

## A SYSTEMATIC REVIEW OF CARE DELIVERY MODELS AND ECONOMIC ANALYSES IN LYMPHEDEMA: HEALTH POLICY IMPACT (2004-2011)

N.L. Stout, R. Weiss, J.L. Feldman, B.R. Stewart, J.M. Armer,  
J.N. Cormier, Y.- C.T. Shih

Bethesda, MD (NLS); Porter Ranch, CA (RW); NorthShore University HealthCare and University of Chicago (JLF), Chicago, IL; University of Missouri (BRS,JMA), Columbia, MO; University of Texas MD Anderson Cancer Center (JNC), Houston, TX; University of Chicago (Y-CTS), Chicago, IL, USA

### ABSTRACT

*A project of the American Lymphedema Framework Project (ALFP), this review seeks to examine the policy and economic impact of caring for patients with lymphedema, a common side effect of cancer treatment. This review is the first of its kind undertaken to investigate, coordinate, and streamline lymphedema policy initiatives in the United States with potential applicability worldwide. As part of a large scale literature review aiming to systematically evaluate the level of evidence of contemporary peer-reviewed lymphedema literature (2004 to 2011), publications on care delivery models, health policy, and economic impact were retrieved, summarized, and evaluated by a team of investigators and clinical experts. The review substantiates lymphedema education models and clinical models implemented at the community, health care provider, and individual level that improve delivery of care. The review exposes the lack of economic analysis related to lymphedema. Despite a dearth of evidence, efforts towards policy initiatives at the federal and state level are underway. These initiatives and the evidence to support them are examined and recommendations for translating these findings into clinical practice are made. Medical and community-based*

*disease management interventions, taking on a public approach, are effective delivery models for lymphedema care and demonstrate great potential to improve cancer survivorship care. Efforts to create policy at the federal, state, and local level should target implementation of these models. More research is needed to identify costs associated with the treatment of lymphedema and to model the cost outlays and potential cost savings associated with comprehensive management of chronic lymphedema.*

**Keywords:** lymphedema, policy, payment, chronic disease

Lymphedema is a chronic disease affecting an estimated 3-5 million Americans, presenting a significant public health problem (1-4). Although evidence-based, best practice guidelines have been outlined in consensus documents (5-7) lymphedema is a relatively under-recognized condition in both medical and public domains. The reasons for this include a lack of public awareness of the condition, insufficient education and knowledge among health care providers regarding its etiology and management, and limited reimbursement coverage to support lymphedema care models.

Implementation of care models for

lymphedema faces several barriers. First, population-based prevalence studies are lacking, rendering the magnitude of the condition and concomitant population need unknown (1,3). Furthermore, little is known about the economic burden of this chronic, life-long condition as cost data related to lymphedema management and related complications are sparse. Lastly, although myriad studies and reviews report clinical efficacy of lymphedema management techniques (8-10), this evidence has not been adequately presented in a delivery model framework. In lieu of such infrastructure, coverage and reimbursement for condition management is relatively absent, thereby serving to create disincentives for providing adequate care.

It is critical that these issues be addressed at the local, state, national, and international levels by health policy initiatives with the primary goals to promote awareness, education, optimal treatment, and adequate coverage and reimbursement (2,11-14). The objectives of this review are to identify the evidence-base related to care delivery models and the costs associated with lymphedema management, as well as to provide recommendations for health policy initiatives targeting best practice for lymphedema management in the United States.

## METHODS

Two members of the executive committee (JNC, JMA) of the American Lymphedema Framework Project (ALFP) coordinated the literature search and article retrieval process. A research librarian assisted with initial searches using the search terms defined in the *Best Practice for the Management of Lymphoedema* (2006), with additional terms identified by topic authors (NLS, RW, Y-CTS) related to lymphedema (2004-2011). Standard databases were searched including Pub Med, CINAHL, the Cochrane Database of Systematic Reviews, Cochrane Controlled Trials Register, PapersFirst, ProceedingsFirst,

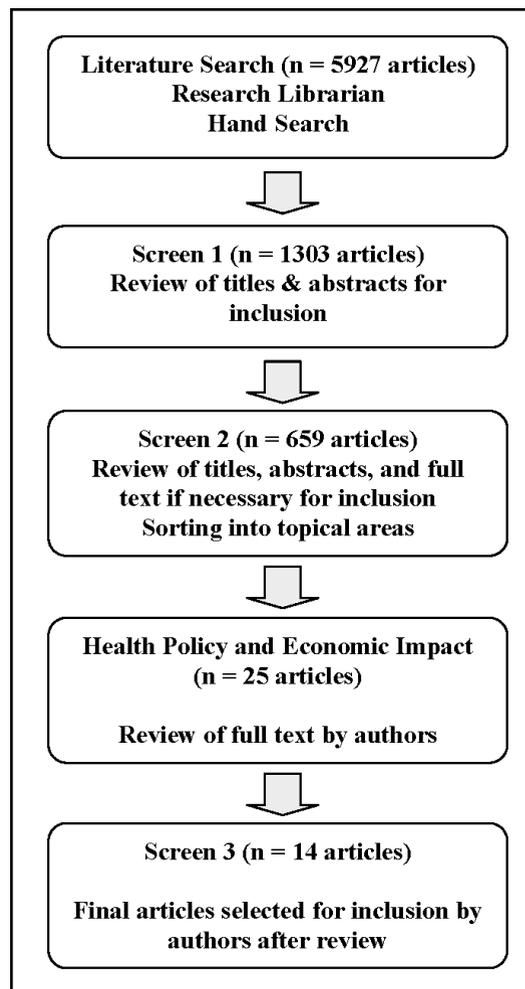


Fig. 1. Retrieval of manuscripts in systematic review.

Worldcat, PEDro, National Guidelines Clearing House, ACP Journal Club, and DARE. In addition, articles from the authors' archives were examined. These articles were nominated for inclusion by the topic authors and reviewed by the ALFP editors (BRS, JMA, JNC).

