma*. Both issues include comprehensive reviews of the literature.

It seems to me that one of the first steps, and a very easy one to take, would be to develop a comprehensive bibliography to include the broad range of review articles related to specific survivorship domains. A list of these could be published and distributed, or an online virtual text could be created which could be kept updated.

To get a better understanding of CME opportunities in primary care, I surveyed offerings at meetings convened by the AAFP and the American College of Physicians (ACP). Survivorship was rarely covered, and when it was there was a narrow focus on such topics as genetics and the use of hormone replacement therapy among breast cancer survivors. I gave one lecture at the AAFP on cancer survivorship and, based on the poor attendance, learned that this issue is not yet on their agenda. We have got to get it there. There is an excellent AAFP resource that I would like to call to your attention. The AAFP published a comprehensive, 60-page monograph on cancer survivorship which covers all the major areas including risk of recurrence, follow-up, late effects of treatment, psychosocial issues, sexuality, health behaviors, alternative medicine, disability, and discrimination. It was published as part of a home-study self-assessment program in 2001, and it is only available through a subscription at a cost of about $375 (Hamblin and Schifeling, 2001). They got 6,000 subscribers, and it has subsequently been sitting on their shelf. There are no plans to distribute it or update it so it represents a huge lost opportunity. The ACP CME activities related to survivorship were very sporadic, usually in the form of case studies.

When I surveyed ASCO on their survivorship CME about three years ago, I found that there were some fragmentary efforts. But by this year, there were quite a few opportunities, in large part, through the efforts of Patti Ganz. Patti is our Erin Brokovich. I can hardly wait until Julia Roberts plays you in the movie.

Committee member Betty Farrell helped us review the status of the oncology nurse workforce and nursing education. We recognized that nurses with advanced training can assume important roles in survivorship management, but found there are only about 19,000 oncology-certified nurses, and about 1,500 nurses with advanced oncology certification out of a total of 2.2 million licensed registered nurses nationally. Of great concern is that nursing programs are actually decreasing their oncology emphasis. In a review of 17 programs with an oncology focus, 11 of the 17 programs had

curricula that covered survivorship issues, but only 3 programs covered rehabilitation. So, nursing programs also have to be ramped up to ensure an adequate survivorship workforce.

In conclusion, survivorship as an educational focus is infrequently addressed in primary care training programs, but is getting increased attention in oncology training. When survivorship is addressed, it tends to be presented in a fragmented manner. A shortcoming of available survivorship education is that problems are often delineated without offering information about evaluation or treatment. To overcome these challenges and provide comprehensive training, we really need our professional organizations to step up and accept the survivorship paradigm.

Let me move on to guidelines. Recommendation three in the IOM report states that "health care providers should use systematically developed, evidence-based clinical practice guidelines, assessment tools, and screening instruments to help identify and manage late effects of cancer and its treatment. Existing guidelines should be refined and new evidence-based guidelines should be developed through public- and private-sector efforts" (IOM, 2006b). According to the IOM, clinical practice guidelines are "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (IOM, 1990).

There are a couple of models to consider in developing survivorship guidelines. The guidelines could be specific to a particular cancer as is the case for treatment guidelines. Here, each type of cancer has its own work-up and treatment guideline, and also a type-specific survivorship guideline. Another model has generic guidelines that are applicable to several types or possibly all cancers. Accordingly, each type of cancer may have unique treatment guidelines, but could have the same survivorship guideline. This is the palliative care model. It does not matter what tumor you have, if you have pain at the end of life, it really generates a single guideline.

What is survivorship? Does it follow the multiple or the generic model? If you compared Hodgkin's disease and breast cancer, most of the survivorship syndromes—I call them syndromes—are primarily tumor-specific. There are some components, such as anthracycline cardiomyopathy, which are generic, and for others, we do not know. Are the psychosocial problems of a survivor of Hodgkin's disease different from those experienced by a woman with breast cancer? A lot more research has to be done to determine which model applies, but at this point, I think we are going to have hybrid guidelines. A bigger share of them will be tumor-specific, but they will also include generic components.

How should survivorship guidelines be structured? Supportive care guidelines developed by the National Comprehensive Cancer Network (NCCN) include the following steps: screen to see if something is going on; if something is going on, perform a risk assessment; triage according to the

TABLE 2-3 Content Analysis of 24 Breast Cancer Survivorship Guidelines

Topic	Number
• Follow-up schedule and testing	12
• Monitoring for second primary tumors; Chemoprevention for second primary tumors	11
• Menopause; Hormone replacement	8
• Locus of care	5
• Reconstruction	4
• Lymphedema	4
• Sexuality/fertility	4
• Psychosocial	4
• Genetics	2

risk assessment providing specialized evaluation and specific interventions when indicated; re-evaluate; and follow-up. This type of model would seem to work well in the development of survivorship guidelines. The IOM recommendation calls for the development of screening and risk assessment tools which are consistent with this paradigm for guideline development.

The IOM committee attempted to assess the status of survivorship guidelines and reviewed 24 guidelines for breast cancer, 15 for colorectal cancer, 4 for prostate cancer, and 2 for Hodgkin's disease. Breast cancer is at the forefront on survivorship, and there are many available guidelines. In contrast, there are relatively few survivorship guidelines for prostate cancer and almost no survivorship guidelines for Hodgkin's disease. What characterizes these guidelines is their tremendous variation. Among the 24 breast cancer guidelines, for example, content varies widely (Table 2-3).

When you look at the areas that are discussed in the guideline, half address the appropriate follow-up schedule and testing, 11 cover issues related to second primary tumors, and then there is a marked drop-off. Lymphedema is only addressed in four of the guidelines. It is interesting that locus of care, that is, who should take care of the patient following primary treatment, is an element in the European guidelines, and very rarely appears in the American guidelines. We are not used to telling physicians where care should be delivered, but we may have to consider it.

In our review of survivorship, we found that the overall consistency of guidelines is good when the evidence underlying them is of high quality. If the evidence is soft, there tends to be variation in emphasis or in the strength of the recommendations. In the case of equivocal evidence, guideline recommendations may be contradictory. A recent example of guideline variation can be found in a comparison of various organization's recommenda-

TABLE 2-4 Guideline Recommendations on Liver Imaging for Post-Treatment Surveillance Among Colorectal Cancer Survivors

Organization	Cancer site	Test and recommendation
ASCO	Colon, rectum	Annual chest and abdomen CT scan for three years for patients who are at higher risk of recurrence and who could be candidates for curative-intent surgery
ASCO	Rectum	Pelvic CT scan, especially for patients with several poor prognostic factors, including those who have not been treated with radiation
ESMO	Colon	Abdominal CT scan, restricted to patients with suspicious symptoms; abdominal ultrasound every six months for three years then yearly for two years
ESMO	Rectum	No imaging studies recommended
CCO	Colon, rectum	Liver ultrasound or CT scan every six months for three years and then annually for three years
NCCN	Colon, rectum	Abdominal CT scan for patients at high risk defined as poorly differentiated cancers or those with perineural or venous involvement (no frequency)
ASCRS	Colon, rectum	No imaging studies recommended

ACRONYMS: ASCO, American Society of Clinical Oncology; ESMO, European Society of Medical Oncology; CCO, Cancer Care Ontario; NCCN, National Comprehensive Cancer Network; ASCRS, American Society of Colorectal Surgeons; CT, computed tomography.
SOURCE: Desch et al., 2005.

tions for liver imaging following treatment for colorectal cancer (Table 2-4) (Desch et al., 2005). ASCO has just updated their guidelines and recommends annual computed tomography (CT) scans of the chest and abdomen for three years for colorectal cancer survivors. ASCO recommends that rectal cancer survivors also get a pelvic CT scan. The European Society of Medical Oncology (ESMO) recommends that abdominal CT scans be restricted to colon cancer survivors with suspicious symptoms, but it recommends ultrasound examinations every six months for three years. The ESMO recommends no imaging studies for rectal cancer survivors. Cancer Care Ontario (CCO) recommends an ultrasound or a CT scan every six

months for three years. The NCCN says that abdominal CT scans should be considered for patients at high risk. The American Society of Colorectal Surgeons (ASCRS) recommends no imaging studies.

Given the conflicting recommendations, there needs to be an amalgamation of the forces that develop guidelines. This example is provided, not to disparage the work of these groups, but rather to point out how variation is encouraged when evidence is deficient. How to deal with this is very challenging.

To summarize where we are with survivorship guidelines, the IOM committee concluded that there is no comprehensive set of survivor guidelines for any type of cancer; the guidelines that exist are fragmented and variable in their content; survivorship guidelines will likely have to be tumor-specific with some generic and modular elements; guideline development will optimally be multidisciplinary and interdisciplinary; and lastly, guideline development is instrumental in pointing out areas of deficient evidence and areas for further research.

The IOM committee also recommended that a set of survivorship care measures be developed. Quality measures fit well into a mechanism for trying to improve care. The mechanisms by which this works were elucidated well in the 1920s and 1930s by Elton Mayo, a Harvard Business School professor. He studied productivity at the Western Electric Company's Hawthorne Plant in Cicero, Illinois, and found that when you pay attention to workers, that is, you measure their performance, you can actually get them to be more productive. Individuals altered their work behavior because they knew they were being studied. This, so-called Hawthorne effect is now widely recognized, but first identified by Elton Mayo.

Quality measures can be used as part of accountability and public reporting programs, internal quality improvement programs, and surveillance for policy setting and resource allocation. Using quality measures to direct our own internal quality improvement programs is the application that most professional associations are most comfortable with and that may be the way to start. What you try to do is drive performance by reporting who is good and who is bad. We will discuss this a little bit more in the breakout group.

One of the difficulties applying quality measures in these contexts for survivorship is that we are going to have to decide how to attribute performance on aspects of care. If a woman does not get her mammogram following breast cancer surgery, whose fault is it: the surgeon, the medical oncologist, the family practice physician, the hospital, or the health plan?

In our review, the committee found very, very few survivorship-related measures out there. And some that have been looked at like follow-up mammography or follow-up colonoscopy have shown that there is varia-

tion in care, so that in fact there is room for measuring something. We really need efficiency measures, and one of the easiest ways to look at that is overutilization of tests—patients who are getting follow-up tests that they do not need. And most importantly of course, we need measures of patient-centered care, which may involve health surveys. The whole performance measurement movement needs to move forward and consider issues related to survivorship.

In conclusion, the committee found the training and management programs required to prepare healthcare professionals to appropriately manage the full range of survivorship needs to be rudimentary. A necessary next step is the development of formal and well-designed educational programs, guidelines, and quality measures through public-private partnerships.

Dr. Greenfield: Do we have a couple of questions?

Bob Weiss, National Lymphedema Network (NLN): I would add to your CME resources a session for physicians on the diagnosis and treatment of lymphedema held at the NLN's biennial seminar (next conference will be in Nashville, Tennessee, in early November). There is also usually a half-day session on wound care for individuals with lymphedema. Such training is needed because doctors must know how to treat the 20-30 percent of cancer survivors who will develop lymphedema. These CME opportunities are a wonderful source. NLN also has available videos for self-care.

Dr. Winn: Thank you. Actually, I have given you a little bit of short shrift in terms of the available opportunities. There is a whole chapter on professional educational opportunities in the IOM report, and I urge you all to read that chapter, because there is a much greater universe of potential teaching resources than I have described.

Dr. Greenfield: Let us now turn to John Ayanian to hear about research issues.

ADDRESSING GAPS AND NEW PRIORITIES IN CANCER SURVIVORSHIP RESEARCH

John Z. Ayanian, Associate Professor of Medicine and Health Care Policy, Department of Health Care Policy, Harvard Medical School and Brigham and Women's Hospital

Thank you, Shelly and Ellen. It is great to be here. What I find particularly exciting about the process that our committee embarked on, and that we are bringing to the next stage of development today, is really moving

from thought and reflection to priority setting and action. A very important part of that process is the role of research.

My presentation this morning will focus on our tenth recommendation, which addresses the research needs related to cancer survivors, and really, the opportunity to move beyond addressing gaps. So, I have modified the title of my talk from what is in the program. In addition to addressing research gaps, I will be focusing on new priorities in cancer survivorship research. Looking at research gaps is really an observational experience. What has been exciting about our committee's work has been moving forward from the identification of those research gaps to identifying important priorities for policy and for practice. I would like to focus in my talk on a discussion of research that would really move this field forward and make care and quality of life better for cancer survivors.

As background, I am a primary care physician, a general internist at Brigham and Women's Hospital, and also a researcher in the Department of Health Care Policy at Harvard Medical School, focusing on issues of access to care and quality of care. And in my primary care practice I very much enjoy and am challenged by the opportunities to care for cancer survivors in collaboration with my colleagues in medical oncology, surgical oncology, radiation oncology, and other fields involved in the care of cancer survivors. And so, my talk today is a reflection on what our committee identified as priorities, combined with my own experience caring for cancer survivors and working with colleagues, and really coming to the recognition in my own practice and research that well-coordinated care is one of the most important goals that we should be striving for here; care that is well coordinated between primary physicians and specialists. It is often difficult, and it is a challenge going forward, to define what we mean by well-coordinated care. But when patients experience it, when their families experience it, when doctors participate in it, they know what it is. And people know it when they see it, when they experience it. So, that is one of the research priorities that I want to highlight going forward.

The committee's tenth recommendation states that the National Cancer Institute, the Centers for Disease Control and Prevention, the Agency for Healthcare Research and Quality, the Centers for Medicare & Medicaid Services, the Department of Veterans Affairs, and private organizations, particularly the American Cancer Society, and others involved in cancer care should increase support for survivorship research and expand mechanisms to conduct this research. As Dr. Mullan suggested earlier this morning, a concluding recommendation for more research is in some sense a "gimme" for an IOM report. But it is important to emphasize that we are not just saying more research, we are really emphasizing who should be setting the agenda and investing in further research. I would like to focus on the goals of a research portfolio that we believe would

actually help us to move forward to improve quality of life and the quality of care for cancer survivors.

The first priority for new research is assessment of late effects of cancer and its therapies. Here, there is a need for some basic, clinical, and epidemiologic research, looking at the prevalence and risk factors of cancer late effects and cancer treatment late effects, as well as their mechanisms, because understanding those factors will help us to move forward in terms of improved and more targeted care. That then needs to be translated into improved guidelines and assessment tools, and understanding which interventions are best applied to reduce symptoms and improve functioning for cancer patients. And I think what is important about the research recommendation here, as you will see as I move through my slides, is that it is really a cross-cutting recommendation that draws on and advances many of the other nine recommendations in our report.

A second major priority for new research is improving quality of care. And this draws on three other recommendations in our report addressing the survivorship care plans that Dr. Ganz has discussed, the quality indicators that Dr. Winn has discussed, and the coordination of specialty care and primary care. At the same time, we can address the issue of resources and trying to do things more efficiently and effectively. We need to understand from a research perspective, which care models and surveillance strategies are the most effective and which are the most cost effective, so that we can use resources and help the maximum number of people with the resources that we have available, while at the same time pushing for a greater investment of resources in these areas.

Improving quality of life, as a third area of priority, moves forward in several dimensions in terms of our seventh recommendation regarding educating healthcare professionals. We not only need to develop programs to educate professionals, but to also involve our colleagues who are experienced educational researchers in studying which of those educational programs are most effective. From my perspective, one-time continuing education courses will only set the stage. We really need to build some mechanism for ongoing education and continuous learning into our training programs of health professionals, as well as for health professionals in practice. We need to understand what works in terms of making them effective providers for cancer survivors.

We need to understand the factors that facilitate return to employment following cancer treatment, drawing attention to our eighth recommendation. What types of programs, from a research perspective, help people to return to work, and work effectively? We also need to understand the financial burdens that cancer patients face. I had the opportunity to serve not just on this committee, but on the Institute of Medicine committee addressing the consequences of uninsurance that concluded its work last

year after issuing six reports on the topic. And what was very interesting to see in our own committee's discussion about cancer survivors is this intersection of priorities from previous IOM reports such as the consequences of uninsurance, with the special needs of cancer survivors. Cancer survivors are a high-risk, high-need group who are vulnerable in terms of the financial burdens of treatment costs and their potential limited ability to work. We need research to assess what we can do to ensure that people have good quality insurance and access to appropriate services.

Enhancing support for family caregivers is a hidden topic that is just beginning to get more attention and research. We need to think of cancer survivors not just as individuals, but as members of families and households and communities. We need to support the cancer survivor and, in addition, address the physical and psychological needs of people providing care to loved ones.

And finally, there is that whole domain of research that could pursue the role of legal protections such as the Americans with Disabilities Act, the Family and Medical Leave Act, and the Health Insurance Portability and Accountability Act (HIPAA). All of these legislative actions create both opportunities as well as potential risks for cancer survivors in terms of how they navigate the healthcare system, the insurance system, and the employment system. And we need to understand how those legal protections are working for cancer survivors.

What are some mechanisms to expand survivorship research? As a committee, we came to the conclusion that one of the most important mechanisms is more attention to long-term follow-up of enrollees in clinical trials. What I would suggest is thinking of cancer survivors with forethought, instead of afterthought in our research agenda. Here we have a group of people who have already committed themselves as willing participants in research to help us understand more about the acute treatments for cancer. They are an underutilized or untapped resource for understanding the long-term effects and the ways that we can improve their care and quality of life. And I would venture that many participants in clinical trials would be very willing to participate in survivorship studies going forward if we made those opportunities available to them.

Another important resource is special studies in our various national registry programs including the Surveillance, Epidemiology, and End Results Program supported by the National Cancer Institute, the National Program of Cancer Registries, supported by the CDC, and the National Cancer Database, supported by the American College of Surgeons' Commission on Cancer. All of these registries have been designed to count people who are diagnosed with cancer, in some cases to understand their acute treatment (initial treatment within four months of diagnosis), and then potentially to track whether they survive. With targeted investment, each of these re-

sources could do a much better job of following people after their acute treatment, and really provide a foundation of opportunity for studying cancer survivors' quality of care and quality of life experienced after the initial treatment period. Within the cancer registries, a special focus needs to be on cancer recurrences. Right now, many cancer registries track whether people survive or die, but do not have the resources needed to track whether they develop a recurrence of their initial cancer, or develop a second cancer. There are opportunities through links to Medicare data and electronic data from health plans and other organizations to understand the whole domain of cancer recurrence in much greater detail.

We also have large cohort studies and research networks in place that could be used to further survivorship research. One that I am actively involved with is the Cancer Care Outcomes Research and Surveillance Consortium (CanCORS). We have enrolled nearly 10,000 patients with colorectal cancer and lung cancer. We are supported by the National Cancer Institute and the Veterans Administration to study this group's health care and outcomes in the first year after diagnosis. With further investment, it represents a great opportunity to study what happens to people after that first year of living with cancer. The Cancer Research Network is another resource funded by the National Cancer Institute. It is a consortium of health maintenance organizations around the country that have large enrolled populations, and the ability to track with electronic data systems who is developing cancer, and what happens to them over time. We also have practice-based research networks supported by the Agency for Healthcare Research and Quality that typically involve networks of primary care practices around the country that are willing participants in research. These networks are advantageous because they have a connection to the community and could move cancer survivorship, which is now largely in the domain of comprehensive cancer centers, out to a broader array of delivery settings, all of which have a very important role to play. Most cancer survivors are treated in community-based practices, not in comprehensive cancer centers.

Finally, our committee felt that national surveys have an important role to play in furthering the survivorship research agenda. Our federal government has made a strong investment in collecting health-related data on a representative cross-section of Americans through surveys such as the National Health Interview Survey, the Medical Expenditure Panel Survey, and the Behavioral Risk Factor Surveillance System. In some cases, there is great opportunity to focus on cancer survivors, identifying who they are in these national samples, and then developing modules to learn more about their quality of life and quality of care. We could get a much more representative understanding of how people are living with cancer through such surveys.

The committee also identified challenges in survivorship research. First, we need to recognize that long-term follow-up is labor intensive and expen-

sive. It will require investment of resources, but we believe that the dividends paid by those investments could be substantial. It is also challenging because many studies are multi-institutional in nature, and thus require multiple institutional review boards (IRBs) to approve them and monitor them, often with widely varying standards. Consequently, there is a role for the federal government to help the research community to develop more common standards for IRBs. One particular IRB could potentially be designated as a coordinating IRB for multi-institutional studies. There may be models for this in the world of clinical trials, and we also need to develop them in the domain of survivorship research. Finally, we have continued to grapple with HIPAA standards over the past two years. There is a lot of uncertainty among patients, family members, and healthcare providers about the privacy of medical information, and how privacy can be assured in the context of research. In some cases, there has been an overreaction by community practitioners, leading them to defend their medical records and to be very cautious about releasing them for research. We need to educate both patients and providers about the value of research. With appropriate confidentiality and privacy protections we need to partner with hospitals and community-based practitioners to gain access to medical records in a way that is compliant with HIPAA, but not stymied by HIPAA.

To conclude, cancer survivors' needs must become a research priority. This is a clarion call from our report today. Research is essential to improve quality of care and quality of life for cancer survivors. It is not something that can be done on the side. Instead, it is really a central springboard to addressing many of the issues that we have been talking about today, and will continue to discuss. We need to better understand how quality of care and quality of life should be measured, and how they can be improved in practice. The research agenda that we are addressing today would advance multiple recommendations in the IOM report. Finally, there are opportunities to build on the existing infrastructure that we have with new federal support focused on an expanded role for clinical trials, cancer registries, large cohort studies, and national surveys. We have the building blocks in place. Now we have to make them work for cancer survivors so we can improve their care and quality of life.

Dr. Greenfield: We have some time for questions for John, and then for the rest of the speakers as well.

Dr. Anna Meadows: I want to thank you for putting research in such an incredible perspective in terms of the rest of the report. I only wish the research chapter had come at the beginning of the report, because I think everything follows from that. I have been doing research in cancer survivorship for 30 years, and I was a part of the Childhood Cancer Survivor Study

in the beginning. This large cohort study requires an enormous amount of resources to follow. I was also recently part of the development of guidelines for the Children's Oncology Group, so I know it is important to have consensus for guidelines.

One of the problems that I see in both the Childhood Cancer Survivor Study and the development of guidelines and the way to provide clinical care is that unless we really have guidelines that we know are not just based on the consensus of opinion of people who take care of patients, but are truly developed from research that we can conduct, then the care plans that we give to patients are almost touchy-feely. How often do you do cardiac studies in patients who have had anthracycline? And what is the dose of anthracycline that requires that you do such studies twice a year, rather than once a year? These are questions that need to be addressed with research. And unfortunately, not putting the research first, really misses the point.

The other problem is that when we do the research, or will do in the future, if we do not follow all the patients, we will not get the right results. We have been missing at least half of our childhood cancer survivors in our research studies, and we do not know about the other half of this cohort. We started with 20,000 eligible patients in the Childhood Cancer Survivor Study, and we are down to 10,000 now. Admittedly, these were patients who were treated a long time ago, but we do not have information on their outcomes. So, I really think that the thrust for research is so important, again, I am surprised it was not the topic for the first chapter.

Dr. Ayanian: The chapter on research is the final chapter of this report, but we should also think of it as the first chapter of our work going forward. That is what our committee has tried to lay out in the agenda today.

Dr. Beth Kosiak: I am from the Agency for Healthcare Research and Quality, but this comment that I would like to make is coming more as a stage 3 melanoma survivor. And what I would like to say is that one of the issues that came up for me in looking at the excellent research agenda laid out on cancer survivorship is how critical that research agenda is for informing newly diagnosed patients. Because as a newly diagnosed patient, you want to know what happened to people who chose different courses of treatment, because often times, as in my case, there is not an obvious course of treatment that is clearly recommended by the clinical community. And because they are divided, then you have to look at your own choices, and look for resources to make a choice. Having the information that you would get from the cancer survivorship research focus would really help newly diagnosed patients make that choice, because there would be that longitudinal information to help them look at what happens if I do nothing,

which was one of the choices that was offered to me. So, again, there are a lot of other comments that we will be able to make later in the day, but I just wanted to note that it really closed the loop for me, and I think it is an important aspect of the research.

Dr. Jerome Yates: I am from the American Cancer Society, and from my perspective one of the real difficulties in looking at the research agenda is the intersection of the physical factors such as the disease stage and the treatment selected, and the social factors such as age, where people live, and access to health care. These are so complex, that they are going to require many, many analytic compartments. And this means that we have to use information systems to better advantage to sort out the information, and also to develop accessible educational materials that may be available.

Just to follow-up on what Anna has said about the loss of the children to follow-up, in my former life at a cancer institute we provided free follow-up for the children for as long as they came back to the institution. The further out they get from their initial cancer, the more unlikely they are to come back, even if you provide them with transportation when it is needed, and the other things to encourage follow-up.

The last comment I would make is that we have to do something about litigation because there are opportunities for lawyers to sue for things that we know were not known at the time of treatment. This raises real difficulties for the physicians. The classic case of this is the retinal changes with oxygen in the young children, and the recent Vioxx (rofecoxib) story are just two examples of how we cannot afford to not do something about the litigation issues.

Dr. Greenfield: If I might just respond to the legal issues that Dr. Yates brought up. These legal issues are why Rodger Winn's slide about the different organizations agreeing and not agreeing about guidelines is so very important. If there is an overwhelming consensus, if you will, about doing or not doing something as we have seen in diabetes and some aspects of heart disease, it blunts a lot of the potential for litigation. Let's have general questions for any member of the panel now.

Dr. Archie Bleyer of Cure Search, the LIVESTRONG™ Young Adult Alliance, and the Children's Oncology Group: The survivorship care plan is a place to start. Dr. Greenfield asked earlier about resistance to implementing the care plan. The video was superb, the presentations were outstanding, and the report speaks for itself, but I wonder about a potential downside. Dr. Winn has described the cancer care trajectory, and Dr. Ganz has shown in Figure 2-4 the shaded box representing survivorship care. We now recognize the box. This conceptualization takes the patients or survivors out of

the trajectory from the oncologist, puts them into a different sphere, and then probably takes the survivor back to the oncologist with a recurrence or later in life. Although I support the survivorship care plan, are we turning this care back to the generalist, to the primary care providers, including two of our panelists, a little too quickly? Is the "hand off," the term used in the video, too abrupt, too definite? Will we use the survivorship care plan as oncologists to close the book, as Patti put it, write the final chapter, and turn the patient over to that shaded box? As a pediatrician, that is not what we have done. So, I am worried about that potential downside.

Dr. Ganz: I would like to comment on a few things. Number one, ASCO's Cancer Prevention Committee did a survey, and we actually asked medical and radiation oncologists and surgeons who care for adult cancer patients about whether they cared for cancer survivors. The vast majority, 60 to 70 percent, of these providers said that survivors were a major part of their practice and that they provided many aspects of routine care for them. So, in fact most oncologists, at least in this survey, said that they were providing survivorship care. Isolating and defining that shaded box in the care trajectory, does not specify how care is to be delivered. It just says that it is a phase in the care trajectory. And as you will hear later from other discussions, one of the models applicable to survivorship is a shared model of care. Many practice according to this model. For example, I continue to follow all of my breast cancer survivors. I have patients that I have taken care of for 15 to 20 years. I see them once a year, so I am not attending to all their interim health care needs. These patients have primary care physicians that feel very comfortable approaching me if something comes up in relation to their cancer history. There was no intent in discussing the survivorship plan to convey a cessation of treatment by the oncologist. When I mentioned "closing the book," I was referring to getting closure on the acute phase of treatment. There is a beginning and there is an end of acute treatment. And we need to summarize what went on in between, and that is what the retrospective part of the plan includes. But the perspective of the rest of the plan is really looking forward. And as I discussed in quite a bit of detail, it is defining who is going to do what in that follow-up plan. What is the oncologist going to do? What is the primary care physician going to do? What is the nurse practitioner going to do? What is the social worker going to do? So, I think you may have seen it in that way, but I do not think that was our intent.

Dr. Winn: Let me just chime in. Archie, I think the model you describe is a failed model that pervades in medicine. It is a linear model of hand offs and no feedbacks, *et cetera*. I think what we really are talking about here is a parallel model with interconnections between the parallel streams, and that

is the only way it can work. I think one of the most exciting things from the IOM's point of view may be in cancer taking the lead in trying to show other chronic disease models how, in fact, you should be coordinating this care moving forward.

Ms. Stovall: At the end of the process of completing the committee's work I had some conversations with IOM staff and fellow committee members about what was next. And the NCCS made a decision to sponsor a workshop next spring to show what it would take to bring people together to implement this care plan and answer a lot of the questions that have been raised. There are a lot of recommendations that are intended to take ideas and flesh them out. They can not be done right away. But this recommendation has been sitting around a long time because the need is so great. I think that one of the frustrating things in the advocacy community and the patient community over many years is that people always say, bring us the evidence, bring us the evidence. And when does a body of anecdote become enough evidence? We now have studies that quantify the problems and we have people's stories that illustrate in excruciating detail the gaps in the care system. And if it is not ready for public health now, when will it be? So, we have to arrive at a place where reasonableness is a justification that we are willing to accept in order to implement some of these things that just make sense. I am excited about the recommendation, if only for the fact that it gives us an opportunity to flesh it out even further. And I know the Lance Armstrong Foundation has indicated a willingness to work with the NCCS, ASCO, and NCI to further this work. So, we will be back to you with more on that in the future.

Dr. Greenfield: We will take a couple more questions and then take a break.

Dr. Runowicz: I am from the University of Connecticut as a representative of ASCO's Survivorship Committee, and I am also president-elect of the American Cancer Society, so I wear multiple hats. In response to Ellen Stovall and also to Anna Meadows, in terms of evidence for decision-making, I think it is not an either/or situation. It is important to keep in mind that expert opinion is a level of evidence. It may not be the best that we have, but if it is all that we have, then that is what we go with while we are trying to get the answer to how many scans we do of the heart in patients who have had adriamycin, or do we need any? I think we have interim guidelines, and then we replace them with evidence-based guidelines when data are available.

Ms. Stovall: Thank you for that comment. I just also want to say that maybe being in Washington as long as I have breeds discontent on a lot of

levels. One of those levels is that as an advocate and an activist to go to the Hill with either a universal healthcare message or another message. The reaction is often "show me the evidence." Sometimes, this response is a way to keep things from happening. It is used as a reason to deny the things we need, rather than to promote the things that we know would help us.

Dr. Antonio Wolff: I am a breast cancer medical oncologist at Johns Hopkins, and also chair-elect of ASCO's Health Services Committee. One of the things that strikes me the most, and I always like to say that, ultimately, the enemy is us, because I think somehow every time that I see my ear, nose, and throat (ENT) physician, and he spends five minutes doing a nasal endoscopy and charges me $600 and then I see how much money my department charges for my medical oncology consultation when I spend an hour with a patient, I think the incentives are wrong. And when you see the way we created Medicare and other systems to provide acute care, you realize that as a society, we focus on acute care that is perceived to be sexy and fancy. But we do not focus on things like survivorship care. I think all of us are very well intentioned, and we want to do the right thing. It is the same as with the clinical practice guidelines. As clinicians, we want to do the right thing. Between all the pressures and all the incentives, and for many providers the need to make a living, pay your expenses, make a profit, *et cetera*, I think until the system changes, all the beautiful products that we are putting out, and educating individuals, it is going to be difficult to get the message out.

Dr. Greenfield: Rodger Winn, do you want to respond to Dr. Wolff's comment from the viewpoint of efficiency and resource use?

Dr. Winn: Use of time and resources is a very important consideration. I did a little back-of-the-envelope study on cancer patient follow-up for a breast cancer doctor who treats half his patients with adjuvant chemotherapy, and where they do beautifully and they live. Five years down the road, 26 percent of your practice is going to be those survivors, and 10 years down the road 40 percent of your practice is going to be delivering survivorship care. You are going to have people with acute concerns with cancer treatment waiting to get through the door. And this forecast for resource use is an example of why shared models, nurse-led models, or survivorship clinics have to be explored going forward so that the incentives are right to give these patients the care they need.

Dr. Greenfield: A lot of big employers are pushing very hard for efficiency measures, now more euphemistically termed "resource use." And most of it comes from big companies. That is the stimulus. These mechanisms involve

consideration of cost and may be useful, but as physicians, we do not like to hear about them. Pressures to reduce cost may limit the overuse of unnecessary services and free up resources to counter underuse of necessary services.

Dr. Susan Weiner: I am from the Children's Cause for Cancer Advocacy. I was involved in the first survivorship report on childhood cancer. I would like to first congratulate everybody who worked on this report. It is an absolutely fabulous companion piece to the childhood cancer survivors report that the IOM produced about a year and a half ago. My question has to do with issues related to hand offs and transitions. Survivors of childhood cancer have problems that are more dramatic perhaps than those of adults. They develop and change, they grow, and they become adults, and they end up in clinicians' practices. My question is for Dr. Ayanian, but also for the panel generally. I would like to know whether you would be willing to address the question of transition to adult care for childhood cancer survivors either in one of the breakout sessions or in whatever follow-up activities there are?

Dr. Ayanian: It is a great point that you raise, and something that I face in my clinical practice at Brigham Women's Hospital across the street from Children's Hospital of Boston. It is not infrequent that we care for survivors of childhood chronic disease, including cancer or other conditions such as sickle cell anemia or severe asthma, who then need to transition to adult care sometime in their late teens or early twenties. Because of their chronic condition, sometimes these adolescents and young adults end up with their pediatric providers into their late twenties and early thirties. It is certainly a topic that we need to pay more attention to. In areas of the country where pediatricians and internists are accustomed to working closely together, often in major academic centers, where children's hospitals and adult hospitals are side by side, these centers should be leading the way in studying and developing new care models to ensure there is continuity of care. These young adults are a special group of patients who are particularly at risk of getting lost in transition and we need to pay more attention to them. From a professional standpoint, we have a growing number of people who are jointly trained in pediatrics and medicine, and many of them are starting to address questions just like the one you raised about how care should be transitioned for patients with childhood cancers who survive into adulthood.

Dr. Greenfield: Let's have one more response, and then we're going to have to close.

Dr. Winn: This issue came up during our committee's deliberation. Who, for example, should follow childhood Hodgkin's disease? Steve Woolf is

sitting there with the family practice hat on saying, give us a good guideline, and we will do it. Sara Donaldson is there from Stanford saying, "Over my dead body." And the answer is we do not have all the answers. But certainly, the issue was addressed, and what it really did is bring the two participants to the table, because that is the only way that this is all going to move forward.

Dr. Greenfield: We are going to have to close this session. I think your question and many others that came up earlier will be discussed and answered during the breakout sessions.

3

Morning Breakout Sessions with Invited Speakers

IMPLEMENTING THE CANCER SURVIVORSHIP CARE PLAN AND COORDINATING CARE

Moderator: Sheldon Greenfield, University of California, Irvine

Dr. Greenfield: We're going to have each of the speakers, Deborah Schrag, Peter Bach, Phyllis Torda, and Doug Ulman, talk for about five minutes. We will leave a little time for clarification or one or two questions after each speaker, and then hopefully we will be able to have some more long-term discussion following the presentations.

Deborah Schrag, Memorial Sloan-Kettering Cancer Center

Thank you for the opportunity to present to you this morning. I would like to discuss an initiative spearheaded by Patricia Ganz and Ellen Stovall, called the Treatment Plan/Summary. It is directly related to the transition to survivorship treatment summary. Although I am a medical oncologist at Memorial Sloan-Kettering Cancer Center, in a sense, I am here representing ASCO and the NCCS on this initiative. Many of you in the room have participated in this initiative, and I welcome you to chime in. The goals of the Treatment Plan/Summary are to improve patient-physician communication; to improve coordination of care across disparate healthcare settings; to streamline the burden of documentation; and to foster standards for documentation in our increasingly digital age; and ultimately, they are to facilitate our ability to evaluate outcomes.

So, what is the proposal? Essentially, the goal is that oncologists should prepare a written treatment plan at the initiation of a course of cancer therapy. Typically, that includes chemotherapy, but it might include radiation, alternative treatment; other modalities are possible. Furthermore, oncologists should prepare a treatment summary at the end of a treatment course. The transition to survivorship care plans, which you heard so much about from Dr. Ganz and others this morning, we conceive of as a more detailed and extensive type of this particular summary. To get there, oncology professionals need to achieve consensus about the key elements for a treatment plan and summary. Professionals also need to specify standard formats that can accommodate free text, synoptic as well as fully digitized versions, that are made available to a variety of practice settings and types. And that these should adopt open source models.

