

**MEETING SUMMARY
PRESIDENT'S CANCER PANEL
ASSESSING PROGRESS, ADVANCING CHANGE: CHALLENGES
IN CANCER SURVIVORSHIP**

August 25, 2005
Washington, DC

OVERVIEW

In 2003–2004, the President's Cancer Panel (PCP, the Panel) conducted a series of meetings focusing on cancer survivorship issues throughout the lifespan. As a result, the Panel learned that many cancer survivors are leaving treatment without adequate documentation of care received or a written description of recommended follow-up care and available resources. This 1-day meeting, on August 25, 2005, brought together key stakeholders and decision makers, with the goal of identifying actionable steps that can be taken to implement select recommendations made by the Panel in its report, *Living Beyond Cancer: Finding a New Balance*. The information generated at the meeting will be used to prepare a report to accelerate implementation of the Panel's recommendations regarding treatment records and follow-up care plans.

PARTICIPANTS

President's Cancer Panel

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* Finished for Dr. Clanton, who had to leave early

OPENING REMARKS—DR. LaSALLE D. LEFFALL, JR.

Dr. Leffall welcomed invited participants and the public to the meeting. He introduced Panel members, provided a brief overview of the history and purpose of the Panel, and described the aims of the current series of meetings.

The specific purpose of the meeting was to identify actionable steps that can be taken to implement recommendations made by the Panel in its 2003–2004 annual report entitled *Living Beyond Cancer: Finding a New Balance*. Dr. Leffall explained that the meeting would employ a roundtable format, with the first discussion centering on treatment records and the second focusing on follow-up care plans.

Invited participants were asked to prepare and submit a short summary describing their current position and their organizations' efforts relative to the recommendations being addressed. This information was shared among the roundtable participants prior to the meeting.

Participants were asked to address three questions relative to each recommendation: *What has happened with regard to this recommendation since its issuance in June 2004? What needs to be done to implement the recommendation?* and *What should the priorities be in this area over the next two years?* Discussants also addressed next steps, concentrating on specific courses of action to move identified priorities forward.

ROUNDTABLE DISCUSSION I—TREATMENT RECORDS

The first roundtable focused on the following recommendation:

Upon discharge from cancer treatment, including treatment of recurrences, every patient should be given a record of all care received and important disease characteristics. This should include, at a minimum: diagnostic tests performed and results; tumor characteristics (e.g., site[s], stage, and grade; hormonal status; marker information); dates of treatment initiation and completion; surgery, chemotherapy, radiotherapy, transplant, hormonal therapy, gene, or other therapies provided, including agents used, treatment regimen, total dosage, number and titles of clinical trials (if any), indicators of treatment response, and toxicities experienced during treatment; psychosocial, nutritional, and other supportive services provided; and full contact information on treating institutions and key individual providers.

Key Points

- Over the years, the Panel has provided a body of evidence based on public testimony from survivors. However, advocates using the Panel's published reports have encountered resistance and questions about the lack of real evidence. Is there demonstrative evidence, for example, that treatment summaries improve health care by identifying possible late effects

and allowing providers to attend to them earlier? The cancer community needs to ask organizations that can gather evidence, such as the Institute of Medicine (IOM), to follow up on this type of recommendation. Connecting the Panel reports with hard science will help move the field forward.

- A few organizations have been reporting on and/or addressing the issue of treatment records: The American Society of Clinical Oncology (ASCO) has formed a group; the National Health Service in the United Kingdom has constructed a record template for survivors and providers; the Lance Armstrong Foundation (LAF) and the Centers for Disease Control and Prevention (CDC) have published a National Action Plan; and the IOM has a report in press. However, little has been accomplished in terms of actually providing records to patients.
- ASCO is committed to implementing the Panel's recommendation. To that end, the organization has developed a Survivorship Task Force headed by Dr. Sandra Horning, a cancer survivor and current ASCO president, and co-chaired by Dr. Patricia Ganz of the University of California, Los Angeles. ASCO's Health Services Research Committee, chaired by Memorial Sloan-Kettering Cancer Center's Dr. Deborah Schrag, was charged with creating a template for practicing physicians to outline in a summary format the therapy and care each patient received. This template serves two purposes: (1) it helps keep patients fully informed regarding their illness, the therapies they have received, and the potential consequences of those therapies, both short- and long-term; and (2) it informs patients' future physicians concerning important needed follow-up care, testing, and monitoring of therapy side effects and possible recurrence. This template is currently in development. The Committee will deliberate on a preliminary draft of the template at its September 2005 meeting. Other ASCO activities also focus on survivorship.
- The Department of Veterans Affairs (VA) has developed a computerized medical record system, My Health Vet (www.myhealth.va.gov), which has been the subject of several news articles, including an article in *The Washington Post*. Currently, users are able to obtain information on contacts, prescriptions, tests, and immunizations; in the future, entire medical records will be available via the Internet. The VA has also considered using a summary template to simplify medical records for patients.
- Clinical trial groups should be represented at meetings such as this. There is a tremendous potential role for the clinical trial groups in mandating that clinical care summaries be formulated for every patient involved in a trial. In the past, NCI has been reluctant to implement this idea as a requirement; however, the concept should be revisited, as many of these groups are supported by the NCI. Communicating the importance of clinical care summaries for each patient in a trial would set in motion the practice of providing summaries for all patients.
- Providing pretreatment care plans to patients could encourage development of medical care summaries; describing in writing how the patient will be treated would make it easier to summarize treatment afterwards.
- Preparing treatment summaries should be a reimbursable activity for providers. Including representatives from insurance companies and the Centers for Medicare and Medicaid Services (CMS) in these types of meetings would help address such reimbursement issues in real time.
- Discharge summaries are a basic part of the clinical interaction with a patient. Scheduling 45 minutes with a patient who has completed therapy to review what has happened works as risk management and is reimbursable. Some practices dictate a treatment summary in the presence of the patient. This also helps cover liability risk for the provider because if the patient is unaware of the treatment and its associated risks, the provider is liable. A discharge

visit is simple and easy to implement in the short term. Oncologists must be educated in the benefits of these visits.