The process of the systematic review is detailed in Fig. 1. In brief, the reference librarian and AFLP research staff screened the search results to determine that inclusion criteria were met. Selected references were reviewed to ensure applicability to lymphedema. ALFP editors (BRS, JMA, JNC) sorted

**TABLE 1**  
**Assessment Criteria for Systematic Review (15)**

I	Strong evidence from at least one published systematic review of multiple well-designed randomized controlled trials.
II	Strong evidence from at least one published properly designed randomized controlled trial of appropriate size and in an appropriate clinical setting.
III	Evidence from published well-designed trials without randomization, single group pre-post, cohort, time series or matched case-control studies.
IV	Evidence from well-designed non-experimental studies from more than one center or research group
V	Opinions of respected authorities based on clinical evidence, descriptive studies, or reports of expert consensus committees.
<a href="http://www.medicine.ox.ac.uk/bandolier/band6/b6-5.html">http://www.medicine.ox.ac.uk/bandolier/band6/b6-5.html</a>	

abstracts and articles according to pre-defined topic areas. Full texts of each article were then assigned to topic authors (NLS, RW, Y-CTS) for review, verification of inclusion, summarization, and quality evaluation. Non-refereed articles, abstracts, and dissertations were excluded.

Each article was summarized by one topic author (NLS) and reviewed by the other authors (Y-CTS, RW) to ensure accurate representation of the material. Topic authors categorized the quality of the evidence using the research grading system from *The Oxford Medical Journal: The Bandolier model for evidence ranking (Table 1)* (15). Grading was by author consensus and the process was facilitated and confirmed by the editors. The final studies selected for inclusion are displayed in *Table 2* along with their assigned evidence ranking.

### *FINDINGS*

The literature search yielded studies in two primary domains: evidence-based care delivery models and cost analysis. Care delivery models were further stratified into educational interventions and clinical intervention models.

#### *Evidence-Based Care Delivery Models*

The delivery of care for lymphedema requires not only direct medical intervention to mitigate the condition, but also educational efforts to improve awareness among health care providers, patients, and communities as to the integral components of lymphedema management.

#### *Educational Interventions*

Matthews et al (2007) (16) demonstrated improvement in knowledge and attitude scores when a lymphedema educational program was provided to public participants and health care providers. This work supports the premise that targeted educational interventions may be effective in raising lymphedema awareness in both the community setting and in clinical domains.

Seymour et al (2005) (17) described the effectiveness of a collaborative provider educational model. This education exchange model was effective at increasing provider knowledge and awareness of evidence-based practice and demonstrated changes in clinical care delivery among participants at follow up. Additionally, increased patient adherence resulted in improved clinical outcomes.

Nandha et al (2007) (18) used a community-based educational model through school systems in a district in India endemic

**TABLE 2**  
**Abstracted Article Summary and Evidence Ranking**

Study Citation	Study Design	Evidence Ranking
<b>Models of Care Delivery</b>		
Mathews, M, et al (2007) (46)	knowledge and attitude change (n=36)	III
Nandha, B, et al (2007) (18]	Pre-test/ Post-test assessment of awareness (n = 8 villages in Tamil Nadu, India)	III
Yahathugoda, et al (2005) (19)]	Survey (n=101)	IV
Linnitt, N (2005) (22)	Case Study	V
Seymour, E (2005) (17)	Opinion	V
Armer, J, et al (2009) (21)	Expert consensus report	V
Morgan, P, et al (2006) (47)	Expert consensus report	V
Howell, D, et al (2005) (23)]	Descriptive study(n=4)	V
<b>Economic and Cost Analyses</b>		
Cherry, GW, et al (2005) (26)	Pre-test/ Post-test (n=29 patients with 33 ulcers )	III
Arsenault, et al (2011) (30)	Pre-test/post-test (n=21)	III
Shih, YC, et al (2009) (24)	Retrospective analysis of claims data (n=1,877 )	IV
Cheville, AL, et al 2010 (29)	Methods study to quantify utility values using subjective reports of Time Trade-off (TTO) and Euroqol 5D (EQ-5D) responses	IV
Stout, NL, et al 2011 (28)	Comparison of direct treatment costs of women with breast cancer lymphedema	IV
Bulley, C (2007) (27)	Qualitative Interviews with delphi analysis (n=44 )	IV
<b>Other Abstracted Articles – Not Relevant to Inform</b>		
Anderson, RT, et al (2004) (48)	Random sample survey (n=600)	N/A
Byrne, B (2001) (49)	Literature review	N/A
Chang S, et al (2010) (50)	Pre-test/Post test (n=53 patients undergoing inguinal lymph node dissection for melanoma)	N/A
Clegg-Lampthey, J, et al (2007) (51)	Descriptive study (n=158)	N/A
Domann, U, et al (2007) (52)	Systematic Review (14 papers includes 24,685 patients in 57 rehab clinics)	N/A
Haines et al (2010) (53)	RCT (n=89)	N/A
Ogbonnaya, L, et al (2004) (54)	Qualitative study using survey and focus group	N/A
Ridner, S et al (2011) (55)	Cross-sectional survey	N/A
Rockson, SG, et al (2008) (41)]	Literature Review	N/A
*This classification is based on the Bandolier system ( <a href="http://www.jr2.ox.ac.uk/bandolier/band6/b6-5.html">http://www.jr2.ox.ac.uk/bandolier/band6/b6-5.html</a> ) Abbreviations: DEC = Diethylcarbamazine, BCRL = Breast cancer-related lymphedema, OR = Odds ratio, ILF = International lymphedema framework, CME = Continuing medical education, DVT = deep vein thrombosis, LF= lymphatic filariasis, TTO = Time trade-off, EQ-5D = Euroqol 5D, N/A = not applicable		

with lymphatic filariasis. A significant improvement in lymphedema awareness and in adherence to preventive strategies was

found. The findings support the premise that a community-based educational model can improve awareness and increase adherence to

lymphedema management strategies.

Using a dermatology life-quality index, Yahathugoda et al (2005) (19) demonstrated poor quality of life and poor knowledge base among patients with lymphedema; concluding that the need existed for a community-based educational program to promote standard lymphedema treatment and management.

