

Cost Considerations Regarding the Prospective Surveillance Model for Breast Cancer Survivors*

Andrea L. Cheville, MD, MSCE¹; John A. Nyman, PhD²; Sandhya Pruthi, MD³; and Jeffrey R. Basford, MD, PhD¹

For this article, the authors examined the cost implications of the prospective surveillance model (PSM) for breast cancer (BC) survivors, a comprehensive framework designed to preemptively reduce the incidence and virulence of common impairments. The model clearly has the potential of providing significant benefits. However, its accompanying costs and resource requirements remain unclear and may be substantial. Thus, it is critical to examine which BC survivors may benefit from the PSM, how much they will benefit, and the costs of this benefit before its implementation. Because the PSM is not rigidly prescriptive, its examination must allow for different scenarios with emphasis on 4 critical determinants of cost—whether all or only high-risk BC survivors participate, assessment frequencies and locations, the credentials of the assessors, and requirements for supportive equipment. Another issue is the distribution of its cost: hypothetical implementation strategies vary widely in their distribution of fiscal burden across key stakeholders—survivors, providers, and payers—whose financial responsibilities will be an important factor in whether and how rapidly they adopt the PSM. Accurate valuation of the PSM will require capture of direct and indirect cost savings and benefits. Currently, a lack of data regarding these parameters, as well as outcomes that can be reliably attributed to the PSM, impedes cost-effectiveness analyses. Because the PSM may enhance many health state characteristics, assessments that integrate overall composite measures with evaluations of common, discrete impairments may be required to comprehensively assess its benefits. *Cancer* 2012;118(8 suppl):2325–30. © 2012 American Cancer Society.

KEYWORDS: breast cancer, physical impairment, cost effectiveness, screening, survivorship.

INTRODUCTION

The prospective surveillance model (PSM) for breast cancer (BC) survivors outlined by Stout et al in this supplement¹ represents a long overdue effort to advance our medical efforts toward a pre-emptive, rather than an after-the-fact,²⁻⁴ approach to reducing the occurrence and progression of BC treatment-related impairments. The PSM, which is a framework of suggested clinical activities designed to proactively assess and educate patients in impairment risk reduction, is more than just pertinent to BC survivors. If successful, it may provide a framework for similar initiatives in other cancer patient populations. Realistically, however, enthusiasm must be tempered by the need to assess its associated costs and determine who may benefit from the PSM, how much they may benefit, and how much this benefit will cost.

Implementation of the PSM is not a trivial undertaking, because its introduction potentially would affect all BC survivors and would have an impact on the nature and cost of their care that has yet to be quantified. Although scrutiny will take a concerted effort by many individuals, the role of this article is to provide an overview of the considerations that need to be taken into account to comprehensively assess the cost implications of the proposed PSM. The increasingly competitive medical landscape demands that current and future costs as well as quality of care and patient centricity become central to health care decision making.⁵

The rationale for the PSM lies in its potential to reduce the incidence and severity of the broad range of physical impairments experienced by BC survivors. Facts argue that a prospective surveillance approach is needed. First, it is estimated that there are over 2.5 million BC survivors in the United States who will enjoy relatively normal life expectancies.⁶ Therefore, a failure to treat their physical impairments may adversely affect their well being and functionality for decades. Second, BC treatment-related physical symptoms and impairments (eg, restricted shoulder motion, pain, and fatigue⁷⁻⁹)

Corresponding author: Andrea L. Cheville, MD, MSCE, Department of Physical Medicine and Rehabilitation, Mayo Clinic, 200 First Street SW, Rochester, MN 55905; Fax: (507) 266-9936; cheville.andrea@mayo.edu

¹Department of Physical Medicine and Rehabilitation, Mayo Clinic, Rochester, Minnesota; ²Division of Health Policy and Management, School of Public Health, University of Minnesota, Minneapolis, Minnesota; ³Division of General Internal Medicine, Mayo Clinic, Rochester, Minnesota

The articles in this supplement were commissioned based on presentations and deliberations at a *Roundtable Meeting on a Prospective Model of Care for Breast Cancer Rehabilitation*, held February 24-25, 2011, at the American Cancer Society National Home Office in Atlanta, Georgia.