- Preparing a discharge summary is not always a straightforward task. However, at the completion of therapy, radiation oncologists use templates to summarize exactly what therapy the patient received, time intervals, etc. A generic template could begin with this kind of information and then be tailored over time by experts in different cancer specialties. Because much is still undecided about appropriate cancer care guidelines, it may be best to develop a baseline treatment summary template and refine the summary as guidelines are developed. The cancer care community should not wait for rigorous guidelines to be completed before adopting standard treatment summaries.
- The IOM's National Cancer Policy Forum includes representatives from government agencies, academic institutions, private companies, and nonprofit organizations. With the help of the Panel and the National Coalition for Cancer Survivorship (NCCS), the Forum would like to bring its members together under the aegis of the National Academies and encourage them to move on the Panel's recommendation. The intention would be to answer questions, make commitments, and produce an IOM Cancer Forum product that would provide accountability. CMS, in particular, must be made aware of the need for reimbursement policies that will help providers.
- The Texas Children's Cancer Center has developed the Passport for Care program, which will be implemented in partnership with Children's Oncology Group (COG). The program is an Internet-based resource for survivors and caregivers that enables them to access individualized guidelines and resources with the eventual goal of portability such that resources will be generated according to the patient's home ZIP code—even when the patient moves.
 - The Passport for Care will be implemented in all 231 COG member institutions, representing the care of 90 percent of children with cancer in the United States.
 - Passport for Care has several elements. With permission of the survivor and/or survivor's parents, a clinical summary is created and becomes part of the Passport system. Through a computerized system of algorithms, specific follow-up guidelines are generated relevant to the specific therapies the patient received, when the patient received them, etc. A personalized list of possible side effects and a follow-up care plan to monitor the patient for those side effects is also created. The program is automated such that the survivor sees only those guidelines specific to his or her case.
 - The Passport for Care also identifies a list of individualized resources. For instance, a survivor who has had an amputation would receive appropriate resource information for that particular circumstance. Online educational resources are available to research possible side effects, for instance, with appropriate information and links to specific, relevant MedLine articles.
 - The survivor will be able to control provider access to the Passport. Survivors can make their information available to providers by printing out information or providing a reference ID number for online access. The survivor can also limit how much of the Passport is accessible by the provider.
- The LAF would like to be a catalyst for change. Current treatment-record development efforts seem focused on pediatric patients, but the adult side is important as well. There is an opportunity for LAF to talk with ASCO and the Oncology Nursing Society (ONS) about further collaboration in developing adult treatment summaries.
- There are two stages to following through on this recommendation: First is the initial investment in developing methodology and instruments; second is dissemination into the

community. Survivor organizations can help with dissemination by demanding that survivors receive summaries and encouraging survivors themselves to demand them. If every patient receives, at a minimum, a treatment summary upon discharge, this will become standard practice, and survivors will feel more empowered to demand information.

- There are two models for translating the recommendation into the community. The first is a “bottom-up” model, wherein the consumer community demands the service, eventually leading to change within the medical community. Demand for information must be coupled with a demonstration of the cost to the system. The second is a “top-down” model, wherein organizations, insurance agencies, governmental agencies, and professional societies create a standard out of the recommendation and eventually measure adherence to that standard. The models are not mutually exclusive and may be employed simultaneously to move the recommendation forward.
- NCCS has suggested legislation, supported by ASCO, addressing comprehensive quality care. Written pretreatment care plans and end-of-treatment summaries are included as fundamental precepts of quality care. It is hoped that including these care plans and summaries in the legislation will encourage CMS to reimburse for them.
- Most survivors do not go to their oncologists for follow-up care; instead, they see family practitioners or internists, who generally know little about specific cancers, specific therapies, protocol-based care, and side and late effects of specific cancer therapies. Programs like the Passport for Care provide not only empowerment for the survivor, but also educational tools for the provider. The medical educational community needs to teach physicians, family practitioners, interns, etc. about cancer survivorship and side effects and what kinds of patients may come to them 20 years after being treated. Toward that end, ASCO is developing a curriculum that includes survivorship, with available information from experts and literature on aspects of follow-up care. This effort is being led by Dr. Jamie von Roenn of Northwestern University. Also, the American Board of Internal Medicine has adopted the ASCO curriculum outline for its oncology board-certification examination, in which questions will now be included relating specifically to issues of survivorship.
- The COG has been visionary in developing evidence-based guidelines for long-term survivorship care for children; these guidelines have been key in the Passport for Care. Guidelines for adult survivors are in development, but funding is a major barrier.
- The Passport for Care model is successful because 90 percent of children with cancer are treated in major cancer centers and on clinical trials. Eighty to ninety percent of adult cancer patients are treated in the community and are not on clinical trials. Engaging the members of COG is very different than engaging community oncologists and general practitioners.
- Literature on follow-up of adult cancers does exist. For example, randomized trials have been conducted related to different tests for some cancers, most notably breast cancer. There is also research comparing outcomes for patients receiving general follow-up (physical evaluation and history) versus multiple examinations (bone scans, CT scans, etc.). The data show no difference in death rates due to cancer or psychological factors. In fact, patients who receive fewer tests do better than patients who receive more tests, an outcome that is quite different from what would be assumed according to traditional thinking in the oncology community. Similar data are available for other adult tumors, but they have not been well utilized.
- ASCO’s Web site lists follow-up guidelines that were developed by a series of experts. These guidelines have been promulgated in the oncology community. However, follow-up is not confined to oncologists; general surgeons, for example, also conduct follow-up with patients. The existing guidelines must be filtered into the entire medical community.