#### *Clinical Intervention Models for Lymphedema Management*

Morgan et al (2006) (20) published a review article examining the standard of care for the diagnosis and treatment of lymphedema in various medical domains. This review highlights the evidence base for complete decongestive therapy (CDT) and describes successful policy initiatives in the United Kingdom. These initiatives may serve as a model for other countries, including the United States.

Armer et al (2009) (21) reported the outcomes of an expert lymphedema stakeholder meeting on lymphedema management in the United States. Multi-disciplinary experts in the field of lymphedema made recommendations to collate evidence and promote best practice through policy initiatives. These recommendations are currently being implemented by the ALFP to shape the direction of best practice and policy in the United States.

Linnitt et al (2005) (22) published a case study illustrating clinical outcomes and cost savings associated with appropriate lymphedema management. This report demonstrated cost savings with appropriate lymphedema management and an overall decrease in lymphedema-related complications, such as cellulitis infections and associated hospitalizations, over time after the completion of appropriate treatment.

Howell et al (2005) (23) reported on a nurse-led community-based treatment program which integrated clinical and educational interventions to promote best practice for lymphedema management.

The intervention was clinically effective, yet demonstrated the substantial burden that lymphedema placed on the patient's quality of life even when appropriate and comprehensive care was rendered, suggesting the need for on-going supportive care using a clinical and community-based approach.

#### *Economic and Cost Analyses Associated with Lymphedema and its Treatment*

Shih et al (2009) (24) estimated the incidence of lymphedema and medical cost of treating lymphedema in breast cancer patients using claims data in the United States. The study reported that the two-year medical costs are significantly higher for patients with lymphedema (\$23,167) compared to those breast cancer survivors without lymphedema claims (\$14,877). Patients with lymphedema were twice as likely to have lymphangitis or cellulitis, known to contribute to a more advanced condition and compound medical costs (25).

Cherry et al. (2005)[26] estimated cost savings of approximately £8,000 per episode of care when a vibratory device was included as a modality to treat lymphedema associated with venous leg ulcers. To what extent the cost savings documented in this study are generalizable to lymphedema in the absence of venous pathology needs to be explored in future studies involving a much larger sample size.

Bulley et al (2007) (27) examined the physical and psychosocial burden associated with lymphedema, noting that patients with lymphedema experience greater burden than those without lymphedema, but this detriment may be alleviated with treatment interventions. This is a novel study reporting that the psychological burden of lymphedema is an important factor which must be considered when estimating the total cost of lymphedema.

Stout et al (2012) (28) compared the direct costs associated with early detection and treatment of early lymphedema using a novel Prospective Surveillance Model (PSM)

of care to the direct cost of treating advanced stage lymphedema over the first year following surgery for breast cancer in the United States. The PSM with early intervention demonstrated a significantly lower cost (\$693 per patient) as compared to treating advanced lymphedema (\$3,212 per patient). No indirect costs were included in this analysis. While cost per patient was much lower for patients in the PSM group consideration should be given to the potential for progression of lymphedema.

Cheville et al (2010) (29) quantified utilities in a cohort of patients with lymphedema in the United States. Utilities values provide a quantification of how a condition impacts quality of life (QOL) using a single value on a scale of 0 (death) to 1 (perfect health). Lymphedema-associated utilities were reported to be on average 0.80 (range 0.72 to 0.86). Utility values were lowest for patients with cancer-related lymphedema suggesting a greater QOL impact associated with the condition. The authors build an important foundation for cost-effectiveness analyses, as utility values are an important factor used to calculate quality-adjusted life years (QALYs), an outcome measure commonly used in cost-effectiveness studies.

Arsenault et al (2011) (30) assessed the impact of a CDT program on the cumulative incidence of hospitalizations for patients with recurrent lymphedema-related cellulitis. Prior to CDT intervention, they reported a cohort with a mean of 8.5 hospitalizations per year; following CDT and a 24 month follow up, there was a decrease in the number of hospitalizations to 0.63 per year. Although costs were not quantified in this study, the associated reduction in hospitalizations infers a significant cost savings that would be enabled by adequate CDT intervention for patients with lymphedema.

#### *APPLICATIONS TO CLINICAL (BEST) PRACTICE FOR LYMPHEDEMA*

This review substantiates the premise that lymphedema education models can be successful when implemented at the community, health care provider, and individual levels. Level III evidence exists to support educational interventions that can successfully improve awareness and promote positive attitude changes among clinicians and the public. Additional evidence demonstrates that education impacts the practice patterns of clinicians and motivates patients towards achieving better results through self-management. Targeted clinical education programs are associated with improvement in clinical outcomes.

Interval and on-going lymphedema management is carried out through implementation of clinically effective interventions. This review highlights level V evidence supporting the translation of these clinical interventions into comprehensive models of care. Consensus reports and expert opinion suggest that health care delivery models, when aligned with evidence-based guidelines, reduce disease burden, enhance outcomes, and positively impact both the individual and society (20,31-36). There is merit to recognizing a comprehensive care model that targets the life-long spectrum of lymphedema management based on this evidence.

This review exposes the paucity of currently available economic analyses pertaining to lymphedema management. One of the most rigorous studies is an analysis of claims data which demonstrates higher medical cost associated with lymphedema in a group of breast cancer survivors (24). While these findings are noteworthy in that they highlight the cost impact of condition management in women with breast cancer, caution must be exercised in extrapolating these estimates to other populations. It is widely recognized that costs estimated from administrative claims data under-estimate true incidence rates and costs due to the constraints of payment policies, coding systems, and reporting mechanisms. Theoretically, a stream-lined, evidence-based

care delivery model that uses a prospective approach for early detection and treatment of lymphedema could significantly reduce the overall costs of management. However, this has not been fully explored beyond a single direct cost analysis (37). The cost findings reported demonstrate that persons with lymphedema are faced with higher medical costs, likely throughout their lifetime. This should be recognized and warrants economic modeling to assess the total cost burden as well as studies of cost-effectiveness to improve condition management.

