J Cancer Surviv (2007) 1:64–74
DOI 10.1007/s11764-006-0003-9

Long term care planning for cancer survivors: a health services research agenda

Craig C. Earle

Abstract
Introduction The recent Institute of Medicine report *From Cancer Patient to Cancer Survivor: Lost in Transition* recommended that 'survivorship care plans' be created for patients as they complete primary therapy for cancer in order to ensure clarity for all involved about patients' diagnoses, treatment received, and plan for surveillance. It should explicitly identify the providers responsible for each aspect of ongoing care, and provide information on resources available for psychosocial and other practical issues that may arise as a result of the prior cancer diagnosis. The IOM stated that survivorship care plans 'have strong face validity and can reasonably be assumed to improve care unless and until evidence accumulates to the contrary.'
Materials and methods As an example of how to approach evaluation of a new health care delivery service, this article reviews the health services research agenda that will have to be carried out in order to refine and determine the clinical utility of survivorship care planning.
Results For any change in medical practice such as this to really occur, not only is advocacy needed from a number of different stakeholders, but there must also be convincing, scientifically sound evidence that the change is cost effective, improves outcomes of interest, and is feasible.
Conclusion It is incumbent on the research community to rigorously evaluate each element of survivorship care plans in order to justify their widespread adoption. Similar approaches can be taken to evaluate other health care delivery questions.

Keywords Cancer survivorship · Health services research · Outcomes research

Introduction

The recent Institute of Medicine (IOM) report '*From Cancer Patient to Cancer Survivor: Lost in Transition'* recommended that 'survivorship care plans' be created for patients as they complete primary therapy for cancer in order to ensure clarity for all involved about patients' diagnoses, treatment received, and plan for surveillance. The survivorship care plan should explicitly identify the providers responsible for each aspect of ongoing care, and give information on resources available for psychosocial and other practical issues that may arise as a result of the prior cancer diagnosis. Creation of such a document would likely require a dedicated 'off-treatment' or 'transition' consultation in most cases. The IOM stated that such survivorship care plans 'have strong face validity and can reasonably be assumed to improve care unless and until evidence accumulates to the contrary.' This may be true, but it was an unusual step to make such a strong recommendation in the absence of much evidence. The logistics and resources required to implement survivorship

---

An earlier form of this article served as a background paper for the '*Implementing Survivorship Care Planning*' Workshop, an Institute of Medicine National Cancer Policy Forum in collaboration with the National Coalition for Cancer Survivorship, Lance Armstrong Foundation, and National Cancer Institute, May 15 and 16, 2006, The National Academies Keck Center, 500 Fifth Street, NW, Washington DC

C. C. Earle (✉)
Center for Outcomes and Policy Research,
Dana-Farber Cancer Center,
44 Binney St., SM 271,
Boston, MA 02115, USA
e-mail: craig_earle@dfci.harvard.edu

care planning are non-trivial. If evidence eventually does not support their use, a lot of time, money and effort will have been wasted. Therefore, it is incumbent on the health services research community to quickly yet rigorously evaluate each element of the survivorship care plan and the effects, both good and bad, of its implementation.

The hypothesis implicit in this focus on optimizing the transition from cancer patient to survivor is that if treatment summaries and survivorship care plans become part of standard practice and included in the medical record, they can facilitate communication among providers about the treatments patients have received and what the known toxicities have been while also providing information as to the late effects they should be on the lookout for. This would lead to prompt identification and management, with resultant improved outcomes. Cancer care is often fragmented among many different specialists, and there has traditionally not been adequate communication back to primary care physicians (PCPs), for example, of such basic information as the specific diagnosis, stage, and treatment received. Moreover, the lack of clear practice guidelines for survivors creates uncertainty about what, if anything, non-specialist providers should be doing to help follow cancer survivors. Survivorship care plans would provide clear direction about what should be done for a given patient and who should do it. Moreover, if standardized and available in electronically searchable formats, they may also assist broader efforts to monitor care patterns and evaluate the quality of care delivered.

Barriers to achieving the IOM's vision of survivorship care planning include: reaching consensus about what information these summaries should contain; making it feasible for busy oncologists to take the time to create them carefully; changing the oncology culture so that treatment summaries become part of expected practice; and educating patients about the potential benefits of such planning in order to maximize adherence to its content. Clearly, the summary described in Table 1 would be a labor-intensive undertaking. On a larger scale, there are already manpower concerns in the oncology workforce brought about by the aging population, improved cancer therapeutics, and previous policy decisions limiting the training of specialist physicians. [1] Spending more time on survivorship means there will be fewer available man-hours to care for patients with active cancer.

This review will not address the critical role of basic science research to elucidate such things as the mechanisms of long-term and late effects, and will not get into specific questions regarding surveillance for particular cancers. Rather it will focus on the general health services research questions around evaluating the implementation of various aspects and models of survivorship care planning at the point of transition off of active cancer therapy.