The opinions or views expressed in this supplement are those of the authors, and do not necessarily reflect the opinions or recommendations of the editors or the American Cancer Society.

*A *Prospective Surveillance Model for Rehabilitation for Women with Breast Cancer, Supplement to Cancer*

DOI: 10.1002/cncr.27473, **Received:** October 20, 2011; **Accepted:** November 7, 2011, **Published online** April 6, 2012 in Wiley Online Library (wileyonlinelibrary.com)

are far more common and persistent after BC treatment than is usually recognized. Third, such physical impairments seldom are detected by oncologic care providers.^{4,10} Fourth, many treatment-related impairments either can be prevented or their effects can be meaningfully ameliorated through the early introduction of effective therapy. And last, evidence suggests that few survivors receive such care.^{4,10-12}

Determinants of Cost

The proposed PSM framework suggests a need for several on-going measures: 1) screening, which may include objective measurements, patient-reported outcomes, and/or physical examination; 2) patient and provider education; 3) individualized counseling; 4) provision of assistive devices (eg, compression sleeves); 5) manual and pharmaceutical treatment; and 6) improved care coordination.¹ The relative contributions of each of these components to improved outcomes are unknown, and their costs remain undefined. Thus, substantial reductions in costs may be possible without a significant lessening of the PSM's potential benefits.

The PSM screening process is a particularly important consideration, because each increment in precision and earlier detection may be accompanied by a substantial increase in costs. Precision, for example, may be achieved by more frequent screening, more highly trained examiners, or more technologically sophisticated equipment—all of which come at a price. In general, screening processes reflect a balance between precision and cost. The consequences of false-positive findings also must be considered, although increased precision should reduce their occurrence. The PSM, therefore, is subject to the same concerns of other screening programs: an incorrect diagnosis may lead to needless testing and potentially harmful treatments.¹³

Because the PSM is not rigidly prescriptive, its implementation may take a wide range of forms. Examination of its financial implications must consider various scenarios with attention to financially relevant features, such as: 1) whether all or only BC survivors at high risk for physical impairments participate; 2) assessment frequency, 3) the skill levels and training of assessors; and 4) the need for specialized equipment.

Treatment characteristics of prospective surveillance model participants

A BC survivor's risk of developing physical impairments relates directly to the nature of the treatment they received. The majority will present with lymph node-negative disease.¹⁴ Among this group, those who elect for breast-conservation treatment have a low risk (perhaps 5%-10%,^{15,16}) of BC-related complications, because

most do not require completion axillary lymph node dissection (CALD) or lymph node irradiation. The yield from PSM activities and the return on the invested resources would likely be greatest among those who required more invasive treatment, such as CALD, particularly if they also underwent mastectomies or received radiation placing them at higher risk of developing impairment. Other risk-defining characteristics (eg, prior upper extremity injury, obesity, etc) also may be pertinent, but data for their systematic integration into PSM candidate selection are not yet available.

Assessment frequency

The PSM developed and described by the group from Bethesda Naval Hospital assesses patients 5 times: preoperatively and every 3 months for the following year.^{17,18} Little information is available regarding treatment and subsequent assessments once an impairment or concern (eg, a frozen shoulder) is identified or whether assessments continue beyond the first year. Clearly, these issues impact costs. The incremental benefit of surveillance activities at 3-month versus 4-month or 6-month intervals warrants study.

Assessors

Assessor expertise is another important factor. The use of more highly trained assessors may incur greater costs, but the benefits of their potential ability to detect impairments earlier and the extent to which earlier detection would improve clinical outcomes are unclear. Physical or occupational therapists (PT/OTs) have performed assessments in case series that have suggested benefits related to the PSM.¹⁸ This level of data alone may be insufficient to support the implementation of a program directed toward a large population like that represented by BC survivors. Costs may be reduced substantially by having PT/OT assistants or technicians perform assessments; however, as noted above, the impact of their differing diagnostic and interventional capabilities is unknown.