#### *Regulatory and Legislative Applications of Evidence*

Evidence-based medicine informs health care delivery models. Models are assessed based on their outcomes, resource utilization, and associated costs (38). A large body of evidence highlights clinically effective interventions for lymphedema management. However, assessment of the full comprehensive model for chronic lymphedema management has not yet been accomplished.

Despite this paucity of evidence, policy efforts for improving lymphedema coverage at the federal and state level in the United States have been undertaken. In 2009, a lymphedema measurement and treatment technology assessment was commissioned and presented at a public meeting of the Medicare Evidence Development and Coverage Advisory Committee (MEDCAC) (<http://www.ahrq.gov/clinic/ta/comments/lymphedema/>). The panel convened health care experts to examine the evidence-base for clinical lymphedema treatment. This panel reported an intermediate-level of confidence (1=Low confidence, 3=Intermediate confidence, 4- 5=High Confidence; <https://www.cms.gov/faca/downloads/id51a.pdf>) that complex decongestive therapy (CDT) alone, CDT with adjuvant compression devices, compression bandaging/compression garments alone, and pneumatic compression devices alone produce meaningful

improvements in health outcomes for lymphedema patients. These findings have the potential to impact Medicare coverage policies and can serve to inform the private payer community of the benefits of a comprehensive clinical model for lymphedema management.

Several state-based legislative efforts have resulted in proposed and enacted policy mandates specific to lymphedema. Analyses of state mandates have shed light on the potential economic burden of ubiquitous coverage for lymphedema medical management. *Table 3* provides a comparison of the mandate analyses from three states including an analysis of costs based on claims data covering the first seven years of the Virginia mandate. These data demonstrate that the cost of clinical management of lymphedema is low considering the prevalence of the condition among the risk pool of those included in the analysis. These data, however, may falsely under-estimate the true burden and costs associated with the lymphedema as claims data from private payers may under-represent the prevalence of lymphedema. Furthermore the purported costs, based on existing coverage allocations and current fee schedules, neglects consideration of durable medical equipment (DME) costs and other services not covered by the insurance plan. DME costs are not currently covered by many private payers, but may be required for care. On the other hand, none of these analyses consider the anticipated reduction in burden due to the prevention of lymphedema-related complications, including cellulitis hospitalizations among other issues which may result in cost savings (39,40). This review highlights level III evidence from an analysis of CDT in patients with recurrent lymphedema-related cellulitis (n=10) which reported an absolute risk reduction of 7.83 hospital admissions per year among the cohort studied, potentiating a significant cost savings (30). Reasonable extrapolation of this preliminary finding supports potential cost savings through adequate condition management.

**TABLE 3**  
**State Mandate Analyses of Lymphedema Legislation in the United States**

<b>Criteria</b>	<b>California*</b>	<b>Massachusetts†</b>	<b>Virginia</b>
<b>Bill</b>	AB 213 (Liu 2007)	S. 0896 (Spilka 2009)	HB 1737 (Wardrup 2003)‡
<b>Coverage required</b>	<ul style="list-style-type: none"> <li>• Physician diagnostic services and plan of care</li> <li>• Standard of care treatment</li> <li>• A supply of medically-required compression garments, compression bandages and associated compression materials</li> <li>• Patient education for:                             <ul style="list-style-type: none"> <li>• Self-treatment</li> <li>• Compression use</li> <li>• Techniques for self-measurement</li> <li>• Skin care</li> <li>• Recognition of infection</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>• Equipment and supplies</li> <li>• Complex decongestive therapy</li> <li>• Outpatient self-management training and education for the treatment of lymphedema</li> </ul>	Coverage for the treatment of lymphedema including: <ul style="list-style-type: none"> <li>• Supplies</li> <li>• Equipment</li> <li>• Complex decongestive therapy</li> <li>• Outpatient self-management training and education services by health care professionals who are qualified by specific education, experience, and credentials to provide the covered benefits.</li> </ul>
<b>Limits of applicability</b>	<ul style="list-style-type: none"> <li>• Individuals &lt;65 years with private insurance (group and individual)</li> <li>• Public plans including CalPERS HMO, Medi-Cal managed care, or Healthy Families</li> <li>• People ≥ 65 enrolled in Medi-Cal managed care plan</li> </ul>	<ul style="list-style-type: none"> <li>• Commercial insurers and MassHealth fully-insured market</li> <li>• Health Maintenance Organizations (HMOs), and Blue Cross Blue Shield plans,</li> <li>• Group Insurance Commission (GIC)</li> </ul>	<ul style="list-style-type: none"> <li>• Each insurer proposing to issue individual or group accident and sickness insurance policies providing hospital, medical and surgical, or major medical, coverage on an expense-incurred basis</li> <li>• Each corporation providing individual or group accident and sickness subscription contracts</li> <li>• Each health maintenance organization providing a health care plan for health care services</li> </ul>
<p>* “California Health Benefits Review Program: Analysis of Assembly Bill 213, Health Care Coverage for Lymphedema”, CHBRP 05-03, April 7, 2005. <a href="http://chbrp.org/documents/ab_213final.pdf">http://chbrp.org/documents/ab_213final.pdf</a></p> <p>† Massachusetts Division of Health Care Finance and Policy, “Review and Evaluation of Proposed Legislation Entitled: An Act Relative to Women’s Health and Cancer Recovery, Senate Bill 896” Provided for The Joint Committee on Public Health, December 2010.</p> <p>‡ Report of the Special Advisory Commission on Mandated Health Insurance Benefits, House Bill 383, Mandated Coverage of Lymphedema, Commonwealth of Virginia, 2003, <a href="http://leg2.state.va.us/dls/h&amp;sdocs.nsf/fc86c2b17a1cf388852570f9006f1299/45c3e11e8d10b10485256cfa005258ca/\$FILE/RD15.pdf">http://leg2.state.va.us/dls/h&amp;sdocs.nsf/fc86c2b17a1cf388852570f9006f1299/45c3e11e8d10b10485256cfa005258ca/\$FILE/RD15.pdf</a></p> <p>§ Virginia Report of the State Corporation Commission to the Governor and the General Assembly of Virginia The Financial Impact of Mandated Health Insurance Benefits and Providers Pursuant to Section 38.2-3419.1 of the Code of Virginia: Reports RD191, RD289, RD246, RD322 and RD294 covering reporting periods 2005-2009.</p>			