- CMS reimburses for demonstration projects based on oncologists interviewing patients about fatigue, nausea, etc.; doctors in these trials receive extra money for participating. In the coming year, CMS should focus similar efforts on survivorship records, reimbursing a reasonable amount to participating doctors. This would make oncologists aware that summaries are important as well as compensate them for creating such summaries.
- In general, physicians are not reluctant to use computers and would like a good electronic medical record. However, the health care industry has failed to keep up with the informatics industry, as documented by Andy Grove, former CEO of Intel, in a recent editorial published in the *Journal of the American Medical Association*. Many practitioners are paralyzed by the options available to them, and there is no standardization among systems. Initial investments to convert to computerized records can be substantial and will be in vain if a particular records system does not integrate with those of other health systems. There must be standardization among health care systems for this recommendation to be successfully implemented. In this regard, it would be helpful to include representatives from the technology industry in these types of deliberations.
- One problem is that it is not clear who should conduct follow-up care: the oncologist or the primary care physician. The oncologist's treatment summary may be quite different from that of the primary care physician. It may be beneficial to have two or more discharge plans: an oncology discharge plan, a general practice discharge plan, etc.
- Per the last Panel report, the HHS was to establish a consortium of public, private, institutional, and community health providers to create a nationwide electronic records system. Development has begun, and the President has appointed Dr. David Brailer to the position of National Health Information Technology Coordinator, located in HHS under Secretary Leavitt. Dr. Brailer is in charge of setting up standards and is working closely with CMS. There will eventually be fully integrated, computerized medical records that will make compiling treatment summary information a matter of a few mouse clicks. Cancer treatment summaries should be part of this initial planning process in order to facilitate their speedy integration into future systems.
- Grassroots operations have become creative in managing cancer patient care. A community health center in New York is 100 percent paperless and gives each patient a copy of his or her medical record at discharge. For adult cancer patients who have an outside oncologist, the center doctor will call the oncologist to work out the follow-up plan. The center doctor often later shares this knowledge of cancer follow-up with other doctors at the center. Thus, they are in effect forming their own guidelines.
- Some insurance companies recognize the need for information technology and are making grants directly to health centers to purchase software and consulting services to move the effort forward.
- The IOM should host a workshop to discuss concrete implementation of Panel recommendations.
- The National Quality Forum (NQF) has established a group of best practices for safety in 28 areas.
- There is a sense of frustration in the health informatics industry because there are no standards yet for electronic medical records. As for any medical technologies, there must be a standard way of reporting data. There should be an emphasis on developing standard ways of representing data and integrating those data among systems rather than a separate standard for each technology. Without having to wait for a fully developed and improved standard, institutions can almost immediately begin using some technologies that are currently

available, especially in the XML community, to represent their data so that they could be integrated and shared across different systems. This may happen over the next year or two.

- Oncology nurses may be the prime people for following up on survivorship issues; there should be a concerted effort to involve them.
- Patients must also take responsibility for collecting and keeping their medical records and pathology reports. A simple tabbed notebook would suffice.
- There is no single issue that is the most important in this discussion. If the electronic medical record is implemented, the oncology community must still go back and change the way evidence is disseminated. If the way evidence is disseminated is changed, the community must go back and improve the way evidence is gathered. Systems thinking is necessary to connect these issues and address them simultaneously.
- Other groups that should be involved in the discussion include the internal medicine community, the family practice community, the technology community, and the insurance/payor community.
- The following are obstacles to implementation of the recommendation:
 - There is no standard treatment record template in place.
 - Most community-based physicians lack electronic medical record systems.
 - Practitioners need to learn to provide medical information and treatment summaries as part of routine care. Changing current practice to include this routine will require a change in provider mindset.
 - Practitioners are reluctant to spend time preparing treatment summaries when insurance companies and CMS do not reimburse for that time. Existing payment codes may be inadequate; it is unclear whether unique codes are needed.
 - There are many ways to make treatment records available, but there is no agreement on a standard method for doing so.
 - Patients sometimes cannot retrieve their medical records directly, and the Health Insurance Portability and Accountability Act of 1996 (HIPAA) restricts access by caregivers/family members. This creates barriers for patients trying to assemble their own treatment summaries. Further, information on a patient's cancer diagnosis and treatment is often in a variety of places with separate providers and may be difficult to compile.
 - Not all providers are knowledgeable about care plans for various cancer diagnoses. Likewise, it is not always clear which provider should be responsible for follow-up cancer care.
 - Concrete evidence is needed that treatment records and survivorship care plans improve patient outcomes.

NEXT STEPS—TREATMENT RECORDS

Key Points

- There are several treatment summary templates available, developed by different organizations, that can be used immediately.
- A summary template should not be simply a treatment report; there should be a uniform format. This would empower the patient and provide evidence to build guidelines later.
- Electronic records must represent what has actually been done.
- Educating, and thereby empowering, survivors will force change to occur. However, the medical community must take some responsibility for beginning these processes.