Alternatively, PSM assessments might become part of the routine medical and surgical follow-up visits that would occur irrespective of the PSM. Survivors with early signs of impairments could be counseled, scheduled for more frequent assessment, or referred for PT/OT services. Whether these providers would be willing or able to assume the additional burden remains unknown. If, in fact, they were willing to do so, then the additional charges for their services would likely be relatively modest given the strictures of the Centers for Medicare and Medicaid Services (CMS) fee schedules. Although this

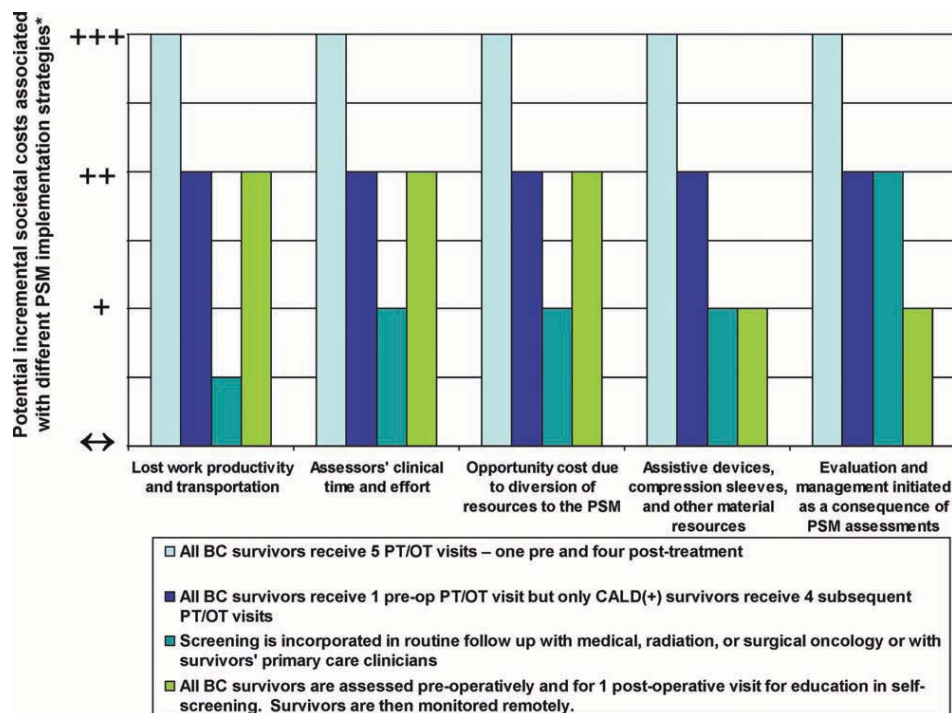


Figure 1. This histogram illustrates the estimated societal costs associated with 4 hypothetical Prospective Surveillance Model (PSM) implementation strategies. An asterisk indicates that cost unit and magnitude are not comparable across categories. BC, breast cancer; PT/OT, physical or occupational therapists; CALD(+), positive completion axillary lymph node dissection.

approach may be attractive from the perspective of cost and convenience, it suffers from long-standing evidence that physical impairments often are neither detected nor treated by oncologic providers.¹⁰

Perhaps the least costly assessors would be the patients themselves. Data are lacking regarding how education in self-assessment followed by prompts to promote adherence to self-assessment activities compare with clinic-based clinician assessments.

Requirement for specialized equipment

Recommendations that include a need for expensive and specialized equipment will influence providers' and payers' enthusiasm. The PSM approach described by Stout et al,¹⁸ for example, used an infrared volumeter to quantify a limb's volume. These devices typically cost roughly \$20,000—a significant outlay for a small, community-based practice—and have the additional concern that their measurements, although rapid, are not typically reimbursed. In contrast, some private insurers reimburse for lymphedema screening assessments performed with the ImpediMed L-Dex U400 bioimpedance device (ImpedimMed, San Diego, Calif; J. Butler unpublished results and private communication regarding the return on

resources invested in the ImpediMed devices for measuring limb edema). This instrument costs roughly \$30,000; and, although it reduces assessment time, it also minimizes inter-assessor differences. If private insurers continue to reimburse for these measurements (approximately \$500 per measurement session), then providers may be more eager to embrace a version of the PSM that incorporates their use. Underlying all this is the finding that well developed, inexpensive, but often time-consuming screening alternatives already are available in the clinic.