What would be the key elements of a Treatment Plan/Summary? Well, the idea is not to produce 15-page informed consent documents. The goal is for something relatively succinct. Think about operative notes, pathology reports, radiation oncology summaries, which are absolutely standard. Think about the people in Hurricane Katrina, who all of a sudden had to change their sites of care quickly. The idea is not full disclosure of everything, but to provide a succinct summary. We have vetted this around quite widely, trying to achieve consensus about what those elements ought to be, and the ones that appear again and again are shown in Box 3-1.

So, what is the development strategy? How are we going forward with this? Well, I would say that having spoken about this in a number of settings, I think it is fair to say that we have achieved consensus among oncology practitioners, and I include physicians and nurses, that this is a good idea. And that if we could accomplish this and streamline the burden of documentation, it would be a good thing both for us as providers, and for our patients, and for our ability to communicate with our colleagues in other medical disciplines, dentists, teachers, all kinds of people, who may want these documents and need them.

What we are grappling with are the specifics in what those ought to look like. We are in the process of trying to develop some standard formats and templates, and are incorporating feedback we have received as part of this process. Then there will be some pilot testing, which we hope to conduct in a variety of settings, specifically through some of the NCCN institutions, and through QOPI, which is ASCO's Quality Oncology Practice Initiative. It is a group of private practitioners who are very motivated to participate in quality improvement initiatives. And then ultimately, when we think about dissemination and implementation of this, we have to get involved with software developers and, healthcare payers to, as Dr. Ganz said earlier, make sure this activity is appropriately reimbursed. And, of course, advocacy organizations have spearheaded this effort from the very

BOX 3-1
Treatment Plan/Summary: Key Elements

Plan

- Diagnosis, including histology stage at original diagnosis
- Disease status
  - Symptoms
  - Physical manifestations
  - Radiologic evidence
  - Tumor markers
- Treatment purpose
- Treatment regimen
  - Drugs, route, frequency, toxicity
- Re-evaluation strategy
  - Timing
  - Modality

Summary

- How was the treatment tolerated?
  - Hospitalization for toxicity
  - Grade 3-4 toxicity
  - Dose reductions
  - Agents discontinued/stopped early
- What was the response to treatment?
  - Disease-related symptoms
  - Physical manifestations
  - Radiologic
  - Tumor markers
- Reasons for treatment discontinuation
- Long-term sequelae of treatment
- Planned next steps

beginning. This is something that Ellen has been talking about for years and years. So, let me stop there. Hopefully, I have time to take questions. I invite those of you who have participated in this initiative to chime in.

Dr. Greenfield: Is there a question or two?

Dr. James Talcott, Massachusetts General: When you are describing the development of critical content and achieving consensus, you have a list of people involved in the process. And it seems to be people who are trying to provide input. I wonder if it would be helpful to think a little bit about the audience for what we are trying to deliver, rather than people who have information to add to it. We talk an awful lot about patient-centered care,

and obviously the purpose of these things is to serve the interests of the patients. But we are trying to communicate to other oncologists, primary care doctors, and so on. I just wondered if you had some thoughts about the process of identifying the content from those perspectives?

Dr. Schrag: I would say there has been some very spirited discussion in various venues about the extent to which these documents should be focused on and designed specifically for patients. And as you know from informed consent documents, the standards often are that things need to be written at an eighth-grade or a tenth-grade reading level. In our discussions so far, this is not the approach we have taken. These documents are really aimed at and are to be written at the level of the primary care physician. So, they should not have a lot of "onco-speak" and jargon that would only be understood by sophisticated oncologists, with all kinds of abbreviations. They should be understood and intelligible to your typical primary care practitioner. In addition, many dentists, before doing a root canal or tooth extraction would want to know about anticoagulant therapy (e.g., Innohep [tinzaparin], coumadin), the cancer history, recent chemotherapy, and the patient's white count. These providers also would need to understand the treatment plan/summary and have a contact to call if they saw that there was something over their head.

Patients, in looking at the treatment plan/summary ought to recognize the list of drugs that they received, for example, cytoxan and tamoxifen and bleomycin. But the goal was not to pitch it so that patients would necessarily understand every single word. I think having such a document helps fulfill the goal of fostering patient-physician communication. Some patients will look at such a document, and really not want to get involved with all the nitty-gritty issues and the details. We all have patients like that. And others will really push us and ask, "What is that drug? Why is it given this often? What are the side effects?," and it may prompt some conversation. So, the short answer to your question is, at this point the Treatment Plan/Summary is not pitched at the patient level. It is pitched at the primary care physician level. The goals of this effort are to enhance coordination, both doctor-to-doctor and patient-to-physician. A lot of research describes just how problematic coordination is, and I think we can make patients a lot happier if we improve the doctor-to-doctor coordination.

Ms. Stovall: I think that the age of paternalism in medicine may have passed, hopefully, and with it, using such confusing terms as "intent to treat." There has also been resistance to discussing palliative care. We have hopefully moved beyond that. And it will take institutions and leaders, people like Deborah and many of our cancer centers to lead the way, and hopefully those in oncology practice in the community will adopt and adapt

that attitude as well. We have to let patients know about their treatment and what we are really trying to do for our patients. The goals of treatment need to be communicated, and I think we have to be more honest in using these tools to communicate these goals.

Dr. Johnson: I am a surgical oncologist from St. Louis University. Have the legal ramifications of this effort been considered by any of the development entities? If you give a patient a statement of what should be done, and you omit something that might happen, are you legally liable? If you do not suggest that patients have their gated cardiac scan twice a year, and they only get it once a year, and they have a sudden death, would you be legally liable? Have these issues been discussed?

Dr. Schrag: In a preliminary way some of the legal advisors to ASCO and NCCS have taken a look at this. The legal specific disclaimer language has not been specified to the final comma, but essentially, there is a way to avoid liability issues by saying this is a summary and that it does not describe every single thing. Such a summary already exists in radiation oncology, so there is a way to provide clinicians some legal protections. This is an obstacle that will have to be encountered, but I do not think we need to get bogged down in those sort of legal details. We want to do something that we think makes sense for our patients.

We think it makes sense in terms of how I, as a medical oncologist, communicate with you as a surgical oncologist, and with my colleague Dr. Ayanian as a primary care physician. We think that it is just the right thing to do, and we think it ultimately will streamline office practice and office culture. When people call up for notes and records, we all have people who work in our practices who are very busy photocopying, and trying to figure out what to photocopy. And when it comes to your practice as a surgeon, they know what to go for. They go for the operation note, and they go for the pathology report. It is great, and it is easy. When I call your office, I get what I need in three seconds because you are a surgeon. However, when you call my office, you are likely to obtain a large stack of documents that you will have to sift through to find the four to five essential documents that you really need. And what you need may not necessarily be the first new patient note, because at that point the diagnosis and plan are not all formulated. Alternatively, you might receive a flow sheet, but that might not provide any detail regarding the reasons for underlying treatment recommendations. So, you have to spend a lot of time fishing and sifting. I presume you have had that experience. We do not want to get bogged down too much in the legal details before we have achieved consensus on what the content of this document should actually look like, but I agree that we will need to sort legal issues out.

Dr. Greenfield: I think we are going to have to move on, but I just want to say that in the diabetes field, we have encountered this problem, and we have a partial solution. I do not have time to talk about it now. We can talk about it later in the discussion. But we have gone part of the way toward addressing the problem of multiple guidelines, legal threats, and so forth. Let's go on to Peter Bach's presentation.

Peter Bach, Center for Medicare & Medicaid Services

Thank you. I am the senior advisor on cancer policy to the administrator at the Centers for Medicare & Medicaid Services. I want to thank you for having me here, and I am excited about reading today's *USA Today* and seeing banner-like announcements of some major progress and innovation in the cancer survivor arena (Szabo, 2005). I would like to talk about our recently announced demonstration project and how it is directly relevant to some of the ideas emanating from this group. We announced Wednesday, November 2, that in 2006 hematologists and oncologists in office-based practices are going to have another opportunity like they did in 2005, to submit additional information about patients and their care to CMS using our billing system (CMS, 2005). And they will receive an additional payment for doing so.

The information we are gathering focuses on three interrelated areas. And I think this directly bears on the issue of monitoring and management of survivors and patients in an expectant mode, as well as other periods of disease surveillance. We are asking the oncologists in the context of evaluation and management visits, the visits between doctors and patients, to tell us first, the primary purpose of the visit. Dr. Schrag offhandedly mentioned a couple of things that might go on in a practice like a new diagnosic visit, or a surveillance visit, or a visit focused on counseling about potential complications. We are asking doctors to report to us, in the context of particular visits, the primary focus of that visit, with an understanding that all visits are complex and touch on many issues. We want to better understand the spectrum of cancer care, and also appropriately credit doctors for the range of what they do. We are linking the response to that question to another question we are asking them to answer, and again, answer through our billing system, which is whether or not what they are doing follows well-established and accepted practice guidelines that are evidence-based. So, when they are focusing on therapy, are they following practice guidelines, like those from NCCN or ASCO? When they are in a surveillance mode, are they following practice guidelines?

As we elaborate tighter and tighter, more evidence-based, more knowledge-based, and more clinically relevant practice guidelines, we can continue to link what doctors are doing, what they say they are doing, to

practice guidelines that are directly relevant to what they are doing; something we could do in a survivorship mode, something we could do when patients are being actively managed.

We are asking that doctors report a third piece of information, which was on Dr. Schrag's slide as well. We are asking them to clarify the patient's disease status. Currently, what we have in our process of billing, and we do not even have it on every patient on every visit, is the ICD-9 code, which tells us the primary cancer diagnosis in most cases. There are subtypes of ICD-9 codes that give us some discrimination in some cancers. But we do not really know within the context of a visit between a doctor and a patient, and a treatment plan, whether or not doctors are following guidelines, or what the extent of a patient's disease is. For example, patients could be newly diagnosed, they could have a recurrence, they could have new metastatic disease, or they could be in a period where they have no evidence of disease. We now do not have any way of determining disease status through our claims system. Without this information on disease status, we can not understand what is actually going on when the doctors are saying, well, this is the focus of the visit, and these are the guidelines I am following.

We are trying to move, through using our billing system, and using a demonstration project like this, to get a better understanding of what is happening in doctors' offices, and what is happening with the care of patients across the spectrum of illness. And in a sense, we are taking a horizontal approach as was described in Dr. Schrag's treatment summary proposal idea, because embedded in this demonstration is the entire treatment history and treatment course for a patient. That is a quick summary of the demonstration. It pays $23 per event reported, somewhat lower that the 2005 demonstration, which paid $130 per event, but was linked to chemotherapy. Those of you who are in practice know that there are many more evaluation management events with patients, or there certainly should be, than there are chemotherapy events. So, the math works out slightly differently. That is a quick summary of the demonstration. I am happy to take questions.

Dr. Ganz: Peter, if we wanted to develop a mechanism for having a visit that would focus on the survivorship care plan visit, which would be linked obviously to an end-of-treatment summary of some sort, would there be some potential for a demonstration that would create that visit, or could be coded as a specialized visit in that way? Could you see something like that possibly happening in the future?

Dr. Bach: Maybe. This is an issue that we have pondered. We are wrestling with these issues. We compare the practices of radiation oncology to medical oncology providers, and ask if there should be a dedicated visit for treatment planning in medical oncology, because there is an analogous one

in radiation oncology. But that, of course, is not the full story of how we compensate the two professional groups in providing different kinds of services. We have also considered special visit categories. There are a handful of them in Medicare, for example, we have a "Welcome to Medicare" visit where you get to go to the doctor even if there is nothing wrong with you, which we do not really have in other places. My personal view is that the mechanism for getting these sorts of visits in the system is to embed them in the current evaluation management strategy, but also within something like this year's demonstration project, which we hope will be something that continues over time, and we can continue to have a new focus of the visit added, linked to a relevant guideline. This is again where I see we could go. We have a suite of five possible foci for visits in the 2006 demonstration. I could easily see either going to another one, or embedding this in a current category, and linking to a set of relevant guidelines. It is probably easier than creating a separate code. It is challenging to create separate codes for different specialties. I am a pulmonologist, not an oncologist and we do things that may justify separate codes as well. So, this approach is challenging. I would rather redefine the spectrum of what it is that oncologists and primary care providers do.

Joan McClure, National Comprehensive Cancer Network (NCCN): I have been looking at your document and have some questions about how one would code partially concordant care. For instance, the NCCN guidelines, in the work-up phase, frequently call for a wide variety of tests. Sometimes a physician will choose to do many, but not all of the tests. And it was just something that kind of jumped out at me, and I wondered if you thought about it?

Dr. Bach: We have, and by December 1, we will have specific—I do not want to use the word "rules"—but algorithms that oncologists will be able to use to compare what they are doing to the guidelines, and to determine whether or not they are following the guidelines. Obviously, the NCCN and ASCO guidelines are quite elaborate, and are multidimensional. It would not be reasonable to either apply a standard that says that unless you do every single thing listed in the next 30 pages, you are not following the guidelines. Not only is that not reasonable, we will not learn anything of value. So, we are actually going through the guidelines and identifying those areas where we say this constitutes concordant care, and this does not, for the purpose of learning what we want to learn from this demonstration project.

Dr. Greenfield: As Phyllis comes up, let me ask you, Peter, on the third topic in terms of extent, stage, and so forth, are you going to provide specifications for the patient classification?

Dr. Bach: Of course. Those are coming. We did not publish those with the fact sheet, in part, because it was 16 pages long, and they are disease-specific categories that map appropriately to the guidelines, and have been defined by the medical oncology specialty community. But they will be far too broad to finally discriminate between patients the way we do as clinicians, but sufficient to at least stratify. The average cancer has four categories.

Phyllis Torda, National Committee for Quality Assurance (NCQA)

Good afternoon. I am Vice President for Product Development at NCQA, which means that I have responsibility for taking what we know about how to measure quality, and wrapping it into programs on an ongoing basis to improve quality of care, or in Patti's words this morning, routinizing quality care and making it part of ongoing practice. That is really what we are all about. I have been at NCQA doing this for 10 years. Prior to that, I worked for two different consumer advocacy organizations, and I am also a relatively recent cancer survivor myself. In putting together my remarks this morning, I tried to meld my personal thoughts as a cancer survivor, with what I have learned professionally about how to measure quality. And on a personal basis, and thinking about the cancer survivorship plan, I want one. Why didn't I get one? Why can't I have one tomorrow? And I consider myself a very informed consumer. Professionally, I know what the barriers are, so in my remarks I am going to try to summarize a little bit about what we know about how to put one foot in front of the other, and make progress in this area.

We would all like to think about the systematic practice as described in Figure 3-1 that very much builds on the chronic care model that Patti talked about earlier. The systematic inputs of information that the physician has include such things as medical evidence, patient data, customized reminders, and self-management resources. These inputs facilitate an ongoing partnership for health with the patient. Systematic outputs of this model include care management and quality improvement. That is the vision.

Findings from a 2003 survey of U.S. physicians conducted by the Commonwealth Fund summarized here show how short of that vision we are today (Audet et al., 2005):

- 85% of physicians can't generate registry lists by test results or current medications
- 33% of physicians repeat tests because results are unavailable
- 15% of physicians observed abnormal test results not followed up
- Only 18% of physicians have data on patients' outcomes
- Only 13% of physicians can generate their own performance measures

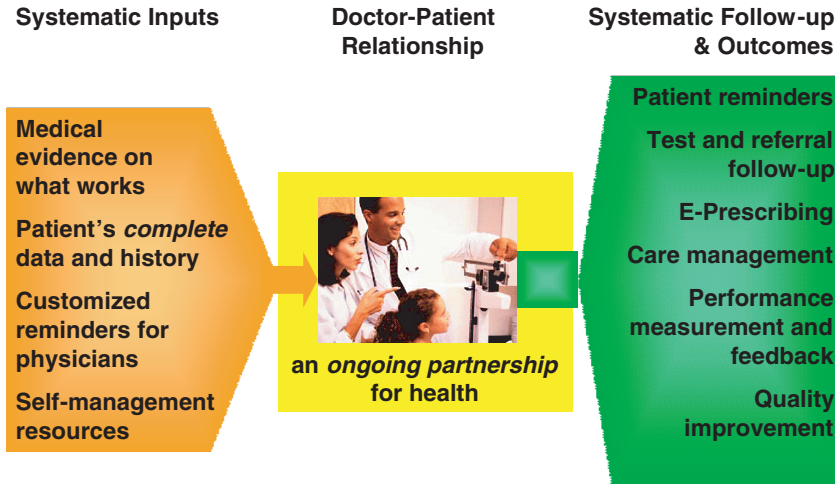
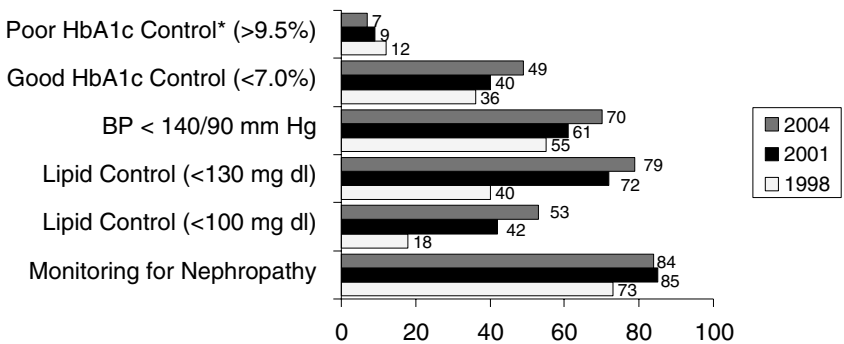


FIGURE 3-1 The systemic practice.

What do we know? We know that measurement leads to improvement. Figure 3-2 shows data from a program that the NCQA operates along with the American Diabetes Association in which physicians apply for what we call recognition in diabetes. On each of the six measures, cohorts of physician applicants have improved their performance over the three years of



Diabetes Physician Recognition Program, average performance of applicants, 1998-2004 data (percent).
* Lower is better for this measure.

FIGURE 3-2 Measurement leads to improvement**:** Physicians achieving "Diabetes Physician Recognition" show substantial improvement in key clinical measures.

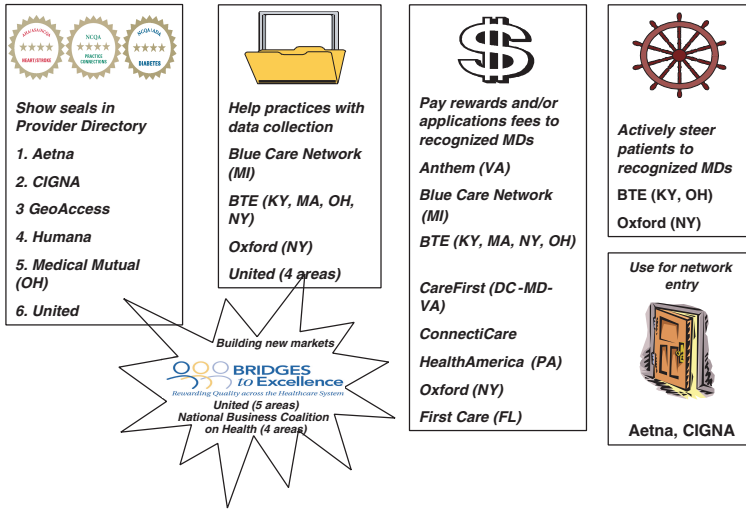


FIGURE 3-3 Health plans and employers use recognition information.

measurement, 1998, 2001, and 2004. So, we know that measurement leads to improvement.

We also know that if we had programs that define excellence in care, that we can get payers—payers being health plans, self-insured employers, potentially Medicare—to use the information. Figure 3-3 shows the various ways that we have been focusing on working with payers to get them to feature the outputs or the lists of recognized physicians that we have developed in our programs. And those ways range from on the left, just featuring the information in provider directories, to helping the practices collect the data, to paying monetary rewards, to using the information to construct products which could be narrow networks or differential co-pays. So, we can get people to use the information in ways that matter.

I tried to think about the vehicles that we could use to begin to implement the cancer survivorship care plan. The NCQA has a program known as Physician Practice Connections. It was created for a group of self-insured employers known as Bridges to Excellence. The program is about systematic practice and about how practices use information in a systematic way to provide care. So, just beginning with that program, and looking over the requirements, I tried to think about where the cancer survivorship plan fit in? There is a requirement in our newest version, which we are just finalizing, that requires practices to have a procedure in place, a process in place for identifying their high-risk patients (Figure 3-4).

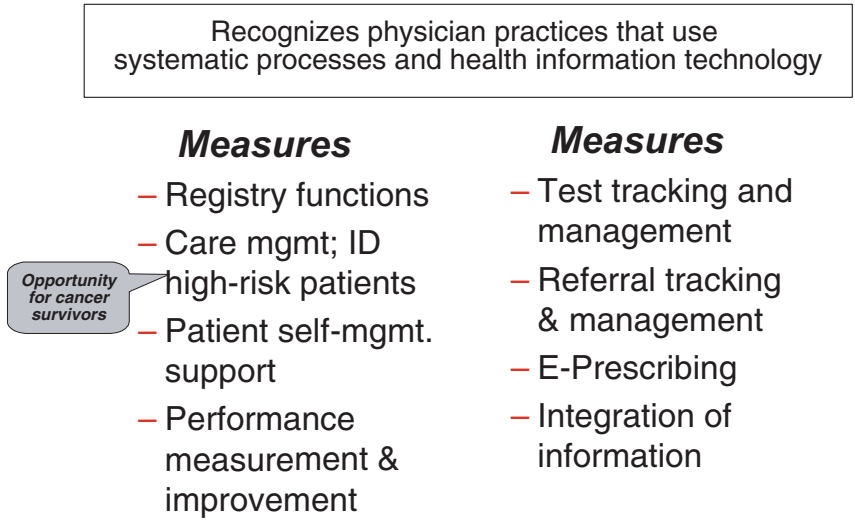


FIGURE 3-4 Physician practice connections.

So, in terms of where the survivorship care plan would come in, I think it would have to start at identifying high-risk patients. If identified as high-risk, physicians caring for cancer survivors in primary care practices would have to think about what needs to be done to care for these high-risk patients in an ongoing way. So, that is one vehicle.

Another vehicle that Deborah Schrag mentioned earlier is the ASCO QOPI program, which evaluates medical oncology practices according to measures in the categories of care shown in Box 3-2. I agree with Deborah that the QOPI program could be expanded to include requirements relating to practices taking an active role in developing the survivorship care plan. This would begin to get at routinizing it, as Patti mentioned earlier.

In thinking about implementation issues, we have discussed a program for medical oncologists whereby they document their care and recommendations. We need to discuss further the role of the primary care physician. If the patient comes in to see his or her primary care physician, and the patient has been identified as a high-risk patient, does the physician say, "Let me see your survivorship care plan?" Does the primary care physician then have any responsibility for reminding the patient of their need for a follow-up referral visit, of tracking those, of doing anything in that regard? Does the primary care physician have a responsibility to think about what self-management resources they can provide to a patient based on their survivorship care plan?

BOX 3-2
ASCO's Quality Oncology Practice Initiative (QOPI) Project measures

- Care at the end of life
- Pathology report
- Staging
- Chemotherapy
- Antiemetic administration
- Erythroid growth factor administration
- Breast cancer
- Colon and rectal cancer
- Growth factors in Lymphoma patients

Likewise, what is the specialist's responsibility on an ongoing basis? They develop the plan. If you miss a visit, does the specialist have a responsibility to contact the patient, and say, "You missed a visit" at least once? What does it mean beyond preparing the initial plan?

And then of course, what is the survivor's responsibility? I think to have effective implementation, all of these roles need to be thought through and delineated, and delineated as a partnership where each party understands their own contribution.

And with that I'll stop and take any immediate questions, or let us move on.

Dr. Jacobs: I am the Director of the Cancer Survivorship Program at the University of Pennsylvania Abramson Cancer Center which has been in existence for about five years. I think this is an incredibly good plan. We do notes, and actually a care plan of sorts that we do send the providers after we see patients. So, we do something very similar to what you are proposing here. And we send it to providers, and we give it to patients if they want one. Many patients say they do not want one. I think there are huge obstacles to the plan. That is not to say that it should not happen, because I think it should. But I am wondering what you have thought in terms of obstacles posed by enormous differences in the way in which people document. Some providers do not document at all, or they barely document just in long-hand, what they need to for insurance purposes, but they do not necessarily dictate notes. I am talking about what happens at our institution. Maybe your experiences are different. And just among 10 people who are caring for the same population of patients, you could have such broad differences.

In addition to that, communicating with say primary care providers, we feel very strongly that many of our patients or most of our patients should be following up with their primary care provider after we have seen them, and we have evaluated them, and provided this care plan. But then we get from patients that they do not want to do that. They want to come back to the oncologist. They do not feel comfortable going elsewhere for care. And then we have the oncologists who do not want to let go of their patients; who want their patients to come back to them. So, it is an enormous problem that we have been encountering for the last few years, and I think that we do need to educate. My point here is to emphasize the need to educate providers, patients, the subspecialists, as well as the primary care providers. I do not really know how that can be done.

Dr. Greenfield: Let's have Phyllis respond to that, and maybe if we have time for questions and answers, other people can respond to that as well.

Dr. Torda: I am sure everybody in this room has thought about the obstacles as much as I have. I think what I am suggesting is beginning to make roles very concrete, to embody them in standardized forms, and to have some measurement programs that incorporate carrying out those responsibilities, and measuring against them, and making those results public in some way or another as a way to move forward. There are lots of barriers.

Dr. Greenfield: Okay, let's go on to Doug Ulman.

Doug Ulman, Lance Armstrong Foundation

Thank you very much. I am the Director of Survivorship at the Lance Armstrong Foundation, and a three-time cancer survivor. It is a privilege to be here, and I want to thank the IOM and ASCO for having me, and for the wonderful report. We are obviously very committed to all of the recommendations, and know that it is imperative that this be an ongoing dialogue that is actually fueled and turned into action.

I want to talk about two issues in terms of implementing the care plan recommendation. I think it is a very exciting recommendation, but also a very complicated one. So, the two things that I want to talk about briefly are empowerment and infrastructure. I think the survivors, and we have talked a little bit about it, and we have heard a little bit just recently about this, but survivors need to be empowered. So, the notion that we can create a care plan and just hand it to individuals and expect that it will alleviate or reduce anxiety, or provide a higher quality of care I think is a little bit unrealistic. And so, I think we need to develop very complex educational

programs that are implemented with survivors and their families in the long-term, so that it is not just a hand off of a document or an electronic record, but yet an ongoing dialogue. And we also need to evaluate when it is appropriate to revisit that plan. Is it a year later? Is it 5 years later? Is it 10 years later?

The care obviously needs to be coordinated, and we have heard a lot about that. But I would advocate strongly that the survivor does need to understand what they have been through, and understand that care plan. And I think Linda's point is interesting that some survivors choose not to receive that. There may be any number of reasons for that, but I think if a survivor or their family understood that there was a companion education piece or program that would help them work through and educate themselves, maybe they would be more likely to want that information, and feel like they were empowered with that information.

Just briefly, I want to give you a case study. A 19-year-old diagnosed while in college, 400 miles from home, treated at three different institutions by six different providers, returns to college and is diagnosed with two additional primary cancers. He graduates, relocates three times in the next three years, and travels more than 4,000 miles to three cities. He is now 28, sees an oncologist in two different cities in addition to a primary care physician for follow-up. That is my story in a nutshell. And I have a cardboard box filled with records and x-rays and scans and documents. On a personal level, having a survivorship care plan would be incredibly exciting for me and reduce a lot of time and energy in terms of showing up at doctors' offices an hour early to complete information.

In terms of infrastructure, we need the guidelines and coordinated program development (to include academic centers, community practices, and primary care physicians). I think the piece about electronic systems is more interesting and exciting now. There is the Passport for Care Program on the pediatric side, which is putting the infrastructure in place to track and update guidelines automatically, so that survivors can have that electronically. I think as was mentioned earlier, the example of Hurricane Katrina, we saw that hospitals and individuals lost everything. So, the paper route, long-term, is probably not the most sustainable.

But I think that we have to empower the survivors, and then build the necessary infrastructure in order to not only implement the care plan, but also to provide quality survivorship care. So, I will stop there and take any questions.

Dr. Greenfield: Actually, as Doug sits down, let me comment before Julia poses her question. Sherry Kaplan and I have given patients guidelines in the form of algorithms, patient level, not doctor level, much oversimplified. And we found the same thing that Doug said. Many of them, maybe even

most of them, never used them. So, we are trying to create solutions. We think we found several around that. But I would also make one other comment. I am very pleased we had this discussion, because what looks like a rather simple notion, turns out to be very complex, and therefore, a lot of research and demonstrations, and if you will, a lot of good thought, have to go into bringing this about.

Dr. Rowland: I want to thank the panel for all their thoughtful commentary here. But I also want to make an impassioned plea. This is a wonderful moment. It comes back to Anna's call for empirical studies. All of us sitting here—educated consumers—are saying we would like these reports. One example of an interactive information system for survivors of childhood cancer, the Passport for Care Program, a wonderful web-based engine that we all drool over when we see it, has already been built. But we do not know if people will use it. You can build it, but will they come to it? I do not want us to be trapped into building something that people do not want. There are important empirical questions to ask: Who does or may not want the report? What would be meaningful to them? What information would they like and when in the course of their care?

I am reminded of some of my work with Patti Ganz. We tried to educate women about what to expect as they were finishing their cancer treatment, because survivors told us, "Gee, I wish I had had that knowledge when I finished treatment." Yet when we did approach them as they were finishing treatment, they said, "I am not ready to hear this information." So the questions we need to ask are: When in the course of care is it best to deliver this information? How should it be delivered? How often might you have to repeat it? These are necessary first order research questions, and I would love to see us build delivery models that would allow us to answer them.

Dr. Greenfield: Do any of you want to respond to that?

Dr. Bach: I agree, but I think there is an analogous research question that you would want to address, which is what is going on in the physician community, and the culture of medical caring that creates impediments for this kind of communication? And it is certainly true that patients at different points in their discourse are ready for different kinds of information. But it is also the case that doctors behave differently during different periods of the disease course that may make patients more afraid, or choose to be less empowered than they could be were the doctor to handle the entire spectrum of their care differently. So, it is challenging for us at CMS who worry about these sorts of issues, to have people respond and say, "Well, if you just paid for this other thing, then we would do it too," when I think the real question is "Is this

something that doctors should intrinsically be focused on doing? And shouldn't that be a part of the culture of the entire community?"

Susan Leigh: I am going to wear my nursing hat. When patients often come in for their follow-up visit, and they see their physician, they are expecting their physician to look for disease. They are expecting them to look for what is wrong with them. And it is a really scary time for lots of people to come in, and so we lose a lot of people. We lose people to follow-up, because they do not want somebody to find something that is wrong. When they come into some nursing clinics, the nurses then say, "Well, we will do a review of the systems here. But let's see how we can help you be well." And we then offer different ways to modify diet, or modify exercise. And if you take the time to help people learn how to be well, and I think that is maybe what Doug was alluding to with some of the issues he was dealing with. So, I think that the way we approach the survivor for that visit is incredibly important. And I think we need to have nurses at the table along with our physician colleagues, because we are working together as a team, and very often the nurse has the time and maybe a different kind of expertise to add to the team.

Dr. Greenfield: A very good point, and I think the role of nursing actually in this report, and in more general terms, has not been stated strongly enough.

Dr. Anna Meadows: When I was the director of the Office of Cancer Survivorship, who and when an individual was considered a survivor was up for argument. Was it now, the minute of diagnosis, the point of ending therapy, or maybe some arbitrary period after? And the point that was just made is important, because until about three, four, or five years after the diagnosis, no oncologist is going to give up their patient. They are going to continue to follow them. Pediatric oncologists definitely will. Medical oncologists also will. So, the time of ending therapy or some short time after that may not be the most appropriate time. They are not ready.

We are actually doing a study in pediatrics at the Children's Hospital now where we are talking to parents—now, admittedly this is parents of children—on their off-therapy visit and about the long-term clinical plan. And we are giving some parents just paper information, and we are having a conference with another group of parents, a randomized trial to see which of these works better, and whether this facilitates their follow-up.

Admittedly, we will not be able to answer that question for a long time, because we do not refer those patients to our follow-up clinic until they are two years off therapy at least, and five years from diagnosis. So, they do not see the survivorship program until then. But we want to see whether this

promotes their coming to the survivorship program and getting all that information. So, that is a small research study, but as always, children will lead the way.

Kym Martin: I am a new member of the National Coalition for Cancer Survivorship. I am a pediatric childhood cancer survivor, a 22-year Hodgkin's survivor. To Julia's point about really taking a look at what the patients/survivors would like in their treatment plan, and when they would like it, yesterday I had a visit with a new oncologist here in the area. I am new to Maryland and like Doug, 22 years of records have followed me around various parts of the country. And to sit down and talk about where I have been, and where I need to go, it was difficult for me to actually go back and review my records again before I had to meet with him. And I am an advocate. I am all for empowering survivors, and I am all for having the information.

I think one of the things that we should also be focusing on is bringing the family of survivors into the fold, because if patients are not ready, at least a family member can act as an adjunct for their care, and kind of keep them on track. So, from my personal experience even though you may think you are ready, you may not be as a survivor. So, let's bring the other survivors that we recognize as family members, and get them on board and find out from their perspective too, how they would like to help the patients if they are not able.

Dr. Greenfield: Thank you for that. I want to ask Phyllis to respond to this, and I will lead into her response. In other diseases there have been ways found to deal with the timing problem, basically which is to say you have a whole year, or some period to do this. In other words, you do not have to do it on the first visit. That is what Linda was talking about, or maybe the second. You can make up a specification, or something like that, that says within a year you will have at least had to offer a survivorship care plan. That would be a quality measure, something like this. Do you have any more comments about that?

Phyllis Torda: Well, certainly there is an art to measurement, and Rodger talked about it a little bit earlier this morning too. Conceptually you need to get agreement on what you want to do, and where the disagreements are. And then you can usually figure out how to design a measure that will be better than nothing, and will be good for a start.

I would just like to comment briefly on the need for research. It is very important to not just assess how people feel in a static way, but to also look at "what ifs." So, can you set expectations that after a course of active treatment, there will be an appointment with a medical oncologist? And the medical oncologist will go over what the care plan is for the future, so you

are not just again, looking at things in a static mode, but how can you help people to move along.

Kevin Stein, American Cancer Society: I would like to thank you for some excellent talks. I want to build on something mentioned earlier and that is that I feel that this treatment plan should be more multidisciplinary, because just doctors talking to doctors is not going to include the full spectrum of issues that survivors have. In fact, many issues are psychosocial in nature. And you are going to make referrals to pain management specialists, to psychologists, to psychiatrists, and to social workers. And a lot of those individuals are going to be involved in these patients' care, especially as they move away from the acute phase where the physical symptoms are important, and the psychological symptoms of cancer-specific distress, things of that nature, become more important. So, we need to include these people in this treatment plan, and make it more comprehensive. And that includes not just the other treatment providers, but also building on what Kym Martin said about the family, and taking into consideration the individual differences, the cultural, the ethnic background of these individuals, and how that impacts on how they are going to engage in the follow-up care.

Dr. Greenfield: Thank you for the comment. Any responses to that? Are there other questions?

Diana Jeffery, National Cancer Institute, Office of Cancer Survivorship: As I am listening, I am thinking of lots of research questions. But the number one question I have is, if this was instituted, whether in demonstration projects or a national kind of effort, would there be a difference at the end of the day or the end of the year, or at the end of 5 years or 10 years? And what would that difference be? And what would those indicators be? What facets of quality of life would be considered success? And who would pick those indicators? I am hoping it is not the provider. I am hoping it is the survivor.

Dr. Greenfield: But even that is a researchable question. For example, you might hypothesize that treatment of certain late side effects could lead to a reduction of symptoms and improvement in function. There are multiple endpoints and I think the point you are making is we have to decide what those endpoints are.