- The community should identify and follow through on opportunities to collaborate in an effort to move these recommendations forward more quickly and develop an evidence base.
- Federal agencies must work more closely together to drive evidence-based reimbursement and dissemination. To that end, the NCI is working in partnerships with the FDA, CMS (to link the evidence-creation process with reimbursement and the ability to drive clinical trial acquisition more quickly), HRSA (through a cancer collaborative), and directly with Dr. Brailer (on a pilot study that includes information about clinical trials and the electronic medical record component of those trials). Also, ASCO and NCCS have convened an alliance of cancer organizations to examine the issue of quality of care.
- Better public-private partnerships must also be forged. It was suggested that C-Change could provide a venue or mechanism by which such partnerships could be explored further. The private for-profit, private not-for-profit, and public sectors must all work together.
- It was suggested that the IOM host a workshop inviting key stakeholders to talk about how to work together and move these issues forward. Many organizations look to the IOM to provide an evidence base because it has the ability to conduct the research, commission papers, hold workshops, and vet an issue to the point of distilling all of the evidence.
- The IOM National Cancer Policy Forum has published a series of reports on survivorship, including breast cancer and childhood cancer survivorship. The Forum will release *From Cancer Patient to Cancer Survivor* in fall 2005. In conjunction with this report, the Forum is hosting a series of events, including a National Press Club rollout, a major symposium, and a major congressional meeting. The Forum is committed to the survivorship issue.
- The corporate world should also be brought into the conversation. A forum could be convened to educate top *Fortune 500* CEOs about survivorship. These companies employ survivors, and survivorship has an impact on their businesses.
- The CEO Roundtable, headed by Robert Ingram of GlaxoSmithKline, was formed a few years ago as an offshoot of the former National Dialogue on Cancer, now C-Change. It is the first entity of its kind in the cancer community. The group has established the *CEO Cancer Gold Standard*, a series of cancer-related recommendations designed to fight cancer through risk reduction, early detection, and ensured access to quality care. Each member, collectively representing a total of 24 million Americans, has pledged to reach the *Gold Standard* level of benefits and programs for its employees. The CEO Roundtable can be held up as an example of something that has a real impact on people and can be made to happen over a reasonable period.
- There is currently little Federal money for developmental initiatives in the area of survivorship. Most of the RFAs that are released are for proving or following up on existing systems or practices; if innovative approaches to problems are to be developed, there must be consideration given to funding them. The activities that many professional societies, such as ASCO, have undertaken are being self-financed, with occasional support from other sectors, such as foundations. CMS has begun to change its policy towards supporting clinical research. It is not a granting agency, but funds that are already in place may be redirected towards activities along these lines.
- An RFA from a Federal agency that would allow the development of a treatment summary template would not require a large amount of money and would be helpful in accelerating the process. The challenge is to have these projects viewed as an investment and not an expense. The CEO Roundtable is another possible funding source. This type of project would be an investment, and the Roundtable possesses the clout to make this happen.
- A collaboration of groups, including ASCO and ONS, should examine the feasibility of using COG's clinical care summary as a basis for adult summaries.

- There is a need to bring the heads of the Boards of Family Practice and Internal Medicine together in a forum highlighting survivorship, perhaps sponsored by the IOM. Leaders in subspecialties or practices focusing on cancer survivors would also be important.

ORGANIZATIONAL COMMITMENTS

- The NCCS is committed to continuing the process begun with the IOM in 1997 to move quality-of-care issues forward. It will fund a workshop, in cooperation with others, in spring 2006.
 - In 1998, the Coalition brought a large group to Washington, DC, to advocate; however, the lack of a concrete message backed up by evidence did not help the cause. The Coalition now backs these recommendations with legislative language and the Cancer Advocacy Now Network.
- The LAF is committed to working with the NCCS to fund a workshop. The LAF is also committed to completing a strategic planning process; one of the key points is to empower, in essence, the LIVESTRONG army of advocates to empower survivors.
- ASCO is committed to continuing current survivorship projects. The Survivorship Task Force is working with the NCCS, LAF, and others, contributing human and intellectual capital to solving survivorship issues.
- ACS is increasingly aware that advocacy is an important part of survivorship. Survivors need to have a role in that advocacy, and ACS has some responsibility to provide the opportunity, mechanism, or venue through which that can be done.
 - ACS is committed to bringing several thousand volunteer survivors to Capitol Hill in September 2006 for Celebration on the Hill. ACS had great success with this event three years ago.
 - In fall 2006, ACS will bring 1 to 5 trained “relay ambassadors”—cancer survivors who volunteer in the Society—to Capitol Hill. Their mission will be to carry a focused menu of key messages to Congress.
- The VA could be a forum for developing evidence regarding cancer care follow-up guidelines for the adult population. While the VA has less funding than the NCI, it has a large patient population. The Cooperative Studies Program is a potential resource that could be made available to help develop an evidence base in this area.

PUBLIC COMMENT—TREATMENT RECORDS

Matthew Zachary—Steps for Living

- The country is at a tipping point with respect to the momentum that survivorship awareness has generated; 50 million wristbands cannot be ignored. Steps for Living, a new nonprofit organization founded by 10-year brain cancer survivor Matthew Zachary, focuses on further enhancing cancer survivorship by taking advantage of public awareness and involving the public more in the process by using music and the arts.
- There should be a national delivery or direct-to-consumer delivery system that would further disseminate to the lay survivor a more digestible version of the ongoing developments in cancer survivorship and how these developments may affect daily life.