Costs Vary by Prospective Surveillance Model Implementation Strategy

There are many options for integrating the PSM into established health care structures. Figure 1 provides a heuristic picture of the incremental societal costs associated with 4 potential PSM implementation strategies:

1. All BC survivors receive the 5 PT/OT visits (1 presurgery and 4 postsurgery), as outlined in the PSM approach described by the group at Bethesda Naval Hospital¹⁸;
2. All BC survivors receive 1 presurgical PT/OT visit, and only those who undergo CALD receive 4 subsequent PT/OT additional visits;

3. Screening is incorporated in routine follow-up with the patient's medical, surgical oncologic, or primary care providers; and
4. Survivors are assessed preoperatively and at a single postoperative visit for instruction in self-screening and then remotely (eg, telephonically) monitored.

Figure 1, although its costs are both hypothetical and qualitative, provides several insights. Among these are that Strategy 1 imposes the greatest visit burden—an additional 5 visits per survivor—over those required for Strategy 3, which integrates PSM services into visits required for the primary BC treatments that would occur irrespective of the PSM. PSM services may prolong these visits, but the visits would require no additional transportation. Strategies 2 and 4, conversely, require fewer additional visits and, thus, are intermediate in burden between Strategies 1 and 3. Additional visits are associated with additional expenses, such as those related to survivor/care giver time and lost work. Similarly, it is possible that Strategy 1 also may incur additional costs because of increased opportunities to provide assistive devices, evaluations, and treatment.

These hypothetical scenarios are designed to illustrate how the fiscal burden of the PSM may vary across survivors, providers, and payers according to implementation strategy. Provider enthusiasm will be tempered by the costs of implementation. For example, a large tertiary medical center is likely to have the infrastructure needed for the capture, storage, and retrieval of PSM-related data; whereas a smaller practice may not. Similarly, patient willingness to participate may vary depending on the magnitude of their PT/OT copayments, transportation costs, and lost work productivity, as well as whether PSM-related services eat into their CMS therapy caps.

Reimbursement approaches that encourage providers to efficiently organize and deliver high-quality, PSM-related services and to monitor outcomes may be the most effective means to encourage cost-effective PSM implementation. Outcome monitoring will afford payers and survivors transparency with respect to the value gained from the invested resources and will ensure that providers have benchmarks by which to gauge the quality of their services. Achieving cost effectiveness may require payment schedules that reimburse care in bundled schemes for care delivered by health care teams rather than particular clinicians.¹⁹ Tiered, case mix-adjusted payments also may encourage the development of various levels of PSM service intensity commensurate with BC survivors' risk of physical impairments and symptoms.

Potential Cost Savings

Justification for this PSM is based on the appealing, but thus far unproven, argument that an earlier addressing of BC treatment-related impairments will lessen future morbidity and health care use. Downstream follow-up costs, achieved by reducing the incidence and severity of new impairments, might be lessened because of the need for fewer provider visits, reduced clinical testing, and a smaller need for resources and medications. These hopes are conjectural, and the accurate capture of these and more indirect benefits will be vital to a comprehensive valuation of the PSM.

The Need for Composite Outcomes

Cost-effectiveness analyses compare differences in costs between treatments in relation to outcome units gained. For example, the PSM could be compared with usual care in terms of dollars spent per degree of shoulder range of motion gained. Reports suggest that the PSM may enhance several health state characteristics, including symptom burden, psychological well being, physiologic status, and level of activity. The incremental costs (numerator) of the PSM, therefore, deserve examination relative to an encompassing outcome measure (denominator) that is likely to be responsive to its many benefits. However, the development of composite outcome measures is challenging. Over time, it may become apparent that reference to a combination of common discrete impairments and overall composite measures will be required to comprehensively assess the benefits of the PSM.

A Case in Point: Lymphedema

Lymphedema affords perhaps the most examined and credible (albeit limited in scope) suggestion that the PSM can reduce health care expenditures. In contrast to other BC treatment-related complications, the natural history of lymphedema, the associated morbidities, and the burden of care have been well described.²⁰ For example, the use of compression sleeves may prevent its advancement to dysmorphism, recurrent infections, and disability—the aspects of the condition that incur high care costs.¹⁸ In addition, earlier use of prefabricated compression garments may alleviate the need for the much more expensive custom garments and alternative compression devices that often are required to control swelling once lymphedema has progressed to more advanced stages.²¹ Such garments and devices are not covered by Medicare or many commercial insurance plans, and the elimination of their need would lessen the financial burden on survivors who require their lifelong use.