<p><b>Codes included</b></p>	<p>A primary or secondary diagnosis of 457.0, 457.1, or 457.2.</p>	<p>Diagnosis of lymphedema</p>	<p>ICD Codes: 457.0, 457.1, 757.0 CPT Codes: 97124 Massage, compression 97140 Manual therapy techniques 97535 Self-care/home management training</p>
<p><b>Sources</b></p>	<p>Milliman Claims database (The Milliman Health Cost Guidelines)</p>	<p>Massachusetts Division of Healthcare Finance and Policy's all-payer claim database</p>	<p>Claims Data from 39-43 insurers and HMOs representing 77-80% of the VA healthcare market 1.4 to 1.7 millions of units of coverage per year for 2004-2010.</p>
<p><b>Current claims for services</b></p>	<ul style="list-style-type: none"> <li>• Overall service utilization: 8.08 services per lymphedema patients per year, at a cost of \$963.31 per patient per year. <ul style="list-style-type: none"> <li>○ Durable medical equipment: Avg. 0.91 items of equipment per patient, at a cost of \$139.61 per patient per year.</li> <li>○ Compression garments: Avg. of 0.52 garments per patient, at a cost of \$50.64 per year.</li> <li>○ Pharmaceuticals: Avg. prescriptions filled = 0.16 prescriptions per lymphedema patient, at a cost of \$23.78 per year</li> <li>○ Physical and occupational therapy outpatient visits: 1.63 services per lymphedema patient, at a cost of \$172.20 per year.</li> <li>○ Visits reporting MLD: 0.86 per lymphedema patient, at a cost of \$87.60 per year.</li> <li>○ Inpatient hospitalization: 0.54 services per</li> </ul> </li> </ul>	<p>2008 Cost of Lymphedema Treatment per Member per Month: <i>Fully Insured:</i> Therapy \$0.006; Devices \$0.006. <i>Self Insured:</i> Therapy \$0.012; Devices \$0.015. (*claim records were limited to those carrying a diagnosis of breast cancer or lymphedema.)</p>	<ul style="list-style-type: none"> <li>• Average cost of \$250 per visit for up to 1.50 hours of treatment.</li> <li>• Average length of treatment ranged from 2 to 4 weeks or up to 20 visits depending on the severity of the lymphedema and the areas involved (unilateral vs. bilateral; arm vs. leg)</li> </ul>
			<ul style="list-style-type: none"> <li>• Claims filed as a percentage of the total claims: <ul style="list-style-type: none"> <li>○ Individual contracts: 0.54% (0.04-.06) corresponding to a cost per contract of \$1.53 (1.12 to 1.79) per year.</li> <li>○ Group contracts: 0.084% (0.06-0.11) corresponding to a cost per contract of \$2.69 (2.16 to 3.73) per year.</li> </ul> </li> </ul>

	<p>lymphedema patient at a cost of \$136.31 per year.</p> <ul style="list-style-type: none"> <li>o Physician visits: 0.54 per lymphedema patient, with an average cost of \$47.31 per patient per year.</li> <li>o Other services provided: <ul style="list-style-type: none"> <li>- 0.40 other unspecified facility visits per patient, at \$70.91 per patient per year.</li> <li>- 0.91 visits to other professionals (not specified), at a cost of \$62.93.</li> <li>- 0.55 unspecified services per patient year, with an average cost of \$114.61.</li> </ul> </li> </ul>	None reported	None reported	Average number of visits per contract for lymphedema treatment was 0.081, and the average number of days per contract was 0.010. No trends in utilization were perceptible over the seven years.
<p><b>Projected Service Utilization Impact</b></p>	<p>Expected to increase overall average utilization from 8.08 services per lymphedema patient to 8.20 services per lymphedema patient per year.</p>	None reported	None reported	Average premium impact as a percentage of the overall contract premium were as follows [Average (Range)]:
<p><b>Projected Premium Impact</b></p>	<p>Per patient cost of treatment could increase by \$12.15 per year based on the increase in utilization. *(The entire increase in per-unit cost is attributed to increased utilization, rather than to an increase in price)</p>	Net premium incremental impacts from 2011 to 2015: + \$0.01 to \$0.12 per member per month (0.00 to 0.02%).	<p>Cost figures range, estimated from survey results:</p> <ul style="list-style-type: none"> <li>• Individual contract: &lt;\$0.15 to \$2.00 per month per standard individual</li> <li>• Group contract: \$0.02 to \$5.53 per month per standard group certificate</li> </ul> <p>Insurers providing coverage on an optional basis estimated figures:</p> <ul style="list-style-type: none"> <li>• Individual contract: \$0.25 to \$5.58 per month per individual</li> <li>• Group contract: \$0.25 to \$3.98 per month per group</li> </ul>	<ul style="list-style-type: none"> <li>• Individual contract: Single 0.474 (0.27-0.64) Family 0.326 (0.28-0.42)</li> <li>• Group contract: Single 0.300 (0.16-0.40) Family 0.237 (0.13-0.33)</li> <li>• HMO Individual: Single 0.087 (0.02-0.11)* Family 0.087 (0.00-0.11)*</li> <li>• HMO Group: Single 0.146 (0.09-0.25) Family 0.117 (0.07-0.16)</li> </ul> <p>*single outlier removed</p>