Evaluation of survivorship care plans

It is essential that we conduct rigorous systematic studies to see what works and what does not work in survivorship care planning. Table 2 outlines key elements to be considered when envisioning such studies. Most study hypotheses or research questions related to survivorship care planning would be based to some extent on the notion that: [an element or elements of the care plan] affect(s) [one or more outcomes].

The essentials of the majority of research proposals could be summarized by describing the study design, population to be studied, the setting in which the care plan would be created and disseminated, and the format of the care plan or care plan element being evaluated. A hallmark of this research is its emphasis on understanding the integration and interaction of multi-disciplinary domains. Based on these considerations and what is already known about the situation in question, an appropriate study design can then be chosen

Care plan elements

The survivorship care plan as described by the IOM is a comprehensive proposal that was arrived at by expert opinion. One can take it for what it is and design evaluation exercises around implementation of the entire plan, or evaluate different parts of the plan in different settings. Some studies would be designed to ask focused questions about a particular element of care planning in a specific population and setting (e.g., the utility of treatment summaries for elderly colorectal cancer survivors being given to their primary care physicians), while others could look at the overall effect of care planning on such outcomes as communication and coordination of care. Although the IOM provided guidance on the elements of the ideal survivorship care plan, there is still much content to be developed and many ways that the same information can be presented. Moreover, resource guides need to be created for issues such as employment and insurance in which medical providers are often not expert. What is outlined below is a discussion of the elements of study design that would contribute to the evidence base to support or refute the inclusion of individual components of the IOM's broad call to implement survivorship care planning as a standard of care in oncology practice.

Treatment summary

While some specialists, by virtue of carrying out discrete treatments, routinely create summaries of their own therapies (e.g., operative notes or radiation completion

Table 1 The Institute of Medicine Survivorship Care Plan

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:

1. Diagnostic tests performed and results.
2. Tumor characteristics (e.g. site(s), stage and grade, hormone receptor status, marker information).
3. Dates of treatment initiation and completion.
4. Surgery, chemotherapy, radiotherapy, transplant, hormonal therapy, or gene or other therapies provided, including agents used, treatment regimen, total dosage, identifying number and title of clinical trials (if any), indicators of treatment response, and toxicities experienced during treatment.
5. Psychosocial, nutritional, and other supportive services provided.
6. Full contact information on treating institutions and key individual providers.
7. Identification of a key point of contact and coordinator of continuing care.

Upon discharge from cancer treatment, every patient and his/her primary health care provider should receive a written follow-up care plan incorporating available evidence-based standards of care. This should include, at a minimum:

1. The likely course of recovery from acute treatment toxicities, as well as the need for ongoing health maintenance or adjuvant therapy.
2. A description of recommended cancer screening and other periodic testing and examinations, and the schedule on which they should be performed (and who should provide them).
3. Information on possible late and long-term effects of treatment and symptoms of such effects.
4. Information on possible signs of recurrence and second tumors.
5. Information on the possible effects of cancer on marital/partner relationship, sexual functioning, work, and parenting, and the potential future need for psychosocial support.
6. Information on the potential insurance, employment, and financial consequences of cancer and, as necessary, referral to counseling, legal aid, and financial assistance.
7. Specific recommendations for healthy behaviors (e.g., diet, exercise, healthy weight, sunscreen use, immunizations, smoking cessation, osteoporosis prevention). When appropriate, recommendations that first-degree relatives be informed about their increased risk and the need for cancer screening (e.g., breast cancer, colorectal cancer, prostate cancer).
8. As appropriate, information on genetic counseling and testing to identify high-risk individuals who could benefit from more comprehensive cancer surveillance, chemoprevention, or risk-reducing surgery.
9. As appropriate, information on known effective chemoprevention strategies for secondary prevention (e.g., tamoxifen in women at high risk for breast cancer; aspirin for colorectal cancer prevention).
10. Referrals to specific follow-up care providers (e.g., rehabilitation, fertility, psychology), support groups, and/or the patient's primary care provider.
11. A listing of cancer-related resources and information (e.g., internet-based sources and telephone listings for major cancer support organizations).

SOURCE: IOM Report: From Cancer patient to Cancer Survivor: Lost in Transition, Box 3–16, pp. 152–153, Adapted from the President's Cancer Panel (2004)

summaries), an overall summary of cancer-related interventions and effects at the conclusion of primary cancer therapy is not part of common practice. The benefit of creating such a document is an open question. While it would seem obvious that such a summary would facilitate care, it could also be that the treatment summary is superfluous for a straightforward clinical situation that is consistently managed in a very standard way. An example might be early stage colon cancer treated with surgery alone: not much more needs to be known as even the histology is expected to be uniform and late effects uncommon. On the other hand, it can be crucial to understanding the risks faced by a patient with lymphoma who received multi-modality therapy. Moreover, information has to be summarized judiciously and in a balanced way so as not to create an inappropriately dire perception of impending disability. Qualitative studies with providers and patients may help determine the elements that would be found most useful. Then the general utility of treatment summaries and their feasibility in terms of collation of information and the resources required for their creation can be evaluated in specific clinical situations.