The PSM also may lead to near-term cost savings in the years after BC diagnosis. Physical therapy after BC treatment may significantly reduce the incidence of lymphedema among survivors who undergo CALD.¹² Costly evaluations initiated by clinicians who are unfamiliar with lymphedema may be lessened. Work by Shih et al suggests that the presence of lymphedema may increase a BC survivor's health care costs by an average of \$7000 per year over the first 2 years after BC diagnosis.²² In summary, although it is unlikely that implementation of the PSM would eliminate all lymphedema-associated expenditures, it is not unreasonable to speculate that its existence might substantially reduce their magnitude by accelerating diagnosis and reducing morbidity.

Discussion and Next Steps

The costs of implementing the PSM, who bears them, and its effectiveness will facilitate or hinder its adoption, as noted above. Five issues seem particularly important:

1. Identification of the essential elements of the PSM, the contribution of those elements to improved outcomes, and means to minimize their costs;
2. Clarification of the primary determinants of PSM costs, including participant selection, assessment frequency, assessor choice, and equipment needs;
3. Implementation strategies that take into account stakeholders' needs and priorities;
4. Definition of the outcomes and databases to be used in estimating the costs and the effectiveness of the PSM; and
5. Collection of longitudinal data that may support refinement of the PSM's fiscal and benefit metrics.

These are not simple tasks. Unfortunately, the importance of accurately estimating costs is matched by the difficulty of doing so. The uncertainties inherent to inferences drawn from observational data and administrative databases are well known.²³ Furthermore, the severity of BC treatment sequelae is a critical mediator of costs that administrative databases capture poorly, if at all. Leveraging the few data sources that allow precise and granular capture of both cost and clinical information, eg, Kaiser Permanente and Rochester Epidemiology Project data, may be an initial research priority, because these data will allow at least some exploration of the impact of early rehabilitation involvement in the care of BC survivors.

Randomized controlled trials that explicitly prioritize cost effectiveness in their aims would seem a compelling means of evaluating PSM costs. However, again, accurate cost estimation is not trivial given the heteroge-

neity of payers and the well known inaccuracies of patient-reported costs.²⁴ Nevertheless, region-specific or site-specific randomized trials, informed by insights from observational data, likely will be needed to generate the high-quality data required for policy and coverage decisions. "Natural experiments" comparing the expenditures and use patterns of BC survivors with different payment coverages for rehabilitation services pertinent to BC treatment-related sequelae may prove helpful.

In conclusion, there is little question that BC treatment-related impairments are a serious problem faced by a significant proportion of survivors. However, the degree to which the proposed PSM may mitigate these impairments, and at what cost, remains unknown. Research initiatives should be imbedded in the implementation and evolution of the PSM, as for any major health endeavor, to ensure not only that investments are evidence based but also that they yield optimally improved outcomes.

FUNDING SOURCES

Support for this meeting and supplement was provided by the American Cancer Society through The Longaberger Company®, a direct selling company offering home products including hand-crafted baskets made in Ohio, and the Longaberger Horizon of Hope® Campaign, which provided a grant to the American Cancer Society for breast cancer research and education.

CONFLICT OF INTEREST DISCLOSURES

The authors made no disclosures.