Julia Rowland, Ph.D.—Director, NCI Office of Cancer Survivorship

- The pediatric oncology community has been at the forefront of developments in this area in part because they are the vanguard of the survivor community and have always been concerned about long-term and late effects. Because these diseases are so rare in children,

there is not a strong evidence base, but with adults, an evidence base could be established. However, the community does not want to be duplicative in its efforts.

- It will be important to examine what works and what does not. Not everybody wants this information thrown at him or her or knows what to do with it when it is provided. Developing treatment summaries in partnership with patients will create a dialogue about what is going on, what may be needed, and what questions remain to be answered.
- There are many good ideas and processes in the medical community that are not being disseminated well. For example, the NCI redesigned the *Facing Forward Series*, which is a group of booklets to be given to patients as they conclude treatment. ACS has partnered with NCI to distribute the *Series*, but at this point, it is most likely not getting into patients' hands.
- Preventive medicine is as important as monitoring for recurrence. Recovery packages should include guidelines for health behaviors that should be attended to that may alter morbidity associated with the illness.

ROUNDTABLE DISCUSSION II—FOLLOW-UP CARE PLANS

The second roundtable focused on the following recommendation:

Upon discharge from cancer treatment, every patient should receive a follow-up care plan considering evidence-based standards of care. This should include at a minimum a description of recommended cancer screening and other periodic testing and examinations as well as the schedule on which they should be performed; information on possible late and long-term effects of treatment and symptoms of such effects; information on possible signs of recurrence and second tumors; information on the possible future need for psychosocial support; specific recommendations for healthy behaviors, [including] diet, exercise, sun and virus protection, [and] smoking cessation; referrals to specific follow-up care providers, support groups, and/or the patient's primary care provider; [and] a listing of cancer-related resources and information (Internet-based sources and telephone listings for major cancer support organizations).

Key Points

- The best way to advance the electronic medical records and promulgate standards is to support HHS Secretary Leavitt's 500-day agenda. Developing electronic medical records, creating standards, and improving how information is recorded and used is central to the 500-day agenda.
- The National Health Council, with more than 100 members from mostly volunteer organizations, formed the National Advisory Commission on Patient-Centered Care. The centerpiece of its deliberations is electronic medical records.
- Based on what has been expressed at previous meetings, CMS would like to be involved. It would play an integral role in moving the recommendations forward.
- The Panel might consider including timelines in its reports for the recommendations to reach different stages. Timelines may create more urgency in the community.
- CMS should develop specific codes for evaluation and follow-up of cancer survivors. If physicians see codes for reimbursable services, it will make them more aware that such services can be provided.
- Disease- and evidence-specific guidelines for long-term survivors should be developed. These guidelines should include best practices for each disease. For instance, physicians who care for breast cancer survivors need to know what specific side effects to look for. An NIH- or IOM-sponsored consensus conference could work on these guidelines. ASCO may be

interested in taking part in these kinds of multidisciplinary activities should the NIH or IOM not be interested.

- These initiatives will be difficult to implement. When discussing reimbursement and a zero-sum gain, it becomes apparent that putting money into one initiative takes it away from another. The oncology community has been discussing these issues for years without change.
- For pediatrics, the Passport for Care addresses the second recommendation. It will be implemented in the first clinic at the end of this year and in four additional clinics before being implemented nationwide in the next 2 to 3 years through COG.
- Recommendations should be based on evidence when it is available but should also take into account expert opinion; if consensus and expert judgment are not used, it will take months or years to develop meaningful research and guidelines.
- There are few randomized comparative assessments of one form of follow-up versus another. These assessments will always be difficult to conduct for a variety of reasons, not the least of which is patient bias in decision making.
- CMS could put together a registry of patients and compare practice patterns, which are known to be different in various parts of the country. The outcomes will be crude, but it is one way of using CMS data.
- The VA would also be a rich source of information and could conduct information gathering in a more rigorous fashion. A VA study group for lung cancer used to exist; there could be a VA study group for follow-up of cancer survivors. One could pick the diseases that are common in veterans, such as lung, colon, prostate, and breast cancers.
- A large-scale NIH grant, similar to the Prostate, Lung, Colorectal, and Ovarian Screening Trial (PLCO) grant, could be useful. The PLCO grant was an effort to understand what, if any, value comes from screening. A similar large-scale grant with data collection on several thousand patients with a major disease could be offered. Patients would receive different types of follow-up. One could conduct this study in a rigorous way with 35,000 participants and gain valuable knowledge from the information obtained. Insurers could contribute funds to pay for the study.
- There is a limited amount of funding available; if all of it is spent on follow-up research, there will be none left for treatment and vice versa.
- The CMS database does not include stage of cancer; thus, one cannot follow survivors in a meaningful way. Including that one item of data would allow researchers all over the country to conduct meaningful patterns-of-care studies.
- CMS is considering outsourcing its data archiving and structuring its data to make them more accessible. A project is being conducted that will make 5 years' worth of data available and easy to access, unlike the current 2 to 3 years' worth that is currently available but difficult to obtain. CMS is soliciting NIH input regarding what should be part of the data-warehousing project. A recommendation could be made to CMS that cancer staging information be added in order to enhance the SEER-Medicare cancer data linkage.
- The LAF is developing a consortium of adult survivorship centers around the country, which will provide a great opportunity to conduct intervention and, perhaps, follow-up care studies. A pilot program has been started at the Dana-Farber Cancer Institute; that program is now being increased to six locations. In the next few years, there will be as many as 15 centers.
- Community-level practitioners and representatives from the United States Preventive Services Task Force also should be involved in these discussions. Prevention is an important issue for cancer survivors, who tend to be in poorer general health than those who have not had cancer.