Possible clinical course

Several elements of the survivorship care plan can be summarized as being descriptions of the possible clinical course a patient will take. This includes estimating the time frame over which acute toxicities would be expected to subside, long-term effects that would not be expected to substantially improve, and/or late effects that could occur at some time in the distant future. It would also include advice about what signs and symptoms could portend a relapse and should prompt medical attention. In most cases there is still a need for more research on the incidence, risks, clinical characteristics, and outcomes of these effects. Such information can be useful in alerting patients and providers to things that might not otherwise be recognized as being

Table 2 Constructing studies to evaluate survivorship care plans

Care plan element	Outcome	Population	Setting	Format of the care plan	Study Design
Entire survivorship care plan	Patient-level	All survivors	Oncology specialist	Oral/informal	Qualitative
Treatment summary	Knowledge	Specific cancer types	NP or other allied provider	Written	Observational
Possible clinical course	Satisfaction	Age groups	Other specialists	Electronic	○Cross-sectional surveys
Surveillance plan	Symptoms	Racial/ethnic groups	Dedicated survivorship clinic	Standardized	○Medical record review
Lifestyle recommendations	○Anxiety, depression	Socioeconomic status	Other organizational characteristics (insurers, etc)	Portable	○Administrative data analysis
Psychosocial issues and available resources	○Physical	Geography			Interventional
	Quality of life	Family/caregiver effects			○Prospective cohort
	○Functional status, perceived health, utility				○Quasi-experimental
	Survival				○Before/After
	Systems-level				○Natural experiments
	Communication/coordination				○Randomized controlled trials
	Practice patterns				
	Processes/quality of care				
	Efficiency				
	○Resource utilization, time, cost				

related to the antecedent cancer. Hopefully such recognition would lead to earlier intervention that could improve outcomes. On the other hand, they could also lead to increased anxiety and over-investigation with potential resultant complications. Consequently, the optimal way to provide such information and the effects, both good and bad, of raising this awareness need to be considered in a research program.

Surveillance plan

Surveillance for recurrence Recommendations for surveillance for cancer recurrence are unique to each type of cancer, stage, disease histology, and the presence of any suspected genetic predisposition. They are generally thought to be important because of an expectation that they can affect survival. However, they are often controversial. Surveillance of the primary tumor site can in some cases detect salvageable local recurrences, for example, in anal, rectal, and breast malignancies. For disease that has spread beyond the primary site, there are some cancers, like colon cancer, renal cell carcinoma, and some sarcomas in which a small proportion of patients who recur distantly with oligometastatic disease can undergo surgery for possible cure. [2, 7, 8] In many situations, however, there is not even a plausible rationale to intensely monitor asymptomatic patients in order to find incurable distant metastases, as it has not been shown in most cancers that palliative chemotherapy in asymptomatic patients is advantageous. The resources consumed in such futile activities can be enormous on a population basis.

Surveillance research presents several methodological challenges. Randomized trials are required because non-randomized studies are susceptible to lead-time and length-time biases. Randomized trials are logistically difficult and expensive to carry out, however, because they have to be very large to detect usually small differences in survival. Furthermore, what is tested is generally a complex strategy, and so the chosen components, frequency, and the duration of surveillance are open to challenge. Moreover, differences in overall survival outcomes may be lessened by ever improving treatment for relapsed disease. In the absence of high-quality evidence, there is in most cases little agreement about surveillance recommendations among experts. [4]

Surveillance for late effects of treatment Long-term effects are those that first occur during cancer treatment and persist after completion of primary therapy. An example would be scarring from surgery. Late effects, on the other hand, are toxicities that are not apparent during primary treatment but that manifest clinically some time later, such as second cancers from radiation or chemotherapy. Specific late effects vary greatly depending on the site of disease and treatment modalities involved. Surgery and radiotherapy are local treatments and so their long-term and late effects are mostly confined to the structures in and around the primary tumor, although there can also be systemic effects from removal or destruction of an endocrine gland or the spleen. On the contrary, the effects of systemic therapy are related to the specific drugs involved. The challenge when following cancer patients is to recognize potential problems related to their prior cancer treatment, but still to monitor and investigate symptoms judiciously. Cancer survivors, like the rest of us, are aging and will develop other comorbid conditions. [6] It is important to understand whether survivorship care planning can help increase the likelihood of appropriate workup of symptoms that may portend cancer recurrence or treatment late effect while not causing overly aggressive investigation of vague unrelated symptoms.