REFERENCES

1. Stout NL, Andrews K, Binkley JM, Schmitz KH, Smith RA. Prospective surveillance model for rehabilitation for women with breast cancer. *Cancer*. 2012;118(suppl 8):2191-2200.
2. Lehmann JF, DeLisa JA, Warren CG, deLateur BJ, Bryant PL, Nicholson CG. Cancer rehabilitation: assessment of need, development, and evaluation of a model of care. *Arch Phys Med Rehabil*. 1978;59:410-419.
3. Guadagnoli E, Mor V. Daily living needs of cancer outpatients. *J Commun Health*. 1991;16:37-47.
4. Cheville AL, Troxel AB, Basford JR, Kornblith AB. Prevalence and treatment patterns of physical impairments in patients with metastatic breast cancer. *J Clin Oncol*. 2008;26:2621-2629.
5. Berwick DM, Nolan TW, Whittington J. The triple aim: care, health, and cost. *Health Aff (Millwood)*. 2008;27:759-769.
6. American Cancer Society. Available from: <http://www.cancer.org/Cancer/BreastCancer/OverviewGuide/breast-cancer-overview-key-statistics>. Accessed August 22, 2011.
7. Gartner R, Jensen MB, Nielsen J, Ewertz M, Kroman N, Kehlet H. Prevalence of and factors associated with persistent pain following breast cancer surgery. *JAMA*. 2009;302:1985-1992.
8. Rietman JS, Geertzen JH, Hoekstra HJ, et al. Long term treatment related upper limb morbidity and quality of life after sentinel lymph node biopsy for stage I or II breast cancer. *Eur J Surg Oncol*. 2006;32:148-152.
9. Bower JE, Ganz PA, Desmond KA, et al. Fatigue in long-term breast carcinoma survivors: a longitudinal investigation. *Cancer*. 2006;106:751-758.

10. Cheville AL, Beck LA, Petersen TL, Marks RS, Gamble GL. The detection and treatment of cancer-related functional problems in an outpatient setting. *Support Care Cancer*. 2009;17:61-67.
11. McNeely ML, Campbell K, Ospina M, et al. Exercise interventions for upper-limb dysfunction due to breast cancer treatment [serial online]. *Cochrane Database Syst Rev*. 2010;(6):CD005211.
12. Torres Lacomba M, Yuste Sanchez MJ, Zapico Goni A, et al. Effectiveness of early physiotherapy to prevent lymphoedema after surgery for breast cancer: randomised, single blinded, clinical trial [serial online]. *BMJ*. 2010;340:b5396.
13. Fisher ES. Medical care—is more always better? *N Engl J Med*. 2003;349:1665-1667.
14. Jemal A, Siegel R, Xu J, Ward E. Cancer statistics, 2010. *CA Cancer J Clin*. 2010;60:277-300.
15. Goldberg JI, Wiechmann LI, Riedel ER, Morrow M, Van Zee KJ. Morbidity of sentinel node biopsy in breast cancer: the relationship between the number of excised lymph nodes and lymphedema. *Ann Surg Oncol*. 2010;17:3278-3286.
16. McLaughlin SA, Wright MJ, Morris KT, et al. Prevalence of lymphedema in women with breast cancer 5 years after sentinel lymph node biopsy or axillary dissection: objective measurements. *J Clin Oncol*. 2008;26:5213-5219.
17. Springer BA, Levy E, McGarvey C, et al. Pre-operative assessment enables early diagnosis and recovery of shoulder function in patients with breast cancer. *Breast Cancer Res Treat*. 2010;120:135-147.
18. Stout Gergich NL, Pfalzer LA, McGarvey C, Springer B, Gerber LH, Soballe P. Preoperative assessment enables the early diagnosis and successful treatment of lymphedema. *Cancer*. 2008;112:2809-2819.
19. Luft HS. Economic incentives to promote innovation in healthcare delivery. *Clin Orthop Relat Res*. 2009;467:2497-2505.
20. Rockson SG. Lymphedema. *Am J Med*. 2001;110:288-295.
21. Cheville AL, McGarvey CL, Petrek JA, Russo SA, Taylor ME, Thiadens SR. Lymphedema management. *Semin Radiat Oncol*. 2003;13:290-301.
22. Shih YC, Xu Y, Cormier JN, et al. Incidence, treatment costs, and complications of lymphedema after breast cancer among women of working age: a 2-year follow-up study. *J Clin Oncol*. 2009;27:2007-2014.
23. Bosco JL, Silliman RA, Thwin SS, et al. A most stubborn bias: no adjustment method fully resolves confounding by indication in observational studies. *J Clin Epidemiol*. 2010;63:64-74.
24. Doshi JA, Glick HA, Polsky D. Analyses of cost data in economic evaluations conducted alongside randomized controlled trials. *Value Health*. 2006;9:334-340.