- Since there is no national or Federal vehicle or agency for developing practice guidelines (as there is in Canada), the commitment to develop a full range of survivor guidelines for each tumor would advance the field and give professional oncologists the tools to do their job well. ASCO and the National Comprehensive Cancer Network (NCCN) are developing guidelines; perhaps it should be a collaborative effort. Recommending that appropriate professional organizations and groups develop a set of national guidelines is enough to give impetus to the issue and find funding to support it. It may be more palatable to practicing physicians if a public-private partnership developed guidelines that would then be utilized by CMS, as opposed to CMS developing guidelines and imposing them on practitioners.
- The NCI research portfolio concentrates more on evidence generation than evidence configuration and communication. However, it is part of the NCI's Division of Cancer Control and Population Sciences' mandate to translate evidence into usable, disseminated standard practice. To help fulfill this mandate, more partnerships are needed between NCI and the professional societies that interact with cancer care practitioners.
- Professional groups must take the lead in developing guidelines. However, one of the biggest frustrations for patients and advocates is the proprietary nature of guidelines. Organizations that have not participated in developing particular guidelines often resist adopting them. There is a significant disagreement over whether and how to use guidelines developed by others.
- The development of guidelines is an expensive undertaking. There is a limit to what an organization like ASCO can do; collaboration with other organizations is necessary. Survivors should also take part in the process.
- The Ontario, Canada, approach is appealing and was, to a degree, federally funded. In developing guidelines, the focus was on disease areas (i.e., lung, breast, prostate cancers) that consumed a majority of resources; in that case, approximately 20 percent of activities consumed 80 percent of resources.
- As new and different therapies come into use, their potential side effects require time to be understood. How is that information delivered to survivors and their physicians? Guidelines cannot be static. It was suggested that a task force be set up among subspecialists to alert other subspecialists about changes that are relevant to the survivors they treat. Also, if treatment guidelines are electronic, they can be updated instantly and made immediately available. With appropriate controls, people can be included in the day-to-day aspects of guidelines, and it would be easier to alert them about updates.
- Ongoing research is needed; the NCI can and should take a leadership role in this area. Through a Specialized Program of Research Excellence (SPORE), the NCI is currently funding a worldwide pancreatic cancer registry at the Eppley Cancer Center in Omaha, NE. One of the faculty developed a Web-based system where patients, physicians, nurses, and caregivers/family members can enter data over time into a warehouse; these data can then be analyzed by researchers. The project has ongoing support. Patients always have access to their data and can give their physicians access. These warehouses then become the central point for researchers to examine issues related to survivorship.
- Biomedical research is extremely categorical. Categorization is necessary to fund research, but much of what is being discussed falls between categories. There is a systemic problem in making connections. To that end, the NCI is examining delivery systems and organizing a portfolio that allows it to fund research in some of these areas that do not fall into traditional biomedical categories.
- Before beginning to develop guidelines, a 1-day strategic planning meeting might be helpful. The meeting could address basic strategy questions, such as what role patients/consumers

would play and how to involve them. Also, there is the question of developing one psychosocial support guideline that would transcend all cancers or specifying different guidelines for different cancers, such as breast and Hodgkin's disease. These kinds of issues need to be addressed before actual content is decided upon.

- Survivors need a network or infrastructure of survivorship centers. Survivors want a place to go, people to talk with, and information and should not have to wait until guidelines are prepared. At the same time, if a network or infrastructure is in place that can conduct clinical research on these multidisciplinary topics, it is easier to update guidelines in response to advances in the science.
- There are various levels of guidelines one can suggest. For example, the simplest one would be for people who have had a certain form of chemotherapy who are at risk for subsequent cardiotoxicity, osteoporosis, and other effects; those patients can be provided with a list of possible aftereffects. There is, however, evidence of long-term consequences of cancer therapy that the patient and provider may not necessarily know about.
- There are two components: a physician-directed guideline and a patient follow-up guideline. Physicians and patients are at varying levels of sophistication. A follow-up guideline alerting patients to side and late effects could be produced at a simpler level than physician-directed guidelines.
- Guidelines can be updated relatively quickly using available teleconferencing and Internet technology. A comprehensive review would not be necessary each time an update took place.
- When survivors are being followed, they would be screened for symptoms. Based on those symptoms, the physician would perform a risk assessment, and based on that assessment, a clinical evaluation would be conducted, followed by clinical intervention and follow-up. These five steps should be fairly straightforward.
- This recommendation might be easier to address if the term *evidence-based* was replaced with *best practices*. *Evidence-based* connotes a different level of evidence than the Panel may intend. It is not always necessary to have level 4 or 5 evidence; however, there should be a caveat that it is important to obtain evidence-based information whenever possible.
- Once a guideline is in place, there are medical and legal implications in using it that are different from simply giving patients a list of potential symptoms. This is a major issue that may prevent the oncology community from narrowing specific guidelines.
- There has not been much research to provide an evidence base for guidelines—partly from a lack of funding and partly from an inability to efficiently collect information through an electronic medical records system. Evidence would be easier to collect if data were in electronic formats.
- Another issue that must be addressed is the way in which HIPAA regulations impact survivorship and the translation of research. A group from Dr. Brailer's office is considering this issue and developing recommendations on how to proceed.
- Health plans are in a unique position to assist with implementation of standards and guidelines.
- Once guidelines are promulgated, there needs to be a sufficient number of trained practitioners to perform the recommended services. *The Wall Street Journal* recently wrote that if everyone in the United States were to comply with current colon cancer screening guidelines, it would take 31 years to screen them all, since there is a finite number of providers who perform colonoscopies. Cancer survivors are competing for practitioner resources with the general population. How and whom to prioritize becomes an issue.