**TABLE 4**  
**Policy Approaches for Lymphedema Management [adapted from Stout et al (11)]**

<ul style="list-style-type: none"> <li>Promote national policies on equitable, accessible, and culturally-sensitive health care services.</li> </ul>
<ul style="list-style-type: none"> <li>Consider a comprehensive multi-disciplinary societal approach to lymphedema management, including clinical care, health education counseling, and socio-economic support, as well as psychological, social, economic, and educational services.</li> </ul>
<ul style="list-style-type: none"> <li>Develop reimbursement and payment strategies for risk reduction and prevention programs based on known risk factors.</li> </ul>
<ul style="list-style-type: none"> <li>Enhance epidemiological surveys on lymphedema prevalence and incidence rates, utilizing standardized disease definitions and classifications.</li> </ul>
<ul style="list-style-type: none"> <li>Conduct standardized research on disease burden to evaluate the importance of lymphedema as a public health issue.</li> </ul>
<ul style="list-style-type: none"> <li>Implement a minimum basic care intervention for lymphedema management appropriate to the resources available.</li> </ul>
<ul style="list-style-type: none"> <li>Integrate lymphedema identification and management in the general practice of health care systems and general practitioners</li> </ul>

#### **RECOMMENDATIONS FOR FUTURE WORK**

Lymphedema is a chronic condition (41) that requires a comprehensive model of care for optimal management. As outlined in two articles by Bodenheimer et al in the *Journal of the American Medical Association*, successful components of chronic care models include: a focus on patient self-care management; wide-spread community-based education and awareness of continuing and on-going disease management strategies; increased provider awareness; and appropriate applications of interventions at pivotal points along the disease continuum (31,38). This approach has been extrapolated to lymphedema management by Stout et al (11) who propose a novel construct for basic, intermediate, and advanced levels of lymphedema management. The policy initiatives suggested by these authors (*Table 4*) outline the basis for community and provider integration for implementing these recommendations. This

model of care strives to develop a comprehensive approach for life-time management of lymphedema.

In the United States, lymphedema is a common sequela of cancer treatment (42). In 2006, the Institute of Medicine (IOM) (43) characterized the needs of adult cancer survivors relative to the trend of increased survivorship and the myriad of consequential late effects associated with treatment (42,43). The IOM report defines optimal survivorship care models, proposes steps to improve current care constructs, and outlines strategies to prevent or mitigate the late effects of cancer treatment. These recommendations should be foundational to informing U.S. policies supporting education and clinical care for lymphedema.

#### *Policy Options and Recommendations*

A streamlined approach to bridge the public health needs and the available health care resources for optimal lymphedema

management is needed. The chronic care model provides a suitable means to this end through public education and awareness initiatives, community-based interventions, health care provider education, and risk reduction and treatment strategies, and is supported by the findings of this review.

A framework for lymphedema-specific policy options that is based on the existing evidence for care delivery models, informed by available cost data and extrapolated based on the construct of chronic disease management, will have profound impact in the U.S. Policy options should target federal laws (Title XVIII of the Social Security Act, ERISA, FEHBA) and state laws (employee health plans, state employees, private insurance) as well as combinations of these matrices (Medicaid). Optimal integration of a care delivery model for lymphedema will require participation of stake-holders across a broad continuum. Health care providers are an obvious target of such effort. Additionally, both public and private payers are key stake-holders in enabling this model through reimbursement schemes designed to support condition management. Patient advocacy organizations and professional associations also play an important role in raising awareness and promoting optimal care models.

At the federal level, policies governing service coverage and payment under the guise of clinical practice guidelines could expand the availability of clinical models of care. The Center for Medicare and Medicaid Services should promote policy in which all aspects of evidence-based treatment intervention are adequately reimbursed. This act would align with the recent MEDCAC findings and enable treating providers to select effective, patient-centered treatment interventions. The Agency for Healthcare Research and Quality has released clinical practice guidelines specific to secondary lymphedema (<http://www.guideline.gov/content.aspx?id=15699&search=lymphedema>) and identified educational and clinical interventions suitable for its management. A demonstration project

could aid in expanding the provision of lymphedema care by tracking utilization, as well as measuring the cost impact of such care.

These federal and state policies and policy options should also be applicable to other countries with similar healthcare systems as well as to countries with other healthcare models allowing review and modification of treatment options on national, regional, or state and local levels.

To successfully track lymphedema-related diagnoses and treatment, a uniform coding system is required. In the United States, enhanced ICD-9 codes, Common Procedural Terminology (CPT) codes, and the formation of a comprehensive compression garment coding system under the Health Care Procedure Coding System (HCPCS) are initiatives that can substantially improve the tracking of condition incidence, prevalence, severity, and utilization through claims data or medical record analysis. Alternative payment models are being put forward by various U.S. health care professional associations (44) and these models should be examined and warrant consideration based on the dynamic natural course of lymphedema.

Organizations such as the American Lymphedema Framework Project (ALFP), the North American Lymphedema Education Association (NALEA), the Lymphology Association of North America (LANA), and the National Lymphedema Network (NLN), along with other professional (e.g., International Society of Lymphology and regional/national chapters) and advocacy organizations worldwide can target educational initiatives to increase awareness of the condition and its life-long implications on the patient, health care provider, and society. The Canadian Lymphedema Framework project was initiated in 2009 with parallel goals to those of the ALFP and could also serve as a collaborative partner (45). These organizations should establish and promote a health services research agenda to

investigate the natural history of lymphedema, as well as to study cost-effectiveness of various evidence-based care delivery models for lymphedema management.

State policy is another target for lymphedema-specific initiatives. Historical data on state-based legislation is highlighted in *Table 3* and provides an overview of feasible coverage mandates for third party payer consideration. These initiatives also have local education and awareness components at their core. Furthermore, the clinical and economic impact of state-based legislative initiatives should be evaluated and their extrapolation and expansion piloted.

Lastly, grassroots efforts are not to be overlooked. Community-based awareness, patient and provider education, and adequate delivery models are priorities for advocacy organizations. To date, grassroots efforts have been successful in supporting state mandates for lymphedema coverage. These local efforts should be expanded utilizing large-scale advocacy organizations, including the National Lymphedema Network, the American Cancer Society, LiveStrong, and others.