Psychosocial issues and resources

The challenges of cancer survivorship go beyond physical issues. It can affect interpersonal relationships in many ways and raise concerns related to insurance, employment, and finances. The IOM report suggests that the survivorship care plan include information on these possible effects and recommends referrals for assistance where possible. It is reasonable to question how much of this need is currently going unfulfilled, and whether proactive identification of these problems is actually able to result in better resolution. For example, can we really improve their employment situation? Are the necessary services widely available, or is the recommendation for something that cannot practically be implemented in many settings? Do they have appropriate insurance coverage, or are they able to pay for such services? Is provision of cancer-related resources and information in the form of web addresses and telephone numbers enough? How do culture, age, and educational attainment affect the utility of these services? It seems likely that if we could ensure that survivors know their rights and put them in contact with available help, they will do better in these areas, but this is an empirical question.

Lifestyle recommendations

The end of primary treatment for cancer has been called a ‘teachable moment.’ [3] This recognizes that with significant events in a patient’s life, there is a greater opportunity than at other times to have an impact on health with programs that have been shown to help change risk behaviors. As a result, a comprehensive survivorship care plan should include specific recommendations about things that survivors can do to reduce the risk of cancer recurrence (chemoprevention), second primaries (e.g., diet, exercise, stopping smoking), or of developing other unrelated diseases (e.g. immunizations) now that their cancer is cured. It is well known that health behavior change is difficult to implement and maintain. Studying how best to operationalize this recommendation and its effect on altering behavior over the long term is important to justify expending this effort at the already overwhelming time of transitioning off of cancer treatment. The idea of a teachable moment might have face validity but the data could tell us otherwise.

Outcomes

There are several outcomes on which survivorship care planning can have an impact. Most can be assessed using existing measures, but development and validation of instruments able to capture important constructs specific to the survivor population will likely be necessary as well. The challenge in designing research is to choose endpoints that are responsive to the effects of survivorship care planning so that change can be detected, yet still important enough to justify the effort of care planning. It would be optimal for the health services research community to converge as much as possible on a set of consistent outcome measures so that separate research groups can assess different models of care and still produce results that can be compared across studies.

Knowledge and communication

At the patient level, several elements of the care plan are designed to increase patients’ awareness of their disease and the treatment they have received. Instruments to measure such knowledge can be developed and compared with situations in which there has and has not been a care plan implemented. Similarly, the availability of this information to practitioners is a practical measure of communication among providers. Other constructs like decisional conflict, which may be decreased when patients make decisions in the setting of enhanced knowledge about their situation, could also be evaluated.

Clarity around who will be delivering various aspects of care to cancer survivors is often missing. One study found that a third of cancer survivors were not sure which physician was in charge of their cancer follow-up. [5] While many patients are aware of this and are able to take responsibility for obtaining at least some of their necessary care there are many who are uncertain of what the next steps should be regarding their long-term comprehensive care. Others can be empowered if made aware of what the plan should be. There will always be a proportion of patients, however, who lack the knowledge or personality to advocate for themselves. As a result, one of the most valuable features of holding cancer providers responsible for a survivorship care plan may actually be in defining explicitly which providers will take responsibility for different aspects of a patient's care. Assessing whether the survivor and involved providers are aware of and agree on who will take on the various roles of cancer surveillance, screening for other cancers where appropriate, and non-cancer and preventive care is an important endpoint to consider studying. Research needs to be done to determine optimal ways to facilitate this coordination in community as well as tertiary care settings.

Acceptability and satisfaction

As different methods of implementing survivorship care plans are developed and tested, the satisfaction with and acceptability of the format of care planning needs to be assessed. For example, will patients accept an off-treatment consult with an NP in a survivorship clinic, and are they as satisfied with this as if their oncologist had done it? Will they interact with web-based applications or do they prefer written documents? There are several instruments designed to measure satisfaction that could be adapted to be relevant to questions related to survivorship care planning.

Survival

Quantity and quality of life are generally considered to be the primary outcomes of biomedical practice and research. Survivorship care plans have the potential to affect overall survival by improving adherence to important medical and behavioral health surveillance recommendations, ensuring optimal non-cancer care, and/or by facilitating positive lifestyle changes. It may be worthwhile to measure these outcomes in some studies. However it should be recognized that it may be difficult to detect what would likely be relatively small survival differences, and follow up would have to be at least several years in most diseases.

Quality of life/well being/functional outcomes

Quality of life may be affected more directly than survival by survivorship care planning. Having specific recommendations about what to do for follow up may decrease patient anxiety and ameliorate depressive symptoms. Early identification of late effects with appropriate intervention may decrease physical symptoms and improve functional status. On the other hand, highlighting all of the long-term or late effects that are possible may actually increase distress. Perceived health and self-esteem may be improved for some patients while others may become overly focused on their previous cancer experience, have increased fear of recurrence, and have trouble moving on with their lives. Predictors of response to a comprehensive care plan that included some individual characteristics (coping style, problem solving style etc) of survivors could potentially inform this practice. Also the preferences for information regarding future health state described in a survivorship care plan may impact perceived utility and actual outcomes.