Dr. Schrag: I think there are lots of ways to operationalize that question. One obvious thing is to make sure that cancer survivors go on and get the care that they need. That is, that they are appropriately assessed and receive screening mammograms and cholesterol checks. And if they are Hodgkin's

survivors that there is special attention paid to breast cancer. So, I think we already have a set of quality metrics. And Rodger Winn and many other people in this room are working hard on figuring out what those quality metrics should be. But I think the other thing is that increasingly the science of measurement is really a more complicated and sophisticated construct than patient satisfaction. But I point to things like the Picker Institute measures. John Ayanian and others of you in this room have used them very successfully. These are based on patient surveys. They are more often focused on inpatient care. The American public still trust their doctors, they like their doctors, they think their doctors are doing the right things. Where we fall down, more doctors than nurses, but nurses too, is on communication and coordination. We have got countless surveys and countless disciplines that show that. I think we need to do before and after assessments, and use some of those metrics to see whether this stuff makes a difference.

And what I would say to the NCI folks is "You put out the RFAs (requests for applications), and let those of us who are out there respond to them." And we will try, and be sure to help us, because I would say, having tried to do this research, and Mary McCabe who is in the audience can probably speak to it better than I, when I think about doing these kinds of research projects, a lot of it is pilot work.

Let's try this and see whether it makes a difference. And we want to be nimble about it. And we have to decide whether we are going to do this as operations research, sort of quick and dirty. Let's try it, measure the impact, regroup, revise, and do it again. Or, consider whether we are going to do it in the context of Institutional Review Board (IRB)-approved research. And IRB-approved research, whether you are at a big place or a small place, it just takes six months to get it through an IRB. By the time you have written it, and approved it, and vetted it, and then the patient has to sign a very scary looking form. And that is a tremendous obstacle to us being nimble. So, what I would say to our NCI colleagues is "Help us be nimble." We would love to do this research. Help us intervene with IRBs to explain that maybe this does not really need six months of an IRB protocol, that this area may fall under the area of operations research.

Dr. Greenfield: Let me respond to what Deborah said. In many places, what is called quality-of-care research is either exempt or it is expedited. So, we and others have built a lot of pilot work on the backs of that. But your plea has got to be heeded.

Dr. Antonio Wolff: We clinical trialists have implemented, and I think it is working very well, the concept of a central IRB. We are talking about low-risk research. We are not talking about giving poisons to people. This model may be applicable in the survivorship context. The other issue is that

resources are needed in this area. I was wondering about the beautiful video that was produced to accompany the IOM report (IOM, 2006a). It was very moving for me to watch, and I am very curious to hear what is going to happen with that, how widespread is it going to be disseminated?

We are all preaching to the converted here. And when we have congressional representatives and others saying we cannot shake up the status quo, those are the people that need to be talked to so that the NCI and others will have the money they need for research.

Dr. Greenfield: Let's have Ellen respond to that with the final word.

Ms. Stovall: Well, the NCCS has prevailed upon the Institute of Medicine to give us enough copies of both the DVD and the report so that it will be distributed to our friends on Capitol Hill.

Dr. Greenfield: And thank you very much, and we thank the panelists for their comments.

BUILDING BRIDGES BETWEEN ONCOLOGY AND PRIMARY CARE PROVIDERS

Moderator: Steven Woolf, Virginia Commonwealth University

The topic that we are going to focus on now is this notion of building bridges between primary care and survivorship care. Our first speaker is Kevin Oeffinger. Kevin is a family physician and medical director, as of July, for the Living Beyond Cancer Program at the Memorial Sloan-Kettering Cancer Center.

Kevin Oeffinger, Memorial Sloan-Kettering Cancer Center

Thank you so much, Steve. Let me begin by providing a rationale for why bridging oncologists and primary care physicians is important. First, we will talk about the study by Craig Earle and associates where they looked at 15,000 five-year survivors of colorectal cancer (Earle and Neville, 2004). They looked at the type of health care that survivors had received and the type of healthcare provider delivering that care. When you look at the acute care, preventive care, or overall care, the survivors that had a primary care physician and an oncologist were most likely to have recommended care (Figure 3-5).

This finding of better care associated with both specialty and primary care is not limited to cancer. In a study of over 35,000 patients who had had a myocardial infarction, when investigators followed up and looked at the two-year mortality rate, patients that were followed by both a generalist

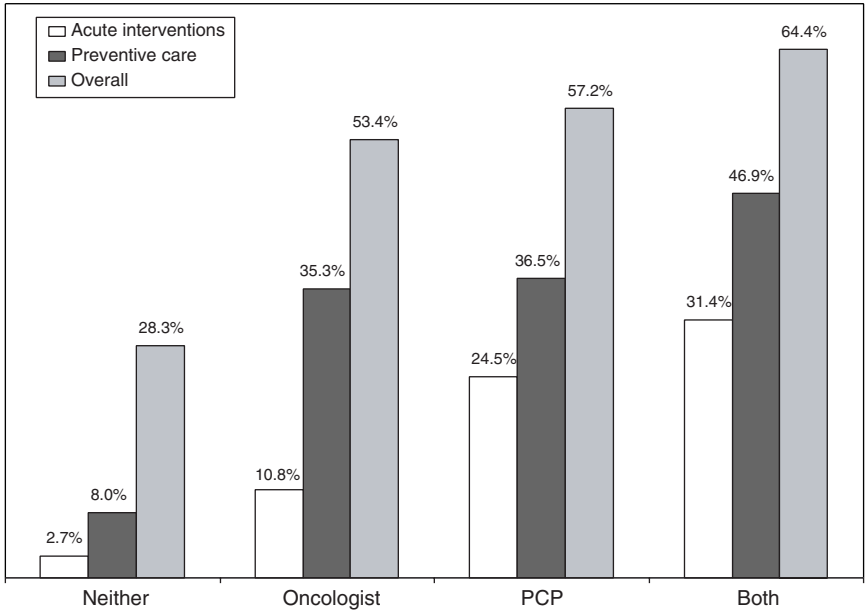


FIGURE 3-5 Percent of patients receiving recommended care by type of provider. PCP=primary care physicians.
SOURCE: Earle and Neville, 2004.

and a cardiologist within three months after hospital discharge had a lower mortality rate (Figure 3-6).

There are a number of other studies that have shown that patients have improved outcomes when they are followed by both a specialist and primary care physician for a chronic disease. What I would like to emphasize though, is that most of the studies have focused on either the simple presence or absence of a healthcare provider, and have not systematically looked at whether there was shared care.

I have illustrated in Figure 3-7 the distinct needs of oncologists, survivors, and primary care providers. We must acknowledge that survivors need physicians with time to devote to them, some knowledge of the dynamics of the cancer experience, and someone to answer questions and address fears. Are my symptoms the results of my cancer experience? Is this shortness of breath something that is a sequela of my cancer therapy? In other words, how to evaluate that patient with a perspective of what their cancer therapy was.

From the oncologist's point of view, if there is a recurrence, there will not be a delay in diagnosis given their expertise in surveillance. And importantly, seeing survivors in an oncology practice also provides a psychological balance in a setting where death is a frequent occurrence.

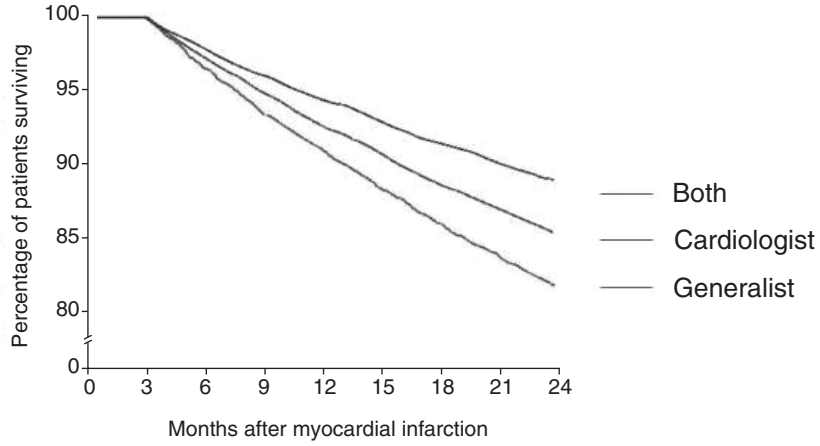


FIGURE 3-6 Patient surviving after myocardial infarction by type of provider. SOURCE: Ayanian et al., 2002.

Primary care physicians have a need for continuity with their patients, not only after cancer diagnosis, but through cancer therapy, and then on to survivorship. We need targeted information to understand how cancer chemotherapy or radiation affects the survivor's long-term health.

So, if we look at the different ways that oncologists or primary care physicians might fill this role, we recognize that both are important and needed in this model. The problem that was highlighted earlier is that most care in the United States is provided in a haphazard fashion. So, what I am showing in Figure 3-8 is an adaptation of a three-component "re-engineered" model proposed by Dietrich that has been shown to be effective in reducing poor outcomes with patients with chronic disease.

In this model, a care manager, usually a nurse, educates, anticipates, and guides the cancer survivors by telephone using guidelines and algorithms. The oncologist provides supervision for the care manager, consults with the primary care physician, and takes the lead to increase the quality and the quantity of survivorship resources. In some primary care practices, education is provided not only for clinicians, but also for the office staff in order to implement processes that not only enable, but reinforce the quality of survivor care.

The electronic health record has a key role to play in promoting survivorship care. The technology is currently available and the cancer care team can create an electronic health record and then populate the record with key elements of the cancer survivorship plan outlined earlier. Guidance for the primary care physician regarding possible late effects, recommendations

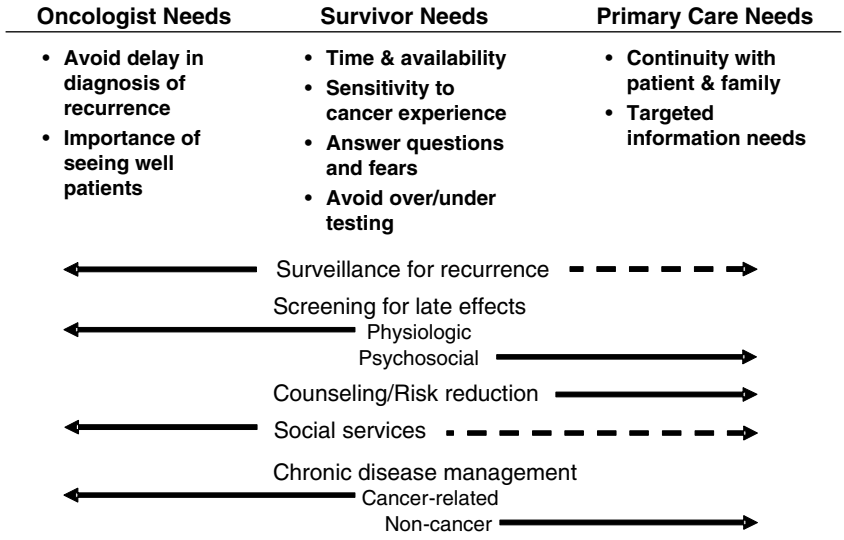


FIGURE 3-7 Bridging survivor health care.

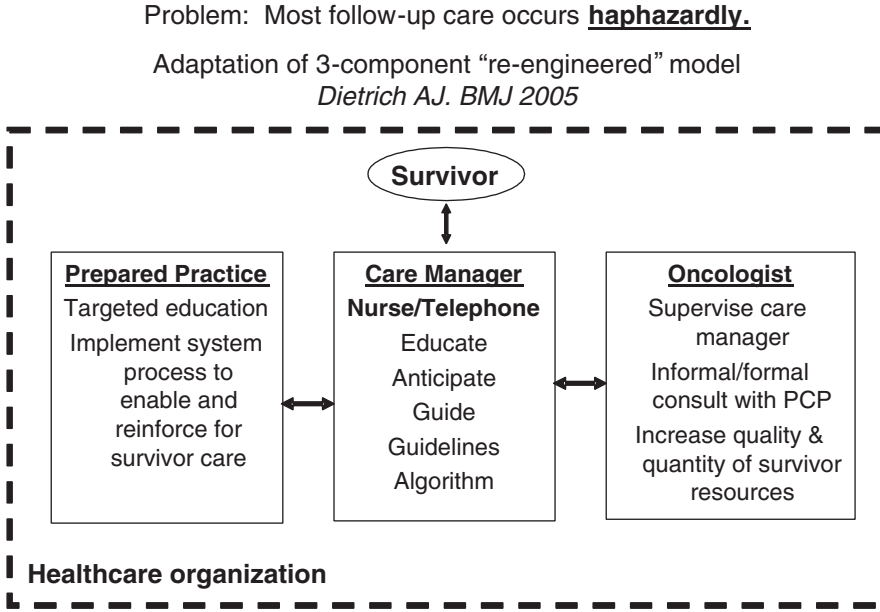


FIGURE 3-8 Bridging through shared care.
SOURCE: Dietrich et al., 2004.

for screening, and a problem and medication list can become part of a shared record. Through the use of simple computer software you can translate this into lay terms. And survivors, through a HIPAA compliant web-based interface, can access this information, deposit new information if they are monitoring symptoms or signs, and communicate in an asynchronous fashion with the cancer team. Very importantly, there is a physician portal where a primary care physician can access this information, contribute outcome data, including information on any meeting with the cancer team and the survivor. This system unifies the survivor, cancer team, and primary care provider and provides an opportunity for communication. It enhances outcomes data, and it empowers the survivor.

I would like to address research as it provides an important bridge between the work of oncology and primary care. One of the success stories of the National Cancer Institute in the last 20 years has been the development of the Community Clinical Oncology Program (CCOP), which encourages cancer centers to engage in community-based cancer research, in the areas of both cancer care and cancer control. There are currently about 4,000 physicians, primarily community oncologists, participating in 61 CCOPs.

Practice-based research networks (PBRNs) are a mechanism to develop research opportunities in primary care, family medicine, internal medicine, and primary care pediatrics. Within the Federation of PBRNs there are now 65 networks, including over 6,500 physicians providing care for over 16 million patients in the United States and Canada. The PBRNs represent an opportunity to launch new research to test models of care and to conduct generalizable survivorship research. Importantly, they enhance our work by fostering a working together towards a common goal of maximizing the health of our cancer survivors.

Dr. Woolf: Thank you, Kevin. That is a helpful perspective from your experience as a family physician in a cancer center. Now, we are going to hear from Pat Legant, who is a medical oncologist in community practice in Salt Lake City, Utah.

Pat Legant, Community-Based Medical Oncologist

I have practiced medical oncology in the community for over 20 years, and I am pleased to report that I follow a great many cancer survivors. In this way, I think that my experience parallels that of most oncology specialists, in that most adult cancer survivorship care in this country is supervised by an oncology specialist who works in cooperation with a primary care provider, in some version of the model of shared care that is described in the report from the Institute of Medicine.

This model has much to recommend it, and in fact there is some evidence that patients prefer it. There are a number of advantages of the shared care model. In particular, the physician supervising the cancer care has specific expertise and experience in oncology. The primary care doctor and the oncology specialist see the patient with a different set of eyes. We need both perspectives.

The chief disadvantage of the shared care model, as cited in the IOM report, is a dwindling supply of oncology specialists in the face of an increasing population of cancer survivors. However, one can make the same comment about primary care providers in that they will be faced with the non-cancer related care of us baby boomers.

The IOM report maintains that cancer care in this country is poorly coordinated and often fragmented. This may be less a failure of the shared care model than of the way it functions. There are certain requirements for effective shared care. First, to work optimally, the model requires close cooperation among the oncology specialists, the primary care provider, and the patient. It assumes a culture of team work, in which the oncologist serves as the primary provider for the cancer-related care, and the primary physician supervises the non-cancer-related care.

Second, there must be clear communication between the oncology specialist and the primary care provider, whether by letters and faxes as now, or electronic medical records in the future. This communication must include individualized content, providing the survivor's disease status, suggested tests for follow-up, and also management guidance for this patient specifically as opposed to cookbook recommendations. So, for example, if I have a patient on tamoxifen, I have to know who is doing the pelvic examination, because somebody needs to do it every year. Communication must also specifically address the recipient to guarantee that responsibility is passed securely. Communication must be multidirectional. Right now, most of the communication goes from the oncology specialist to the primary care provider, but it should be back and forth among all the specialists. So, for example, if my patient gets congestive heart failure, I need to be sure that it is not a late side effect of treatment or relapsed cancer, or I may simply need to assure the patient that the heart failure has nothing to do with the past cancer.

Third, the system should allow for flexibility of relative involvement of the oncology specialist and the primary provider. The baton of responsibility should pass back and forth over time, rather than just once, to reflect the variability and the unpredictability of malignancy. Involvement should also depend on the course of the cancer, the course of the co-morbidities, the risk of relapse, and the patient's geographic and social circumstances. If I have a patient who lives in Wyoming, I will communicate extensively with the primary provider in the winter in hopes of sparing the patient a three-

hour drive to my office in the snow. There should be no artificial barriers to this kind of give and take, for example, things like insurance limits on how many times a patient can see the oncology specialist per year, or higher co-pays to see the oncologist specialist, who after all is acting as the primary provider for the cancer-related care.

Fourth, the patient should be explicitly recognized as part of the communication team. This then mandates patient education on how and what to report. If there is a new lump or back pain persists after a couple of weeks, I want the patient to call me, as well as the primary provider. The proposed treatment care summary is an excellent first step, but this is an ongoing process over a very long time.

Finally, communication and education are critical elements of optimal cancer care. Some of this can be streamlined, with checklists and electronic medical records and the like, but much of it is not delegable, and it is time intensive. Insurers must offer adequate reimbursement, or else these activities cannot happen.

The shared care model has served us well for many years, and will continue to be the predominant model in the foreseeable future. We owe it to our patients to identify the critical elements of the model and to make the model better. Improving communication within the oncology care team is one way to do this.

Dr. Woolf: Thank you, Pat. Our next speaker, Ann Partridge, is going to give us a perspective about additional special issues in thinking about this linkage. Ann is a medical oncologist at the Dana Farber Cancer Institute. She is also instructor of medicine at Harvard Medical School. Her clinical research has focused on psychosocial, adherence, and communication issues in oncology, and breast cancer in particular.

Ann Partridge, Dana-Farber Cancer Institute

Thank you. It is a true pleasure to be here today. I want to focus on two particular issues. You have all addressed today how survivorship, up until the last several years, has been something that has been somewhat of an afterthought for the vast majority, aside from the people in this room. The two issues that I want to address are viewed even more so as afterthoughts, but nevertheless very, very important. The first one, and I think we could all agree as we watched that video this morning, relates to the generally tremendous psychosocial impact of cancer on an individual. This is something that we pay attention to on some level, because sometimes you can not help but pay attention to it, because someone is crying, or because they are not coming in for treatments, because they can not deal with it. But short of that, especially during or after treatment, it is something that gets

pushed aside so you get someone through their treatment. Or people themselves push it aside so they can buckle down and get through their active treatment.

A couple of the survivors on the video talked about it today, especially early in that transition time, that is when a lot of people really reach a crisis point in terms of how they are coping with their cancer diagnosis and moving forward. What I would like to introduce today is that we not push the psychosocial issues off to the side as we agree about this care program and care plan. That we face the fact that the anxieties about the future and the psychosocial distress that comes with a cancer diagnosis is not something that goes away, and actually can become bigger when one gets through the active treatment, because they are no longer focusing on the acute side effects and toxicities and will survive. Now, they are focusing on the "what does it mean to me" questions. So, not only do we need to help our patients through a rich communication with primary care physicians and oncologists and other care providers, help them to know who to call when they have an ache or a pain, we also need to help them know where they can seek additional psychosocial support as they grapple with their diagnosis and moving forward in life.

The second point I would like to make is even further out on the trajectory. And it is the long-term follow-up of patients. And in particular, the issue of communication with patients either following a trial in a research study where they received standard care, when ultimately research tells us that those patients are at greater risk for some new disease. The perfect example is Hodgkin's survivors, young women who received mantle radiation for Hodgkin's disease in their teens, who are at dramatically higher risk of breast cancer 15 years down the line. In the future, after we learn more things like this, and follow our survivors better for their long-term outcomes, how are we going to communicate those risks with those survivors?

Another critical piece as we do the "hand off" or the shared care transitions is how we will make sure that primary care physicians and whoever is following these patients 15 years down the line have access to relevant cancer-related information? There are ways to build these communications in either through web sites or staying in contact in some way with an oncologist in the long-term. As you heard Dr. Ganz say today, she still sees many of her patients yearly. But I'll bet that there are many survivors that are 15 years out from their cancer that she does not see any more. They probably go back to their primary care physicians.

Finally, we need to figure out a way that the long-term information about potential side effects from treatments survivors may have received 15 years ago is conveyed. And we can not expect that it all will make the *New England Journal of Medicine, USA Today,* or other outlet such that they will hear about it in the lay press. I think we have to find ways through

this burgeoning world of communication to help facilitate the transfer of that information as well. Thank you.

Dr. Woolf: Thank you, Ann. Our last speaker is Regina Benjamin, who is a family physician in Bayou La Batre, Alabama, just outside Mobile. It is a treat to have all of our speakers here, but I do not know if you realize how special it is to have Regina here. She will comment on that. Regina is going to comment about survivorship from her perspective as a practicing primary care physician.

Regina Benjamin, Bayou La Batre Rural Health Clinic

I am a family physician, and when I finished residency, I opened my practice in a little town, Bayou La Batre, Alabama. It is the furthermost village on the Gulf Coast of Alabama. They filmed the movie, "Forrest Gump," there, if some of you saw it. It is a pretty place, but it is a poor place. I found a community of "working poor," that is, people who are too poor to afford medical care, but too rich to qualify for Medicaid.

Much of what I was going to say to you has been said earlier in our sessions, and by the other panelists. I will just tell you which of the recommendations that I think are most important for me, and why I think they are important. The first one is number one, to raise the awareness of the needs of the cancer survivor. We have 10 million cancer survivors out there. I did not even know we had that many, and many people did not know that. And just the fact that we have that many gives us an opportunity to start to address the issues and needs there. Many of my patients will come in with an acute problem for example sinusitis or a cold, and they do not tell me they have had cancer. I only find out when I do an in-depth history and physical. Patients themselves do not think it matters as far as their acute health problem is concerned. So, raising awareness of patients will really help. They are not hiding it. It is just not a top priority.

It is the same with physicians. There is a patient I saw last week who I have been seeing for several years. I know she has had breast cancer. But until I went to do her annual pap smear and her breast exam did it occur to me, oh yes, this person has had breast cancer, and I need to start to follow-up on some things. And that is why recommendation number two is really important, that a survivorship care plan is needed. If I could put the plan on the front of the chart it would remind me of the things that I need to be looking for, the things I need to be doing, what the patient has experienced, and just continuously have a reminder. We do that for cholesterol. We do it for pap smears. We do it with mammograms. It would be a good document for us to have. I think that this recommendation for a survivorship care plan, in particular, is the most important.

Primary care providers often lose our patients to follow-up. When a patient of mine has an elevated PSA I send him to a urologist, and he is diagnosed with prostate cancer. It can be a year or two before I even get him back out of the oncology system, unless his family calls me up and says, "Do you know what those doctors want to do? Do you think they should do it or not?" Otherwise, I may lose them for a couple of years until they have completed their cancer treatment and care. The cancer survivorship plan would really open the communication between all providers, because the oncologist did not get the patient from me, they got the patient from the urologist to whom I had sent him. So, the oncologist may not even know I am in the loop. So, I think that the care plan would really help pull it together, so that when I do finally get this patient back in a year or so, I will have something to go by.

The clinical guidelines and assessment tools that are called for as part of recommendation number three, can help primary care providers manage the late effects. These could really help those of us in the boondocks, if you will, to basically know what we need to do. I am not an oncologist. I do not plan to be an oncologist, but I want to know what to look for, and I want to give my patient the best care I can. I want someone to give me some guidelines so I know what to look for, and I know when to send them back. And if my patient starts feeling fatigue or has other symptoms, I need to know what to look for, what tests I need to be doing, what laboratory tests I should conduct, and generally, how to follow up. I think survivorship guidelines would really help us as primary care physicians very much.

And the last thing that is important to me, because it is important to my entire medical career, has been access to adequate and affordable health insurance. The patients that I see work, but the majority of them do not have insurance. And when you get a diagnosis of cancer, you can often not get insurance. And if patients are uninsured, we have to find ways to advocate for them to make sure that they can always purchase insurance if it is available, and make sure that it is affordable.

Hurricane Katrina hit my town and brought us a 25 foot surge of salt water, and of the 2,300 people in the town, 2,000 have no homes. Many of my patients are cancer survivors, and they did not have insurance in the beginning. Now, unemployment has doubled, making health coverage even harder to get. And as we have discussed, stress from such difficult circumstances can manifest as physical symptoms. So, we have to be sure to identify anything that comes up, particularly with cancer.

Lastly, I would just like to say that many of us know cancer survivors who eventually lost that battle. I just want to remind us that as we talk about these issues, that we remember those folks that have contributed so much for us to get here today, and always keep them in our thoughts. They

had struggles and they survived for a while, oftentimes a long time, and then they lost that battle.

Dr. Woolf: I want to thank the speakers for achieving our goals and staying on schedule. We have a good block of time for discussion.

Dr. Susan Weiner, Children's Cause for Cancer Advocacy: I would like to address some questions about this notion of a shared care model to the speakers. There seem to be two versions of it. In one version, there is a nurse intermediary, and in another version there is not such a nurse. I typically do not speak in public about my personal experience. I was the parent of a child with cancer, who was diagnosed as an infant, and then died when he was nearly 14. I was his case manager, of course. And one of the things about not having an intermediary in coordinating specialty care and primary care is that the burden of decision-making is on the family as to who to call and what to do. And from a parent's perspective, I can tell you that is one of the most stressful things one can endure. But one also hears from adults, as well as parents, that one does not want to "bother" the physician. So, this is a situation in which there is no intermediary, where there is no nurse. When there is an intermediary, the risks of course are that that person may serve as an inappropriate gatekeeper. There have to be personal dynamics that work. There has to be the bond of trust. So, that is my first set of concerns about the shared care model, and things that I think have to be worked out.

The second set of challenges has to do with the notion of the culture of team work. One of the things that I have experienced, and that others have experienced as well, is that there is frequent and intense competition between caring physicians, especially if it is a rare cancer. And in some instances, if it is between institutions, it can be like the army and the navy. It is extremely difficult to manage, because one wants to have not a competitive view, but an insightful view that is empirically based or based in practice. It is tremendously difficult to sort that out from the patient's perspective.

And then the final point about the culture of collaboration relates to patient loyalty. Will I be unfaithful? Will he be hurt if I went to see X in order to ask a question about my condition? This is a very difficult problem to face, since one does not want to bias the care that one receives for a loved one. So, I think that in looking at the shared care model, as it becomes more articulated, I am not sure that those things need to be alternatively evaluated, but they sure need to be looked at *a priori*.

Dr. Woolf: Those are good points. Panelists, do you want to address them, or do you have some additional comments?

Dr. Partridge: I just wanted to address the first point and the last point related to the need for an intermediary as a part of the shared care model. Based on my experience, one of the most important things, as we think about caring for the adult survivorship population, is that the volume is tremendous. And in terms of allocation of resources, there are going to have to be intermediaries to some degree to try and care for the volume and to give people the appropriate attention they need to deal with all the survivorship issues for various cancers. What is probably the best way to fold that into the long-term care of survivors is, if one has the opportunity, to build it in from the beginning. And if you work with a physician or a nurse-practitioner or a physician's assistant or a nurse, to have the patients know that person from the beginning. Such teamwork helps with time and resource issues, and also to facilitate better care. This early introduction makes it less of an acute transition to another provider. This model, at least in our institution (Dana Farber), seems to work in terms of how we follow our patients long-term, and does not make them feel like they are seeing someone who is unfamiliar or an inappropriate gatekeeper, because they already know this gatekeeper and they are part of the team.

Dr. Woolf: Kevin, do you want to make a comment?

Dr. Oeffinger: I will make a couple of comments. Nurses are very important, as are many other providers. Survivorship care, more than probably most other areas of medicine, involves a team approach. And whether that is a nurse within the cancer team, or whether it is a nurse in the prepared primary care practice that works as an intermediary, it is going to vary from practice to practice. The other thing that I want to highlight is we used the term "shared care," and I am going to be the devil's advocate, and say we do not know what shared care is. We have not tested shared care. What we describe in most of the studies is "both" care. And it is truly haphazard, it is not systematic, and it is not planned. It usually is "I talk with you, you talk with me," but we do not pay attention to those that get lost to follow-up. The biggest group that is lost to follow-up from every study, my study included, is that large group of patients that do not go to the oncologist, that do not go to the primary care physician, and nobody knows it.

Dr. Benjamin: There is also a large group out there called "caretakers." The Rosalynn Carter Foundation focuses on rural caretakers, but there is an international organization as well. We need to make sure we involve family caretakers in any model that we intend to put together, because oftentimes they know more about how to get around the system than we do, and we can learn a lot from them. Oftentimes we do not think of these systems

issues as scientists, as physicians, or as nurses. We need to encourage utilizing the caretaker in our models as well.

Dr. Woolf: If I may use my liberty to stand outside my role as moderator and also respond. As a primary care physician, we often have this habit of looking across diseases, because we take care of multiple conditions. Some of the concerns you raised when I listened to you are specific to cancer survivorship. Many others I see encountered by other patients and families and caregivers who are dealing with chronic, ongoing, recurring, and potentially life-threatening diseases that are other than cancer. So, it might be congestive heart failure, diabetes, or Alzheimer's. The primary care physicians and specialists work together in managing those conditions all the time. And this is the theme that I am going to come to in my talk later.

Many of the challenges that you have raised, the need for a case manager to deal with navigating the system, deciding who to go to, and whose feelings are going to be hurt, and so on, are encountered by these families as well. My point is to say that the solution to the general problems that have been raised is a system solution. That it is not necessarily a cancer care solution, but a healthcare solution.

Dr. Susan Weiner: I agree with you entirely. I think though that there is one difference. And one encounters this difference in the pediatric community between the care of kids with special healthcare needs, and the care of kids with cancer. And that is the societal perception that cancer is like an infection. It is an acute disease. It is treated, and then it is done. And I think if anything, a big impact this report can have is to change that perception.

Dr. Woolf: Yes, that is what we intended to be the most important message of the report.

Bob Weiss, National Lymphedema Network: There is something that I do not hear here in terms of shared care that I think is very important from my own experience. And I am talking now as a patient advocate, my wife being the patient. I heard communication between the various people, but I do not hear knowledge. And in our experience—my wife is a 13-year breast cancer survivor, and she has had lymphedema, from the very beginning—the medical people that we deal with have virtually no knowledge of first, lymphedema, its pathologies, its physiology, and second, its modern treatment. And the reason for this, in my opinion, is the fact that in Europe there is in medical schools, a department of lymphology. Every medical student that goes through school in Europe is exposed to the lymphatic system, its

pathologies, and its treatment. In Europe there is also a method of treatment that was developed over the last 50 years that has been found to be very effective. The insurance companies cover the specialized treatment. In the United States it is viewed as alternative medicine, and we don't believe in alternative medicine. That is a quote from a newly graduated MD that treated my wife for a respiratory health problem. And when I told her what the treatment of lymphedema was, she said, "Oh, we don't believe in that. We doctors do not believe in that." Now, there is an information gap here. My wife's oncologist said, "The further away you get from chemotherapy, the fewer the symptoms will be." She completely neglected the long-term effects of the radiation my wife had, which are far worse than any of the chemotherapy she had. My wife's treatment was involved, she had 21 affected nodes and had chemotherapy, a mastectomy, hormonal treatment, radiation, she had the works. And thank God, she is still alive and still kicking. And she very often reminds me that all of the effects of chemotherapy and the radiation and everything pales in terms of her quality of life in comparison to the daily care that she has to take for lymphedema.

Dr. Woolf: Let's get a reaction to the panel on the issue of gaps in knowledge, and how the partnership between the primary care physician and the oncologist can help deal with those gaps in understanding.

Dr. Benjamin: There is a case study in the book. I do not know if it is your wife, but it sure sounds almost just like it. We had a similar case study with lymphedema, arm swelling, and nobody diagnoses it for a while. All of a sudden it is lymphedema several years later after her breast cancer treatment. The gaps are there, and that is what we are trying to highlight, trying to bring to the attention of the scientific community, to each other that we do need to close those gaps, because they are there. And patients are the ones who will tell us.

Bob Weiss: Yes, but if you do not have the knowledge, very often the doctor, the physician, says, "Oh, your arm or your leg is swollen? Please take this diuretic I will prescribe for you. Raise your limb when it starts swelling, and go home, goodbye." And it is stage two lymphedema. It is not going to do any good. Furthermore, the diuretic is contraindicated and makes the lymphedema worse. So, there is misinformation also given by the physicians in the case of treatment of this.

Dr. Benjamin: Recommendation number three in the IOM report is give us some clinical guidelines, some scientific, evidence-based clinical guidelines, so that we can close some of these gaps.

Dr. Partridge: There do need to be efforts based, in part, on the experiences of the Institute of Medicine and ASCO and this report, to improve the knowledge base of general oncologists and primary care physicians providing long-term survivorship care. We need to, for example, increase CME credits and access to this information. In our state, you have to have all your CME credits handed in when you want to get relicensed and some of those credits have to include risk management. At some point, some of the CME credits may have to include long-term issues for cancer, or long-term issues for something else. I hate to have to have things mandated. You can not force people to learn.

Dr. Woolf: This also circles back to Kevin's point about the electronic health record. There will be a point in time where integrated information systems will provide prompts to the clinician about lymphedema for example, and the ability to quickly pull out current recommendations and evidence-based guidelines on how to manage that.

Dr. Diller, Dana-Farber: In response to your point about lymphedema, this may seem tangential, but recently there was an article published by Lois Travis on the risk of breast cancer in survivors of Hodgkin's disease. And I am a pediatric oncologist with an interest in care of survivors. I got an e-mail from a primary care provider who had read the article, or read the press release, or read some lay version of it, and wrote me and said, "Should I be getting mammograms in patients who had been treated a number of years ago that I now follow in primary care?" So, in some ways, the system does work. We do research. We publish. The publication gets read, or it gets disseminated, and then that gets back to the primary care provider taking care of the patient, who then starts to think, "I have a patient like that. I may think about taking care of them a way I haven't considered before." So, the processes that Dr. Meadows described this morning of research driving the process in a lot of ways, the process I described is one of the most traditional ones in academic medicine, but one that sometimes ends up working.

Dr. Grunfeld: I'd like to suggest an approach to the concept of shared care, which is somewhat different. I would like to suggest that along with shared care, we focus on appropriate care, which brings in the expertise that is needed at the time that it is needed. If we look at the epidemiology chapter in this book, what really comes to my mind, and really was the impetus for the research I have done for years on this topic, is that for the major prevalent cancers, breast, colon, and prostate cancer, the majority of survivors are over 65. The majority of people have one if not multiple comorbidities. Regina brought up the point, which we have certainly experi-

enced in Canada, which is that the diagnosis of cancer often creates a separation between patients and their primary care physician, so that the cancer treatment, diagnosis, and follow-up care become the focus of attention. If we really look at what the patient's needs are, ultimately after the acute treatment phase, for those people who do not go on to develop recurrence, it is management of multiple co-morbidities. So, I would suggest our idea of the shared care should encompass the concept of obtaining the relevant expertise at the time that they are needed. During the diagnostic and treatment phase, absolutely, secondary/tertiary level expertise are required. But I would challenge the concept of Patti Ganz seeing patients 10, 15 years after their diagnosis, and say, "What is the real benefit for the patient? And what are the opportunity costs?" Because if Patti is seeing patients 10 or 15 years after diagnosis, what about the patients who she won't be able to see. She will make a huge quality of care and symptom management difference if she sees them during the palliative phase.

Dr. Woolf: Did everybody in the back hear the question? Let me do my best to restate it. Over the course of cancer survivorship health needs are changing. There are co-morbidities. And at any given point in time, it might be the case that the patient's co-morbid conditions other than cancer may be the dominant health need. And the expertise that might be required at that time might be different than say during an acute recurrence of the cancer at some point. So, the model of shared care needs to be in flux, depending on what expertise is necessary to deal with the care needs at the time. Is that fair?

Dr. Grunfeld: I think that is fair. I would just make an ancillary point to that. There were two figures that Kevin showed from administrative data on what preventive care cancer survivors get (Figures 3-5 and 3-6). This research illustrated how when cancer survivors see the family doctor, they receive recommended general preventive care, and when they see the oncologist, they receive the recommended cancer specific preventive care. I would say that both are important for the patient. And a facilitation process of guidelines should include patient responsibility. It can help achieve continuity.