### CONCLUSION

This review supports widespread implementation of educational and clinical interventions as a means to improve health care delivery for patients with lymphedema. Policy initiatives should aim to elucidate the evidence-based lymphedema management interventions in an effort to guide coverage and reimbursement decisions for both public and private payers. Further, a collective effort is needed to develop policy targeting: (1) improved public and provider awareness of lymphedema; (2) promotion of effective care delivery models; (3) analysis of the cost-effectiveness of lymphedema management strategies; and, (4) assessment of the total economic burden of the condition. Future research should substantiate and integrate evidence from state mandate analyses, as well as the peer-reviewed literature so that these

data may inform sound policy. Concerted efforts that leverage resources at the federal, state, and local levels are instrumental to the success of lymphedema policy initiatives.

### ACKNOWLEDGMENT

The views expressed in this article are those of the author(s) and do not necessarily reflect the official policies or positions of Kaiser Permanente, University of Chicago, University of Missouri, or University of Texas.

### REFERENCES

1. Moffatt, CJ, PJ Franks, DC Doherty, et al: Lymphoedema: An underestimated health problem. *QJM* 96 (2003), 731-738.
2. Morgan, P, D Doherty, C Moffatt, et al: The National Lymphoedema Framework Project. *Nurs. Times* 101(2005), 48.
3. Lymphatic filariasis: The disease and its control. Fifth report of the WHO Expert Committee on Filariasis. *World Health Organ Tech. Rep. Ser.* 821 (1992), 1-71.
4. Rockson, SG: The broad spectrum of lymphatic health and disease. *Lymphat. Res. Biol.* 8 (2010), 101.
5. The diagnosis and treatment of peripheral lymphedema. 2009 Consensus Document of the International Society of Lymphology. *Lymphology* 42 (2009), 51-60.
6. Hsu, YL, MH Yen, PL Kuo, et al: San-Zhong-Kui-Jian-Tang, a traditional Chinese medicine prescription, inhibits the proliferation of human breast cancer cell by blocking cell cycle progression and inducing apoptosis. *Biol. Pharm. Bull.* 29 (2006), 2388-2394.
7. Chen, CM, SJ Cano, AF Klassen: Measuring quality of life in oncologic breast surgery: A systematic review of patient-reported outcome measures. *Breast. J.* 16 (2010), 587-597.
8. Mondry, TE, RH Riffenburgh, PA Johnstone: Prospective trial of complete decongestive therapy for upper extremity lymphedema after breast cancer therapy. *Cancer J.* 10 (2004), 42-48.
9. Badger, C, N Preston, K Seers, et al: Physical therapies for reducing and controlling lymphoedema of the limbs. *Cochrane Database Syst. Rev.* 4 (2004), CD003141.
10. The diagnosis and treatment of peripheral lymphedema. Consensus document of the

- International Society of Lymphology. *Lymphology* 36 (2003), 84-91.
11. Stout, NL, P Brantus, C Moffatt: Lymphoedema management: An international intersect between developed and developing countries. Similarities, differences and challenges. *Glob. Public Health* 7 (2012), 107-123.
  12. Donaldson, N, SD Horn, JC Edwards, et al: Evaluating the impact of partnerships to improve clinical quality. *Jt. Comm. J. Qual. Patient Saf.* 33(12 Suppl) (2007), 27-36.
  13. Goetzel, RZ, RJ Ozminkowski, VG Villagra, et al: Return on investment in disease management: A review. *Health Care Financ. Rev.* 26 (2005), 1-19.
  14. Rose, C, E Stovall, PA Ganz, et al: Cancer quality alliance: Blueprint for a better cancer care system. *CA Cancer J. Clin.* 58 (2008), 266-292.
  15. Assessment Criteria: Type & Strength of Evidence [<http://www.medicine.ox.ac.uk/bandolier/band6/b6-5.html>]
  16. Matthews, CE, S Wilcox, CL Hanby, et al: Evaluation of a 12-week home-based walking intervention for breast cancer survivors. *Support Care Cancer* 15 (2007), 203-211.
  17. Seymour E: Managing and promoting change: Implementing the Leg Club model. *Br. J. Community Nurs.* 10 (2005), S16, S18-19, S22, passim.
  18. Nandha, B, K Krishnamoorthy: School-based health education campaign—a potential tool for social mobilization to promote the use of DEC-fortified salt towards elimination of lymphatic filariasis. *Hlth. Educ. Res.* 22 (2007), 539-546.
  19. Yahathugoda, TC, D Wickramasinghe, MV Weerasooriya, et al: Lymphoedema and its management in cases of lymphatic filariasis: the current situation in three suburbs of Matara, Sri Lanka, before the introduction of a morbidity-control programme. *Ann. Trop. Med. Parasitol.* 99 (2005), 501-510.
  20. Morgan, P, C Moffatt: The National Lymphoedema Framework project. *Br. J. Community Nurs.* 2006, 11(4):S19-22.
  21. Armer, J, J Feldman, MR Fu, et al: ALFP: Identifying issues in lymphoedema in the US. *J. Lymphoedema* 4 (2009), 85-91.
  22. Linnitt N: Case study detailing treatment of bilateral lower limb lymphoedema. *Br. J. Community Nurs.* 2005, Suppl:S28-31.
  23. Howell, D, M Watson: Evaluation of a pilot nurse-led, community-based treatment programme for lymphoedema. *Int. J. Palliat. Nurs.* 11 (2005), 62-69.
  24. Shih, YC, Y Xu, JN Cormier, 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.* 27 (2009), 2007-2014.
  25. Vignes, S, M Arrault, A Dupuy: Factors associated with increased breast cancer-related lymphedema volume. *Acta Oncol.* 46 (2007), 1138-1142.
  26. Cherry, GW, TJ Ryan: Using cycloidal vibration to heal venous leg ulcers: a cost-analysis based on retrospective data. *J. Wound Care* 14 (2005), 177-178.
  27. Bulley, C: A needs assessment of lymphedema services in Fife and resulting recommendations. *Prim. Health Care Res. Develop.* 8 (2007), 128-140.
  28. Stout, NL, LA Pfalzer, B Springer, et al: Breast cancer-related lymphedema: Comparing direct costs of a prospective surveillance model and a traditional model of care. *Phys. Ther.* 92 (2012), 152-163.
  29. Cheville AL, M Almoza M, JN Courmier, et al: A prospective cohort study defining utilities using time trade-offs and the Euroqol-5D to assess the impact of cancer-related lymphedema. *Cancer* 11 (2010), 3722-3731.
  30. Arsenault, K, L Rielly, H Wise: Effects of complete decongestive therapy on the incidence rate of hospitalization for the management of recurrent cellulitis in adults with lymphedema. *Rehab. Onc.* 29 (2011), 14-20.
  31. Bodenheimer, T, EH Wagner, K Grumbach: Improving primary care for patients with chronic illness. *JAMA* 288 (2002), 1775-1779.
  32. Gagliardi, AR, MJ Dobrow, FC Wright: How can we improve cancer care? A review of interprofessional collaboration models and their use in clinical management. *Surg. Oncol.* 20 (2011), 146-154.
  33. Harris, SR, MR Hugi, IA Olivotto, et al: Clinical practice guidelines for the care and treatment of breast cancer: 11. Lymphedema. *CMAJ* 164 (2001), 191-199.
  34. Kligman, L, RK Wong, M Johnston, et al: The treatment of lymphedema related to breast cancer: A systematic review and evidence summary. *Support Care Cancer* 12 (2004), 421-431.
  35. McCabe, MS, J Jacobs: Survivorship care: models and programs. *Semin. Oncol. Nurs.* 24 (2008), 202-207.
  36. Stroebel, RJ, B Gloor, S Freytag, et al: Adapting the chronic care model to treat chronic illness at a free medical clinic. *J. Hlth. Care Poor Underserved* 16 (2005), 286-296.
  37. Stout, NL, LA Pfalzer, B Springer, et al:

- Breast cancer-related lymphedema: Comparing direct costs of a prospective surveillance model and a traditional model of care. *Phys Ther.* 92 (2012), 152-163.
38. Bodenheimer, T, EH Wagner, K Grumbach: Improving primary care for patients with chronic illness: The chronic care model, Part 2. *JAMA* 288 (2002), 1909-1914.
  39. Ko, DS, R Lerner, G Klose, et al: Effective treatment of lymphedema of the extremities. *Arch. Surg.* 133 (1998), 452-458.
  40. Földi, E: Prevention of dermatolymphangioadenitis by combined physiotherapy of the swollen arm after treatment for breast cancer. *Lymphology* 29 (1996), 48-49.
  41. Rockson, SG, KK Rivera: Estimating the population burden of lymphedema. *Ann. NY Acad. Sci.* 1131 (2008), 147-154.
  42. Cormier, JN, RL Askew, KS Mungovan, et al: Lymphedema beyond breast cancer: A systematic review and meta-analysis of cancer-related secondary lymphedema. *Cancer* 116 (2010), 5138-5149.
  43. Hewitt, M, S Greenfield, E Stovall: *Cancer Patient to Cancer Survivor: Lost in Transition*. Washington, DC, 2006.
  44. Guccione, AA, KJ Harwood, MS Goldstein, et al: Can "severity-intensity" be the conceptual basis of an alternative payment model for therapy services provided under medicare? *Phys. Ther.* 91 (2011), 1564-1569.
  45. Hodgson, P, A Towers, A Kennedy, et al: Lymphoedema care and management in Canada. *J. Lymphoedema* 6 (2011), 12-15.
  46. Mathews, M, G Bursey, A Park, et al: Increasing public and provider knowledge of lymphedema: Evaluation of the lymphedema roadshow. *J. Cancer Educ.* 22 (2007), 105-107.
  47. Morgan P, Moffatt C: An update on the Lymphoedema Framework Project. *Br. J. Community Nurs.* 11 (2006), S20-21.
  48. Anderson, RT, K Dziak, J McBride, et al: Demand for continuing medical education programs on cancer care among primary care physicians in North Carolina. *NC Med. J.* 65 (2004), 130-135.
  49. Byrne, B: Deep vein thrombosis prophylaxis: the effectiveness and implications of using below-knee or thigh-length graduated compression stockings. *Heart Lung* 30 (2001), 277-284.
  50. Chang, SB, RL Askew, Y Xing, et al: Prospective assessment of postoperative complications and associated costs following inguinal lymph node dissection (ILND) in melanoma patients. *Ann. Surg. Oncol.* 17 (2010), 2764-2772.
  51. Clegg-Lampsey, J, W Hodasi: A study of breast cancer in Korle Bu Teaching Hospital: Assessing the impact of health education. *Ghana Med. J.* 41 (2007), 72-77.
  52. Domann, U, S Bruggemann, H Klosterhuis, et al: [Guideline development for rehabilitation of breast cancer patients - phase 2: Findings from the classification of therapeutic procedures, KTL-data-analysis.] *Rehabilitation (Stuttg)* 46 (2007), 212-219.
  53. Haines, TP, P Sinnamon, NG Wetzig, et al: Multimodal exercise improves quality of life of women being treated for breast cancer, but at what cost? Randomized trial with economic evaluation. *Breast Cancer Res. Treat.* 2010, 124(1):163-175.
  54. Ogbonnaya, L, J Okeibunor: Sociocultural factors affecting the prevalence and control of lymphatic filariasis in Lau local government area, Taraba State. *Intl. Qlty. Community Hlth. Educ.* 23 (2004), 341-371.
  55. Ridner, SH, MS Dietrich, N Kidd: Breast cancer treatment-related lymphedema self-care: Education, practices, symptoms, and quality of life. *Support Care Cancer* 19 (2011), 631-637.

**Nicole L. Stout, MPT, CLT-LANA**  
**Independent Consultant**  
**7500 Woodmont Avenue #1209**  
**Bethesda, Maryland 20814**  
**Phone: 301-718-7338**  
**E-mail: nlstout90@gmail.com**