Processes and quality of care

While not enough is known about the efficacy of treatment summaries and survivorship care plans to establish the simple fact of their creation as indicators of quality cancer care, some of the processes embedded in the care plans do have sufficient evidence base to be evaluated as measures of quality. In this way, quality of care becomes an outcome by which different models of care can be evaluated. For example, it is widely accepted that colorectal cancer survivors should undergo regular endoscopic surveillance to detect recurrence, new primaries, and/or to remove pre-malignant polyps. Therefore, studies comparing different 'best practice models' could be evaluated to see which one produced the most adherence to this recommendation.

Health care resource utilization

On a systems level, efficiency is a very important outcome. Any form of care plan implementation is going to consume resources, especially provider time. On a larger scale, health care costs may be affected in uncertain ways. For example, formal plans could decrease patient anxiety and result in fewer interval visits to physicians. Clear information about the likely course of disease and surveillance plan may avert inappropriate workup of probably unrelated symptoms by providers who are less familiar with specific cancer situations. Alternatively, survivors may seek investigation for potential problems they have been made aware of by the survivorship care planning process and would not otherwise have pursued. Also, if successful, survivorship care plans may cause patients who currently are not receiving appropriate surveillance measures to receive them, thereby resulting in increased appropriate health care utilization and costs. Hopefully these latter interventions would also improve health outcomes, however, allowing evaluation of the cost-effectiveness of survivorship care plans. A consideration when studying the economics of this is that the analytic methodology of discounting generally makes interventions like survivorship care plans that have up front costs but benefits that often do not accrue until many years in the future appear relatively unattractive. Consequently, being mindful of the economic implications of a proposed surveillance strategy is important in order to keep it relevant from a policy perspective.

Population

The next consideration when designing research is to define the population to be studied. The notion of survivorship care planning applies to all cancer survivors. However, certain elements are more important for some than for others. Patients with very early stage cancers may not need a specific surveillance plan, as the risk of relapse is vanishingly small. Lifestyle recommendations may be more important for head and neck cancer survivors as a group, i.e., smoking cessation, than they are for lymphoma survivors treated only with chemotherapy. Psychological distress may be more likely in a patient who has undergone disfiguring surgery (mastectomy or colostomy) than one who has had little long-term effect from cancer treatment. On the other hand, there may be an increased prevalence of depressive symptoms in both groups justifying a non-targeted screening approach. The concerns of an adolescent or young adult cancer survivor may have little overlap with those of a geriatric oncology patient. The emphasis of the survivorship care plan will have to be tailored to the situation of each survivor, and as such, studies focused on the specific concerns relevant to relatively homogeneous populations of survivors will usually be most informative.

Even a study focused on a narrowly defined clinical situation will have to consider the diversity of the survivor population, however. Investigators will need to decide whether they want to study a representative sample of all patients or to focus on the priority areas of a subgroup. For example, how does the information needs of Spanish-speaking Latino survivors differ from those of White English-speaking patients? Should surveillance recommendations be modified in the presence of significant comorbidity? If so, how? Is a web-based application as helpful to elderly survivors as younger ones? How does socioeconomic status affect the importance of employment and insurance assistance? Are survivorship resources accessible to survivors in different geographic locations across the country and across the continuum of urban and rural settings? Should children and adolescents be included? The tradeoffs necessary when studying defined populations involve balancing the efficacy of a care planning intervention against effectiveness and generalizability, while also considering practical matters of ease of survivor recruitment and statistical power.

Caregiver burden

Cancer survivorship affects more than just the cancer patient. There is a growing literature on the burden of cancer treatment on caregivers, and the challenges cancer survivors face can similarly affect the health and quality of life of their loved ones. As a result, it is appropriate for investigators to design studies that inquire whether survivorship care planning could affect satisfaction and health-related quality of life outcomes for caregivers as well.

Setting

There is no single organizational model that must be adopted in order to deliver high-quality care to cancer survivors. Although the National Coalition for Cancer Survivorship (NCCS) articulated the proposal that ‘long-term survivors should have access to specialized follow-up clinics that focus on health promotion, disease prevention, rehabilitation, and identification of physiologic and psychological problems’, in reality, whether follow-up is provided by oncologists, PCPs, or specialized survivor clinics is not the important issue. Rather, it is by ensuring that a named provider is responsible for each aspect of follow up that the chances of quality care occurring will be maximized. In fact, the IOM’s Committee on Health Care Quality in America affirmed that ‘care based on continuous healing relationships’ is important. In other words, patients shouldn’t necessarily be removed from the care of their treating PCPs and oncologists in order to receive specialized survivor care. Additionally, other specialists may be involved, and/or a ‘shared care’ model of cooperation between specialists and primary care physicians in the follow up of the cancer survivors could be attempted. The logistics of implementing formal survivorship care planning would be quite different if it was envisioned to occur in an oncologist’s office, primary care practice, or specialized survivorship clinic. Therefore, in most cases, possibly with the exception of patient-driven care planning formats discussed below, investigators will have to decide and clearly specify which model they will study and the evidence that emerges will better inform us in the future regarding the cost effectives of various models of care.