Dr. Woolf: Does anyone on the panel want to respond?

Dr. Legant: In my presentation, I talked about the flexibility of involvement and was trying to get at exactly this point. During the acute treatment phase of care, to a certain degree when a medical oncologist is involved, he or she will actually take over the co-morbidity management, which is largely in the field of internal medicine. We may not do quite as good a job as the

internist, but at least we know to call somebody when we get in over our heads. But down the road a piece, you need even more give and take. And long-term, I think there are still reasons to follow people once a year. It is not very often that they will touch base with their oncologist. I hope when people do studies of survivorship care, they will look not only at whether screening tests were getting done, but also whether late relapses are picked up quickly. We also need to consider reassurance of the patient, because many patients just like that sort of connection still with their old oncologist. Which is very important just to reassure them that when their best friend down the block gets a brain mass from a breast cancer 20 years ago, that it is not going to happen to them given their circumstances.

Dr. Benjamin: I agree with your points, particularly, your point that it is not an either/or situation. It is both. And it is this team concept that we oftentimes find in medicine. If someone has a heart attack, I send them to a cardiologist. But they come back. And if a year later they start to have some chest pain and symptoms, I send them back to the cardiologist. The same thing should occur with cancer. When you need them, you need to be able to refer them back, and it should not be either/or, it should be both.

Dr. Woolf: In the interest of time, because we have to break for lunch, let me just make John's the last question. I am sure the panel will be available afterwards.

Dr. John Ayanian: My question is in follow-up to Regina's point. And that, as we talk about these models of shared care, I think it is going to be very important to bring the primary care physician organizations to the table in partnership with ASCO. It will not be enough for ASCO to educate its members, the American College of Physicians, the American Academy of Famliy Physicians, and the Society of General Internal Medicine. Essentially the AMA (American Medical Association) is an overarching organization that brings physicians from different disciplines and fields together. I think there is a good model for this in terms of the way the American Heart Association, the American College of Cardiology, and the American College of Physicians have worked together on evidence-based guidelines for patients with heart disease. They together bring both the primary care and specialty care perspective to the table to weigh the evidence as a group to get to what the guidelines should be, and the models of care. So, my question would be what can we do, what will it take to bring the leading organizations of primary care physicians into this process? I think many primary care physicians are just grappling with the needs of cancer survivors in the ways as best they can as individuals. But we haven't really made this

an area of focus within the leading physician organizations. What could we do to do that to form a partnership with ASCO and other oncology groups?

Dr. Benjamin: In the AMA and the Academy of Family Physicians we could take this report and present a resolution to the house of delegates in both organizations saying exactly what you just said. And then it becomes policy in those organizations. And the leadership then would be forced to work with the leadership of ASCO. So, that is the simplest mechanism to do it. And the AMA meeting is actually going on right now. The next one would not be until June, but it certainly could be done.

Dr. Woolf: I think the release of this report is a leverage point. And I think we can galvanize momentum to take that forward at an organization level. So, I think moving quickly on this might be a good idea. Please join me in thanking our speakers.

4

Luncheon Address

Fitzhugh Mullan, Institute of Medicine

Just a couple of comments as somebody who has had the privilege of revisiting the survivorship world after having been less involved than in recent years. One anecdote that I wanted to share with you came back to me this morning from way back in my experience. And I think it perhaps suggests how far we have come. If we think what we are doing now is important, to me anyway, this anecdote tells how really important it is.

I am guessing the year was 1980 or 1981, well before the National Coalition for Cancer Survivorship (NCCS) was born, or before "survivorship" was a term of activity in the oncology world. The American Cancer Society (ACS), to its credit, held a meeting that I attended in Baltimore called the Cured Cancer Congress. My recollection was this was an initiative on its part, so there may have been other such meetings around the country. As a "recently off the emergency list" cancer patient at the time, I got asked to come and say a few words. I do not recall at all what I talked about, but I know after the session during a break a woman came up to me and very furtively, and I do not think I am overemphasizing, she sort of looked over one shoulder and then the other and said, "I know I am not supposed to be here. I am a breast cancer patient and I was only diagnosed three months ago, as in I am not cured."

She was terribly apologetic, but wanted to hear. Which reminds me of what the world was like before this broader based use of the term and the concept "survivorship" was with us. Again, the notion she wasn't cured, so she belonged in some other domain. And that actually was very helpful to

me, because I struggled afterwards thinking about where she did belong. I felt like we were both there together. I was a few months down the road from her, but basically, our commonality was far greater than our difference. And she was sort of treating me like I was back together again, and she wasn't, which of course was not the case.

Just a couple of thoughts on the survivorship care plan, which I read about and was elated about as I mentioned earlier, and have now had another few hours to think about it. And particularly for those of us who were in this last session, the very provocative, and even in some cases knotty, issues about what is entailed in this effort. I began thinking, sort of stepping back from the technicalities and the problems of "Is this a treatment plan?" or "Is this a patient guidance plan?" or "Is this some sort of cheerleading after the fact plan?" What exactly might go into this document or these documents? Or was it a document at all? And saluting the complexities of all of that. I tried to think in my experience, what longstanding documents, or what documents I had engaged that helped me either as a physician or as a person. First, in terms of practice in pediatrics, there is something known to some of you I suspect, the Denver Developmental Screening Test, the DDST, which was developed in Denver some years ago to provide a way of measuring pediatric development, or child development in a fairly simple, fairly straightforward way. But it has been kind of dumbed down and has been made pretty straightforward. It is an excellent tool for taking on what can be a difficult field of how is a child doing. So, a DDST kind of thing for cancer survivors. Now, immediately the image falls apart, because cancer is a family of diseases, and there are different stages. But a document of that sort that would be a standard part of an oncology chart might be a thought.

A second common pediatric item is the shot record. The shot record bears things in common, of course, with oncology care, although again, it is far simpler. But you have got shots that are given over time for people who are moving around, for a disease or a vaccination portfolio itself that is evolving. And the standard shot record, of course, was some piece of paper carried by the parent, usually yellow, often tattered, most often incomplete. Recently, as part of a CDC initiative, there is now, and I don't know the extent of its use, there is a computerized record which is light years better than the paper record. This group needs no exhortation that if whatever the material that is to be tracked is computer available, it is just ever so much better. And having lived through the yellow tattered record into the computer record, it is just a world of difference. And that again, I commend to those deliberating this.

And a final provocative but perhaps totally irrelevant example comes to mind. When I step back in my life and think about what is the most interesting record about myself that I stumble on from time to time, there

aren't many that I can think of that are easily available. But some years ago when I turned a certain age, I am not quite sure what it was, but the Social Security Administration began to send me an annual letter that told me when I was eligible for Social Security benefits. It also included my earnings history back to the first paycheck I earned as a teenager. I mean $114 recorded in 1950 something. I thought, "Whoa, where did that come from?" It was actually fascinating to see this record. Now, again, we are tracking one thing, which is income which is far simpler than the variety of things we track in medicine. But again, having that available to the customer, and these are again fairly simple data, is key. But that ability for a survivor to look back on key points in their survivorship would be invaluable. I do not quite know what the key points might be, but such a record might get filled in by both oncologists and primary care physicians along the way, and would be a track record that they would have of the essence or elements of their health and health care.

These are thoughts to consider, none of them tailor made. But I think the discussion that we are having is absolutely terrific, and the outcome in terms of cancer care and quality cancer survivorship stands to be terrific. So, for the IOM for hosting, the committee for doing the work they have done on the report, and for those of you who were involved in the follow-through and follow-on in the report, I just think this is terrific work. I salute you, and have a good lunch.

5

Afternoon Breakout Sessions with Invited Speakers

DEVELOPING AND TESTING MODELS OF SURVIVORSHIP CARE

Moderator: Patricia Ganz, University of California, Los Angeles

We have four individuals with us who will be discussing and representing different types of models for delivering survivorship care. There may certainly be other models that are available. Our first speaker is Steve Woolf, a member of our committee who is a primary care physician in Virginia.

Steven Woolf, Virginia Commonwealth University

I am a family physician in the Department of Family Medicine at Virginia Commonwealth University. Let me begin by introducing the three models of survivorship care that were discussed in the report: shared care, nurse-led care, and survivorship follow-up clinics. I am going to focus mainly on the first one, but I want to set the stage for the discussions that will follow. The following figure from data reported in the IOM report shows the number of cancer-related physician office visits, by specialty, estimated from the National Ambulatory Medical Care Survey (NAMCS) (Figure 5-1). One of the points that it makes is of the 36.6 million physician office visits made for cancer care, nearly one-third (32 percent; 11.7 million visits) are made to primary care providers. That is the perspective I am trying to represent.

From the perspective of the primary care physician, however, these 11.7 million cancer-related visits made by adults are a very small fraction of

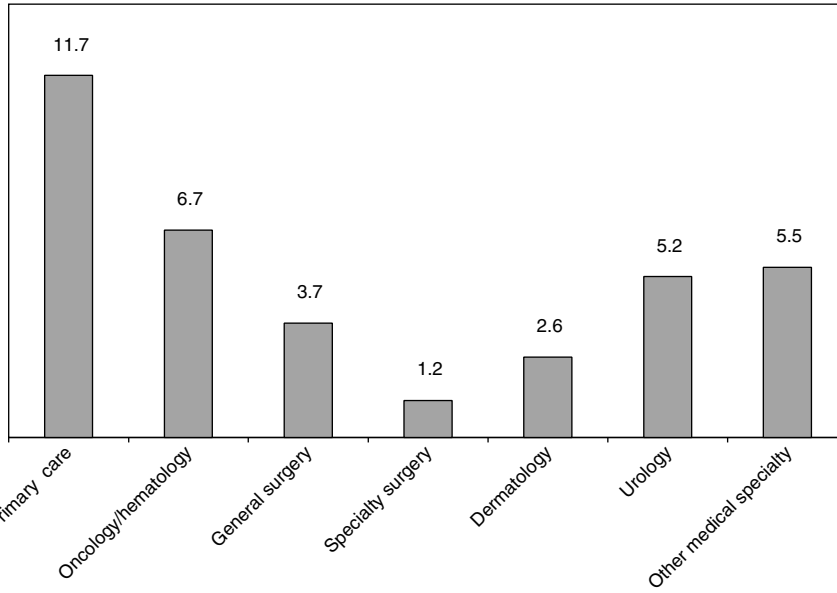


FIGURE 5-1 Cancer-related physician office visits made by adults (ages 25 and older), by specialty, United States, 2001-2002 (average annual, in millions).

their practices. There were 558.4 million visits made to primary care physician offices in 2002 (all ages), so again, the relative proportion of visits that are designated in NAMCS as cancer-related visits is small. The point of showing this contrast is to say that there is a larger holistic perspective that occurs in primary care. This notion of shared care is very prevalent across the spectrum of health conditions that primary care providers care for, not just cancer. Primary care providers report that other physicians share care for the patient's problem in nearly one-in-five visits (18 percent) (Woodwell and Cherry, 2004).

We talk about shared care in the report and at this meeting as a new, evolving idea. How exactly would it work? Are the delivery systems available to do it? Whose role would it be to handle which aspects of care? Is the primary care provider capable of dealing with it? These issues are well traveled territory in the primary care world, because it is already done for a wide variety of conditions. There is a regular relationship of shared care between primary care providers and specialists that often works very well and has been in place for many years. In the management of coronary artery disease, primary care physicians and cardiologists work together regularly in well-coordinated systems. There are lots of exceptions, and I

am not saying that we never have problems in those areas, but this is not uncharted territory. The management of diabetes is very complicated and involves multiple different care providers and different areas of expertise. Epilepsy, neurologic disorders, Alzheimer's disease, bipolar disorder, and end stage renal insufficiency—these are all conditions that primary care providers regularly care for in shared care relationships with specialists. These conditions obviously differ in important ways from cancer care and from survivorship care, but nonetheless involve very serious diseases that are chronic, recurring, potentially life threatening, and complicated.

What is the ideal arrangement under shared care that we aspire to, whether it is for cancer care or for these other conditions? Looking at it from the perspective of primary care, the first goal is to address all physical and emotional needs. The primary care provider's responsibility is to deal not just with the specific condition, but the totality of conditions, both physical and emotional that the patient is facing. In the context of cancer survivorship it is not just taking care of their cancer needs, and the late effects, and other consequences of their cancer treatment. It is taking care of their renal insufficiency, chronic obstructive pulmonary disease, depression, family violence issues, and all the other things that occur in primary care.

Primary care providers also assume responsibility for chronic care needs that are feasible. Primary care physicians can only do so much, both in terms of their knowledge base and in terms of what is possible in their busy office visits. The role of the primary care physician is to do what is possible and then coordinate with other providers to handle the aspects that are not. Primary care physicians should also be referring patients to specialists for periodic evaluations and to address issues that require focused expertise. They also consult with specialists to get advice on how to deal with particular problems that are outside their knowledge.

Ideally, that is the way it ought to work on the primary care side. The way it ought to work on the side of the cancer team is to provide guidance. Based on what is going on with the patient, they should see the patient and provide specialized treatment as needed. They need to keep the primary care clinician informed of the treatment plan. That is where the whole notion behind the survivorship care plan comes in. The cancer team also needs to return the patient to primary care for implementation of the plan and for care of other health needs. This is something that people disagree with as being part of the ideal, but my bias is that it is ideal to return patients to primary care.

The challenges to achieving this ideal are front and center in our IOM report. One is that both the primary care folks and the cancer team have to have a common understanding of the expected components of care. Roles need to be clear, and everyone needs to be on the same page about who is responsible for what. There needs to be a common play book. The absence

of clear, consistent guidelines that was discussed this morning is problematic in this regard. Without them, the primary care clinician and the specialist may not necessarily agree on what ought to be done.

There needs to be clear communication between the cancer specialist and the primary care clinician. I hear oncologists say that they regularly communicate with the primary care clinician and vice versa. There are cases where that actually happens, but unfortunately not often enough, and not where I practice. There needs to be confidence in what the primary care clinician can do. In some settings, there is undue skepticism about the capability of primary care clinicians to handle certain things, when in fact they regularly deal with very complicated diseases on a daily basis.

There also has to be clarity about what primary care clinicians cannot do. What are the limits of their knowledge? What are the limits of their capabilities? The primary care clinician needs to know what is realistic, what is feasible, and what one's limits are. There also must be an understanding among specialists of what they can count on the primary care provider to do. Finally, there has to be a supportive infrastructure within the healthcare system that facilitates the transfer of information. This is where we need electronic health records and other changes in our system of care to overcome some of the gaps.

Dr. Linda Jacobs, University of Pennsylvania: I just wanted to ask one question. How is this actually implemented at your institution, or are you speaking more generically? How successful is it?

Dr. Woolf: First of all, this idea is not for academic medical centers or similar institutions. The world that I am representing is the community practice physician, not somebody working in a large infrastructure like an academic medical center. The way it is implemented varies, and the integrity with which it is implemented varies from setting to setting. For lots of other conditions, although perhaps not as much for cancer care as there should be, there is a clear understanding of what the roles are. It is understood what the cardiologist does, and what the endocrinologist does, and what the primary care clinician does in the management of these conditions. The details of how primary care physicians partner with specialists to manage other conditions are probably too elaborate to go into in just a few minutes. Infrastructure and good models do exist for other conditions, though.

Dr. Archie Bleyer, American Society of Clinical Oncology: I am waiting for this to happen, and the sooner, the better. I would like cancer to be at the lead, and have all of those other diseases, such as diabetes and renal failure, learning from us. You mentioned six challenges. Another challenge I would

raise is reimbursement. I have been in the private sector now for half a year and watched the practice of oncology. If reimbursement rates for those sharing the responsibility of care are unequal, the person who is reimbursed more will get the burden. Having seen that firsthand on a daily basis, I wonder how that affects implementing this model.

Dr. Woolf: That point was also made this morning. The misalignment of reimbursement and the priorities of health care is a systemic problem that is not limited to cancer. It is something we addressed in the report. It is a larger issue than cancer care. The things that will do the most good to improve the health of the population are not reimbursed accordingly. I will be paid hundreds of dollars to take off a sebaceous cyst, which has absolutely no benefit to a patient. However, I am paid a paltry amount for smoking cessation and cancer prevention. The reimbursement system in the country is askew.

Dr. Noreen Aziz, National Cancer Institute, Office of Cancer Survivorship: Thank you for an excellent presentation. When you talk about the partnership between the cancer specialist and the primary care clinician, I think we do need to acknowledge that an integral part of the partnership is the patient or the survivor. Clear communication to the survivor about who is going to do what is going to be really critical as well. I know we all acknowledge that, but it needs to be said.

Dr. Woolf: Patient-centered care is something we all espouse and emphasize, but it has to be operationalized.

Dr. Aziz: That is a big challenge.

Dr. Woolf: Yes, it is, I agree.

Dr. Ganz: You say that specialists and primary care doctors both know what is going on in the care of patients with diabetes or heart disease. Is that because there are written documents, or is it just that over time enough family practitioners have taken care of patients with diabetes that they know when it is out of their league and they should refer to the endocrinologist?

Dr. Woolf: It is both. Those conditions differ in some respects. There are much clearer guidelines about what needs to get done: How often should diabetic retinopathy screening occur? Therefore, how often do I need to send my diabetic patients to an ophthalmologist? There are clear guidelines, and it is very well known, chapter and verse, among all family physicians. Also, roles are pretty clear. When faced with a patient with acute myocar-

dial infarction (MI), or an exacerbation of their congestive heart failure (CHF), or exertional chest pain from their angina, most primary care physicians are pretty clear when it is time to engage the cardiologist, and when it is time to pick up the phone and make a call.

In the case of cancer survivorship, there is a lack of guidelines. There is a lack of an evidence base to support clear guidelines, as we noted in the report. Roles are still unclear. Specialists may be a bit uncomfortable with the primary care provider playing an active role in the management of the condition. The primary care provider is not exactly sure of the limits of the specialist's role. Those need to be more clearly defined and articulated.

Dr. Ganz: One last question. Do you think there is a role for collaboration between professional societies? I am thinking about the fact that hormone replacement therapy (HRT) is no longer being given to the general population of women. Primary care physicians have had to learn how to use alternative approaches to HRT. Treating breast cancer survivors for menopause and osteoporosis should be very similar since they generally should not receive HRT. I can imagine that there are probably a lot of areas where the domains of survivorship care are probably already guidelined in a way in primary care. Collaborations could share that between primary care and specialties.

Dr. Woolf: John Ayanian highlighted the need to get the cancer organizations and the primary care organizations working together at the end of the last session. We have a moment of opportunity here. The release of this report is a leverage point where momentum has been created that can be carried forward at the organizational level to try to expedite that.

Dr. Ganz: Thanks very much, and thanks for your contribution. Linda Jacobs from the University of Pennsylvania is going to talk to us about the model at her institution.

Linda Jacobs, University of Pennsylvania

I am going to present a concrete example of what we are doing at the Abramson Cancer Center at the University of Pennsylvania with our Lance Armstrong Foundation Living Well After Cancer Program. I just have a few slides, so that I can then open it up to some discussion.

Our initial and ongoing funding is from the Lance Armstrong Foundation. The funding was initiated in 2001 to set up an infrastructure to develop an adult survivorship program. In designing this program, we hoped it could be a model for the development of other programs across the country. Since we began the program we have acquired some additional

funding from the NCI and the Department of Defense for a few specific research studies looking at particular issues in survivorship. This program bridges the Children's Hospital of Philadelphia (CHOP) Survivorship Program, which has been in existence for over 20 years, with the Abramson Cancer Center. My co-director is Anna Meadows, who is sitting here in the audience. The CHOP program is staffed by a multidisciplinary team.

One of the strong aspects of our program is consistent team leadership. It helps to have one person who is 100 percent involved in the program as the director. I am a nurse practitioner in oncology, as well as primary care, and I am also a researcher and an educator. We also have very strong institutional support from the University of Pennsylvania, both financially and philosophically. We are a patient-focused program that integrates clinical care, research, and education. Believe me, it has not been easy to get this program up and running. It has really been a trial and error experience. We piloted lots of different approaches until we came upon something that actually worked for us.

What we are trying to do in our program is build upon established surveillance guidelines. We have heard a lot about the lack of evidence-based guidelines, and it is true that there are very few. There are no existing tools or guidelines for the care of adult cancer survivors, other than a few focused on treatment-related issues. However, there are some data-based and consensus guidelines for the care of children. We actually reference the Children's Oncology Group guidelines quite a bit when we are making decisions such as whether or not someone should have a particular test based upon the treatment that they received.

Our program has several other goals. We hope to establish a standard evaluation approach for our patients. We are developing a database that includes information from a number of research protocols. We aim to disseminate our findings by collaborating with our Penn network of hospitals, which consists of hospitals within a couple hundred mile radius. We also disseminate our work through presentations and publications. In addition, we hope to collaborate with other survivorship centers down the road. Finally, we plan to serve as a model for other survivorship programs in the country.

Our program is an adult cancer survivorship program, with a focus on clinical care, research, and education. However, a relatively new component of our program includes young adult survivors of childhood cancer. We have recently developed a transition program with CHOP to refer the care of young adult survivors to us. We have patients anywhere from 21 years of age to 40 who are still being seen there. They will be seen one last time at CHOP, and then it is recommended that they move their care to us. When they come to us, they are accompanied by a summary of their care, and what treatment they received. It is usually two pages, and it is very

comprehensive. It guides us as we determine what we need to do for the patient. We, in turn, write the same type of report to send to primary care providers and the patient if they want it. We try to involve families as well as providers in the care. In many cases families do come with these patients.

Our team is multidisciplinary. We have a number of medical oncologists and advance practice nurses, as well as psychiatrists, cardiologists, and rehabilitation medicine specialists. Our advance practice nurses are all nurse practitioners, so they can bill. We also have a number of primary care providers who have an interest in survivorship working with us.

Our research is also multidisciplinary. For example, some of the primary care providers are doing research in complementary and alternative medicine. Our rehabilitation specialist does research in lymphedema. We also have an exercise physiologist working with us who is very interested in lymphedema. We have a medical geneticist working with our team looking at the genetics of testicular cancer. We also have an entire service of nutrition and psychosocial counselors. It is actually funded by a grant from another source. We refer almost all of our patients to counseling. Whether or not they go is up to them, but we recommend it. It can include families. We also recommend nutrition counseling for a number of people who have issues related to weight gain, weight loss, lipid profiles, and other problems.

What we have discovered over the last five years is that one model of care does not necessarily work. There are lots of reasons why one model will not work. I think it is institution-dependent, regionally-dependent, and patient population-dependent. We found that we have two different models. We have what we call the practice model, and then what we call the consultative model. I will just briefly go over these.

The practice model is one where we actually see the patients. We tell them that the focus of their care is disease surveillance, health promotion, and disease prevention. A number of protocols and ongoing studies are made available for patient enrollment on an optional basis. If they choose not to enroll, they are still cared for in our program.

Our focus in the area of health promotion and disease prevention is on developing an individualized risk profile largely based on the treatment that they received. It is more treatment-focused than disease-focused—mantle radiation, certain drugs, *et cetera*. Family history is, of course, a big component of this risk assessment. We recommend screening according to this risk profile. We are using this model with testicular cancer survivors and survivors of childhood cancers.

With such a large population of cancer survivors at our institution, we discovered that we cannot see everyone in the clinic. For example, we have a very large breast service at Penn with 10 different breast oncologists. We could not manage to see all those survivors. It was also a territorial issue, with oncologists not wanting to give up patients, and patients not wanting

to leave their oncologist. For these reasons we have developed the consultative model for our breast cancer patients, which is our largest and growing endeavor. We have a breast cancer survivor protocol which incorporates a questionnaire that elicits information about symptoms and quality of life. We have pilot tested the questionnaire with the patients and after about six months we stepped back to revise and revamp it. We are about to re-submit the protocol revision to move forward. Because of issues related to IRB approval and HIPAA, we cannot put patient information into a database at Penn, even if it is protected and coded, unless the patient has given us permission to do so. Everything that we do is consent-driven. Our research program is evolving.

Our ultimate goal is to adopt this model with each of the disease types. We hope to have a lymphoma survivor protocol, a lung cancer survivor protocol, *et cetera*. Personnel-wise this can be very expensive, and we do not have designated oncologists who are going to practice exclusively with cancer survivors. Instead we have collaborative practices at Penn that are oncology and nurse practitioner partnerships. We have solid tumor, breast, and bone marrow transplant teams. Each team has a group of physicians and nurses that coordinates their schedules. If we are going to open, for example, a lung cancer survivor protocol, we meet with that group of oncologists and advance practice nurses, and talk to them about our program. The infrastructure will be there, meaning the database for entering the data. We will develop the tools. Then we will say to them, "Who would like to take the lead on this?" It does not really matter whether it is a nurse practitioner or an oncologist who takes the lead as being the PI (principal investigator) on that particular protocol. Their responsibilities will be to make sure that the questionnaires and the tools are distributed or mailed to the patients in their practice. We will have research coordinators who track their return and ensure that the data get entered into the database. This very large database includes different patient populations, but allows analyses of similar variables among the groups. Different populations of cancer survivors can be compared for research purposes. Even though we call this aspect of our program a research protocol, the activity is not driven by hypotheses or specific questions. It is really an effort to gather descriptive data to provide a baseline of information on our survivor population. We re-mail the questionnaires annually, so that we can see if there are changes in the symptoms that people are reporting. Many of the late effects we might expect will not appear for four or five years. Just because they are not having a particular symptom today, does not mean they are not going to be having it a year from now.

I close with a little note of special thanks to the Lance Armstrong Foundation, because we could not be doing this and could not have started doing it without their help. Thank you.

Dr. Ganz: Is there a specific question for Linda?

Susan Leigh: Linda, thank you so much for describing a clinic that many adult survivors have wanted for years. We have always looked at pediatrics and said, "Why can't we have something like that for adults?" There have been any number of excuses, but now it is happening. Now that we have a number of models of adult clinics around the country, it will be interesting to see the difference in the needs for the adult clinic versus the pediatric clinic. When you were the only one around, there were a number of survivors to whom we have said, "Go to the University of Pennsylvania and see if you can get in and have a consultative session yourself." Can you give me an idea of how much it would cost for somebody coming from around the country? Is there any kind of a ballpark figure for the cost associated with coming to your clinic for your general consultation?

Dr. Jacobs: We went through trying to develop a billing number when we first started the program, but were not successful. We see survivors in our program as part of their routine follow-up. For example, we will tell people if you are going to come to our program, this replaces your yearly follow-up with your oncologist. The patient has to make the decision whether or not they choose to do that. We do follow-up surveillance, and this is considered a routine medical visit. We have had patients come to us, for example some testicular cancer survivors, who say that their oncologists discharged them from care. They have not seen an oncologist in two years. They want to know what they should be doing now. They can come to us and it is billed as a routine visit, or as a new patient visit if it is their first time coming to us. We do not have an issue with that because patients generally come as part of routine care. If they are having an acute medical issue, the visit can be usually justified through an ICD-9 code.

Dr. Ganz: Linda, can you say your fee for a new patient consultation is such and such or your fee for a follow-up visit is such and such? Do you have a number on that?

Dr. Jacobs: We do, but I generally refer them to the billing office. I do not deal with the numbers.

Dr. Mary Vargo, Case Western Reserve University: I work within a physical medicine and rehabilitation program, and I am interested in the subspecialist component of your program. Specifically, from a rehabilitation perspective, it can be relatively easy to figure out who has lymphedema and needs a referral to our service. However, there are other issues, such as debility, musculoskeletal pain issues, and fatigue. Do you have specific

screening tools that you find useful for capturing patients that have those sorts of needs, or is it a more global kind of assessment?

Dr. Jacobs: As part of the screening we have a list of simple, patient-focused questions. The patient checks off whether or not they are having any of those symptoms. We then get computer-generated feedback for the patient and the patient will get a letter listing the symptoms that they complained about, the issues that they had, and the recommendations that we make for follow-up. Generally, if we have patients who present with those types of symptoms and complain of fatigue and certain musculoskeletal things, we will refer them to our rehabilitation collaborator, Andrea Cheville. They make an appointment with her for an evaluation. Andrea does use the Disabilities of the Arm, Shoulder, and Hand (DASH) measure and a few other assessment tools. We also have physical therapy right there.

We do not incorporate specific tools other than very simple things into our protocols because everything has to get approved by the IRB. If you are going to send a screening instrument to one patient, you would have to send it to the entire group. We would be collecting more and more data. Our general line is that we are collecting this as baseline data. You can query the database, see if there is an issue that you would like to study, and then write a research protocol for it. Then you can collect the data yourself in a research protocol, for example, to test one particular tool. The database is available for people to access patients for further study.

Mary McCabe, Memorial Sloan-Kettering: I would like to thank Linda and her group for being very generous to us when we first started our survivorship efforts. They were enormously helpful in preventing us from making some initial big mistakes. I have a question about your consultative model and its potential for expansion. In the future, how do you see the communication with the oncologists who are continuing to see these patients, but also with the primary care physicians? How might that work?

Dr. Jacobs: As part of our program, a summary letter is dictated for every patient. The initial evaluation is summarized to include treatment information, risk information, side effects the patient has experienced, family history, and medical problems experienced since treatment. Everything is in that initial letter. We also compose subsequent letters for follow-up appointments saying what has or has not been done. Recommendations are also listed under health promotion and disease prevention, such as a recommendation for a baseline echocardiogram. The recommendations are made, and they are sent to the primary care providers or whoever the patient tells us to send them to. The patient has to provide us with that list. The patient also receives a copy of the letter.

The letter summarizing symptoms that is generated from the data that patients give us on the tools, which I mentioned before, goes to patients. We recommend that if they want to follow-up, they need to take it to their primary care provider, their oncologist, or their gynecologist. We have empowered the patient to take responsibility for follow-up. We found when we piloted this and sent letters to the oncologist, it just was not working. The oncologists were too busy. The letter would get lost in their pile in their office, or they would say we are already following up on these things. We found that it was most helpful to provide the patient with this information. They can then say, for example, "My gynecologist is the right person for me to go to about sexual function, or the hot flashes I am having." That is how we are handling that right now.

Dr. Ganz: If someone has hot flashes, you are not managing that?

Dr. Jacobs: We are managing them, because in many cases we are the only ones the patient is seeing. They do not all have primary care providers. That is definitely a huge issue. We strongly recommend that the people have one. We also refer them to primary care providers that are part of our team who are interested in following survivors. We would choose to have someone else follow them, but if the patient does not want to do that, we certainly treat those things.

Dr. Ganz: Thank you for the clarification.

Lisa Diller, Dana-Farber Cancer Institute

I think it is fitting that my talk follows that of Linda Jacobs because I represent another Lance Armstrong Foundation Center recently established at the Dana-Farber Cancer Institute. We are grateful to the group from Penn for their help in starting our program. I am speaking in the place of Craig Earle, the medical director of the Lance Armstrong Foundation Clinic for Adult Cancer Survivors, who could not make it today. In the spirit of full disclosure I am a pediatric oncologist and run our pediatric survivor program, but I will try to do justice to the adult survivor program.

The Dana-Farber Cancer Institute, as most of you are aware, is a part of the Dana-Farber/Harvard Cancer Center (DF/HCC), a federally designated comprehensive cancer center and affiliated with the Harvard Medical School and its teaching hospitals. The institute is highly focused on research and has a busy disease-center-based outpatient oncology service for adult cancer patients. There is really no primary care, and very limited medical subspecialty care within the building. All the medical subspecialty care is provided at the Brigham and Women's Hospital.

BOX 5-1
Role of the Lance Armstrong Foundation Center at the Dana-Farber Cancer Institute

Clinical Care
- Provide multidisciplinary care
- Provide subspecialty care with cancer survivor expertise
- Develop collaborative relationships with referring oncologists and primary care providers

Research
- Coordinate survivorship research across a large institution
  - Develop research tools in conjunction with clinical practice
  - Design and initiate a comprehensive survivorship registry
- Reduce morbidity of upfront therapy by studying survivors
- Prevention, screening, and treatment of morbidity in the already treated patient

Programs
- Educate patients
- Centralize survivor resources
- Complement, not duplicate, existing programming

Our center, and the Lance Armstrong Foundation Clinic in particular, has a three-pronged approach of clinical care, research, and support programs (Box 5-1).

One of the things I want to focus on that we have not talked about much today is the way in which we can educate and empower survivors apart from one-on-one traditional medical communication. We have found that as pediatric survivors become adults, group sessions of teaching about survivorship become very important and very empowering. We are also using this delivery model in the adult survivorship program.

We saw our first patient in February 2004, so we are really still in our first year. Our care delivery model relies on advanced nurse practitioners. We have two nurse practitioners who provide a written treatment summary to patients, a comprehensive overview of their expectations, and risk-based recommendations. We have conceptualized survivor care as unique and decided to provide our clinical care separate from acute care. We also wanted it to be separate in the mind of the oncologist who is seeing the survivor, so we have established the clinic in a different physical location and schedule from where acute care is provided.

We also wanted to provide subspecialty care with a focus on cancer survivorship. Even subspecialists in fields like cardiology and endocrinology feel that cancer survivorship is a sub-subspecialty. As Dr. Woolf mentioned earlier, oncologists may think that primary care providers do not really know how to take care of cancer survivors. I have also found that endocrinologists and cardiologists who specialize in cancer do not think that general community-based endocrinologists and cardiologists know how to care for survivors. I do not know whether this is true or not. I know that we have developed sub-subspecialty expertise in what I think is appropriate in a quaternary care setting. We felt that drawing those researchers and clinicians into Dana-Farber would add value to the care of our survivors.

Patients treated for cancer at Dana-Farber are treated within disease-specific centers and tend to stay with their disease center for their follow-up care. Follow-up care is available from our cancer survivor specialist nurse practitioner and an oncologist on a weekly or monthly basis. We provide care flexibly depending upon the preferences of the disease centers or providers. Some of the providers agree to do quick 15 minute or 20 minute visits around disease recurrence. That allows the nurse practitioner to have the rest of the 40 minute hour to have a more educationally-focused visit, and time to talk about some of the anxiety or other psychosocial issues around being a survivor. Other providers take responsibility for every other visit, alternating with the nurse practitioner. We are finding our way with the different oncologists to figure out how they want to work with us and participate in survivors' care.

We also have a fairly robust survivor center practice which is independent of the disease center visits I just described. These visits are mostly from patients who have been lost to follow-up. If you call Dana-Farber today as a long-term survivor of X disease, you will likely end up in our survivor center practice, although it is not guaranteed. You could also be sent to the "new patient" coordinator of the relevant disease center. In either case, you will probably have an independent visit in the survivor center practice. As I mentioned, we have the ability to do subspecialty consultation with a committed cardiologist, endocrinologist, and genetic counselor.

We have been successful so far because we have committed, experienced nurse practitioners who are really, really good. We also have oncologists who have bought into this model. It is a very academic group of both pediatric and adult survivorship professionals, with a high research focus, so we have cross-fertilization around research ideas. Also, we are fairly unconstrained financially because we do not have to depend on what we bill for our pay. We have a lot of philanthropic support, institutional support, and some grant support to allow us to build a program without waiting for payment from the insurers.

In terms of the future, I am worried about expansion. I am worried that we will soon be overwhelmed in this model by having too many survivors wanting this very time-intensive method of care. I would like to find the right balance between a flexible system that works in different ways for different patient groups, and at the same time provides a consistent standard of care. I think the important goal for the next step is to collaborate with our community partners, including community-based oncology practices and primary care practices, to figure out how we can export certain pieces of this care outside of a tertiary care center. Thank you.

Dr. Vargo: Congratulations. The programs all look really wonderful. I have two questions. First, is there an *a priori* articulated program goal that you can measure? What is the goal of your program?

Dr. Diller: We are trying to respond to the needs articulated before we started the program. Patients expressed that their needs were not being met by the kind of care they got at a tertiary care center once they became survivors. They were seen in the same clinics where they received treatment, and they felt guilty asking questions because the person next to them was sick from their chemotherapy. They were not sure that their questions were being answered by their primary care provider in the community, nor by their busy oncologist. We were responding to a specific articulated need in that group of patients.

How do we measure progress toward that goal? We are doing a mailed survey after every patient is seen that asks about some patient satisfaction issues. We are early in the process, so we do not have a particular outcome today that we will be measuring a year from now. We are developing that from our first set of surveys.