- Efforts to develop standards meet resistance partly because people equate standards with requirements. Also, members of standards committees wonder about their own vulnerability to litigation because they have established a standard. Standards work positively with some groups and negatively with others. Those who are negatively affected by a standard have a right to complain. The model used by the National Institute of Standards and Technology (NIST) might be appropriate. NIST sends its employees to become involved in and aid standards development organizations that are external to NIST and, often, external to the Government; this helps advance NIST's mission of helping business.
- There is a growing idea that instead of developing standards, there are methods of developing standard ways of using and developing data. Questions about evidence could be translated into simple questions about organization of data, which are not much different than evidence. However, organized data can be examined and different conclusions drawn. There should be a growing awareness over the next few years regarding standard ways of representing and organizing data that could make those data available to doctors and patients in a timely manner.

NEXT STEPS—FOLLOW-UP CARE PLANS

Key Points

- The Panel should consider modifying its recommendation to focus on specific cancers—e.g., cancers of the breast, colon, prostate, testes, and thyroid, as well as lymphoma—for the next 2 years and another set of cancers the following 2 years. Many of the existing adult survivorship centers have selected three or four cancer sites and started with those survivors in terms of providing resources and support. This may in turn drive demand by survivors of other cancers that their diseases be addressed with follow-up plans and support.
- The NCI should consider supplements to cancer centers or some other form of establishing Centers of Excellence for survivorship investigation. This could start as a small add-on but would quickly stimulate work on the kind of evidence that is needed.
- The Panel could assist by communicating with the White House and the community at large about how to help cancer survivors navigate the health care system. ACS received 1.35 million calls at its call center in the last year; 60 percent of those calls were from survivors or caregivers trying to navigate the health care system. If the public were aware of how to navigate the system, it could make a huge impact on quality of care and life.
- Studies should be conducted to examine what types of follow-up cancer care are most efficacious. Insurers in particular will benefit from studies of long-term survivors. This could be a forum for insurance companies to participate in major research initiatives, perhaps in collaboration with the NCI.
- CMS is becoming materially involved in paying for collection and analysis of evidence to improve standards of practice and quality of care. The evidence-under-coverage process provides the financial means to do this. CMS can serve as an example of the benefits for insurers/payors in supporting this type of research and evidence development. Private insurers are already paying claims for post-cancer surveillance. Since there is no evidence base regarding the most effective follow-up care, private insurers cannot distinguish among claims. Ascertaining what type of follow-up care is preferable, both medically and economically, is in the insurers' best interest.
- The National Committee for Quality Assurance, Joint Commission on Accreditation of Healthcare Organizations (JCAHO), and American College of Surgeons Commission on Cancer should be encouraged to use and disseminate developed standards. JCAHO has worked with lists of problems that may have arisen during treatment, ensuring that they are

present in all medical records. If the Commission begins to require clinical summaries, it will happen quickly.

- There is a good deal of preliminary developmental work to be done to implement this recommendation that does not fall into any traditional funding category. Likewise, there is a set of activities for which there is no obvious source of support or infrastructure that must be ongoing, integrated, and coordinated.
- Educate the individual; he or she will drive change by bringing that education to the physician.
- There should be an overarching national task force on survivorship that can develop a strategic plan, coordinate efforts, track implementation and movement, and have a larger perspective of the different players in this area. This task force could accelerate progress by pushing initiatives forward.
- The LAF/CDC National Action Plan addressed the wide range of issues being discussed and should be revisited.
- Existing research infrastructures and consortia, such as the SEER-Medicare data linkage, were not designed specifically for cancer survivorship research. It would be helpful to consider the design of the ideal cancer survivorship research infrastructure, focusing on the most critical questions regarding survivorship outcomes and intervention. It may or may not be similar to existing research infrastructures.
- Practice patterns are vastly different among regions, cities, and neighborhoods. Prospectively designed studies can be conducted within a much shorter time than is imagined currently. These could be done within the context of a population for which data have been captured, such as the VA or CMS (Medicare and Medicaid).
- Guidelines should be developed within the next 2 years. Diagnostic tests should also be evaluated through research or trials.
- Public organizations—be they NCI, Cooperative Groups, or individual organizations—should partner with the private insurance industry. Insurers may not want to pay for an administrative infrastructure, but they could contribute to studies conducted as part of routine care, particularly if patterns of care are being examined.
- Guidelines about what is feasible, reasonable, and cost-effective in a primary care setting should be based on expert opinion; the oncology primary care and health services research communities should be included in these discussions. Currently, primary care communities are integrated into research through the Cancer Research Network, which comprises 14 managed care organizations with a funded initiative to use large managed care organizations as a research platform for health care delivery research related to cancer. Many of them have electronic medical records and are able to conduct ambitious studies, a large number of which have been published and are informative.
- Another issue is how to move beyond large care systems to realistically capture data from the community setting and the interactions between survivors and primary care providers. Family practice organizations would be one way into these communities. The family practice, internist, and preventive medicine communities and their allied organizations should be utilized as dissemination channels, particularly as they are already set up for dissemination of other primary care practice evidence. The idea would be to simply increase the presence, strength, visibility, and quality of survivorship-related information through these channels rather than create new channels or independent education programs.
- The Ambulatory Care Quality Alliance brought together health care plans and provider groups to advise and inform CMS about issues in ambulatory care. A similar effort is being

organized for cancer care quality, welcoming all organizations in the interest of advising CMS and developing best practices, best examples, and good models that can be replicated.