Even within a setting there are questions to be addressed about the efficiency, acceptability, and quality of survivorship care planning when it is carried out by treating physicians, allied providers such as nurses or nurse practitioners familiar with the patient, or by providers specialized in survivorship care planning but not familiar with the individual patient, as would be encountered in a specialized survivorship clinic. Few dedicated survivorship clinics currently exist, and they are all quite different. Some only take over the mechanics of surveillance, while others focus on providing primary care, especially to disadvantaged populations. Still others take on a consultative role looking for signs and symptoms of long-term and late effects and then making appropriate referrals, as well as assisting with the transition consultation and creating a survivorship care plan. In this way, specialized clinics could help with the workload barrier, however, patients and physicians may fear losing contact with each other and so the feasibility of such a model is a question requiring study. Consequently, the fifth recommendation of the IOM report calls for funding organizations to 'support demonstration programs to test models of coordinated, interdisciplinary survivorship care in diverse communities and across systems of care.'

Care plan format

If survivorship care planning is currently carried out at all, it is usually in the sense of informal discussions with patients near the end of treatment about what the plan will be going forward. The IOM report suggests that that should change and provides examples, but does not give a specific prescription about what form the survivorship care plan should take. Simply having a consultation in which all the elements of the plan are discussed, leaving the patient responsible to write down or remember the salient points, would probably still be a large improvement over current transition practices. However, it is expected that some form of documentation of the process that can be shared with the patient and other providers would be even more successful. A written consultation note or letter will achieve some of the aims of the IOM, but because of a lack of standardization it is quite likely to miss some of the suggested elements.

Standardization of the survivorship care plan to some extent is probably desirable. Some clinics use a combination of general and tailored information to develop a plan for patients. For example, templates can have spaces for a provider to fill in the elements of a treatment summary and surveillance plan on forms preprinted with standard lifestyle recommendations and lists of available resources. There are several examples of this sort of program in individual pediatric oncology clinics, a larger province-wide program in the Canadian province of Ontario, and the patient-centered materials developed by the Lance Armstrong Foundation. Electronic and/or handwritten versions of the templates can be available as necessary and each evaluated scientifically.

Creating even a standardized survivorship care plan is time consuming and difficult, however. Providers could attempt to create a document as they go along during the course of care, but realistically, busy oncologists are usually stretched to their limit dealing with the acute toxicities of treatment and are unable to also work consistently on post-treatment care planning. Templates could increase feasibility if non-physician staff like nurses or nurse practitioners could assemble much of the data. Automated systems can be envisioned in which drugs, cumulative doses of chemotherapy, and radiation sites and fractions could be pulled from pharmacy and other administrative records and fed into the evolving treatment summary. Even with standardization and automation, however, creation of a survivorship care plan will still require significant time and resources. Advocacy organizations like the American Cancer Society and Lance Armstrong Foundation have tried to support patient-directed models by providing information on survivorship issues for common cancer types and helping survivors summarize for themselves their medical treatment and plan for follow-up care. It may be that such an approach, or a hybrid of physician and allied worker input into transition planning is more realistic than a solely physician-based model.

Another big challenge of survivor care is the mobile patient population. A wonderful care plan can be developed, but if the patient subsequently moves to a new area, changes insurers, or even just changes doctors, the information can become practically inaccessible to his/her new providers. Because of this, an important area in need of research is the evaluation of technologies that could create care plans that are truly portable and accessible from almost anywhere. Options include 'smart cards' or other media that a patient could physically carry with a large amount of electronic data in a more portable form than a paper record. Another exciting possibility is web-based applications. Patients could control access to a web-based record through standard Internet security measures (passwords, USB keys) and still be compliant with privacy rules. Physicians with limited electronic resources in their practices but with Internet access could contribute to and edit information for the treatment summary and care plan over the web. In this way, a patient's plan could have input from all relevant providers. If a provider did not have Internet access, they could still provide the information for the patient or another provider to input. If the patient does not have Internet access, the final product could be printed in a hard copy version, thereby getting around the problem of disparities in electronic resources among patients that currently exist. Such formats have been implemented in some controlled settings, but their utility as population-based interventions remains to be established.

Study design

Qualitative research

The evaluation of survivorship care plans can involve most types of health services research study designs. Because this is a new intervention, not actually in widespread use, there is a lot of qualitative work to be done to understand the current problems in, for example, coordination of follow up, or what the most important barriers are to implementing survivorship care planning in practice. Focus groups or key informant interviews could be undertaken with different stakeholders (survivors, oncologists, PCPs) to explore these issues and inform the design of larger quantitative studies. Case reports can increase awareness of uncommon late effects or describe anecdotal situations in which survivors may find themselves related to work or insurance.

Observational research

If the important questions are known, observational studies can be designed to attempt to quantify and prioritize the areas of need. Cross-sectional surveys can address current practices in the various aspects of survivorship care planning. They can look for deficiencies in patients' knowledge of their disease and its treatment, the surveillance plan, possible late effects, and resources available to them. They can inquire of physicians about the amount of communication that has taken place between the various specialists and with PCPs. They can also assess satisfaction and acceptability of different models of survivorship care among diverse stakeholders.