We have a very strong research goal. Our goal in developing research protocols in survivorship is to inform current care of patients. Because we are a center where new clinical trials are often being developed, I think it is important to understand the late effects of those clinical trials, and using what we understand about late effects to develop new clinical trials. That is where we see ourselves.

Dr. Vargo: I mention that because of the importance of process evaluation. It is good to sometimes do process evaluations rather than evaluations of outcome only, and you are early enough in your development that you could do that.

Dr. Diller: We are looking at what we are doing in the first year. We saw 75 patients last month. We saw 4 patients the first month, so that is a pretty

steep trajectory. At the end of the first year we will sit down and ask ourselves exactly the question that you just asked.

Kym Martin, National Coalition for Cancer Survivorship: I am a 22-year Hodgkin's survivor. Dana-Farber was one of my stops along the way. I have a question about the development of the program. I hear a lot about clinicians' perspectives. I am just curious, do you have anybody working within the center that is actually a survivor as well as a clinician?

Dr. Diller: One of our nurse practitioners is a survivor. He is a bone marrow transplant survivor, having had leukemia, and is very involved in patient advocacy, as well as professionally involved in patient care. At Dana-Farber we have a patient family advisory council with a high representation of survivors. We report to them about our developments. We have not brought a specific survivor in as a patient advisor, but we have used those two mechanisms.

Kym Martin: I was curious because you are at an early stage in development, as is the program at the University of Pennsylvania. It seems like a good opportunity to really engage the survivors who are active and find out what they would like to see. Surveying the community is one avenue, and a good one. I would be concerned that you are not going to get as much rich information as you would as if you had someone who was involved in program development.

Dr. Diller: We did a needs assessment early on, but it was done using a convenience cohort of people who happened to come to a couple of survivor events and filled out the forms. It was very informative, nonetheless, about which needs were being met.

Kym Martin: At the NCCS, obviously our focus is survivorship and we are led by a survivor. Developing a survivor program seems like a good window of opportunity for you to have survivors leading the way, in addition to the clinicians.

Dr. Diller: I agree.

Mary McCabe: Lisa, I was interested in your mention of the need to export services to community partners. The reason it comes to mind is that we have clinics at Memorial Sloan-Kettering where 40 percent of the patients who come in are long-term follow-up patients. It presents a conundrum because it makes it harder to see new patients. Are you thinking about how you might partner with primary care, or to hand patients off?

Dr. Diller: Yes, that is exactly what we are thinking about. We are thinking about both the primary care providers and community-based oncologists, and the idea of exporting the care of survivors, or exporting this whole programmatic look at survivorship care. This care does not actually have to be provided at a tertiary care cancer center. A community-based oncology practice can handle pieces of what we do, and a primary care provider other pieces. Our program right now does not really fit into that shared care model that has been talked about. We are very rarified, and we do not represent anywhere near the numbers of cancer survivors out there.

Iris Portney: I am a Y-ME volunteer advocate, and also a seven-year survivor of a stem cell transplant. I have been very involved in follow-up studies on survivorship, although not with your program. I would like to follow-up on the question about whether or not you had any survivors at the center. This is really a process suggestion reinforcing this idea. I heard you say that you are doing surveys. As a person who has answered many surveys that were directed to survivors of my treatments, I hope you have survivors review the questions before you send them out. Many times I have answered questions and found maybe 60 percent of the questions to be sensible. When the survey is over, I feel like I know what it was trying to get at, but it lacked the right questions. Then the researcher or interviewers says, "I am sorry, I can only take answers of the questions I have been told to ask."

Dr. Ganz: Thanks very much, Lisa. Our last speaker is Eva Grunfeld, who is from Dalhousie in Nova Scotia. She is a primary care physician who has done some very interesting work in the area of collaborative care.

Eva Grunfeld, CancerCare Nova Scotia

Good afternoon. I am going to present to you today a program of research that I have conducted over the past 15 or so years that attempts to test the basic hypothesis that the family physician can provide routine follow-up care to breast cancer patients, which is equivalent to specialist follow-up care. It is a pretty provocative hypothesis. We have done a sequence of studies, and I am going to describe their methodology and some of the key findings.

When we started out, we needed to get some descriptive information. The first study was a series of patient focus groups that we conducted in two district general hospitals in England in the early 1990s. Patients were prevalent cases who were healthy at follow-up. We wanted to know from these patients what was most important to them in their follow-up program. Three really important themes emerged. One was continuity of care. They felt that it was very important to have some continuity, for the clini-

cian to know them specifically. The second was the quality of the consultation, which included information to be provided but also the quality of the physical examination that they received at their follow-up visit. Third was access to specialists when they needed it. Specifically, they were concerned about access to specialist tests. This was a unique aspect of care in England at that time, where certain tests could only be ordered by specialists. You had to see a specialist in order to get specialized tests. These were the three themes that emerged from patients.

We also interviewed family physicians and we conducted a postal questionnaire survey of all breast cancer specialists in the U.K. We included medical oncologists, radiation oncologists, and surgeons who are major players in the follow-up care of breast cancer patients. We asked them mirror image questions about what they considered to be important about follow-up, and the results of those two surveys were very revealing. The first finding was that very few of the oncologists or the specialists followed their patients because they thought it was important for clinical reasons. They did not think that the follow-up was important to improve clinical outcomes for their patients. Rather, they thought it was important for audit and general medical education. They thought it was important for psychosocial support for the patient and for research, but they did not identify clinical outcomes for the patient as important.

When we asked general practitioners, we found that they felt that they had the skills to provide follow-up care to their patients, and felt that they should play a larger role in the follow-up of their patients. We asked both groups what model of follow-up care they most preferred. This, I think, reveals the mismatch between the specialists and the primary care physicians, and the mismatch that I think we are identifying in this session today. Lo and behold, the most preferred method of follow-up according to the specialist was follow-up with the specialist. The most preferred method of follow-up according to the primary care physician was follow-up with the primary care physician. The only agreement we found was that "no follow-up" was not a model either group preferred.

We then went on to conduct a randomized controlled trial in England in 1993. This was an 18-month study that involved prevalent cases of women on well follow-up at these two district general hospitals. We defined delay in diagnosing recurrence as our primary outcome. We had a very rigorous definition of delay. It was from the first presentation of symptoms that were related to recurrence to the time that the patient was seen again by the specialist. Our idea there was that it was not sufficient for the primary care physician to be plugging into the fact that there might be recurrence, but the patient had to be seen by the specialist in order to initiate treatment. We found a median delay of 22 days in the general

TABLE 5-1 Primary Care vs. Specialist Follow-up

	Primary Care Provider (n=148)	Specialist (n=141)	Difference (95% Confidence Interval)
Time to diagnosis of recurrence (days)	22	21	1.5 (–13 to 22)
Total time with the patient (minutes)	35.6	20.7	14.9* (11.3 to 18.4)
Cost per patient (£s)	65	195	–130* (–149 to –112)
Time cost to the patient (minutes)	53	82	–29* (–37 to –23)

*significance at $p<0.001$.

practice group, and a median delay of 21 days for the specialist group (Table 5-1). So, there was no difference in our primary outcome.

We also looked at a series of cost factors, both for the healthcare system and for the patient (Table 5-1). Patients who were seen by the family physician had significantly more time in their follow-up visits than patients seen by the specialist. The costs per one visit for primary care follow-up were less, as you would expect, than costs for follow-up in the specialist clinic. It took significantly less patient time, including travel time and waiting time, to see the primary care physician than to see the specialist. Not only did it take less time, but they also spent more face time with the physician.

Our secondary outcomes were health-related quality of life, and there were no differences in health-related quality of life on any of the standardized subscale measures that we used. Also, there was no difference in anxiety and depression. We hypothesized that anxiety was a particular domain of importance. Patients in the general practice group were more satisfied on a whole range of questions about patient satisfaction.

We then went on to conduct a phase 3 randomized controlled trial in Canada in 1997. Patients were enrolled in the study one year after diagnosis, so that all of their primary treatment was completed. They were followed for a median of 3.5 years, meaning they were 4.5 years from the time of their diagnosis at the end of the study. That is important, because in that interval the majority of recurrences will be diagnosed. We had almost 1,000 patients in the study, and they were randomized to receive follow-up with a primary care physician or a specialist.

TABLE 5-2 Number and Rate of Serious Clinical Events (3.5 median years of follow-up)

	Primary Care Provider (n=483)	Specialist (n=485)	Difference (95% CI)
Number (rate) of serious clinical events	17 (3.5%)	18 (3.7%)	0.19% (–2.26 to 2.65)

There are two points that I want to highlight about this randomized trial and the previous randomized trial. In both cases our goal was an effectiveness study that would be as generalizable as possible. That meant that the family physician was the patient's own family physician. It was not a special cadre of family physicians that were trained to do the work. We provided the family physician with a one-page guideline on follow-up, but that was the extent of the educational intervention.

We defined two primary outcomes for the Canadian trial. For patients who developed recurrence, we determined that the most important outcome is a clinical event related to recurrence that is potentially preventable and would be a catastrophe for the patient if it were missed. Therefore, we defined as primary outcome any one of a series of serious clinical events, which were pathological fracture, spinal cord compressions, hypercalcemia, and uncontrolled local recurrence. For patients who did not develop recurrence, we identified the fact that quality of life was the most important outcome.

For patients who developed recurrence, there were a small number of events in both groups (Table 5-2). I think that is a very important finding of this study, because we have documented prospectively how rare these events are. Over the five years of the study and almost 1,000 patients, 4 percent of cases had a serious clinical event. Clinical events occurred in both groups regardless of who was primarily responsible for follow-up care. In our primary outcome there was no significant difference between the two groups.

In terms of health-related quality of life, we used a range of standardized measures, and described both median differences in quality of life, as well as change scores from baseline. We found no differences in the two groups on health-related quality of life. Now, we have also looked at patient costs and patient satisfaction, but I cannot give you those results now because those data are in the process of being analyzed.

In terms of our original question about the acceptability of primary care follow-up, we found that in this study 55 percent of patients agreed to participate in this study, and in a previous study 67 percent agreed to

participate. That is identifying all prospectively eligible patients. In terms of primary care physicians, 83 percent of family physicians agreed to provide follow-up care to their patients with breast cancer.

Our conclusion from these studies is, first of all, that primary care follow-up of breast cancer patients is a safe and acceptable alternative. We have shown this now in two randomized controlled trials looking at it in two different ways. We think it is a proof of principle for the other of the major prevalent adult cancers, such as prostate cancer and colorectal cancer.

In terms of implementation tools, we used a very simple one page guideline. We were focusing on medical follow-up. Needless to say, there are a range of issues, such as psychosocial issues and late sequela of treatment, that one would want to include in any new guideline. We have published guidelines that include those issues. I like to stick to the paper versions of things until we have confidence in electronic ways of doing things. When we get there, electronic guidelines will be fabulous, but in the meanwhile, paper versions are very useful.

A discharge letter was used in our randomized trials to facilitate communication. Needless to say, Web-based medical records is the brave new world that we are all waiting for. In the interim, a well-structured discharge letter would be very useful.

One of the tacit things that has been discussed, and a couple of people brought it up overtly, is the importance of the patient in all of this. There is evidence to show that when you want to implement guidelines, providing the patient with a version of the guideline and actually having the patient as an active player in the whole process does improve outcomes. When we talk about a care plan, what we are really saying is that we are including the patient in the process of improving their care and improving follow-up care. Thank you very much.

Dr. Ganz: This is just to clarify, you did in fact have a survivorship care plan or a discharge summary that went to the primary care provider?

Dr. Grunfeld: We had a one-page guideline that went to the family physician.

Dr. Ganz: You said there was a discharge summary?

Dr. Grunfeld: There was just a letter that was dictated saying, "You are now taking on responsibility for follow-up care." Many aspects of it were like the care guideline.

Dr. Ganz: And you did in fact give the same guideline to the patient that you gave to the primary care physician in your study?

Dr. Grunfeld: We did not, not in our study.

Dr. Ganz: So, giving a guideline to the patient has not been tested?

Dr. Grunfeld: That has not been tested, although we have just written a protocol in order to test that component of it.

DEVELOPING GUIDELINES, INSTITUTING QUALITY IMPROVEMENT, AND STRENGTHENING PROFESSIONAL EDUCATION PROGRAMS

Moderator: John Ayanian, Harvard Medical School

I am a general internist at Brigham and Women's Hospital in Boston, and a health services researcher in healthcare policy at the Harvard Medical School. It is my pleasure to moderate this session on developing guidelines, instituting quality improvement, and strengthening professional education. If we can solve these three issues in the next hour, I think we will have tackled the cause of cancer survivorship. We have four interesting presentations by our panelists today. First, Charlie Shapiro, will be joining us by speaker phone to discuss the ASCO Survivorship Task Force's guideline effort. Melissa Hudson will then describe the childhood cancer survivorship guidelines that have been developed for young adults. Next, Rodger Winn from the National Quality Forum will discuss quality indicators and their relationship to guidelines and quality improvement. We will wrap up with LuAnn Wilkerson from UCLA, who will describe a new model for educating medical students about cancer survivorship. We will hope to have time for a discussion of how health professionals could be introduced to cancer survivorship and remain well-educated and well-informed about it. We will start with Dr. Shapiro, who will be presenting by speaker phone.

Charles Shapiro, Arthur James Cancer Hospital, Ohio State University

I am a medical oncologist specializing in breast cancer at Ohio State University Medical Center and Comprehensive Cancer Center. I have a long-standing interest in survivorship issues, particularly on the implications of chemotherapy-induced early menopause on osteoporosis for breast cancer survivors. I co-chair the ASCO task force on adult survivor guidelines. Our mission in this effort is to provide healthcare professionals with a blueprint to obtain the necessary knowledge and expertise to decrease morbidity and improve quality of life for adult cancer survivors. We define survivorship as the period following the diagnosis and treatment phases, and the population includes adults who have survived childhood cancers.

This is a very important population, because as you will see from Melissa Hudson's presentation, the transition period from pediatric oncologists and healthcare professionals to other providers is difficult in that nobody is clear what to do and who is going to take responsibility. We have taken it on ourselves to include adults who have survived childhood cancers. There will be overlap in this population between the guidelines that the Children's Oncology Group has created and the ones we are in the process of creating.

Why is this effort important at this time? Well, the existing survivorship guidelines are very limited. In the review of the guidelines that is included in the IOM report you can see how limited they actually are. I think it is an opportunity for us to take stock and highlight what we know in terms of care of survivors, and perhaps more importantly, what we do not know. This will suggest areas for future survivorship research and education of healthcare professionals. I think that this effort is timely for several reasons, and I am happy to be a co-chair in this important effort.

We face substantial challenges in creating these guidelines. As I noted before, there is a really limited database of relevant evidence. Furthermore, the science of late effects represents a moving target. The most mature data on late effects come from clinical trials conducted 20 to 25 years ago. The techniques and treatments in these trials differ greatly from treatments we use today. This is most apparent in the radiotherapy literature, and specifically radiotherapy effects on the heart. Twenty to 30 years ago radiation was delivered in a different manner than it is today. They relied on low-energy sources, used larger fraction sizes and a field arrangement that exposed the maximum amount of normal tissue to radiation. Nowadays with modern radiotherapy techniques we use higher energy sources, limited fraction sizes, and techniques that really minimize normal tissue exposure.

In studies conducted 20 to 30 years ago, heart disease induced by radiation exposure was prevalent in the second and subsequent decades following treatment. More recent studies using modern techniques, show no increase in radiation-associated heart disease, or at least no detectable increase. The most mature data on late effects may have limited generalizability because of the changing nature of treatments.

Another difficulty in this area is potential biases associated with data sources. Much of the research on late effects is conducted using information from cancer registries where there can be under- or over-reporting of treatment exposures. Another methodological challenge is confounding due to the prevalence of co-morbid conditions of aging such as heart disease. When a pediatric patient is treated with anthracycline at age 4 and develops congestive heart failure at age 18 or 19, the association between treatment and late effect is pretty clear. However, when a 60-year-old woman receives anthracycline for breast cancer, and at 70 she develops heart problems, it is not as easy to sort out the effects of aging versus the treatment exposure on

the heart. Similar problems arise in studies of treatment-induced osteoporosis. Osteoporosis is a disease of aging. We are again challenged in trying to figure out what is due to the exposure and what is due to simple aging.

It is obvious, but worth stating that the decision to adopt a new therapy is based on studies that assess short-term improvements in efficacy. For example, many will be familiar with the herceptin story that was recently published in the *New England Journal of Medicine*. A dramatic reduction in recurrence rates were observed among women with early breast cancer treated with a combination of herceptin and chemotherapy as compared to chemotherapy alone (Romond et al., 2005). The combined treatment was associated with a 3 or 4 percent incidence of cardiac toxicity when evaluated in the short-term, however, the ejection fractions improved indicating that the cardiac toxicity appears to be reversible. However, the long-term effects of herceptin are not known, so longer-term studies are needed. Other new treatments might have other long-term consequences.

The ASCO guidelines effort is focused on four areas: cardiovascular late effects; neurocognitive and psychosocial late effects; endocrine disorders; and second cancers. The task force felt that these four areas cover most of the problems of cancer survivors, irrespective of cancer site. For example, we relate exposures like anthracycline and radiation and herceptin to the incidence of long-term cardiac effects, and identify when screening for cardiac effects should be conducted. We also identify lifestyle changes that might be able to mitigate the cardiotoxicity for cancer survivors who are exposed to potential cardiotoxins. In terms of neurocognitive and psychosocial effects, we look at whether there is a role for screening survivors to identify problems in these areas. We also identify certain treatments that, in pilot studies, begin to address the issue of neurocognitive function and psychosocial interventions. Endocrine is a big area which includes addressing sexual dysfunction and osteoporosis. Identifying exposures and risks of second cancers and then specifying screening strategies for second cancers will be an important area for the task force. Lifestyle changes, the obvious one being smoking reduction in cancer patients, are important and these preventive measures will be considered in the guidelines. Again, these four areas will be those that we initially focus on in the ASCO guideline effort.

Finally, I think the future of survivorship, and cancer treatment in general, is dependent on improved drugs that are more selective and improved methods of selecting patients for therapy. In the next 5 to 10 years we can look forward to better methods of selecting patients who really need therapy, and sparing patients who do not. Sorting out who really needs treatment from who should be spared treatment will do a lot for survivorship in that it will eliminate the exposure for a population of patients that we are ordinarily treating at this time.

I think that the other side of the equation is host factors, or individual factors that might influence quality of life and influence the likelihood of developing treatment-related effects. Those are pharmacogenomic considerations. A recently described study related pharmacogenomic incidences in enzyme metabolism to quality-of-life considerations (Sloan, 2004). This is only the first study, but I think that it makes sense that quality of life could be affected by differences in metabolizing enzymes.

I think it is time now for adult survivorship guidelines to summarize the state-of-the-art of what we know and what we do not know in 2005. That will set the stage for future directions in survivorship research. I thank you very much for the opportunity to present, and I appreciate your indulgence in letting me present by speaker phone.

Dr. Ayanian: Any questions for Dr. Shapiro about his comments regarding the ASCO survivorship guidelines?

Dr. James Talcott, Massachusetts General Hospital: I want to thank Charlie and his group for organizing this body of information. However, I noticed, for example, that in describing the four topic areas for the ASCO guidelines, sexual function ended up in the endocrine category, and there was a psychosocial category in which it could have been included. There is a tendency to take a somewhat reductionist focus in medicine to deal with specific medical events that we define, count up, and hopefully try to pare down later. I wonder to what extent your group thought about the broader existential psychosocial issues of survivors?

Dr. Shapiro: These are supposed to be evidence-based guidelines that follow a careful review of the literature. We will be trying to come up with guidelines based on evidence. I think that Jim's point is well taken in that this effort will have to go beyond the data to really truly get at the heart of survivorship. There are a whole host of issues beyond the medical considerations, including psychosocial issues such as employment. The IOM report is a comprehensive report and it deals with these issues and medical issues on an equal footing.

ASCO, in this effort, is taking a first step. Our goal is to first review the available evidence on these four topics, appreciating that these four topics are not inclusive of everything we need to address. There is so much to consider, and we did pare it down. On your specific point, I agree with you that there is overlap between sexual dysfunction and psychosocial issues and a focused look at mechanical and functional issues is incomplete. Your point is well taken, but the ASCO initiative is really an initial crack at a comprehensive attempt at survivorship guidelines.

Dr. Ayanian: I am curious how the ASCO process integrates with the NCCN process for guideline development.

Joan McClure, National Comprehensive Cancer Network: We went a short way down the road of trying to develop survivorship guidelines and found that there were very disease-specific issues that were coming up in our discussions. I was wondering to what extent the ASCO guidelines are going to be global guidelines for all survivors versus disease-specific guidelines for particular problems, long-term toxicities, and second primaries that follow-up on individual diseases?

Dr. Shapiro: Whether the guidelines are disease-specific versus global in application remains to be sorted out. I think that there are certainly instances of cancer-specific exposures that merit awareness, such as chemotherapy-induced menopause, androgen deprivation in prostate cancer survivors, and second cancers specific to exposure late effects. I would not be surprised if we come up with some overarching general principles applicable to all cancer survivors, and then specifically focus on the exposures or specific cancers that are related to the late effects. I think it is a work in progress, and I am not sure that I fully understand how the ASCO effort will integrate with NCCN guidelines.

Dr. Ayanian: Our next speaker will be Dr. Melissa Hudson, who is speaking on behalf of the Children's Oncology Group about the guidelines they have developed for survivors of childhood, adolescent, and young adult cancers.

Melissa Hudson, St. Jude Children's Research Hospital

I am a pediatric oncologist, and I supervise the After Completion of Therapy Clinic, which monitors long-term survivors treated at St. Jude Children's Research Hospital. We have almost 5,000 five-or-more-year survivors that we are monitoring. I also have the privilege of co-chairing the initiative for the Children's Oncology Group (COG) developing long-term follow-up screening guidelines for children, adolescents, and young adults who have survived cancer, and I want to share a little bit about that experience with you now.

I would like to start by setting the context of our work. Children come to pediatric cancer centers seeking curative therapy with their cancer diagnosis, and we provide these primary interventions and administer therapy based on core prognostic factors, tumor responsiveness, and their specific risk for treatment complications. We may even modify their treatment for cancer in light of known late effects. As these children achieve long-term

survival, which we typically designate as five or more years from diagnosis, we begin to lose them as they transition into the adult healthcare system from the pediatric healthcare systems. This transition occurs just when it is important for us to intervene with secondary interventions such as health education, cancer screening, and risk-reducing interventions that are going to encourage health and resilience. Providers in the adult healthcare system are generally unfamiliar with our children's specific issues.

There are challenges in providing this type of care across this continuum, this age spectrum. First, pediatric cancers and treatments are heterogeneous. They are very diverse, and it is impractical and improbable that any one provider will be familiar with the host of pediatric cancer treatments. There is a relatively low incidence of pediatric cancers, so there is really no incentive for providers to have a great deal of knowledge of these cancers and treatments. Our therapies even now continue to evolve, as do the late effects of treatment. There is a very long latency with some of these effects. We discovered early on we had to have children complete their growth to really understand musculoskeletal effects and neurocognitive effects. Now we are in the second phase of that understanding, and we are seeing what is happening as our survivors are aging.

Multiple factors contribute to cancer-related morbidity. Cancer treatment is just one of them, but there are many others including genetics and behavioral factors that can be discussed with the survivor. We have some unknown effects associated with aging, but we do have a fair amount of experience with the general population. Survivors' cancer-related risk may be enhanced through the aging process or specific treatments.

Overall, there is a lack of consensus regarding screening guidelines and risk reduction methods. While we have a huge body of literature about treatment complications, we do not have a good evidence base to support recommendations for screening and risk-reducing interventions. In fact, in contrast to what Dr. Winn said of the medical oncology literature, we have textbooks on late treatment complications after pediatric cancers, and we have many medical manuscripts that have been published. It is important for us to move forward in that direction.

The main problem we have in providing survivorship care is the lack of familiarity and lack of comfort by providers, particularly community providers, in accepting these patients who move into their busy practices. Among pediatric oncology providers, the buzz words, when seeing cancer patients for long-term follow-up, is that they deserve "risk-based" care. I want to tell you what "risk-based" care implies. This is the screening and prevention planning that integrates the cancer experience with their healthcare needs. We have to consider risk associated with a variety of issues: the host; the age at diagnosis; race; their age at follow-up; the cancer location; their specific treatment modalities, and if there were treatment complica-

tions; genetic and familial predispositions, some of which we know, many of which we do not understand; and certainly include areas for which we need to pursue research. Finally, there are lifestyle issues that can certainly contribute to an increased risk of morbidity. It is important to work with the survivor on these issues, since this is the one area of risk reduction where they can personally be involved. Of course, many patients and survivors bring into their cancer experience co-morbid conditions or later on develop co-morbid health conditions that should be considered during the follow-up.

After the childhood cancer survivorship report that came from the Institute of Medicine (IOM, 2003) a few years ago, the COG undertook a huge initiative to organize survivorship guidelines. These are clinical practice guidelines for survivors, specifically of childhood, adolescent, and young adult cancers. They are exposure related. We did this because of the heterogeneity I discussed earlier. We wanted to have a broad compendium of information to guide providers. They are risk-based, accounting for all factors that I just discussed—host, genetics, and lifestyle issues.

The recommendations for screening and management are drawn from the literature in that we have an evidence base linking a late effect with a treatment exposure. However, the specific screening recommendations that we made are based on the consensus of late effects experts, because we do not have the evidence base to guide those recommendations. In developing and working through this process of organizing the guidelines, we have been able to identify priority areas of research. Further research will help us gain the evidence base to make more appropriate recommendations.

We have patient education materials called health links. There are now 35 health links that accompany the guidelines. They are meant to broaden the application of the guidelines, and deal with topics such as heart disease, kidney risk, psychosocial issues such as insurance access, and neurocognitive issues, in a format that can be downloaded, printed, and used within clinics.

The goals of the guidelines are to educate providers and patients about late effects, and to standardize and enhance follow-up care over the age spectrum. We also want to facilitate early identification of late effects. Our aims are to promote a healthy lifestyle in long-term survivors, to provide ongoing monitoring of health status, and ultimately to provide timely interventions for late effects.

I will leave you with the URL: www.survivorshipguidelines.org. This web site has Version 1.2 in the PDF format. We have 18 task forces that are system-based, cardiovascular, endocrine, *et cetera,* that have reviewed the literature since we distributed or made available Version 1.2 of the guidelines. The guidelines have been completely updated, and Version 2 will be posted probably sometime this spring.

We are working with Baylor College of Medicine researchers on a Passport for Care application that will ultimately make these guidelines interactive and more user friendly. We have not started our health services research initiatives to judge how the guidelines are being used, but we are tracking their use on the COG web site. We would love to have a more user-friendly application of the guidelines, because currently it is a huge document. You can go and see the guidelines and how we have done it: exposure-related, whether a specific therapeutic agent, specific radiation volume, or specific surgery. I think this will be of use to the guideline development for adult cohorts. Even though they are focusing specifically on some target areas, some of the information that we have can be readily applicable to the adult populations.

Ms. Shawn Kennedy, *American Journal of Nursing*: With your guidelines, do you have a standardized care plan type of thing that you use to communicate this information?

Dr. Hudson: Yes, we do. In order to use the guidelines, you have to have a treatment summary to know the specific exposures. A treatment summary template was developed by the nursing late effects group through the Children's Oncology Group. Their plan is ultimately for everyone who is exiting or completing COG trials to have that information. Then from that treatment summary, the guideline provides information such as potential late effects, recommended screening, health counseling, and the frequency of the recommended screenings and interventions. Does that answer your question?

Ms. Kennedy: Yes, I was curious as to when the care plan comes into play, because especially at St. Jude's you have people coming from different parts of the country. At what points in treatment follow-up does all this get done?

Dr. Hudson: The timing varies. The COG guidelines pertain to care provided at least two years after completion of therapy. They are for the asymptomatic survivor who has had these specific exposures. How individual institutions are using the guidelines to develop a care plan may vary. The St. Jude After Completion of Therapy Clinic does not accept our patients until they begin long-term follow-up, when they are at least five years from diagnosis, and we develop a care plan. It is given once a year. We outline a treatment summary, and we update it. It has not only their specific late effects, it has a problem list that is system-based, and then it has the recommendations for screening, along with our special concerns, whether it is increased risk of heart disease, infertility, *et cetera*. However,

I think the process really varies across the centers regarding how they are using guidelines and care planning in providing follow-up care.

Participant: How much does it vary within St. Jude's?

Dr. Hudson: With the After Completion of Therapy unit, we have a fairly large initiative. I work with two other oncologists. We are fortunate in that our institution funds this initiative. So, we have three days of long-term follow-up clinics. One is for brain tumor survivors, one is for solid tumor survivors, and one is for survivors of hematologic malignancies. The oncologist works with the staff physician who is a generalist, specifically, an internist. In this case she has medical oncology training as well. At St. Jude, I am the only one who does long-term follow-up within the context of the treatment sections. I would expect if you go to any other institutions, their application or adherence would not be very consistent. It is going to vary according to individuals.

Dr. Ayanian: Next, I would like to introduce Dr. Rodger Winn from the National Quality Forum.

Rodger Winn, National Quality Forum

I would like to start by examining where we stand vis-à-vis a measure set that could realistically assess the quality of survivorship care. If we look at the three interventions that are the topic of this breakout session, education, guidelines, and measures, I would say on a scale from 1 to 10, that education is probably at step seven. Mechanisms are in place to improve educational opportunities, and it is now just a question of tooling up the content. I think the guidelines still need some work in conceptualization and methodologically, so I put them at about a four. I think measures are very solidly on square one. What I want to suggest, though, is that square one is real, and that there are enough general precepts of what measures should look like that we can go ahead.

Just to let you know, the National Quality Forum, which endorses measures, recently looked at a set of symptom and end-of-life care measures and found virtually none that were ready for long-term use. The field of cancer is really lagging behind other fields in terms of measures.

Very briefly, what are the purposes of measures? Are we where we can really talk about accountability and public reporting yet? Obviously, that takes very rigorously derived measures. The problem is there is a tsunami coming at us where people in fact are demanding that we have accountability and public reporting measures, not the least of which is the Centers for Medicare & Medicaid Services. It is also driven very heavily by our con-

BOX 5-2
Aims of Quality Care

Care that is:

- Safe
- Effective
- Timely
- Patient-centered
- Efficient
- Equitable

SOURCE: (IOM, 2001).

sumer and purchaser constituencies who are saying, "We want to make decisions, and we cannot make decisions unless we are given information." The drive is very real.

Most of what we as professional organizations look at are quality improvement measures. We use them internally to monitor trends and compare to benchmarks. We use the results, not to "blame" providers for their performance, but instead to develop approaches to improve the performance of a system of care.

Finally, there is a surveillance role for measures. How do you use these measures to look at our national priorities? Measures can be used to monitor at the community, regional, or national level to establish policy and to allocate resources.

The IOM actually came out with a list of the aims of high-quality care (Box 5-2). Most of what we use are effectiveness measures that look at how well an intervention leads to a clinical outcome. In reality, there are these five other domains. If the goal is, in fact, a comprehensive measure set, we are going to have to look at all of them.

Safety—what does that mean in survivorship? A question addressed to a patient, "How confident are you in knowing when to call your doctor about an emergency?" might be a realistic measure of safety for survivorship.

Timeliness—are follow-up studies done on time?

Patient centeredness—does the patient participate in shared decision-making? Does the patient get adequate information?

Efficiency—a lot of what we look at in this area are measures of overutilization. An example of this might be, "Does your stage I breast cancer patient still get a bone scan and a liver scan?" Such measures of overutilization could be put in place, but they are really not great efficiency measures. What you really want to look at is given the amount of resources, what kind of outcome did you get?

Equitable—these measures could assess the extent to which patients have access to specific services.

The criteria used to evaluate measures include, first, that they be evidence-based. This appears to be straightforward, but sometimes it takes on some complexity. We measure structure and processes of care that we know are linked to outcomes. Unfortunately, there is a paucity of data that allow us to make those linkages in the area of survivorship. What would be a good structural measure for survivorship? Did you have clinical practice guidelines in place? A process measure might be, "Were the guidelines implemented in your system?" In order for these to be good measures, we have to be able to link their presence to a favorable outcome. In other words, if the patient achieves this status, which is an outcome, was it due to the fact that something happened to their healthcare delivery, or was it something totally unrelated?

Once you have an evidence-based indicator, then you can move on to the measure. There has to be some parsimony in developing the measure set. Unfortunately, it would be nice if every one of us had a Cray computer in our kitchens to measure 800 measures, but it is not going to work that way. We are really going to have to try to pick the 6, 7, or 8 measures, whatever they are.

Having said that, then the next question is, "How important is the measure?" The measure has to make a difference to the patient. There are many scales that have been developed to gauge relevance to patients. Dana-Farber, for example, has a model to assess how to balance patient preferences. Another important attribute of a measure is the extent to which it varies. There is no use looking at something if 98 percent of clinicians are already doing it. Having a measure for a healthcare attribute that can, in fact, be improved is also very important. If you measure and find a deficit, can the healthcare delivery system, in fact, work on improving it?

Once all of these criteria are met, then the measure must prove to be scientifically acceptable. This is a formidable task. This is high tech. This is rocket science. This is not back of the envelope and it would be impossible to invent a measure today and go out tomorrow and put it into play. Measures must be evaluated for several critical characteristics, for example, their reliability and potential for risk adjustment that relate to their usability. To have value, a measure needs to be understood in the context of quality, and it has to be feasible to implement. For example, data sources must be necessary for measurement.

Once we have a measure set that meets these criteria, there must be agreement or standardization of the measurement. One of the worst things would be to have nine different measures out there of what is good quality care, especially if some of them were contradictory, which in fact can happen. In a plug for the home team, this is what the National Quality

Forum does. We try to collect measures and then put them through an endorsement process. We come out with an agreed upon measurement set to use going forward. Standardization of data is also an issue. Once again a very technical area, but it is important to assess whether valid information is being extracted as part of a quality-of-care program.

There was a mention this morning of attribution, the issue of designating responsibility for meeting a particular quality standard. In the context of the primary care and oncology shared care models, we need to decide who would be responsible for follow-up care and how to make these decisions. Finally, we will have to risk adjust some of the measures to make sure that when you report these you are comparing providers taking into account the risk profiles of their patients, in other words comparing apples to apples.

My overall assessment is that the first step has to be the gathering of evidence, and here, the best way to move forward is through the process of developing clinical practice guidelines. Once those are developed, we can then extract some of the measures that meet these criteria and apply them in areas where we feel we can make a difference.

Dr. Ayanian: Let me just invite brief comments from Phyllis Torda and Beth Kosiak. They represent, in Phyllis's case, the National Committee for Quality Assurance, and Beth, the Agency for Healthcare Research and Quality (AHRQ). They are two of the lead organizations thinking about quality indicators.

Ms. Phyllis Torda: Thank you. First of all, I would like to underscore Rodger's point that measures should be evidence-based, and that good evidence is a prerequisite of quality measurement. I am a little concerned that people might come away overly daunted by his talk. I would just inject that there are actually some tricks of the trade that can be used to make measurement more feasible in the short-term.

Clinical performance measures that are used to compare one entity to another are the gold standard of measures. The broader the number of entities that you want to measure, the more complex the issues become, and rigorous methodology is needed. If your goal is to single out excellence in care and focus on centers, individuals, or certain types of practices rather than others, it can become a little easier. If you were using a series of measures to assess an individual's performance, that also can make it easier. Another trick of the trade is to use a cutpoint. Instead of comparing entities directly on their performance score, for example, one entity scoring 95 percent and another scoring 85 percent, you can look at whether entities scored over 80 percent. These are examples of what I mean by tricks of the trade which can simplify implementation and facilitate quality measurement.

Dr. Beth Kosiak: I want to very briefly mention one aspect of this measurement agenda. The AHRQ is responsible, as some of you may know, for the production on an annual basis of the congressionally mandated *National Healthcare Quality Report* and *National Healthcare Disparities Report*. One of the issues that comes up is what measures should go into those reports. That is where this issue of consensus and standardization and support in the community is critical, because we are going to establish some measures at baseline, and then track them over time. There has to be support for those measures, not only in the community, but also evidence to show that those are the right measures. One of the issues that has come up as Rodger and others have noted is the limited number of available measures. To some extent that means that the national agenda on quality, at least on one level, is missing the degree of comprehensiveness that we would want for cancer care. This represents one of the activities that the AHRQ is involved in that I wanted to bring to your attention.