- Resources must be funneled to the necessary channels to develop clinical care summaries and guidelines.
- If guidelines and follow-up care plans are to be developed, they must come out of the leadership of academic medical centers specializing in oncology. One way to reach that leadership is through ASCO; another is through NCCN. The ASCO Survivorship Task Force was established with this in mind. However, ASCO cannot take on all of these issues alone; partnerships will be critically important. The NCI OCS, LAF, NCCS, and others must partner with professional organizations, such as ASCO and ONS, and payor organizations to tackle elements of the larger issues. Duplication of effort should be avoided wherever possible; thus, coordination is key. Perhaps the IOM's NQF could provide oversight and coordination.
- Developing guidelines is clearly a considerable task if attempted for every single disease. However, if within 2 years, the pediatric community can come up with codified guidelines through COG, a group focused on a primary major adult cancer can do the same. It would be best to focus on one or two cancers that will serve as models of guideline development.

ORGANIZATIONAL COMMITMENTS

- The NQF will develop a tentative plan for coordinating multiple organizations. NCCN and ASCO are fairly narrow organizations; NQF can provide a framework for a steering committee and technical panels, all of which would be multidisciplinary.
- The National Cancer Policy Forum will continue in its partnerships with other organizations.
- The NCI will help support ongoing activity and infrastructure in this area, particularly if it is built around a clear timeline, product, and focus. In order to sustain a continuous infrastructure to address a specific task, partners must work together on a systematic basis, with a defined mandate, timeline, and endpoint. (When a goal is generic, it is difficult to keep partners together and maintain momentum; each partner has different interests.) One model might be the current quality assessment measurement effort. Similar collaborative discussions were held to create a forum to develop consensus measures for quality and outcomes assessment.
- The NCCS is committed to obtaining sponsorship to convene a workshop with the IOM focusing on implementing follow-up care plans. The objective is to have in place mechanisms for all patients to have a treatment summary and follow-up care plan within 2 years.
- The President's Cancer Panel can recommend the establishment of a national task force to be sustained over time; such a task force would need to come from survivor groups or professional organizations. There is currently no formalized mechanism for the Panel itself to evaluate the impact of its recommendations, nor does the Panel have either a mandate or the financial resources to maintain a commission or subpanel to coordinate implementation. It is hoped that meetings such as this will call attention to the importance of the recommendations in a manner that will motivate the health care community to implement them.

PUBLIC COMMENT—FOLLOW-UP CARE PLANS

Julia Rowland, Ph.D.—Director, NCI Office of Cancer Survivorship

- A recent ACS work group addressed the recommendation for nutrition and physical activity. The group came up with core guidelines across the board, then created specific guidelines for specific cancers. Recent updates were completed through conference calls and e-mails.

- David Eddy's differentiation among standards, guidelines, and options is useful in this situation. The recommendations are for standards, because the word *should* is included in the statement.
- Other groups that should be involved in these discussions include social services organizations, NCCN, hospital administrators and leaders, the pharmaceutical industry, and clinical trials groups.
- The NCI is committed not only to finding treatments and enabling people to live longer, but also to making quality of life the best possible. The Office of Cancer Survivorship (OCS) was established specifically with a focus on long-term outcomes for individuals living beyond the 5-year mark, though its portfolio is broader than that.
- There is a huge gap in knowledge regarding older adult survivors. Sixty-one percent of the population of cancer survivors in the United States is 65 and older, but almost nothing is known about comorbidities in this age group. When thinking about guidelines, it is critical that many of these individuals, who are already in some kind of health care system at diagnosis, are followed for comorbid illnesses. The AARP should be included in these discussions since it could provide access to a large group of people who will be directly affected by these decisions, as well as act as an advocate in communicating with legislators.
- The NCI is conducting studies examining where patients receive follow-up care.
- The Cancer Research Network is a consortium of managed care entities, a system within which research questions can be asked.
- The Panel should include a recommendation to convene a meeting to discuss HIPAA and its effects on survivorship and survivorship research.
- It is important for the cancer community to know who is doing what in this area, where the pieces are going to integrate, and who needs to be in touch with whom. The Panel should recommend follow-up to this meeting in 18 to 24 months to discuss what has been done, what has not been done, what the next course of action should be, and what other next steps should be taken.
- Nutritionists and rehabilitation specialists should take part in these discussions; they are integral partners in ensuring an effective follow-up plan.

CLOSING REMARKS—DRS. KRIPKE AND LEFFALL AND MR. ARMSTRONG

The Panel members agreed that the format of the meeting was appropriate and successful. Mr. Armstrong was particularly interested in the discussion of developing guidelines and doing so within designated timelines, which are critically important to cancer patients and survivors. The Panel thanked the participants for their time and expertise.

CERTIFICATION OF MEETING SUMMARY

I certify that this summary of the President's Cancer Panel meeting, *Assessing Progress, Advancing Change: Challenges in Cancer Survivorship*, held August 25, 2005, is accurate and complete.



Certified by: _____

Date: December 8, 2005

LaSalle D. Leffall, Jr., M.D., F.A.C.S.
Chair
President's Cancer Panel