Some aspects of care relevant to survivorship planning can be observed directly rather than relying on patient or physician report in surveys. Retrospective medical record review and examination of administrative claims data are examples of non-interventional study designs that can confirm practice patterns with respect to surveillance for recurrence and management of long-term and late effects. Studies employing such methods can provide important insight into actual care delivered.

Prospective cohort studies

Different settings and formats for the creation and implementation of survivorship care plans can be piloted in prospective cohort studies. Such studies would generally start with a baseline measure of the outcome of interest, say, knowledge or anxiety. The survivorship care plan would then be implemented and follow up determinations of the change from baseline would determine whether the program was considered a success or failure. Other cohort studies would evaluate a non-random mix of patients who did and did not receive various elements of a care plan, allowing assessment of outcomes for hypothesis generation.

Quasi-experimental studies, in which there are both intervention and control groups but without random allocation of subjects into these groups, can also provide evidence of the effectiveness of survivorship care plans. Such studies can take the form of before/after analyses of outcomes divided at the time of implementation of a survivorship care plan program. This type of research is susceptible to secular trends in outcome, however, which could result from increasing general awareness of cancer survivorship among patients and providers. Another quasi-experimental design could be to take advantage of a natural experiment in which some constituents of a care plan are implemented for one group of patients but not for another similar group. Comparison of outcomes between these groups could provide information about the effects of these parts of the care plan.

Randomized controlled trials

The most powerful study design is the randomized controlled trial. Randomization can be at the level of the patient, although this may lead to contamination as a provider may become generally more aware of the importance of planning for survivorship and bias the study towards the null by treating control patients more like the intervention patients than they otherwise would. The problem of contamination also precludes the use of crossover designs for most questions related to survivorship care planning. Alternative designs would be to randomize providers or practices, but then there may be an imbalance in characteristics of the providers in each group, or of the patients in these practices, that could affect the outcome of the study.

Given the IOM recommendation, investigators should be aware that Institutional Review Boards may not consider it ethical to randomize patients to having no survivorship care planning and so a 'usual care' intervention, rather than a placebo, may have to be devised. This could consist of tailored information rather than a formal consultation, for example. Unfortunately, providing an intervention to the control group will bias any study towards the null and necessitate a larger sample size.

Examples of research questions and study designs

- **Question**: what are the practical barriers to implementing survivorship care plans in oncology practice?

Study Design: focus groups with providers from a variety of settings (e.g., private practice versus academic centers, different specialties, managed care versus fee-for-service contractors). Questions could try to elicit ideas for ways to facilitate transition consultations and creation of survivorship care plans in real world settings. Key informant interviews with medical directors and practice managers may provide insight into the feasibility of programs that depend on additional investment in information technology. Estimating the resource burden of creating a survivorship care plan could inform policy decisions about reimbursement for survivorship transition consultations.

- **Question**: in what areas do patients currently need more information: their diagnosis, previous treatment, plan for surveillance and monitoring, possible late effects, resources available, and/or who to turn to for different problems?

Study Design: cross-sectional survey of survivors of all kinds to assess their current knowledge and desire for information in order to find which elements of the proposed survivorship care plan have the greatest gaps between desired and actual knowledge, and to identify sub-populations of patients in which certain needs are particularly prevalent.

- **Question**: is there variation in surveillance practice?

Study Design: administrative data analysis of surveillance practices for patients with stage II and III colon cancer, analyzing practice patterns and outcomes by geography, provider and patient characteristics (age, sex, race, socioeconomic status), organizational and insurance structure, and whether disparities in the quality of follow up care exist.

- **Question**: how much does a transition consultation for survivorship care planning increase patients' knowledge of their previous treatment and care plan?

Study Design: prospective cohort study in which there is a baseline assessment of stage I–III breast cancer survivors' knowledge of these areas just after completion of primary therapy via an interviewer-administered survey. All subjects would then have a transition consultation and be given a written survivorship care plan. Six months later another interviewer-administered survey would assess change in knowledge from baseline.

- **Question**: what are the effects of survivorship care planning on a survivor's family and caregivers?

Study Design: prospective cohort study in which prostate cancer caregivers' burden is evaluated over a two-year period and related to whether the survivor received a survivorship care plan, adjusted for other explanatory variables.

- **Question**: does survivorship care planning decrease anxiety and depression?

Study Design: before/after study in which anxiety and depression levels are measured in a cohort of patients finishing treatment for Hodgkin's disease in a major referral center. A transition consultation and survivorship care plan is then implemented at that institution and anxiety and depression levels are evaluated for patients completing treatment in the following year.

- **Question**: how does receipt of different parts of the survivorship care plan affect satisfaction with the transition off of active cancer treatment?

Study Design: analysis of data from a natural experiment in which different practices have implemented different parts of the care plan. Patients in each practice can be surveyed to assess their levels of satisfaction and differences related to the part of the care plan they received.