Dr. Ayanian: A quick comment?

Participant: The one thing that has not come out is that the standards of care in oncology are changing fairly rapidly with the evolution of treatments. The quality measures are also going to have to evolve right alongside of these developments.

Ms. Torda: I think there has been a resurgence of interest in process measures rather than outcome measures. Ten years ago everybody talked about outcome measures. I think the changing evidence base has informed the shift a little bit back to broad processes of care.

Dr. Ayanian: Our concluding speaker is LuAnn Wilkerson from the University of California, Los Angeles (UCLA). She is going to address the challenge of, "If we knew what the evidence base, quality indicators, and right care were, how do we get health professionals to provide that care?"

LuAnn Wilkerson, David Geffen School of Medicine, University of California, Los Angeles

If there is a gap anywhere, I imagine there is a gap here. How do we get guidelines adopted and measures used? I am going to just give you one example of what we have been doing in a consortium that involves UCLA, the University of California, San Francisco and the Drew University of Medicine and Science. My colleague, Margi Stuber, is here with me. We are funded by the National Cancer Institute on an R25 grant to begin to develop educational tools for cancer survivorship. We invite you to help us

think about adapting these tools for different kinds of health professionals and different levels of trainees.

We began by asking the question, "What do we want our medical students to know about survivorship?" We decided to develop a guideline to help us in this domain. We used 17 experts, drawing heavily on oncology, of course, but also the generalists who cared for those patients following the acute treatment period. We generated at our three institutions a very long list of knowledge, skills, and attitudes, everything in the world that a medical student might need to know. We used a two-round Delphi process to narrow that list down to 19 objectives. Those objectives have served over the last two years as a guide for developing a series of modules.

The objectives are published in the IOM report and shown in Box 5-3. They come down on the side of being general, rather than specific principles and broadly applicable to the training of medical students, residents, and nursing students. We have a cohort study underway to look at the quality and outcomes of educational materials developed from these objectives, both the processes and outcomes of this kind of educational program.

To date, we have developed 20 instructional modules, and they are all patient-based and interactive. They have a flexible format, so that you can choose to use different components of a module, and they are highly adaptable for different healthcare fields and levels of trainee. These are open source materials that you can change, pick, choose, adjust as you wish. They are available free upon request at www.medsch.ucla.edu/public/cancer/, but they do not actually appear on this web site; instead there is a template that describes each tool or module. This web site will also serve as a dissemination point for the video on cancer survivorship that was produced by the IOM committee. It is of wonderful quality, and has raised a lot of interest in the last few days at the Association of American Medical Colleges' (AAMC's) annual meeting that Margi and I are here in town to attend.

Let me just give you a couple of examples of some of the elements of our educational program. In learning to take a cancer survivor history, our objectives are that the students will understand the long-term physiologic and psychological impact of the cancer diagnosis and treatment, appreciate follow-up preventive care, and demonstrate effective communication in counseling a cancer survivor. The format for this particular module is a standardized patient. The standardized patient meets with a group of students, is interviewed with a time-out freeze frame interaction so that the group, which might well include a cancer survivor, can talk about best practices and approaches. The module includes a template for a patient record which we based on the care plan, so that the students can begin to learn what a survivor care plan is like.

The second example I wanted to share with you uses a very different format, a CD-ROM video case. It can be used on the Web for asynchronous

BOX 5-3
Cancer as a Chronic Disease: Curriculum for Survivorship
Required Objectives for Medical School Core Curriculum

Attitudes

1. Comfortable prescribing medications for pain control, including opioids
2. Comfortable asking new patients routinely about previous cancers
3. Willing to ask oncologists for consultation when appropriate
4. Considers general preventative issues as well as those related to cancer survivorship in cancer survivors

Knowledge

1. Understands that all cancer survivors are at increased risk for other cancers as well as recurrence of the original cancer, and need to avoid tobacco, eat right, and use sunscreen
2. Understands basic mechanisms of genetic contribution to risk of cancer
3. Understands common uses of the terms "cure," "disease free survival," and "cancer survivor"
4. Understands differences in cancer survivorship by gender, ethnicity and socio-economic status
5. Understands the variety of social consequences of cancer on survivors, including difficulty getting employment and insurance, stigma, and the impact on the family and friendships
6. Knows the essential elements to obtain about a cancer history, how to get information the patient can't give them, and how to interpret the health implications of the history
7. Understands consequences of cancer treatment for different developmental stages, including impact on growth, osteoporosis, learning, sexual function and fertility

Skills

1. Able to use key screening guidelines to identify people at higher risk for cancer
2. Able to provide appropriate and individualized recommendations for secondary prevention to cancer survivors regarding sunscreen, diet, obesity, exercise, alcohol, and tobacco
3. Able to tailor pain medication and other interventions for pain to the source and type as well as the severity of pain
4. Able to explain and help patients make decisions about a living will, do not resuscitate (DNR) orders, durable power of attorney, and advance health care directives
5. Able to give bad news about second malignancy or relapse, and to move to a palliative approach when appropriate without saying "there is nothing we can do"
6. Able to partner with patients in decision making, respecting what is important to the patient
7. Able to work as the primary care provider with a specialty team, providing continuity of care, and working with family as well as patient
8. Able to get current cancer information for cancer survivors at the appropriate reading level and language (e.g., from the Cancer Information Service and National Cancer Institute)

SOURCE: UCLA (2005).

discussion, or it can be used in a face-to-face group discussion. It features a lung cancer survivor and is focused more on discussing the factors that affect quality of life after diagnosis and after treatment. This product was funded additionally by a grant from the U.S. Department of Education.

We have been developing tools for outcome and process assessment, and these represent other products of our work. In medicine and medical education, including resident education, we provide things called OSCEs, Objective Structured Clinical Exams. In OSCEs, the trainee sees a standardized patient and is scored by either an expert observer or the patient himself/herself using a checklist. We have developed four cases that come complete with a standardized patient script, instructions on how to use that script, and a checklist for scoring. The checklist scores at a more general level, but for higher levels of training it could easily be adjusted to include the more content-specific issues that you might be interested in testing. We have standardized patient scripts on four topics: (1) screening for colon cancer risks; (2) counseling for smoking cessation; (3) assessing cognitive effects of chemotherapy; and (4) planning for advanced directives

We have also developed a knowledge test. This is targeted at the survivorship objectives, and includes two to four questions for each objective. We have only pilot tested it so far, so I cannot tell you anything except that senior medical students know very little about this domain. The last tool that we have developed and then pilot tested is an experience survey. We ask about the students' direct instruction in a number of domains relevant to the objectives, the amount of practice that they have had, and also the number of times they might have seen this particular skill demonstrated by their clinical faculty. We do not have any results yet. The biggest challenge that we face is not so much in educating the younger trainees, but in educating the physicians, particularly in primary care that will need to implement the survivorship modules.

At the recent AAMC meeting, we had two days of exhibiting some of these materials, and cancer as a chronic disease is a very good concept for medical educators to begin to think about. We have a long way to go.

Dr. Ayanian: Thank you. Questions?

Dr. Talcott: This is for Melissa Hudson. There is a rationale for expert opinion-based guidelines, and in particular, in pediatrics where you have a smaller number of patients, so it is harder to do randomized studies. I am just wondering what you have done to try and constrain the recommendations? My experience is that physicians do not pay much attention to punchy, well-supported, evidence-based guidelines when the guidelines consist of a bunch of people getting together and recommending things that look an awful lot like their practice, with no constraints on what they are

recommending. How do you make those things user friendly and really constrain them to the available evidence?

Dr. Hudson: In the context of developing guidelines, it is interesting to think about constraining individuals. Probably 70 percent or more of the guidelines pertain to taking the history, doing the proper examination, ordering a very limited amount of lab work, and only rarely recommending imaging. Some of the health information or the additional information that you would consider for a patient is listed in a separate category specifically because there is no evidence to provide greater levels of testing, but we wanted it on the physician's radar screen. You are absolutely right that somebody could look at that and say, "Well, I will just go ahead and order the X, Y, Z, rather than do the physical examination or sit there and take the history to see if there is a clinical indication to provide this intervention or to do this test."

Throughout the guidelines we have clinician information links. We envision that when this tool is interactive it will pop up when the physician is in a certain section. They discuss more broadly the limitations of the literature. For example, for the guideline about breast cancer surveillance in young women who have had chest radiation therapy, our guideline is comparable to the guidelines for other high-risk populations, such as the BRCA-positive populations. We recommend mammography, with a caveat that you should start within a specified time period after radiation is completed. We also have a very broad clinician information link that discusses the problems with imaging in a pre-menopausal breast, the ongoing, evolving literature about MRI, and the need for future studies. We include all these areas that are very contentious.

Osteopenia and osteoporosis is an additional one. We do not have a broad population database of normative data for making those assessments. We explain what the issues are in some of the measurement tools for some of these outcomes, and how it may not be appropriate within that population. We really have the goal of them understanding that it should be on the radar screen.

I cannot respond more specifically on how to constrain individuals, other than trying to give them information that we hope they will review appropriately, but they may not. They may choose to do the test, which is sometimes easier to do than sitting down with the patient and taking the history and reading through the literature.

Dr. Ayanian: I would like to thank our presenters, including Dr. Shapiro joining us by phone.

MAKING BETTER USE OF PSYCHOSOCIAL AND COMMUNITY SUPPORT SERVICES; ADDRESSING EMPLOYMENT AND INSURANCE ISSUES

Moderator: Ellen Stovall, National Coalition for Cancer Survivorship

Good afternoon. This is the last session of the day, and we are getting down to the nitty-gritty in terms of how to make the best use of one of the most important recommendations of the report, the use of psychosocial support services for people with cancer and their families, and access to insurance for cancer survivors. We have four presenters today. Our first presenter will be Diane Blum from CancerCare.

Diane Blum, CancerCare

I am really pleased to be part of this. I will be talking about the survivorship services in the community. What I related to most in the IOM report was Chapter 4, where it talks about delivering survivorship care. There is a whole section in that chapter about survivorship services in the community, where in fact most people with cancer are. I just heard about wonderful programs at the University of Pennsylvania, Dana-Farber, and Memorial Sloan-Kettering in another session. However, most people are in the community, and they are not necessarily going to access programs that are at comprehensive cancer centers.

I am going to be giving a snapshot of CancerCare, of which I am the executive director, and how we provide survivorship services in the community. There are many other organizations besides us who are also providing services who are represented here: The Wellness Community, the NCCS, the Research Advocacy Network, the Lung Cancer Alliance. I do not want to leave anybody out, as there are many organizations that do this. I want to acknowledge that this really is a group process, with services that are focused on people living in the community.

I will just take a moment to introduce myself. I am Diane Blum, the executive director of CancerCare. I am also editor-in-chief of People Living with Cancer, the ASCO patient web site referred to this morning (ASCO, 2005). I am also on the ASCO Survivorship Task Force.

CancerCare was founded in 1944, and its services were confined to the person with advanced cancer. Most of the work was done with the families of the person with advanced cancer, because that person was dying, and usually died within weeks or perhaps a month or so that CancerCare offered services. That was the total focus of the organization, providing counseling and financial assistance to these families for the care of someone who was dying. However, today, 61 years later, we provide free professional

support to over 90,000 people a year. That support is now provided to people at all stages of cancer, and all diagnoses. The change was made in the early 1980s, when the board of CancerCare decided that providing services to people with advanced cancer no longer reflected the nature of cancer. More and more people were being treated with adjuvant chemotherapy, they were dealing with the issues of being treated aggressively, but they did not have advanced stage cancer. For that reason, the mission was extended to include people at all stages of cancer.

In 1990, CancerCare, influenced by the NCCS, which I became involved with at that time, started to focus on the issues of the work site and employment, and concerns that reflected survivorship. As an organization, CancerCare has evolved along with the needs of people with cancer. Most of our patients live for a long time now. They use our services for a long time, and we see them through all stages of their treatment and into a survivorship period. We offer services to survivors in three broad categories: emotional support, education, and financial assistance.

The first category is providing emotional support to survivors. We provide individual, family, and group counseling to people who are in the post-treatment stage. I am defining survivors here as people who have finished their active treatment. The services are provided face-to-face at 10 offices in the eastern part of the United States, they are provided over the telephone all over the country, and since 1996, online through our web site, which was launched in that year.

The issues that people who are in the post-treatment stage confront were described this morning. They are somewhat different than the issues people that are in active treatment face, as they focus more on uncertainty and fear of recurrence. We hear a lot from people about dealing with old problems. When you are actively being treated for cancer, many of your ongoing problems are pushed aside and you do not have to worry about them for the moment. Then you are told you are going to be okay, and all of these old problems come back and need attention.

People often describe to us their unpleasant sense of uniqueness, particularly those who are in developmental stages of their life where cancer is not common. They will feel very uncomfortable, and different from their peer group because of the fact that they are dealing with cancer.

CancerCare offers a program called the Survivor*Care* Program. This is funded by the Lance Armstrong Foundation. The LAF has gotten a lot of thanks today, and we extend our thanks to them as well. CancerCare employs 50 social workers who are trained specifically to work with people in the post-treatment stage. We provide education, which mirrors our education program for those who are in active treatment. Our education is geared to help the person in the post-treatment stage understand, participate, and anticipate the challenges of post-treatment. Although we have

heard today about the survivorship plan, most of the people we deal with do not have any kind of written document like that. We try to help them understand what they should be looking for, the kinds of questions they should be asking, and how they should be participating.

Education may be done on a one-to-one basis with a social worker and a survivor. It is done most significantly through our teleconference programs, reaching thousands each year. The cornerstones of our educational programs on survivorship are the Annual Cancer Survivorship Series, which is done in collaboration with the National Cancer Institute, the Office of Cancer Survivorship, the NCCS, and the LAF. This past spring we offered three of these programs. More than 6,000 people participated in the live programs, and thousands more have accessed the archives on the web site. They are hour-long programs delivered in a supportive way, available to anyone who has a telephone. These telephone education workshops focus on long-term side effects such as fatigue and cognitive difficulties; insurance, including legal protection and trying to get through the insurance process; workplace issues; and health-promoting behaviors.

CancerCare also provides financial assistance to survivors. One of the gaps that was identified in the IOM report was this terrible problem of financial assistance. CancerCare has been providing financial assistance since 1944, and this last fiscal year we provided over $3 million in financial assistance. Just in the past year we have been able to extend the financial assistance to people with specific survivor needs—transportation for follow-up appointments, unreimbursed medication needs after $500, medical co-payments up to $500, and neuro-psychological assessments up to $750. These are small amounts of money, and our clients have enormous needs. Many people come to us who are uninsured or underinsured. However, small grants do make a difference to people, particularly for people who have little money. The financial assistance is also an entry point into our services. We can then try and work with the survivors to help them apply for entitlements and utilize other community programs. The financial assistance again mirrors what we have been doing since 1944, now extended to survivors.

We have organizational limitations in helping survivors, and I think these are the limitations that we have been talking about today. We are committed to extending our services because we see more and more of the people who we have helped come back post-treatment and say, "We still need help." However, we are one privately funded organization, and many of the post-treatment problems we observe are societal problems. On the issue of insurance, we are just filling a gap. We are helping pay for a ride to treatment, but we are not overcoming a lack of insurance. We are one privately funded organization, joined by a whole group of other privately funded organizations, but I would argue that the problems require solutions beyond the private sector.

CancerCare's mission for 61 years has been to provide free professional support services to anyone with cancer and anyone who cares about them. We are serving survivors now, but we have not made a direct mission change. If we were to go out and say our mission is now to serve anyone who has had cancer, we would have another potential 10 million people who could be making use of our services, and we would have a difficult time meeting the need. We have discussed this with our board, and although we are responding to this need and meeting the services, we have not done a full-fledged mission change to actually reflect this need.

The third limitation is highlighted in the report: the issue of reaching people in need. I personally think we have great resources, and many of you in other organizations also have excellent resources. However, it is highlighted in the report that people do not know about existing resources. One aspect of the survivorship care plan is people should be given a list of resources when they complete treatment. Those lists exist. All of our organizations have these lists, and they are readily available. The challenge is to try not only to develop this comprehensive list, which most of us are well on the way to doing, but also to figure out a distribution mechanism, so that patients actually are able to have access to help when they complete treatment. Many of the challenges that we are discussing today are going to be harder to meet, but this is a test that is realistic to complete. Thank you.

Ms. Stovall: Any specific questions for Diane, before we move on to Bonnie?

Dr. Mitch Golant, The Wellness Community: I am Vice President of Research and Development for The Wellness Community International, and on the board of directors for the American Psychosocial Oncology Society. Diane, thanks for your presentation. As a long-time practitioner in the world of cancer survivorship, it is really a pleasure to hear you talk about CancerCare. I want to make one pitch in this conversation and get the reactions from some of the others on the panel as well.

I was looking at the final presentations, and truthfully I was torn between attending this one and the other one. So, I was imaging this idea of lost in transition, and the challenge of survivorship is really about an evidence-based and community-based level of care. I imagine a workshop someday in which we would be making better use of psychosocial and community support services by investing in survivorship research through community-initiated research collaborations. We as a community have been serving so many cancer survivors, and the challenge has been measuring the effects that we have had historically.

Archie Bleyer gives a talk called "Minding the Gap Between the Needs of Children and the Needs of Adults with Cancer." There is a gap, and I think we in the community have been serving that gap for a long time. I

think there is a need to invest in this kind of collaborative research endeavor. I know many of us in this room are passionate about what we do, and this report, which is like a bible to us, provides direction in some places. So, I would be interested in others' thoughts about those challenges.

Dr. Teschendorf: Actually, I am going to address that in my presentation as well. I think it is critically important that we begin to look at the service delivery in a different way. We need to think very hard about the effects and the impact of our service delivery, and build in a quality improvement process. Then we can come back in another year and say what we know works in the community and what we know we have to modify or change over time.

Diane Blum: I guess the question I have is how do you actually make it happen? Do you use the structure that is already here and proceed?

Dr. Golant: At The Wellness Community we have done randomized clinical trials through the California Breast Cancer Research Program in order to look at the effectiveness of our programs. We work with Stanford University in particular, because that was an academic model, and we wanted to compare that academic model to a community model and services delivered in the community where there are such limited resources. We agree that The Wellness Community could not create an infrastructure like Stanford or Dana-Farber, but we could plug into that mainframe. We could collaborate with the American Cancer Society or others. It is the idea that the community has a plethora of options and services available that could be looked at in order to find out what is best in terms of the needs of cancer patients. So, that is how I would think about it, Diane.

Bonnie Teschendorf, American Cancer Society

I am very pleased to be here today, and as an IOM committee member I was also involved in the work that went on before getting here. It is very exciting for me to see the response of all the people who have come as well. When I started thinking about what we were going to discuss in this particular session, I decided to narrow it down. I am going to respond to four of the recommendations, and try and weave this together in the context of what the American Cancer Society is doing now and what is on our plate at the moment. Next week, we are going to convene a meeting to look at how we can weave these recommendations from this report into our future work. Some issues I want to discuss we are already doing.

We synthesize the science and find ways to translate evidence into practice. When I talk about practice, I am not talking about medical prac-

tice. I am talking about community-based practice, things that we would do for patients and families. We also want to be able to anticipate the needs of survivors and families. I will tell you a little bit about how we do that. It is a very important function, to be able to synthesize this body of information. Linking people to existing community services is also important. Diane addressed this issue. I will tell you a little bit about how the ACS does it. Then I will discuss some designs for targeted applications and service delivery, which I think is what Mitch was raising as an issue.

In terms of synthesizing science, we actually have a couple of departments in our organization at the national home office. The department I am seated in is the Cancer Control Science Department. Our mission is fairly complete, because there are several of us who are involved in taking science from several domains and then weaving together how we might translate that into work that would be done in the Health Promotion Department, the applied portion of our organization. They are using science-based initiatives as we move forward. We are also beginning to think about how we can analyze the portions of our organization that I call the legacy programs, the programs that we have traditionally offered.

Anticipating the needs of survivors and families is really a very important function for us. I think that we have learned that a call center is like a canary in the mine. When we listen to a number of people who are telling us the same story, we consider how we can meet those needs by developing program initiatives or developing new materials to distribute, either at the web site or through actual publications. In addition, the literature reviews that are produced out of our department often lead into some sort of research potential for other departments.

We have a number of relevant publications through our Health Promotions Department. They are not necessarily generated on a schedule or in response to certain time frames as would be the case with our guideline development, but these are focused on what we are hearing from cancer survivors as important issues. We recently published a book on palliative care and also have issued books on lymphedema and pain. Our web site is always in a state of development, if you will, in that we are trying to find new delivery methods and new ideas for engaging people, both families as well as the survivors.

We introduced the clinical trial mapping service about two years ago. It has been very successful, and people have appreciated it. We have most recently had an opportunity to interact more with physicians in clinical practice. One way which we are doing this is that we have started a detailing project, where we have hired staff to go out and talk to physicians in their practices.

I recently had the most interesting experience of being sent to the American Academy of Family Physicians to be an exhibitor. I am not usually an exhibitor, but I went because they needed someone who knew the science.

It was a revelation to me to see how interested family practice physicians were in what we were doing, and the kinds of issues that they raised. I came back with lots of ideas about applications that would meet the needs of this group, which I have now begun to transmit to other departments. We should always be at the AAFP conference. This was a new opportunity for us to learn from physicians and to find out what they want to know about cancer and need in order to work with their patients. They talked about patients who come back to them after they finish their treatment, and how there is a sense that they are not quite sure what they are supposed to be doing, but are working their way through it.

Linking people to community services has been a hallmark for the American Cancer Society for some time. We think that we are really good at it, but I am sure there is room for us to learn. We have a community resource database that has been developed through each of our division offices. In this database we can enter all of the services that are accessible in a particular geographic area. It might be support groups, or it might be some sort of family interaction. It might be information. There are a number of ways in which that information might be delivered, and we are looking for additional ways to respond to people who have requested information about service delivery in their geographic area. How can we link them through more than our call center? Can we do it in another way, maybe through our web site as well?

We will also use our web site to disseminate disease and treatment information. That has been in a steady state of development for some time. In the last two years, we moved from simply focusing on early diagnosis and early treatment, into looking at the whole disease trajectory. And that is a big change for our organization.

We also provide options for patients and survivors to communicate. We have had the Cancer Survivors Network online for some time. People tell their stories there and exchange ideas with one another, and it has been a nice source of emotional support for many of them. We have a call center that is open 24/7. The middle of the night is often the busiest time, or a very busy time, when people really want some answers. They wake up and are unable to sleep, because a particular problem is bothering them. More recently we have developed some navigation models that are being tested. This goes back to Mitch's comment about testing in the community, doing some kind of pilot projects, and then going forward with development of a more detailed product.

Designing targeted applications is going to be part of the future for our organization. We need to help promote the idea of follow-up clinics. We need to move forward with the idea of detailing, and see what our results are, and we will have an analysis of that data. We really want to promote the idea of self-advocacy to get people involved.

Finally, I want to talk about exploring and testing new service delivery models. It has only been in the last several months that we have begun to put together people from several departments to begin to look at how we can use science to drive delivery of new services, and how to evaluate them. The program evaluation process is being formalized and built in as a combination of work from several different departments. Our Behavioral Research Center is in the process of hiring people who are used to doing program evaluation, our Health Promotions Department is coming up with ideas of ways that they would like to have more targeted interventions, and our Cancer Control Science Department is hoping to supply a non-stop service of information about the science. That is a little snapshot of what is going at the ACS.

Ms. Stovall: Bonnie, thank you very much. That is very helpful. Questions for Bonnie?

Ms. Iris Portny: I am a volunteer with Y-ME, and a seven-year survivor of inflammatory breast cancer. I have a couple of questions. First, when you talk about detailing to physicians' offices, can you define detailing? Can you give us a sense of what that means? When you are contacting physicians to ask them if there might be information they want, what exactly are you focusing on there? Are you looking for feedback? Are you trying to find out what they think they need? Are you also giving them suggestions of information that they might need?

Dr. Teschendorf: Detailing is a model that is used in the pharmaceutical industry. There are pharmaceutical representatives that go out to physicians' offices to provide samples and information about new drugs. We have adopted that model, and we are testing it to see if providing information in that way makes a difference in terms of physicians' response. Detailing is very active and interactive.

Ms. Portny: So, it is looking for ways that you can better deliver the information that you already have, as opposed to also looking for new information you might want to be developing and collecting?

Dr. Teschendorf: I think it might be a little bit of both. I am sure that we will learn from this what they need, just as I said I did at the AAFP conference. At that meeting, we learned a lot about what physicians are looking for.

Ms. Stovall: Thank you.

Loria Pollack, Centers for Disease Control and Prevention

Thank you. I am glad to be participating in this breakout session. I am Loria Pollack and I work for the Centers for Disease Control and Prevention. I plan to give a brief overview of comprehensive cancer control, and how it may be useful in addressing psychosocial survivorship issues including those related to employment and insurance.

Comprehensive cancer control is a collaborative process through which communities and partners pool resources to promote cancer prevention, improve early detection, increase access to health and social services, enhance survivorship, and reduce the burden of cancer. Participants in comprehensive cancer control are diverse by design, and include many public and private organizations that come together to address these goals. The CDC's role is to provide support for building an infrastructure for states, tribes and territories to form coalitions, to give guidance in comprehensive cancer control planning, and to assist coalitions in sharing approaches and strategies.

Comprehensive cancer control plans are one outcome of these coalitions. The process of developing these plans facilitates organizations to come together, plan and articulate goals and strategies unique to their state, tribe, and territory. The Colorado plan, for example, has an entire chapter that articulates the survivorship burden, objectives, and strategies to meet those objectives (Colorado Cancer Coalition, 2005). Currently, over 40 states, 2 tribes, and 2 territories have developed a plan, and others are in the process of either updating or completing a new one (Figure 5-2).

Most comprehensive cancer plans recognize survivorship issues, but the plans vary in how they address them. In some, survivorship is an overarching theme. Other plans mention survivorship in terms of a general goal or recommendation. For example, they may aim to ensure access to adequate supportive services, but lack specific strategies to achieve this aim. Other plans have a specific chapter with clear survivorship goals and strategies outlined. Few plans address survivorship-related financial issues, access to care, and legislation and policy as outlined so well in Chapter 6 of *Lost in Transition*.

I propose that comprehensive cancer control coalitions could be a vehicle to educate and advocate on the employment, economic, and other important psychosocial concerns of survivors. The established coalitions could be used to address these issues at a state, tribe, and territory level to help reach target populations and disseminate already established programs.

In the upcoming year, cancer leaders will meet at a Comprehensive Cancer Control Leadership Institute. Survivorship was chosen as one of six specific topic areas for the meeting. These leadership institutes can be a forum to recognize, include, and expand upon the various employment

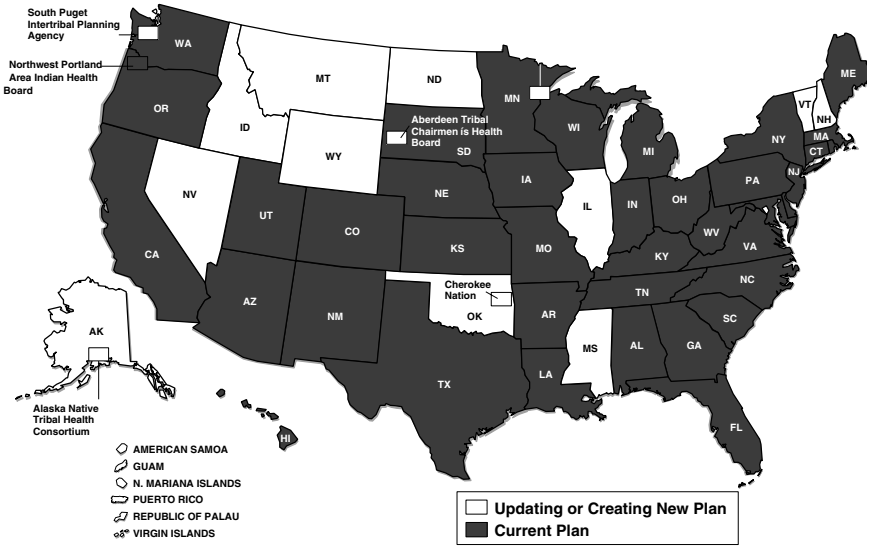


FIGURE 5-2 Status of state comprehensive cancer control plans.

protection policies and legislation, financial aid programs, and other wonderful survivorship programs that are described in this report.

In response to Mitch's question about CDC's role in community-based health, we have established community-based resource networks in which there are community practices that we will ask to answer specific programmatic research questions. In the upcoming year I would like to see existing survivorship educational materials evaluated through these community-based programs so we reach beyond just those people who log on to peoplelivingwithcancer.org, or call CancerCare, or these other wonderful organizations. There are a good number of people who are not connecting with the programs that we are working so hard to develop and improve. CDC's role in survivorship has been catalyzed with the development of the National Action Plan, which is now two years old (CDC and LAF, 2004). We are doing a lot to build upon that plan.

Cancer control planning is a process, not a product, because plans are always being developed and revised. Having the cancer control plans, being involved in the coalitions that are drafting and redrafting these plans, and connecting with the state, tribal, or territorial cancer coalition is a good way to get out to providers and survivors. More information about the CDC's Comprehensive Cancer Control Programs is available at our web site and through recent publications (Pollack et al., 2005; CDC, 2005a; 2005a,b).

Ms. Stovall: Thank you, Loria. Any questions for Loria about CDC's programs?

Dr. Golant: Please elaborate on CDC's role in the planning process. That planning process is so robust, and I am thinking about all the different roles that are so meaningful in the process. Gathering information, planning, and disseminating information among all the community organizations is just so valuable. That is also what makes this *Lost in Transition* report such an important resource. I wanted to hear more about it.

Dr. Pollack: I think our role at the CDC was to help establish these coalitions in the states, but in no way to control or direct what they should be doing. It should be a very bottom-up process. What we can do, since we are a national organization and have a bird's eye view of what different organizations are doing, is to facilitate the sharing of information. If one state has a fully developed chapter on survivorship and talks about incorporating survivorship and addressing insurance programs through the development of a high-risk insurance pool, we can take that to another state that is really struggling to address these issues, and they can use the developed plan as a guide and a model for their state. CDC's role in survivorship with these programs is always to support any research programs that could establish ways to better outcomes and to improve care. However, as we heard today, we cannot always wait for the results of these research efforts, and have to support programs as they are.

Ms. Stovall: Thank you very much. Last, we have Pam Short, another member of the IOM Committee on Survivorship.

Pamela Farley Short, Pennsylvania State University

I am a Professor of Health Policy and Administration at Pennsylvania State University. I am a principle investigator on a grant from the National Cancer Institute that is following a cohort of about 1,800 cancer survivors, looking particularly at the economic consequences of cancer survival. In our cohort, which is from a relatively high socioeconomic status, our focus has been not so much on insurance as it has been on employment. I also have to confess that I am one of the people who, for my entire career, has been working on trying to solve the problem of the uninsured, which may take more than my career. We may have to interest some more young people in thinking about it. I served as one of the thousands of people on the Clinton task force, and had a chance to work in the White House when we were trying to see if we could do something about health security.

As I was sitting at the National Press Club yesterday, listening to reporters ask questions of some of my fellow committee members, I could

not help but think that this report that we have written asks a lot of its audience, because it is actually full of mixed messages. There is good news and bad news. Maybe that comes out of the fundamental ambiguity of being a cancer survivor. The good news is you are going to live, but the bad news is you are going to live with the risks and the unpleasant consequences of your cancer.

As we were reviewing what is known about employment and cancer survivorship, we wanted to bring out both the good news and the bad news. We wanted to emphasize that most cancer survivors continue working and remain productive after their treatment. For them, it is not really an issue of needing a lot of extra services or rehabilitation. For many, the big issue is discrimination of one sort or another, if there is an issue. But at the same time, the bad news is that there is a significant minority of cancer survivors, about 1 out of 5 according to the results from the Penn State cancer survivor study, who have ongoing disabilities that affect them at work (Short et al., 2005). While emphasizing the good news, we did not want the bad news or those problems to be lost.

I have to confess that I am pretty comfortable with these ambiguities in our report because I am an economist. Maybe you know that economists are very well known for using both hands when they give you the answer to any problem. Both of my hands start to twitch when I try to decide how hard we ought to be pushing to get more survivors to work more. The research shows that cancer survivors do work less than otherwise similar people. This is a good news/bad news ambiguous kind of situation, because on the one hand, working is a good thing. As the one survivor said in the film we saw this morning, work is about a lot more than a paycheck. However, on the other hand, working is not always a good thing.

My friend and fellow researcher Cathy Bradley is concerned about the statistics showing that now something like 60 percent of cancer survivors work throughout their treatment. Is that necessarily good? Are they working, wanting to be able to take that time for themselves, but continuing to work because they do not have the sick leave or they are not able to take the time away from work? Are they worried that if they somehow let down the team at work, they will not have the job to come back to?

My response to Fitzhugh Mullan's issue that he raised about 11 percent of cancer survivors who are uninsured is that if you are a cancer survivor and you have any way to keep your health insurance, or if you have any way to get health insurance, you are going to do that. It does not surprise me that insurance rates are higher and that the percentage of cancer survivors who are uninsured is lower than it is in the general population. We even have some public programs like Medicare and Medicaid programs for people with disabilities that are designed to fill in those gaps. However, is it

a good thing that people are working for health insurance, when their health and their long-term quality of life would be better if they were not working through treatment?

It is also not necessarily a bad thing that some cancer survivors stop working and retire. If it is because they faced down a deadly disease, reassessed their life's priorities, and found that their priorities do not necessarily involve going to work 50 hours a week, I am not prepared to say that that is a bad thing.

Now, when we move on to the subject of health insurance, I think there are fewer ambiguities. It is really much more clear-cut in my mind. First of all, clearly the changes in clinical care of cancer survivors that the committee has recommended are going to have to be paid for. That may require an agreement to expand the services covered by most policies, to provide reimbursement for services that are not otherwise covered, or to provide more generous reimbursement to get providers to do the things that we want them to do. I think it is unambiguous that these services are not going to reach cancer survivors who have little or no health insurance. It is not going to happen without the health insurance, and the committee wanted to point that out. That is one one-handed statement.

I will give you another one-handed statement: all cancer survivors live with more economic risks than the rest of us. Although cancer survivors are a very heterogeneous group, I think this is true of all cancer survivors, even the ones who have essentially no long-term effects. If they tell the truth on those applications, they are going to find that they have difficulty getting life insurance. They face risks involving what Karen Pollitz taught us to think of as the three As: access, adequacy, and affordability of health insurance. They may find that the legal protections that experts seem to agree have improved the situation do not necessarily eliminate the more subtle forms of discrimination in the workplace.

I propose one more one-handed statement—I want you to testify that you heard an economist willing to make a few one-handed statements—to say that these economic risks are everyone's risks. We tried to point this out in our report. In this sense, while cancer survivors need healthcare financing reform and universal coverage or universal access to health insurance, I think perhaps that universal coverage and universal access may benefit from the political smarts and the political power of cancer survivors too. We are all at risk for cancer. The statistics are 1 out of 3 during a lifetime. That means we all have a stake in reducing these economic risks associated with cancer.

When I talk to people about insuring the uninsured or healthcare reform, what I try to emphasize—in fact what the health security idea tried to emphasize—is this is not about *them*. It is about *our* security. Knowing that the American public is as afraid as it is of cancer, and that this is an

issue that touches almost all of us, this may be a way that we can make a little progress towards reducing some of these economic risks.

There are things that we can all do. There has been a lot of talk about what oncologists can do, and what primary care physicians can do, and other sorts of specialists, but these are issues for all citizens, for all of us. There are things we can do in our own workplaces, in how we treat our co-workers, in how we make accommodations for our employees, and through our own willingness to pay for public and private insurance that is going to share these risks. These risks are shared through life insurance, they are shared through health insurance, and they are shared through disability insurance.