- **Question**: are transition consultations with a specialized survivorship nurse practitioner acceptable to patients?

Study Design: randomized controlled trial in which head and neck cancer patients are randomized between either having a survivorship care plan created by a specialized nurse practitioner during a consultation in a survivorship clinic or during a routine visit with their medical oncologist near the end of primary therapy, comparing measures of satisfaction between the two groups.

- **Question**: can specific interventions targeted to lifestyle changes to decrease risk behaviors be more successful in the context of survivorship care planning?

Study design: randomized controlled trial in which breast cancer patients completing adjuvant chemotherapy all receive a transition consultation and survivorship care plan, but half are invited to take part in an intensive diet and exercise intervention immediately, while the other half receive the same intervention 6 months later. Acceptance, compliance, and measures of dietary and exercise improvement would be the outcomes.

- **Question**: does survivorship care planning decrease unnecessary health care resource utilization?

Study Design: practices are randomized between usual care: giving patients individually-tailored treatment summaries, informal discussion of surveillance plans, and standard information about available resources, and an intervention group in which the survivorship care plan explicitly lays out the plan for surveillance and which symptoms should prompt medical evaluation. Data collected will include the costs associated with creating the care plan, and enumeration of physician visits and investigations received. This study could also inform cost-effectiveness analyses should improvement in survival and/or quality of life be found to be attributable to institution of such plans.

- **Question**: which format of survivorship care plan is most effective at increasing communication among providers?

Study Design: practices are randomized between web-based and paper versions of the survivorship care plan (with copies sent to all involved physicians). Survivors' primary care physicians are later asked to answer basic questions about the survivor's cancer and its care, using records available in their office.

Conclusion

Over time, as studies evaluating the effects of survivorship care planning on relevant outcomes are carried out, they would serve as the basis for secondary data analyses such as systematic overviews and technology assessments.

Surveillance practices have already been the subject of several meta-analyses and decision analyses but this is only one component of care planning. Rigorous efficacy and effectiveness data would lead to the development of evidence-based clinical practice guidelines for survivorship care planning (the IOM report's third recommendation), thereby creating standards of care. From such standards, quality indicators related to survivorship care (promulgated in the fourth recommendation of the IOM report) could be identified and validated. This would spawn a field of inquiry related to access to care and disparities for different survivor populations.

Why is all of this necessary? In order for change in entrenched medical practice to actually occur, advocacy, even from many different stakeholders, is not enough. Physicians and payers demand strong scientific evidence showing that the change is feasible, worthwhile, and economically sound. The fifth recommendation in the IOM report calls for funded demonstration programs to test models of care, and the final recommendation advocates that public as well as private agencies such as insurance plans should increase their support of survivorship research and expand mechanisms for its conduct. This last recommendation is actually the first step in all of this. Establishing a high-quality evidence base for the creation and implementation of survivorship care plans through the type of health services research outlined herein is necessary to ultimately realize the IOM's vision of reforming cancer care so that attention to the transition from patient to survivor becomes accepted as a routine part of oncology practice.

References

1. Cooper, R. A., Getzen, T. E., McKee, H. J., Laud, P., et al. (2002). Economic and demographic trends signal an impending physician shortage. *Health Affairs(Millwood), 21*, 140–154.
2. Fong, Y., Cohen, A. M., Fortner, J. G., Enker, W. E., Tumbull, A. D., Coit, D. G., et al. (1997). Liver resection for colorectal metastases. *Journal of Clinical Oncology, 15*, 938–946.
3. Ganz, P. A. (2005). A teachable moment for oncologists: Cancer survivors, 10 million strong and growing! *Journal of Clinical Oncology, 23*, 5458–5460.
4. Johnson, F. E. (1997). Overview. In F. E. Johnson & K. S. Virgo (Eds.), *Cancer Patient Follow-up* (p. 4). St. Louis: Mosby.
5. Miedema, B., MacDonald, I., & Tatemichi, S. (2003). Cancer follow-up care. Patients' perspectives. *Canadian Family Physician, 49*, 890–895.
6. Oeffinger, K. C., Mertens, A. C., Sklar, C. A., Kawashima, T., Hudson, M. M., Meadows, A. T., et al. (2006). Chronic health conditions in adult survivors of childhood cancer. *New England Journal of Medicine, 355*, 1572–1582.
7. Pfannschmidt, J., Hoffmann, H., Muley, T., Krysa., S., Trainer, C., Dienemann, H., et al. (2002). Prognostic factors for survival after pulmonary resection of metastatic renal cell carcinoma. *Annals of Thoracic Surgery, 74*, 1653–1657.
8. Pfannschmidt, J., Klode, J., Muley, T., Krysa, S., Trainer, C., Dienemann, H., et al. (2006). Pulmonary metastasectomy in patients with soft tissue sarcomas: Experiences in 50 patients. *Thoracic and Cardiovascular Surgeon, 54*, 489–492.