Ms. Stovall: Thank you, Pam. I love ending on that last message. It was such a privilege to work with both Pam and Bonnie on this committee. I look forward to continuing to work with all of you, every one of you on this panel. Are there any questions for Pam or for anybody else on our panel as we are attempting to end on time?

Mr. Robert Weiss, National Lymphedema Network: Just a comment. I am very heavily involved in legislative issues. I know that many of these organizations here today are either government organizations or 501(c)3 charities, and are not allowed to do much legislative work.

When you realize that eventually the cancer survivor is going to reach the age of 65 and be subject to Medicare, and that Medicare does not cover the treatment of lymphedema, you see that there is a terrible situation. There are something like 1.6 million cancer survivors who are at risk for lymphedema, and when you consider that it is not being covered, that is a terrible situation.

I urge you to consider setting up non-profit or lobbying organizations to do some grassroots work in getting legislation in the various states for insurance, and in the government for Medicare. There are a handful, I think six states now, that cover lymphedema care. Thanks to the ACS of Northern Virginia, which was the first organization that was able to get a state law for the treatment of lymphedema in Virginia. In January 2004 it went into effect. New York, Massachusetts, Connecticut, Georgia, and California have bills in the assembly or the senate right for the treatment of lymphedema. These are all grassroots efforts. There are teams in the various states.

We have had very few words on legislation in this conference. I urge you to get involved with that aspect of providing for the cancer survivor. It is so important. I will help to set up a team in your state. I have all kinds of materials. You just have to provide the people who are going to go into

your legislators' offices with materials and have them urge their representatives to pass this.

Ms. Stovall: Thank you so much for your comment. I think that Bonnie and I were just thinking the same thing. The reason that the rocky road of survivorship has been so long is that we have a lot of reports over the years that have recommended precisely the kinds of interventions and support and reimbursement you are talking about, but they just sat on the shelf. Getting this report done by the Institute of Medicine is going to take organizations like the American Cancer Society and my organization and many others in this room a much longer way toward getting there than anything that has been put out there before, just because of the respect that these reports command with our lawmakers. You are in the right place at the right time.

Mr. Weiss: Thank you for the report. You can be guaranteed it will be used as early as tomorrow when I testify in Georgia to a health committee in legislation in Georgia.

Ms. Stovall: Wonderful. Congratulations. That is a great way to end our workshop. Thank you all very much.

INVESTING IN SURVIVORSHIP RESEARCH

Moderator: Patricia Ganz, University of California, Los Angeles

I would like to welcome our first presenter, Lois Travis, who is from the NCI Epidemiology Program. Lois has a lot of experience with second malignancies, and she is going to be talking to us about that.

Lois Travis, National Cancer Institute

Good afternoon. Chapter 7 of the IOM report was entitled "Research," and in the last few pages the overall findings and recommendations were summarized. The section began, "Research is especially needed to improve understanding of mechanisms of late effects experienced by cancer survivors, how to identify and intervene to alleviate symptoms and improve function, and the prevalence and risk of late effects." Today I am going to focus on the first and third items, which relate to mechanisms and risks. As noted in the report several times, transdisciplinary teams will be needed to further the research agenda.

To understand the mechanisms of the long-term complications of cancer and its treatment, we must first identify the relevant etiologic factors. It

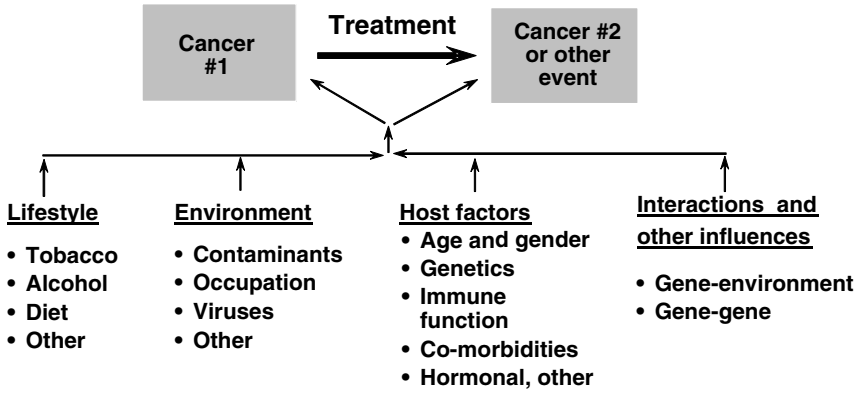


FIGURE 5-3 Long-term complications of cancer and its treatment: Etiologic factors. SOURCE: Travis, 2002.

is well established that radiation and chemotherapy are associated with late effects, however, numerous other factors can contribute to the development of late effects (Figure 5-3). These include lifestyle choices, such as tobacco, alcohol and diet; environmental determinants; and host factors, such as genetic susceptibility and co-morbidities. In addition, interactions between various factors occur.

A promising area for future research is that of gene-environment interactions. These include the effects of individual variability in carcinogen processing and detoxification. For chemotherapeutic agents, these relate to differences in drug absorption, metabolism, distribution, and excretion. The roles of pharmacogenetics, DNA repair, and other host factors should also be studied.

Characterization of interactions between exposures also will be important. A first step is the identification of the individual components, for example, treatment, tobacco, alcohol, or other risk factors. Second, what is the impact of the combined exposures on late effects? Is it additive, multiplicative, intermediate? With this information, high-risk groups of patients can be identified, with implications for screening and prevention.

It is important to be able to estimate the risk or magnitude of late effects. One type of epidemiologic study design that is mentioned in the report is the cohort approach. Well-defined cohort studies with complete follow-up can yield a number of risk measures including the relative risk and the absolute excess risk. The latter measure is frequently expressed as the excess number of events per 10,000 patients per year, and serves as a useful measure of disease burden. The cumulative absolute risk is the per-

centage of patients diagnosed with the event of interest in a specified time interval. For example, Mitch Gail and I, along with other investigators, recently published estimates of the risk of breast cancer after Hodgkin's lymphoma by age, follow-up time, and type of treatment (Travis et al., 2005b). For women treated at age 25 years with a mantle dose of at least 40 gray without alkylating agents, the estimated cumulative absolute risk of breast cancer by age 35, 45, and 55 years was 1.4 percent, 11.1 percent, and 29.0 percent, respectively. This measure seems particularly useful for healthcare providers and patients.

It is always important to keep in mind that the risk of late effects varies not only by treatment, but also by age at exposure, gender, length of follow-up, co-morbidities, and other variables (Travis et al., 2005a). In addition, it should be kept in mind that these estimates may reflect the effects of therapies administered decades ago, which are no longer used.

As a foundation for future research in one area of cancer survivorship, the National Cancer Institute held a workshop last November on genetic susceptibility and second primary cancers. Over the last few decades, the number of second cancers has steadily increased. In 2002, over 120,000 new invasive cancers were reported to the Surveillance Epidemiology and End Results (SEER) program. Of these, second or higher order neoplasms comprised 16.3 percent, or 1 in 6. Second cancers are also important in terms of the significant impact that they can have on morbidity and mortality, often in patients who had considered themselves cured of cancer.

During the workshop, we brought together a trans-disciplinary group of investigators in epidemiology, molecular genetics, statistics, and many other specialties. This group proposed several recommendations for future research which are applicable to cancer survivorship in general, and which are reported in the *Journal of the National Cancer Institute* (Travis et al., 2006). The core recommendations from the workshop include the development of a national research infrastructure for studies of cancer survivorship; the creation of a coordinated system for biospecimen collection; the development of new technology, bioinformatics, and biomarkers; the design of new epidemiologic methods; and the development of evidence-based clinical practice guidelines. Thank you for your attention.

Dr. Ganz: I think in the interest of time we will hear our other presenters, and have questions at the end.

Sandra Horning, Stanford University

I have been interested in late effects of treatment since my initial publication as an institutional and cooperative group investigator. Today I thought I would focus on the American Society of Clinical Oncology activi-

ties and initiatives in cancer survivorship research as a means of demonstrating what a medical society might bring to this area. I mentioned our Survivorship Task Force earlier today, which Patti Ganz and I co-lead. This has been another link in a chain of activities at ASCO.

ASCO has activities and initiatives in: research methods; policy and advocacy; the promotion of scientific exchange; awards for survivorship research; the preparation of guidelines, which can then be used as the basis of survivorship research; and in communications, which we know are important to the many stakeholders in this area.

First, some of the research methods initiatives that are underway deal with barriers to participation. For some period of time ASCO, led by Lowell Schnipper, has been involved in efforts to promote central Institutional Review Boards. We have partnered with many others in this effort. We are co-sponsoring a workshop with the Association of American Medical Colleges and the Office of Human Research Protections (OHRP) to try to further understand the sticking points with central IRBs, and to discuss what the next steps may be.

We are working with the NCI on implementation of the Clinical Trials Working Group (CTWG) recommendations. Jim Doroshow, who was part of our cancer research committee, is helping us to understand how ASCO can best work with others to implement recommendations that will overcome research barriers. This, again, is an effort undertaken in partnership with many others groups.

We also have a number of education and training efforts related to research. One is the Vail Methods in Clinical Trials course, conducted in conjunction with the American Association for Cancer Research (AACR). Survivorship research methods are part of the course, which Patti Ganz participated in last year. We also have a workshop on clinical trials for the community oncology team, which is in its second year. It is important that the community oncologist be involved, because a lot of survivorship research will need to be done in the community. We are discussing efforts to bring this to a larger proportion of community oncologists, and also to integrate this kind of methodology into the training of oncologists who are going to go into community practice. In addition, we have a half-day symposium planned for our annual meeting in 2006, which will be a distillation of the Vail methods course, in order to bring this content to a larger group of individuals.

In the area of advocacy and policy, we have our Government Relations Council and Cancer Research Committee. We have partnerships with the Food and Drug Administration (FDA) and the NCI. We have provided commentary on drug safety issues, and on National Institutes of Health reauthorization and funding. We work with the FDA on critical path and clinical trial endpoints issues. We also work with the Translational Research

Working Group of the NCI; a subgroup of our Cancer Research Committee is currently considering ways to disseminate clinical trial results to study patients.

A major effort in the past several months has been to integrate survivorship into our scientific and educational programs. In our science program, we have a new track which is a home for survivorship research and presentation. Of note, this appeared in the plenary session 2005. We have given special awards for survivorship research. Survivorship has a place in the *Journal of Clinical Oncology*.

Our communications efforts have included our 2004 Meet the Experts media event focused on survivorship. The print media coverage of that event reached more than 110 million people, and there was additional national broadcast media coverage as well. We also have the People Living with Cancer web site (peoplelivingwithcancer.org) featuring articles on survivorship, where we partner with the Lance Armstrong Foundation on survivorship stories and content.

In the area of awards, in 2004, we gave four young investigator and career development awards. In 2005, we are identifying additional award needs and potential partnerships.

In the area of health services research, we are developing guidelines for long-term medical care of adult survivors, which cover cardiovascular effects, hormone replacement therapy, bone health, sexual function, neurocognitive and psychosocial concerns, and second cancers.

We have task forces that are looking at imaging and biomarkers and the integration of translational research. I think this is extremely important as we think about both the therapy that we are delivering now, and how therapy may be changing by early assessment with biomarkers, imaging or both. Changes in therapies may translate into changes in late effects. As we move closer to understanding mechanisms such as DNA repair, biomarkers become even more relevant. Bringing investigators working in these areas into the fold as part of the transdisciplinary research team is an extremely important effort.

In summary, our initiatives and activities fall into these important areas: research methods; advocacy and policy; scientific exchange; awards; guidelines; communications; and strategic partnerships. Thank you for your attention.

Julia Rowland, National Cancer Institute

I would like to take this opportunity to add my deep appreciation to the Institute of Medicine, and in particular the 17 superb members of the committee who were midwives, if you like, of the birth of this report that our office has been very eagerly awaiting. We are very excited that it has

now appeared and is on the street. I also want to publicly acknowledge my gratitude to the Institute of Medicine, ASCO, and the NCCS for convening this symposium, and for putting in place other meetings down the road to really pick up on the momentum generated and not let this report be shelved.

As director of the National Cancer Institute's Office of Cancer Survivorship, I am going to make a public commitment that I will do everything in my power to help us realize and implement the recommendations of this report, as long as I am in this position. In particular, I note those recommendations that have identified the National Cancer Institute as needing to take a leadership role. The most significant of these being to grow, support, and shepherd the survivorship research arena.

I want to also thank my predecessor and founder of the position as the director of the Office of Cancer Survivorship, Anna Meadows, for saying that despite being included as the last chapter in the report, it is all about the research. We cannot have guidelines or develop care if we do not know what the issues are, where they are appearing, who does and does not get them, and what interventions are needed. Anna, my response to your comment about the place of research in the report is that it is the backbone of the book. I am a psychologist, and for those of us who do cognitive therapy and cognitive studies, we know that it is the last thing on the list that you remember. We are all going to walk off knowing that research is the most important thing in there, because it is the last chapter. It is the last piece of information you heard that you will walk away with.

John Ayanian already delivered my talk during the plenary. I told him that and he said, "Do not worry about it. That is the music. You come back and tell them where the crescendos are." My job is to tell you the high points in here. I want to talk about three things: the challenges to doing this kind of research; the opportunities that we have right now; and where I think we need to go in the future.

I think one of the critical points that we forget about or take for granted is that the long-term or late effects of surviving cancer are literally and figuratively a moving target. We heard Doug Ulman speak about the fact that our survivors are a mobile population. It is hard to keep track of them, regardless of whether they are pediatric or adult survivors. We lose them pretty much about two years after the completion of their treatment. Many of them disappear. Furthermore, as they continue to age, the issues are changing over time. If we want to know the long-term and late effects, we must be following survivors long-term. We also know their health is a moving target. If you consider the fact that 60 percent of those who are survivors today are 65 and older, it is quite likely that they had one or more co-morbid illnesses when they were originally diagnosed. Trying to understand and tease out what is cancer-related and what was pre-existent, but may be exacerbated or affected by the diagnosis and treatment of cancer, is

a real challenge for us. When we get five years beyond diagnosis, which is the least-studied time period, we know even pitifully less.

Much of the research that has been published historically has been atheoretical. We cannot go forward in this fashion. We must be thoughtful about why we think these kinds of problems are going to develop, generate a hypothesis, and consider the models that we are testing, because that is the only way we are going to answer the question of what the interventions should be. We have to have appropriate tools. We have outstanding measures now for active treatment, including quality-of-life measures and quality-of-care indicators. Post-treatment, though, there are very few tools that are available to us. There is also the issue of how we are going to look at co-morbidities, and how we measure those and compare these conditions in survivors with those reported in the non-cancer or general population.

We have already heard many speakers talk about reaching this population. The Health Insurance Portability and Accountability Act is not going to make it easier. Institutional Review Boards are a hurdle for many. Informed consent for patients is also going to be an issue. We clearly have to do extra work to include our minority and underserved, harder-to-reach populations. This will require a bigger investment in efforts to understand how to access these individuals, recruit and retain them in our studies and research, and to make these data available.

Then there is the issue of securing funding. Here we need to realize that it is not enough to study the problems of survivorship without developing interventions. NIH-wide, about 40 percent of the studies that were funded in survivorship in fiscal year 2004, 217 if I remember the number correctly, have an intervention component. That is about the right portfolio mix, as we would like to see 40-50 percent at any given time. We know new treatments are going to have new late effects. We have to find out what those are, and then develop interventions. That is going to be very important.

However, we know that intervention research tends to be very expensive if you are not just giving a pill. Behavioral intervention and education, which is the backbone of almost everything we do in the intervention arena, tend to be expensive. They are personnel intensive. We need to monitor for fidelity of delivery of these interventions. They often involve behavior and lifestyle changes and again, we need to be mindful of the costs and difficulties associated with these areas. It is very hard to get this research funded as we are competing with basic science and treatment-focused research. Further, we, specifically behavioral scientists, sometimes defeat ourselves at the review table. If we are going to fund this type of research, we have to take ourselves very seriously and say that we need to be supporting this research, including at the review table.

Finally, the transdisciplinary aspect of this research is an issue (Box 5-4). This really is a very special kind of science. It is not just different disciplines

BOX 5-4
Cross-Disciplinary Research

- *Multidisciplinarity*—different disciplines work within the same organization, independently or sequentially, each from their own perspective
- *Interdisciplinarity*—work jointly "at the intersection," but from each of their disciplinary perspectives
- *Transdisciplinarity*—work collectively, using a shared conceptual framework that integrates discipline-specific theories, concepts, and methods, yielding a new understanding of a problem.

in the same room thinking in their own way. It is not even just an intersection, such as psycho-oncology where mental health professionals are addressing cancer issues. It is truly broad spectrum. You want pediatric perspectives and geriatric perspectives. You want the physiologists, clinicians, and mental health professionals involved. It really is a complicated science that has to be done in a transdisciplinary fashion. Again, that requires attention to recruiting diverse expertise and promoting cross-training.

We also need to sustain the necessary infrastructures that we have already built, and ensure the continuity and support of key resources and repositories. Importantly, it does not matter what resources we have if we do not have the personnel both to support and utilize these resources. That means we need training programs. It is wonderful to hear that ASCO is supporting these kinds of initiatives. Certainly, at the NIH, we need to do better in adding more money to training and retaining dedicated researchers in this field. People get scared when money gets tight. If junior investigators cannot envision a secure future in this field, I am worried we will not be able to recruit them. That is an important concern.

I think we also cannot overestimate the need to change the mindset, as we have heard again and again today, about survivors' care. It has to be conceptualized as spanning the continuum starting at diagnosis and extending long-term. Interestingly, we are seeing some of our cancer survivor population demanding and getting what we do not even provide for many individuals who do not have cancer, and that is preventive health, health promotion, and disease prevention. We do not have that as a standard model of care. We haven't designed a healthcare delivery system for adults that encourages anybody to deliver preventive medicine, ask for it, or to engage in it. It is a real problem. Maybe cancer will be the model or driver for helping us solve this issue. It is something we have to be thinking about all the time.

The final challenge to investment is the competition for funds. I have said earlier that we compete for much of the dollars and resources coming to the NCI, monies that are rarely distributed evenly across the cancer control continuum. We always have to be cognizant of that, and reflect on what the best mix of those dollars is, and what is the most equitable.

Despite these challenges to survivorship research, I am very excited, and feel it is wonderful to be here at this point in time. I think as Patti said we are at a critical juncture. We have tremendous momentum that is building. We have cancer survivors in leadership positions (e.g., NCI, ASCO), which is incredibly empowering. We have this new report on the street that we can build on with an evidence base. And, we have now invested, particularly at the Cancer Institute, in a variety of platforms to pursue survivorship research. These data resources include our clinical trials groups to our cohort and epidemiologic studies that are looking at big populations to see who gets cancer. Within these latter studies, we now have growing numbers of cancer cases that can be used to ask questions such as "What were they like before they developed cancer?" "What can we tell about them on the other side in terms of their survivorship?" "Is there information buried in those studies that we can leverage?"

Various administrative, linked data sources are all well described in the IOM report: SEER-Medicare linkages; the Cancer Research Network; the CanCORs database; and the practice-based research networks we heard about. There are also descriptive population-based data sets from the National Center for Health Statistics, including the National Health Interview Survey and the Behavioral Risk Factor Surveillance System, which you heard John Ayanian talk about earlier. Again, all of these resources allow us to compare our cancer survivors with non-cancer populations, and examine the relative burden of having a diagnosis of cancer. We can use this information to, over time, monitor these burdens, and determine whether we are making progress in reducing cancers' cost.

The ongoing samples of survivors that the American Cancer Society is supporting and various registries abroad that we have heard about represent additional outside sources of information. In summary, we have a rich and broad array of data resources that we are poised to extend and operationalize to address survivorship issues, and to me that represents an incredible opportunity.

I want to end with what I think are several key targets for investment, and I speak on behalf of our office. We talk regularly about these issues, and this list reflects our collective experience (Box 5-5). I want to emphasize two issues in the area of essentially fundamental research.

Understanding the role of, and impact of, survivorship on caregivers is a fundamental research area in need of pursuit. For the most part, these individuals are family members. As more care is being pushed out into the

BOX 5-5
Future Targets for Investment

- Two key research areas:
  (1) Exploration of the basic and biomedical aspects of survivorship
  (2) Understanding the role of and impact on caregivers
- Partnerships (NCI-wide; NIH-wide; other cancer agencies and foundations)
- Delivery systems for survivorship research (e.g., Cancer Information Service, internet, personal digital assistants (PDAs), Community Clinical Oncology Programs (CCOPS), Cancer Centers) and care (e.g., evidence-based, cost-effective, efficient, and equitable models)
- Communication (researchers, healthcare providers, survivors/families, payers, policymakers)
- Identification of evaluation metrics to assess our "success" in improving the health and care of cancer survivors and their families

community, and as more people experience cancer as a chronic illness, caregivers and family members are going to be a key element in sustaining, supporting, providing interventions to, and altering outcomes for survivors. As a consequence they need to be a population that is targeted for research.

Surprisingly, when we look at our nationwide topical portfolio analysis, what is fundamentally lacking in survivorship-focused research are basic science studies. We do not see gene-environment studies that address survivorship questions. We do not see mechanistic studies of what it is about specific drugs and treatment exposures that, whether due to their biological, biochemical, or molecular effects cause toxicities long-term. We do not have an established base of bench science in survivorship research. It is simply not someplace that our scientific community has gone. I think hidden in this neglected arena may be some provocative and rewarding frontiers to explore.

Clearly, nobody is going to achieve the many mandates outlined alone. Fortunately, the IOM and ASCO have brought all the partners together at this meeting. This effort has to be all about partnerships. By way of illustration, we at the NCI need to find a way to integrate what we do not just across the NCI, but also across the other institutes: Aging, Mental Health, Nursing, Neuromuscular Diseases, and Heart, Lung, and Blood. We need to draw upon that collective scientific expertise and bring it into the cancer arena. We also need to interface with our advocacy partners, our voice out there, and our champions if you like, in promoting what we do. We need to

partner with diverse entities so that we can coordinate our efforts, not be duplicative, and use precious resources in the best way possible.

A third target for future investment is exploring delivery systems with the potential to bolster the larger research agenda. Can we use the Cancer Information Service, personal digital assistants, the Internet, and the other new technologies that are available to deliver interventions? Can we use the Community Clinical Oncology Programs to get interventions out there? Are cancer centers using them as delivery platforms for promoting cancer survivorship research or care? Does the research say how survivorship care should be delivered? What is the best way to do it? What are the costs and what are the associated benefits? What are the various models that are going to be most effective, efficient, and equitable that we can use to deliver care that will improve survivors' outcomes?

A fourth area for investment is in communication. It will do us no good at all if we do not communicate what we know or have learned. Fundamentally, what the survivorship care plan is all about is communicating what science has taught us. We have to be able to talk to one another, not just the researchers, but also the clinician, patient, consumer, and payer communities. Communication is going to be very key, and we live in a big communication world. There is more and more information being pushed out there. Helping people access it and understand it is increasingly important. It will be vital to know what they need, when they need it, and how they need it.

Finally, as mentioned earlier, while we are at this very momentous point, we need to think about what our benchmarks for success are going to be. Is it to have 15 million survivors? I do not think so, because knowing that we have 15 million survivors is really not very helpful. We need to know what it is that we are trying to improve. We need to know about the quality of life of those survivors and the quality of their care. We need to know whether we are reducing the cancer burden, or whether this cost is simply escalating. We need to know if we can prevent some of the long-term effects. Importantly, we need benchmarks now before we go too far down the road. I know that even if we set them up, we will later think, "Gee, why didn't I ask that?" as all of us in research have done. However, we have to be thoughtful now, because we have an obligation to mark our progress, and not just programmatically. When you go back down to Congress, or to the cancer institute director for that matter, you need to say where you expect to go and what you expect to achieve with the public's investment. We need to be able to say that we are going in the right direction, and that we are doing what it is that we set out to do. I think that is going to require us to have a thoughtful dialogue, and to look at the many levels of metrics that we may need in place to be able to do that. Thank you.

Dr. Ganz: Next we will hear from Frank Johnson, a surgeon who was a member of our IOM panel from St. Louis University.

Frank Johnson, St. Louis University

Thank you. Our committee has endorsed a previous recommendation of the Institute of Medicine dealing with health insurance. A rational national universal-access medical system that is affordable, accessible, and acceptable to meet society's needs would benefit cancer survivors probably more than anything else that has been discussed today, but I do not want to dwell on this. Quite a bit can be accomplished with the current system that we have, and also could be accomplished within a rational national health-care system that I just mentioned. I am a surgical oncologist, and cancer patient follow-up has been one of my academic interests over the last several years. I am particularly interested in the follow-up of patients that have been treated with primary curative intent surgery, plus or minus chemotherapy and radiation therapy.

Research from this work has shown that existing guidelines, whether published in books or journals, from prestigious societies and institutions, are largely based on the opinions of experts. They vary widely. My colleagues and I have estimated that the cost difference among the recommendations of highly acclaimed institutions and organizations varies, usually by a factor of five, sometimes up to 100 fold. We have also discovered wide variability among experienced, highly credentialed clinicians who are caring for patients with particular cancers in terms of the intensity of follow-up that they provide. Such patient groups include survivors of colon cancer, lung cancer, prostate cancer, melanoma, sarcoma, and rectal cancer. In all of these instances we have found a great deal of variation, which we think is probably unwarranted. This conclusion relates to recommendation 10 of the report: "Answers to the following basic questions about survivorship care are needed: How frequently should patients be evaluated following their primary cancer therapy? What tests should be included in the follow-up regimen?"

How do we get rid of the apparently unwarranted variability in the clinical practice guidelines that have been put forward in the literature? How do we settle on guidelines? How can we get evidence-based guidelines? Low-quality evidence such as expert opinion, retrospective data, and evidence from registries has not proved very persuasive, because we do have variability in recommendations from the leaders of this discipline. We know that randomized clinical trials are feasible. They do change practice, and as evidence for this I cite the two Italian trials of breast cancer patient follow-up that were published over a decade ago (GIVIO, 1994). Over 1 million randomized clinical trials have been published in the literature since the

first one in the late 1940s. Nonetheless, the Institute of Medicine has estimated that only about 4 percent of the medical decisions we make as clinicians are based on high-quality evidence (IOM, 1992). Therefore, we have to select the targets for randomized clinical trials very carefully. We know that prevalent clinical problems can be effectively studied with randomized clinical trials. Things like treatment of hypertension, whether patients with coronary artery disease should be treated with surgery or angioplasty, and tight or routine glycemic control of diabetics have been addressed in clinical trials. I think we all would agree that proper cancer patient follow-up should be subject to randomized clinical trials of the same sort that has proved very effective in defining the standards of care in our country and, for that matter, around the world.

Using reasonable assumptions, I estimate that about 1 million people enter cancer patient follow-up each year in the United States after primary curative intent treatment. Almost all of the trials that have been conducted so far dealing with cancer patient follow-up after initial treatment have been underpowered. Many trials have been based on very few patients and purport to define a standard of care, but they are not persuasive. Large randomized trials, however, are difficult to carry out, as they take a lot of cooperation and institutional support, several years to accrue enough patients to meet the target goals, and several more years to get results. Other speakers have addressed the potential drawbacks of these trials, namely the moving target, different strategies, and improvement in treatment.

The goals of follow-up include, first, detection of the recurrence of the index cancer. This is what patients come to your office or my office and ask about. Has my cancer come back? I think this is job number one. Detection of second cancers is, in my opinion, a very important goal as well, because often these are relatively easy to treat and they tend not to be as advanced as the earlier primary. Quality-of-life issues have been discussed at some length today. Detection of long-term effects of therapy is another very laudable goal. These can be, and have been, inserted into randomized controlled trials.

As I said, there have been a few adequately powered randomized clinical trials of cancer patient follow-up. The two breast cancer trials were done by Italian researchers. The Italians have also almost reached the target for completion of a colorectal cancer patient follow-up trial, comparing intensive versus minimalist follow-up strategies. There is a British trial in the works on sarcoma patient follow-up, comparing minimalist versus aggressive follow-up. There is another British trial of colorectal cancer patient follow-up, which amazingly includes a no follow-up arm. But where are the American trials? There are no American trials of adequate power that I am aware of in any of the solid organ tumors dealing with the best way to follow such patients. The committee feels that the United States should

explicitly set out to design such trials and carry them out. I am glad to know that some of the decision-makers that can authorize such trials are present in the audience.

As Floyd Bloom said in his presidential address to the American Association for the Advancement of Science, there are a huge number of potential variables: a large number of described medical conditions, a large number of drugs and dosages, many guidelines, and millions of rules. We already know that there are hundreds of different kinds of cancers, and many hundreds of potential follow-up tests to be used. We can only focus on the most important problems to deal with in randomized clinical trials. We know that the anecdotal and other low-quality evidence has not been persuasive. We know that the actual practice of expert clinicians varies widely. The variation in actual practice does not seem to be influenced greatly by the age of the doctor, the initial stage of the tumor, the geographic location of the doctor, or by the managed care organization penetration rate in the area where he or she practices. These are the conclusions of some of the research that we have done, and I do not have time to show you the data on which those conclusions are based. We have concluded that the major reason for the variability in actual practice and promulgated in guidelines is the lack of high-quality evidence on which doctors, patients, and insurance companies can base their decisions. This is not news to this audience. This variability, however, results undoubtedly in overuse, underuse, and misuse of medical care resources, and probably costs some patients their lives.

A research finding from Phelps and Parente (1990) indicated that there is some potential that the investment of money in trials to determine the best form of follow-up for patients after potentially curative treatment may actually save money in the long run. It could be by one or two orders of magnitude. Such research has been felt to be beneficial.

What I hope to do today is to help the decision-makers allow us to do what I think everybody in this room would like to do. That is to base the care of patients that have had curative treatment for various sorts of cancers on high-quality evidence. Making these investments in research is working towards a highly attainable and very obvious goal. It involves billions of dollars, because cancer patient follow-up testing, counseling, and administration of corrective actions is very expensive. The benefits of figuring out how best to carry out post-treatment follow-up include better outcomes for our patients, and possibly some cost savings. Thank you very much for your attention.

Dr. Ganz: I think we have about five or ten minutes for questions.

Dr. Eva Grunfeld, CancerCare Nova Scotia: I wanted to thank everybody for their presentations. Julia, you were so exciting, you made me want to

rush out and write that protocol right away. I am on the Research Advisory Committee for the Canadian Breast Cancer Research Alliance, and we have just launched our first ever RFA on cancer survivorship. It has been an uphill battle keeping it on the table as we vied for funds with the basic scientists.

Frank, I would like to comment on your issue about the payback on clinical trials, on the cost of doing the clinical trials, and whether we actually see a cost savings from the results of those clinical trials. We did a modeling study in which we modeled the cost of doing a randomized controlled trial on intensive versus minimalist follow-up for colorectal cancer, and assessed how long it would be before we would get the payback on that clinical trial. We estimated it would be about four years if the results are implemented.

As a slight outsider, I do want to raise one point, because I was a little perplexed about the report, and I wonder if you can give me some insight on it. The report I think is excellent. I was struck, however, that in the models of follow-up care which you identify worthy of further investigation you identified the shared care model, a nurse-led model, and the survivorship clinic models. I am struck by the fact that the primary care model, which has the strongest, largest evidentiary base to it, was not one that was recommended for further testing. I think there is a slight disconnect between the evidence you are presenting in the report and the conclusions that you are coming to. I would be interested in your views on that.

Dr. Ganz: I am not sure if others want to respond to this, but I think your work was in fact cited in the report. One of our concerns is that in the United States many people do not have primary care or they do not turn to their primary care physician as the first source of care in the way they do in the U.K. or in Canada. The shared care model seemed to be more appropriate in our setting.

Dr. Grunfeld: I appreciate that there is a different system. What strikes me is that you are suggesting three models for testing. You are not suggesting three models for implementation. Given that this report recommends a research agenda, it would be consistent with the evidence to include researching a primary care model.

One point, indeed, the two countries in which I tested both of those models have the same response. It is inappropriate. The family care physician cannot do it. They came to it equally cynical. That is an outsider's view on the report that you might be interested in hearing.

Dr. Ganz: I think part of the situation is we have people in this country who never go to see their primary care physician. I have patients who are in

health maintenance organizations who have a primary care physician that they have never seen. They are assigned only in name to that physician. That is often the norm here, rather than a relationship that has been established. We would not even have a primary care physician (PCP) to test the model with. You at least had PCPs that people had identified as caregivers.

Dr. Rowland: Hopefully, we are going to have some data from the SEER registry soon looking at where people are getting their follow-up care for the major cancers in this country. At present, we do not even know where the bulk of our older survivors actually are getting their care. We suspect it is largely with primary care providers. While survivors may come in for specialty care when diagnosed, they go back out into the community after treatment ends. You raise an interesting empirical question for which I hope we can get answers. Also, I cannot wait to see your research. The hook is to get the basic sciences interested in survivorship, and then we will get the money.

Dr. Jerome Yates, American Cancer Society: Julia, I would take the opposite tack. Unless you get funding with RFAs in very targeted, well-defined subsets of populations, I think it will be extremely difficult to get this kind of research funded and to compete with the basic sciences. All you have to do is watch what is going on at the NCI now. At the ACS, 70 to 80 percent of the money goes to basic bench laboratory research. I am hoping to twist that around a little bit in the future, but this is a problem.

One of the biggest problems with research in this area is you are dealing with low event rates. We see only the serious complications in relatively early follow-up. We also have large populations that are really heterogeneous. We need to think about being able to shift some of the administrative data sets from CMS and some of the large insurers to collect the information that will tell us about exposures. Maybe old people who have had a fair amount of platinum lose enough nephrons that they get into renal trouble when they are 75, when they would not have if they had not been exposed to these drugs. We do not have that kind of information, and I think that that is a real problem. It is something that we could try to address and see if we could use these large administrative data sets to help us sort out some of these problems.

Lastly, I think we do know some of the things that cause problems. Clearly adriamycin affects heart disease in combination with atherosclerosis and some of the neurotoxic agent's effects in older people may be worse than they are in younger people. We ought to take some of those things that we actually know can cause problems, subset those populations, and study them in terms of the follow-up, rather than studying the whole general

group of breast cancer patients, or colon cancer patients. We need to break it down if we want to get some payoff with a relatively modest investment.

Dr. Horning: In preparing for this session, and speaking with Lois Travis, I was reminded that earlier this year I got a note from our cooperative group saying that they wanted to discontinue follow-up in as many clinical trials as possible because our budgets are flat and expenses are going up. I was advised to check off the trials for which we could discontinue follow-up in five years. I do think we are missing opportunities to think about economies of scale in coordinating survivorship research with ongoing clinical trials intervention. I agree fully with that last statement that we should be selective about the clinical trials that we choose for follow-up. We should choose trials that are representative of the different questions that we want to ask, such as questions about underserved populations and questions about differences in age and exposure. We have clinical trials now that have very different interventions, and those would certainly be at the top of the list to highlight.

I think that we are missing opportunities to work together in thinking across the broad clinical trials efforts, and selecting the menu that can cross horizontally and vertically to catch most of these areas that we would like to study further.

Dr. Sheldon Greenfield, University of California Irvine: If we followed these notions of imaginatively focusing on a limited number of questions, it could lead to quality measures. We could pick out a half a dozen.

I wonder if an NCI goal for the next two or three years might be to find data, not necessarily from trials, and come up with a half a dozen measures given the pressure that is put upon us by everybody. No institute would ordinarily take up that goal, but the pressure is mounting. If we wait for trials, we may not get there in time. Julia, maybe you could respond to that.

Dr. Rowland: Thanks, Shelly, a very thoughtful comment. The large shift that has occurred at the NCI is the growing commitment to dissemination. We are looking at what the quality indicators should be, and how we push the science out. I think the answer to it used to be that we were content just to be the generator of the evidence base, and then we let everybody else worry about how it is applied. I do not think that is true any more.

There are a number of ongoing projects, including collaborations with other entities, to look at some of the benchmarks. Molla Donaldson at NCI could generate a list of projects better than I can.

Maybe one of the reasons that I put that point at the end of my slides is in part because I am perennially frustrated when people ask me about the

numbers of survivors. Well, 10 million. So what? It just tells me who is alive after a diagnosis. It tells me nothing about the health and well being of that population, or where they are in the trajectory. Just as a simple marker I would love to be able to tell you more about who is in active treatment, who is really in this post-treatment survivorship period, who has progressive disease, what their health status is, and how they are different from peers who do not have a cancer history. I think those are very real questions, and a very appropriate task to ask NCI to take a lead on, but certainly not as the only stakeholder.

Dr. Winn: We really need a parsimonious set of measures moving ahead. The difficulty right now is what they should be. One of the next steps could be to think in terms of a framework of quality measures which would get at the parameters, the scope, the priorities, and the best practices out there. Eventually you can come to say, "Let's look at these 20, and then maybe we can get down to the 5 or 6 that are the ones to go forward."

Dr. Travis: I want to thank Julia for the nice explanation of transdisciplinary science versus interdisciplinary and multidisciplinary science. It is possible to include basic scientists in our research, because we have ongoing a large international study of survivors of Hodgkin's, breast cancer, or testicular cancer. We are looking at second cancer risk in these patients, and have the basic scientists helping us in this new field of molecular epidemiology. They are trying to figure out the markers of DNA repair and other markers that might determine who is at the highest risk of second cancers.

For people who are studying gene-environment interactions, this is a wonderful forum to do this type of research because it is one of the few situations where you have humans deliberately exposed to carefully measured amounts of carcinogens such as radiation and chemotherapy. You can look at the measured doses, compare them to the outcome, look at differences in various DNA repair genes and other markers, and then determine who is at the highest risk and how you predict that. It is possible to incorporate them, and I have several bench scientists involved in our new study.

Dr. Johnson: The American College of Surgeons Oncology Group represents a large group of surgeons. Surgeons, I will remind the audience, are responsible for most of the cures of cancer in this country, with or without chemotherapy and radiation therapy, to give those other disciplines their due. This group has the advantage over other groups of being able to easily obtain a piece of tumor tissue, as well as a sample of normal body tissue or fluid. Important information can be gotten from these carefully stored bits of tissue.

The American College of Surgeons Oncology Group has proposed trials of long-term follow-up in patients treated surgically with or without chemotherapy and radiation therapy, using the repository containing the original tumor tissue and a sample of non-tumor tissue. Those trials have been rejected by the Cancer Therapy Evaluation Program (CTEP) of NCI. I speak for the American College of Surgeons Oncology Group when I say this should change. There should be an acceptance of this group's strengths, and a willingness to fund follow-up trials using the available tissue to do the correlative studies that everybody agrees are so valuable.

Dr. Ganz: I am going to let Dr. Horning have the last word.

Dr. Horning: I wanted to support what Lois just said. My strong feeling is that the integration of the basic science is absolutely imperative to move this field forward. Among the biggest news in science in the last couple of weeks are the results of HapMap project.[1] People are debating about what this is going to mean in terms of the prediction of disease and possibly implications for prevention. There is a feeling that this is going to impact our understanding of how individuals handle different drugs. Cancer chemotherapeutic agents are going to be lead candidates for study.

The other point I want to make is that I do not think it is an either/or situation. It is not, and should not be, that we are competing for the same funding. This is a perfect time for team science. It is a perfect time for multiple principle investigators. I think we have to think about how we can work together and collaborate.

What we really talked about a lot today is the fact that we wish we had more evidence-based guidelines and measures for today's patients. We also know that there is a built in latency period for many of these side effects to play out over time. We critically need the biomarkers and surrogate markers to predict them as early as possible, so that intervention strategies can be employed.

Dr. Ganz: So, I think we are about ready to have the rest of the group join us. Thank you all.

[1]The International HapMap Project is a partnership of scientists and funding agencies from Canada, China, Japan, Nigeria, the U.K., and the United States to develop a public resource that will help researchers find genes associated with human disease and response to pharmaceuticals (www.hapmap.org, accessed December 28, 2005).

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Reports from Breakout Session

Dr. Greenfield: We are going to start with the reports from the breakout groups. I and the other moderators will briefly summarize what happened during their sessions.

IMPLEMENTING THE CANCER SURVIVORSHIP CARE PLAN AND COORDINATING CARE

Moderator: Sheldon Greenfield, University of California, Irvine

There were four speakers during our breakout session. Deborah Schrag talked about developing a strategy for putting the survivorship care plan together, favoring in her case that it be completed by the oncologist for other doctors, not necessarily for the patient, at least at first. She proposed key elements of treatment to be included. She emphasized the need to streamline the burden of documentation amongst patients, oncologists, and other care providers. There were some critical questions asked from the floor such as who is the plan actually written for? Is it for the doctors? Is it for the patients? Should it be in the language that primary care doctors can interpret? What are we going to do about legal issues? Such issues may be raised if something is proposed that other doctors disagree with, or if a patient does not get what is recommended and they go to court. Another issue relates to timing. Not everybody wants the care plan at the same time. And what happens if patients do not pay any attention. The provider gives them the plan, and they do not seek recommended care.

Peter Bach talked about the CMS Oncology Demonstration Project, and said that in this next year they will be asking oncologists to submit information on three things. One is explaining the primary purpose of the visit. Good luck on that. You can always make up something, so I guess it is not that hard. Second, whether they are following evidence-based practice guidelines. Good luck on that one too. And number three, clarifying the patient disease status according to specifications.

Phyllis Torda talked about the NCQA quality initiatives and noted that the survivorship care plan could be incorporated into several of their initiatives such as efforts to identify high risk patients and ASCO's Quality Oncology Practice Initiative. A question asked for all the panelists was, "Who is going to be responsible for implementing the plan?"

Finally, Doug Ulman discussed empowering the patient with information and education, providing electronic records, and coordinating the care infrastructure.

During this session, the role that nurses may be able to play in the delivery of the care plans was emphasized. And that was pretty much it for this session.

BUILDING BRIDGES BETWEEN ONCOLOGY AND PRIMARY CARE PROVIDERS

Moderator: Steven Wolff, Virginia Commonwealth University
Reported by: Regina Benjamin, Bayou La Batre Rural Health Clinic

Kevin Oeffinger began our session by giving us a nice overview of the rationale for the shared care model. Pat Legant then talked about clear communication, how important it was, and the fluidity of specialty versus primary care roles, and how responsibility goes back and forth from one provider to the other, and waxes and wanes over time. Importantly, the patient has to be part of that care team. Ann Partridge discussed the fragmented nature of the healthcare system. She pointed out that we need a clear, direct definition of who is going to do what, and in what setting. Dr Partridge also discussed some of the psychosocial concerns of cancer survivors. Then I talked about how important it is, as is highlighted in the IOM report, that awareness be raised of the needs of the cancer survivors.

Speaking as a primary care physician, it is often the case that cancer patients lose touch with me as their provider. I will diagnose a patient with cancer, for example, and send them to a surgeon, and the surgeon will take care of them. Then the surgeon calls the oncologist, and I am left out of the loop and lose the patient over time. It may be a year or two before I get that patient back unless the family calls and says, "You know what those surgeons want to do?" Primary care physicians need not get left out of that

loop in the early stages of cancer care. The cancer survivorship care plan as well as the clinical guidelines could really help primary care physicians treat their cancer patients a lot better. When available, they will be great tools.

During our discussion, members of the audience talked about case management and how the burden of the decision regarding management is often handled by the family. Family members may be put in that position, but this gatekeeper role may, or may not, be appropriate. Sometimes patient loyalty steps in. A patient may feel guilty for going to get another opinion, or going to another physician. And we need to keep these responses in mind when we are building any kind of model.

We also discussed communication issues and the need for both professional education and training and guidelines to improve knowledge of survivorship amongst physicians. Ultimately, we need relevant care available at the time people need it, and when they need it.

The shared care model was discussed and I would like to say that in family medicine particularly, and most of primary care, we have used that model for a long time, but we just haven't called it shared care. When I have a patient that has a heart attack, I send him to a cardiologist. He is not the cardiologist's patient, and I do not lose my patient. We both treat that patient. If the patient subsequently has chest pain or has other symptoms in a year, I send the patient back to the cardiologist. So, the shared care model exists, we just need to use it a lot more. And in the research arena, we really should be looking at the intersection of primary care and oncology care.

In summary, as oncologists and as primary care physicians we have to provide better care and support for our patients. Oncologists can not do it alone, and primary care physicians can not do it alone. And we owe it to our patients to improve communications and our care.

Dr. Greenfield: Thank you, Regina. And thank you again for leaving your busy practice to join us today. Dr. Ganz, will you discuss your first breakout session on testing models of survivorship care?

DEVELOPING AND TESTING MODELS OF SURVIVORSHIP CARE

Moderator: Patricia Ganz, University of California, Los Angeles

During our session, Steven Woolf discussed the shared care model, and Regina Benjamin did a very nice job covering that topic, so I will not spend more time on that. We had presentations from Linda Jacobs, who is the director of the Living Well After Cancer Program at the University of Pennsylvania Abramson Cancer Center. This program was established about five years ago so it is the oldest contemporary cancer survivor clinic. Several different strategies for incorporating survivorship care into patient

care were pilot tested at their cancer center. They have identified two models that seem to work best. One is a practice model where survivors are followed on a regular basis in their clinic. This approach has been used primarily with the adult survivors of childhood cancer who transition into their care from the children's hospital. This model of care is also used with their testicular cancer patients, who after two years of routine follow-up with their oncologist then come in for regular follow-up in the survivorship program. For other types of cancer, cancer center treating oncologists tend to want to continue to follow their patients, and the survivorship clinic staff have developed a team approach. Here survivorship clinic nurse practitioners and oncologists collect data and may see patients as they are being seen in their treating oncologists' practice, and are also available to see patients for a consultation, education, and information. The survivorship clinic has had to be flexible in terms of the environment in which they are working. These cancer center oncologists seem to be motivated to follow their patients in continuity. There was an interesting question about how much would it cost if I referred somebody, or if I wanted to be seen at the survivorship clinic. Linda had difficulty describing what that fee would be. Essentially, those visits are billed as if they were regular oncology visits for a new consultation, or for a follow-up visit for surveillance. The program is actively engaged in research.

Lisa Diller described the survivorship program at the Dana-Farber Cancer Institute, filling in for Craig Earle, who opened this clinic for adult survivors last February. They have a nurse practitioner-type model in terms of the delivery of care and have had to adapt to the environment of a comprehensive cancer center. They are focusing on clinical care, research and programs, and developing education and support programs for patients. They have also been able to identify subspecialists who are interested in survivorship in each of the disease-oriented disciplines. And as was the case at the University of Pennsylvania, this program has taken a flexible approach, adapting their practices depending on the targeted disease and the local practice patterns. Lisa did mention that there are survivors who call Dana-Farber who have not had any long-term follow-up, or may have relocated to the Boston area and want to be followed. Some of these individuals are being referred *de novo* into their survivorship clinic. Lisa mentioned that they initially had four patients the first month they were open, and last month had 75 visits. Their program is accelerating, and they are doing some process evaluations. They have a lot of philanthropic support, and this is part of the institutional strategic plan, so this obviously helped them in terms of getting their program going.

Eva Grunfeld gave us a very nice presentation describing several randomized trials that she has conducted over a series of years, both in the U.K. and in Canada, really looking at perceptions and needs of care as

expressed by survivors themselves, survivors of breast cancer, and also primary care physicians and specialists. She showed the nice statistic: that about 69 percent of the primary care physicians wanted to follow the survivors, and thought they could do it; and 70 percent of the oncology specialists thought that they could follow the breast cancer survivors. So, you can see that there is a lack of equipoise here.

She was able to randomize patients and did a number of trials looking at survivorship care. The most recent one in Canada randomized nearly 1,000 patients to either follow-up by specialists or primary care. Dr. Grunfeld showed that there was equivalency in terms of the outcomes, in terms of serious events, a very low event rate, 3.5 percent of individuals having severe complications at follow-up to about four or five years, and good quality of life in both groups. And this was facilitated by a one-page guideline that was given to the primary care physician, saying this is what needs to be done. Clearly, more research needs to be done in this area.

We did not have a lot of time, but we did have some discussion. There were a number of survivors in the audience who really felt patient-survivor involvement in these clinical programs would be very important in terms of informing them as to what would be best.

Dr. Greenfield: Thanks very much. I just want to add one note to that, which is to reiterate what Eva Grunfeld and others have said in the context of cancer and other diseases as well. One of the tricks between the primary care doctors and the subspecialists is to decide what is commoditizable. That is, what is surveillance that they can do perfectly well, versus things that need highly specialized knowledge with a lot of experience. People conflate the two, and assume on the one hand, that only I can do that, because I have all this knowledge. Well, that is where the issues lie, and that is why your clinical trials have been so successful. You are not asking the primary care doctor to be an oncologist. That is not what they are. Rodger, will you summarize the guidelines and education session?

DEVELOPING GUIDELINES, INSTITUTING QUALITY IMPROVEMENT, AND STRENGTHENING PROFESSIONAL EDUCATION PROGRAMS

Moderator: John Ayanian, Harvard Medical School
Reported by: Rodger Winn, National Quality Forum

Our session was oriented towards the areas of education, guidelines, and measures. We looked at programs that were getting off the ground as examples of directions that we might go. LuAnn Wilkerson from UCLA presented information on the survivorship education program that has been

initiated at the medical school. It is supported through an R25 grant from the NCI. In principle, the earlier you can educate students, the more you are likely to imprint it on their mind and have them carry it forward. So, rather than try to get the gray-haired oncologists to learn what survivorship is, they have gone to the medical school students who are about to graduate, and put survivorship in their curriculum in an effort to educate them on all of the aspects of survivorship. They are taking a very scientific approach to the development of this curriculum. They have 17 experts coming in to inform the content, and they have catalogued many survivorship issues. They are then trying to prioritize what they will teach. They are pulling in the full range and array of educational tools at this point, including videotaped interviews with patients that can then be rated, and tests that go along with it. I think that this is an approach that, if it spread, would really take survivorship and teach the next generation of professionals how this should go forward.

The next two presentations had to do with clinical practice guidelines. Melissa Hudson from St. Jude Children's Research Hospital talked about the long-term follow-up guidelines for pediatric cancer. Obviously, there are some advantages there: smaller numbers of patients who are somewhat homogeneous; a fair number of diseases; but most importantly, a commitment of the treating and research establishment to follow these patients long-term, and to look at what are the long-term effects.

What was interesting to me as a guideline person is that one of the things that is often overlooked, is that there is more to guidelines than presenting evidence for various clinical practices. There is a whole other dimension to guidelines. Which is that guidelines are there to guide clinical decision-making. Therefore, part of the guideline is to lay out what clinical decisions have to be made. I would call that the logic of the guideline. The pediatric community has based their guidelines on a risk-based and exposure-based conceptualization of how you arrive at decisions. In other words, "What was your tumor? How long have you had it? What drugs did you have?" And that is what informs the decisions that you make going forward. I think pediatric guidelines have a very real conceptual underpinning. Pediatricians run into a little problem, they admit, when there is this interface between pediatrics and adult tumors. And having developed the guidelines, the real issue now becomes one of implementation. The guidelines are out there and are available, but they really do not have good data yet as to how they are being used, how reliably they are being used, or how much they are being used. But certainly, they are the tools to move forward.

Charles Shapiro described an ASCO initiative he is heading, the creation of a set of survivorship guidelines for the adult population. It is a somewhat more difficult task than the pediatric guideline effort, given the greater heterogeneity of cancers. But the effort is to look at long-term

effects of treatment, and specifically how you manage long-term effects in the face of what may be co-morbidity and aging of the population. They will be concentrated on four areas: cardiac, endocrine, psychological, and cognitive, and then secondary and primary tumors. Joan McClure from the NCCN, one of the reactants, asked whether the guidelines would be generic and overarching, or instead be disease-specific. She also wondered how the ASCO survivorship guidelines would relate to the NCCN guidelines, which is the other companion set of guidelines in the country. And the answer is, "We do not know." Dr. Shapiro reported that the effort has just gotten underway, but that initially there will be a focus on these four overarching areas, and then as it develops, see how it goes. Perhaps for the first time, you actually had guideline people talking to each other at the beginning of the process on how to work going forward. So, that may be the real seed that is being planted here.

Finally, I presented where we stand vis-à-vis quality measures. My presentation was more conceptual than practical in that I just pointed out that we really do not have a good set of quality measures yet. We do not have the evidence to derive them, and we do not have the clinical practice guidelines to derive the aspects of quality we should be looking at. I talked about the pressure towards accountability and public reporting that is on us. And therefore, we do not have the luxury of saying let's wait for the clinical trials for 10 years, and then we will do our public reporting. I think we are going to have to sit back, think about parsimonious ways to get some measures out there, and move ahead.

Dr. Greenfield: Thanks very much. Ellen, could you tell us about your session?

MAKING BETTER USE OF PSYCHOSOCIAL AND COMMUNITY SUPPORT SERVICES; ADDRESSING EMPLOYMENT AND INSURANCE ISSUES

Moderator: Ellen Stovall, National Coalition for Cancer Survivors

Our group dealt with some very practical issues, how to make better use of psychosocial and community support services, and also to address issues of employment and insurance. We had an outstanding panel: Diane Blum from CancerCare; Bonnie Teschendorf from the American Cancer Society; Pam Short from Penn State; and Loria Pollack from the CDC.

Diane presented a wonderful overview of 61 years of CancerCare's delivery of direct services to people and communities, communities today being able to be both virtual and teleconferenced, and not only storefront delivery of services. And as she said, the organization has gradually evolved

to meet the needs of extended survivorship over many, many years. When CancerCare first came into existence their staff were focused on helping people who were dying of cancer, and now she is faced with "mission creep" and the new challenge of meeting the needs of 10 million survivors. Luckily in the room were people from The Wellness Community, the Lung Cancer Alliance, Cancer Planet, the Lance Armstrong Foundation, the NCCS, and many other groups who can sustain and support and amplify the wonderful work going on at places like CancerCare. As Diane pointed out, they are only one organization. But the real question is, "How are they and all of us going to meet the needs that this report has so eloquently stated?" Groups like CancerCare provide a lot of financial assistance to people in need: co-payments for drugs, neuropsychosocial assessments, and unreimbursed medical needs, as well as transportation. The American Cancer Society, the Leukemia and Lymphoma Society, have been doing this for years and years as well, but again, it is important to emphasize the need for direct support for people in communities where they live. And as Diane and I have often said over the years, we have lamented the fact that if we all waited for the evidence to show that support was worthwhile, literally hundreds of thousands of people would not have benefited from these wonderful services that clearly help people.

In reaction to Diane's comments, Mitch Golant from The Wellness Community, pointed out that for all of us doing this very important work in these support programs, there is an opportunity for collaborative research that would take all these wonderful cohorts of people that have come to these organizations, and begin to use science to better understand how to meet the needs of people.

This was a nice lead in for Bonnie Teschendorf's presentation in which she illustrated how the ACS was really strategically looking at this as an issue within the society, particularly with regard to three recommendations in the report. How are we going to translate all of this into real practice? How are we going to be able to anticipate the needs of survivors? And these are the questions that the ACS is looking to with their call center open 24 hours, 7 days a week, being a listening post to what is going on out there in the community, and what the stories are that people are telling them. They are trying to identify new delivery methods to meet the needs of these individuals. The ACS will use science to drive the delivery of services of cancer survivors, including she said, detailing physicians' offices. Similar to what pharmaceutical company representatives do, visits will be made to doctors' offices in a very hands-on way, to see exactly what the needs are there.

Loria Pollack from the CDC very nicely showed us what state cancer control plans look like. These plans exist in over 40 states, 2 tribes, and 2 territories, but not all of them are consistent in the way in which they

address survivorship issues. Most of them recognize the need for it. The CDC plans to hold a large conference in 2006 for those involved in these plans, and survivorship will be one of their points of focus. This is an example of how state cancer control programs and survivorship groups can work together to maximize the opportunities in this area.

Pam Short, an expert on employment and insurance issues who was on the IOM committee, pointed out in her presentation that the IOM report supported a good news/bad news scenario for people with cancer. The good news is you are alive and you are well and you are living, but you may not be living as well as you did before your cancer, particularly when it comes to your employability and your insurability. Most survivors continue to work, but their workplace accommodations do not always address the disabilities that they have and that may affect them at work. A job, for many people, is more than just a paycheck. It can be an important part of one's personal identity and a place where survivors can socially integrate back into a life that they once had. It is unclear whether survivors who continue to work following their cancer treatment are working because they want to work, or alternatively, that they have no choice but to work because they need employer-based health insurance. Without employment, many individuals find themselves underinsured to meet their needs as cancer survivors. I can tell you that employers are looking at these issues, and experience rating people in their self-insured plans, which is quite disturbing to those of us who do have cancer as part of our health history. Pam, as an economist, also pointed out that all cancer survivors live with economic risk. She reminded us of that in very subtle but important ways, for example, the risk is not just with health insurance, cancer also affects the ability to obtain life insurance. These products are not as accessible, available, and affordable to all of us as we would like. And that is a very important note to end on and brings us back to the message that Dr. Mullan started us with this morning, the need for universal health insurance coverage. Pam reminded us that universal coverage is not about them out there, it is about all of us. And I extrapolated that to mean that a shared care model is needed for a survivorship care plan, a shared model for assuring that all people in this country have equity and access to affordable cancer survivorship care.

Dr. Greenfield: Thank you, Ellen. Dr. Ganz, could you next tell us about your session on research?

INVESTING IN SURVIVORSHIP RESEARCH

Moderator: Patricia Ganz, University of California, Los Angeles

Our group heard from Lois Travis, who provided us with a very informative presentation illustrating the fact that survivors of cancer treatment have a very high risk of second malignant neoplasms. Perhaps 1 of every 6 new cancers are from people who have been previously treated with chemotherapy or radiation. It is therefore very important that we view this group as high risk. She called for much more collaborative research with basic scientists, looking at the genetics of risk, so we could find out who is predisposed for second cancer. She called for a national infrastructure to support the conduct of this type of research, which would include storage of specimens and characterization of cohorts, and specific guidelines for follow-up.

Sandra Horning talked to us about ASCO's activities. I think we heard about many of these in her introductory remarks. There are broad areas of work that ASCO is working on, including research methods, policy, development of guidelines, and communications, with its web site peoplelivingwithcancer.org, as an example. It is important as a resource. Another ASCO survivorship activity pertains to the scientific education at the annual meeting, which again, hopefully will help to educate oncologists about the shared model of care. We hope to have a session on this model at the 2006 Spring meeting.

Julia Rowland from the Office of Cancer Survivorship talked to us about the many dilemmas associated with trying to find survivors and follow them to evaluate their very long-term effects, those experienced more than five years after diagnosis. Most of the studies that have been done, have been done in the shorter-term. She also discussed the need for tools to actually measure survivorship outcomes, and also the need for transdisciplinary efforts. There were some comments on the panel from Dr. Horning and others that maybe if we can get colleagues in the basic sciences involved in this transdisciplinary effort, that the field will be seen as high profile, high value, and will achieve a number of our goals. Two of the research areas that Dr. Rowland thought were very important from her office were the role of basic and biomedical aspects of survivorship problems or challenges. There is a real paucity of research in this area. Likewise, the impact of cancer and survivorship on family members and caregivers is distinctly understudied. Also discussed, was the idea of trying to build survivorship relevant metrics and benchmarks into our studies as we go forward, linking into some of the topics such as guidelines and quality measures that Rodger Winn talked about. I think if we are going to make progress in these areas, we need to measure it, and that was eloquently discussed.

Finally, Frank Johnson quite persuasively discussed the need for better evidence in terms of long-term follow-up. We now have a very limited data set to direct clinicians in terms of what follow-up strategies they should use. Randomized trials are needed, and these may turn out to be very cost saving if we found out that we did not need to do as much testing and evaluation. His call to action is that we need support for these kind of trials.

Jerry Yates from the ACS made an interesting and important point that with the low event rates in Eva Grunfeld's trial (3.5 percent of women with breast cancer had any kind of serious event in their prospective follow-up) it is very, very hard, even in a very reasonably large randomized trial, to see anything meaningful. He proposed as potentially useful using administrative databases to obtain exposure information associated with treatment, and then look at outcomes across large populations. Another idea is to conduct focused studies on groups with high-risk exposures.

Sandra Horning, again made a very important plea for the value of linking these kinds of research studies to clinical trial populations, where again, we know exactly what the treatment exposures are, and then looking at them long-term, particularly if we could have biological specimens to look at risk and genetic DNA repair of genes, and so forth in terms of subgroups of individuals who may be at risk for late effects.

And again, these are all issues I think that we feel passionately about. The real challenge for all of us is finding the resources, perhaps again, collaborative work, trying to work together, dealing with existing cohorts, existing opportunities, and finding ways to leverage them. Thank you.

Dr. Greenfield: Thank you to all of our moderators, and thank you all. The meeting is adjourned.

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Appendix A

Symposium Agenda

AN AMERICAN SOCIETY OF CLINICAL ONCOLOGY AND INSTITUTE OF MEDICINE SYMPOSIUM ON CANCER SURVIVORSHIP

(with additional support from the National Coalition for Cancer Survivorship)

DATE & TIME:	**November 8, 2005, 8:30 am to 4:30 pm**	
LOCATION:	Washington DC, National Academy of Sciences, 2101 Constitution Avenue, NW (Entrance at 2100 C Street NW)	
AGENDA:		
8:30 to 9:00	**BREAKFAST**	
9:00 to 9:15 *Lecture Room*	**INTRODUCTIONS**	Sandra Horning, *ASCO* Fitzhugh Mullan, *IOM*
9:15 to 11:15 *Lecture Room*	**PLENARY SESSION** **IOM Survivorship Video Presentations**	
	• Meeting the needs of cancer survivors recommendations from the IOM	Ellen Stovall, *National Coalition for Cancer Survivorship (NCCS)*
	• Implementing the cancer survivorship care plan and coordinating care	Patricia Ganz, *UCLA*
	• Developing guidelines, instituting quality improvement, and strengthening professional education programs	Rodger Winn, *National Quality Forum*
	• Addressing research gaps	John Ayanian, *Harvard Medical School*
	Discussion	Sheldon Greenfield, *UC-Irvine (Moderator)*

11:15 to 11:30	**BREAK**	
11:30 to 12:30	**BREAKOUT SESSION I**	Moderators:
Lecture Room	1. Implementing the cancer survivorship care plan and coordinating care	Sheldon Greenfield, *UC-Irvine*
Members Room	2. Building bridges between oncology and primary care providers	Steven Woolf, *Virginia Commonwealth University*
12:30 to 1:30	**LUNCH (Reflections on morning sessions, Fitzhugh Mullan)**	
Great Hall		
1:30 to 2:30	**BREAKOUT SESSION II**	
Lecture Room	1. Developing and testing models of survivorship care	Patricia Ganz, *UCLA*
Members Room	2. Developing guidelines, instituting quality improvement, and strengthening professional education programs	John Ayanian, *Harvard Medical School*
2:40 to 3:40	**BREAKOUT SESSION III**	
Members Room	1. Making better use of psychosocial and community support services; addressing employment and insurance issues	Ellen Stovall, *NCCS*
Lecture Room	2. Investing in survivorship research	Patricia Ganz, *UCLA*
3:45 to 4:30	**REPORTS FROM BREAKOUT SESSIONS**	Session Moderators

BREAKOUT SESSION I

Implementing the cancer survivorship care plan and coordinating care LECTURE ROOM	**Building bridges between oncology and primary care providers MEMBERS ROOM**
Moderator: Sheldon Greenfield, *UC-Irvine*	Moderator: Steven Woolf, *Virginia Commonwealth University*
Speakers:	Speakers:
Deborah Schrag, *Memorial Sloan-Kettering Cancer Center*	Kevin Oeffinger, *Memorial Sloan-Kettering Cancer Center*
Peter Bach, *Centers for Medicare & Medicaid Services*	Regina Benjamin, *Bayou La Batre Rural Health Clinic*
Phyllis Torda, *National Committee for Quality Assurance*	Pat Legant, *community oncologist*
Doug Ulman, *Lance Armstrong Foundation*	Ann Partridge, *Dana-Farber Cancer Institute*

Reactants:
Carolyn Runowicz, *University of Connecticut Cancer Center*
Linda Jacobs, *University of Pennsylvania*

Reactants:
Molla Donaldson, *National Cancer Institute*
William Lawrence, *Agency for Healthcare Research and Quality (AHRQ)*

BREAKOUT SESSION II

Developing and testing models of survivorship care
LECTURE ROOM

Moderator: Patricia Ganz, *UCLA*
Speakers:
Steven Woolf, *Virginia Commonwealth University*
Linda Jacobs, *University of Pennsylvania*
Lisa Diller, *Dana-Farber Cancer Institute*
Eva Grunfeld, *CancerCare Nova Scotia*

Reactants:
Susan Leigh, *cancer survivorship consultant*
Pat Legant, *community oncologist*
Peter Bach, *Centers for Medicare & Medicaid Services*
Mary McCabe, *Memorial Sloan-Kettering Cancer Center*
William Lawrence, *AHRQ*

Developing guidelines, instituting quality improvement, and strengthening professional education programs
MEMBERS ROOM

Moderator: John Ayanian, *Harvard Medical School*
Speakers:
Rodger Winn, *National Quality Forum*
Melissa Hudson, *St. Jude Children's Research Hospital*
Charles Shapiro, *Arthur James Cancer Hospital*
LuAnn Wilkerson, *UCLA*

Reactants:
Sheldon Greenfield, *UC-Irvine*
Phyllis Torda, *National Committee for Quality Assurance*
Joan McClure, *National Comprehensive Cancer Network*
Beth Kosiak, *AHRQ*

BREAKOUT SESSION III

Making better use of psychosocial and community support services; addressing employment and insurance issues
LECTURE ROOM

Moderator: Ellen Stovall, *NCCS*
Speakers:
Diane Blum, *CancerCare*
Bonnie Teschendorf, *American Cancer Society*
Loria Pollack, *CDC*
Pam Farley Short, *Penn State University*

Reactants:
Karen Pollitz, *Georgetown University*
Mitch Golant, *The Wellness Community*
Doug Ulman, *Lance Armstrong Foundation*

Investing in survivorship research
MEMBERS ROOM

Moderator: Patricia Ganz, *UCLA*
Speakers:
Lois Travis, *National Cancer Institute*
Sandra Horning, *Stanford University*
Julia Rowland, *National Cancer Institute*
Frank Johnson, *Saint Louis University*

Reactants:
Arnold Potosky, *National Cancer Institute*
Molla Donaldson, *National Cancer Institute*
Jerome Yates, *American Cancer Society*

Appendix B

American Society of Clinical Oncology Press Release

FOR IMMEDIATE RELEASE
November 7, 2005

Contact: Jenny Heumann

Jeannine Salamone
703-299-1014

SYMPOSIUM ON CANCER SURVIVORSHIP TO FOCUS ON LONG-TERM CARE PLANS FOR SURVIVORS AFTER TREATMENT ENDS

—ASCO, partnering with government and nonprofit groups, working to implement findings of new Institute of Medicine cancer survivorship report—

Washington, D.C. – The American Society of Clinical Oncology (ASCO) is co-sponsoring a symposium on November 8 that will chart a course for care for cancer survivors and fill gaps that have existed in patients' long-term care.

The day-long "Symposium on Cancer Survivorship," co-hosted by ASCO and the Institute of Medicine (IOM), with support from the National Coalition for Cancer Survivorship (NCCS), will focus on implementing the 10 recommendations from the Institute of Medicine's (IOM) new survivorship report, *From Cancer Patient to Cancer Survivor: Lost in Transition*, being released at a press conference today. The symposium will highlight strategies for implementing a central recommendation from the IOM report: the "Cancer Survivorship Care Plan."

The Cancer Survivorship Care Plan is a tool that would summarize critical information needed for the survivor's long-term care. The Plan would be

written by the physician that coordinated the patient's treatment and would provide specific information on the timing and content of follow-up care, recommendations for prevention practices, and information about available psychosocial services, employment counseling, and access to health insurance.

"The transition from active treatment to survivorship care is critical to the long-term health and well being of people with cancer," said Sandra J. Horning, MD, ASCO President and Co-Chair of ASCO's Survivorship Task Force. "With more than 10 million cancer survivors living in the United States today, it is time to focus on all of the issues affecting these patients, both medical and psychosocial, so we can ensure they are getting the specialized attention they need."

"One of the most important recommendations from the report is the need to develop a 'Cancer Survivorship Care Plan' for all survivors after their term of active treatment ends," said Patricia A. Ganz, MD, co-chair of ASCO's Survivorship Task Force and a member of the IOM committee that wrote the report. "Such a plan would allow oncology professionals and patients to work together to develop an individual care plan that summarizes the disease and treatment information patients need ensure high-quality, long-term medical care."

Other discussions at the symposium will address building bridges between oncology and primary care providers; developing and testing models of survivorship care; guideline development and quality improvement; professional education and training; making better use of psychosocial and community support services and addressing employment and insurance issues; and clinical and health services research issues.

"Patient care does not end when the cancer treatment ends," said NCCS President and two-time cancer survivor Ellen Stovall, who also is co-chair of the IOM committee that drafted the report. "Together, we can work to implement actively these recommendations from IOM, and to break down the barriers to ensuring quality, long-term care for cancer survivors."

More than 100 stakeholders in the cancer community, including survivors, advocates, healthcare providers, government officials, insurers and payers, and researchers, will participate in the symposium discussion.

ASCO Survivorship Activities Related to IOM Recommendations
In addition to co-hosting the symposium, ASCO is undertaking a range of other activities to move the IOM recommendations forward, some of which are highlighted below. These are conducted under the direction of ASCO's Survivorship Task Force, formed in December 2004 and co-chaired by Drs. Horning and Ganz. These efforts include:

- *Expert Panel:* ASCO's newly convened Survivorship Expert Panel is developing new evidence-based guidelines on the long-term medical care of adult cancer survivors. The overall purpose of the guideline is to provide health professionals with the knowledge and expertise to

decrease morbidity and to improve quality of life for adult survivors of cancer. The Panel will draft guidelines in the following areas: cardiovascular disease; hormone replacement therapy; osteoporosis; sexual dysfunction; second malignancies; neurocognitive dysfunction; psychosocial disease.

- *Cancer Quality Alliance:* In response to IOM's call for public/private partnerships to monitor and improve the care that survivors receive, ASCO and NCCS are co-chairing the new Cancer Quality Alliance, a forum for diverse stakeholders in the cancer community who will work to improve the quality of the cancer care delivery system. Through this partnership, ASCO, NCCS, and the other members will establish integrated treatment systems to ensure all people with cancer receive the best care possible.

- *New Survivorship Track at ASCO Annual Meeting:* ASCO also will provide educational opportunities to healthcare providers on survivorship through sessions in a new "Patient and Survivor Care" track at its Annual Meeting in June 2006. One session in this expanded track will focus on how to write a "Survivorship Prescription," which will highlight the IOM recommendations for outlining a follow-up care plan. Topics addressed in other sessions will include developing cancer survivorship programs; minimizing long-term consequences of breast cancer therapy; nutrition issues for survivors, and survivorship issues in genitourinary malignancies, among other sessions.

The "Symposium on Cancer Survivorship" is being held Tuesday, November 8, from 8:30 a.m. to 4:30 p.m. at the National Academy of Sciences Building, 2101 Constitution Avenue, NW, Washington, D.C. reporters are invited to attend.

Reporters are also invited to attend a press briefing on Monday, November 7, at 9:30 a.m. in the Holman Lounge of the National Press Club, 529 14th Street NW, Washington, DC, where IOM leaders will discuss the report.

The report is embargoed until 9:30 a.m. EST on November 7. Advanced copies of the IOM report are available to reporters only beginning at 9:00 a.m. EST on Thursday, November 3. Obtain copies of the report by contacting Christine Stencel at 202-334-2138 or by e-mail at news@nas.edu; or Erika Borodinsky at 202-955-6222 or by e-mail at eborodinsky@spectrumscience.com.

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*The **American Society of Clinical Oncology** (ASCO) is the world's leading professional organization representing physicians of all oncology subspecialties who care for people with cancer. ASCO's more than 20,000 members from the U.S. and abroad set the standard for patient care worldwide and lead the fight for more effective cancer treatments, increased funding for clinical and*

translational research, and, ultimately, cures for the many different types of cancer that strike an estimated 10 million people worldwide each year. ASCO publishes the Journal of Clinical Oncology (JCO), the preeminent, peer-reviewed, medical journal on clinical cancer research, and produces People Living With Cancer (www.PLWC.org), an award-winning website providing oncologist-vetted cancer information to help patients and families make informed healthcare decisions.