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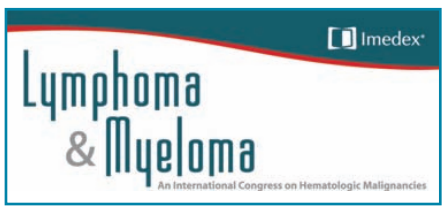

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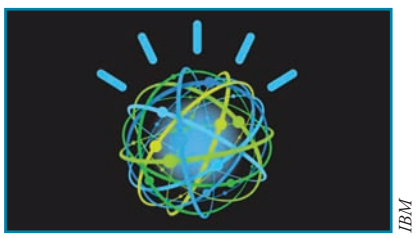

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PERIODICALS

Lymphedema: Early Detection Valuable, But Methods Debated

BY ROBERT H. CARLSON

DALLAS—While the risk of lymphedema after breast cancer surgery may be less today than in the past due to the use of sentinel lymph node biopsy, the problem is still a chronic, disabling condition for many breast cancer survivors.

Early detection and treatment can reduce the risk and severity. A possible model for surveillance and early detection of lymphedema and other debilitating side effects of breast cancer treatment came out of a recent roundtable meeting sponsored by the American Cancer Society. More than a dozen international experts drafted the "Prospective Model of Care for Breast Cancer Rehabilitation," which was published earlier this year in *Cancer* (***2012;118 suppl 8:2191-2200***).

There was less than perfect consensus, however, and two of the paper's authors debated the recommendations in a session here at the most recent National Lymphedema Network Conference, a meeting jointly sponsored by the National Lymphedema Network and the University of Chicago Pritzker School of Medicine.

The paper's first author, Nicole L. Stout, MPT, a certified lymphedema therapist, said the model needs to be the standard of care for women recovering from breast cancer. But Andrea Cheville, MD, Associate Professor and Director of Cancer Rehabilitation and Lymphedema Services at the Mayo Clinic, argued that the model is too vague to implement and that any recommendations need to be evidence based.

> There has been less than perfect consensus about a possible model for surveillance and early detection of lymphedema and other debilitating side effects of breast cancer treatment.

'Embed into Standard of Care'

Stout said surveillance and intervention will decrease the severity or prevent impairment and functional loss at all stages of disease management. "It's not good enough to wait for problems to develop. It's not good enough any more to say, 'we've treated your cancer—you should be happy to be alive.' We can do much, much better than that, and prospective surveillance enables us to do that."

The proposed model includes preoperative assessment on the first visit at breast cancer diagnosis prior to surgery, with baseline limb volume measurement and inter-limb comparison; strength and mobility tests; activity status; and extensive education for postoperative exercise and plan of care.

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ANDREA CHEVILLE, MD, argued that the model is too vague to implement and that any recommendations need to be evidence-based.

Postoperative follow-up for lymphedema would occur at regular intervals for at least one year, she said, citing recent studies that show that severe lymphedema can develop five years or more after surgery.

The model calls for subjective patient reports that can point to early development of lymphedema, and sequential limb measurements that identify segmental changes in volume. Also included would be monitoring for early postoperative situations such as loss of range of motion, infections, and seromas that are associated with the development of lymphedema.

"If we take these in aggregate and continuously monitor our patients to watch for early signs and symptoms, I guarantee we can find [lymphedema] if we use the standardized methodology that is put forward in the prospective surveillance model," she said.

"Waiting until the patient has a 'fat arm' puts the patient at risk for lymphostasis and fibrosis." Moreover, waiting until a patient develops Stage 2 lymphedema triples the cost of care as compared with the estimated costs associated with an early intervention, prospective surveillance model.

"We need to bring this [prospective surveillance model] in and embed this into our standard of care," she said.

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outcome from the whole cycle of care for the patient's problem that really matters."

Adding care coordinators to help users navigate a fundamentally flawed system will not work, he said. "Ultimately we need to change the structure so you don't need a care coordinator—so that care coordination is embedded in the way we organize our care delivery processes."

The U.S. has been competing in the wrong areas of health care delivery, Porter maintained. "We've been competing to aggregate bargain of power, get a higher reimbursement, shift cost to someone else, and capture patients so that we'll get the referrals, rather than what we must do, which is compete on delivering the highest value for the patient."

> "The first step is getting the definition of 'value' right."

He outlined six steps that will move health care delivery into a value-based system (*see box*). The first step is critical, he said: "We need a team that takes overall responsibility for the entire care of the condition, rather than just for the piece of the care that they provide."

He also explained approaches to change the reimbursement model—price bundling (which puts an emphasis on the end solution to the patient's problem, rather than paying for all the individual pieces to get there) and local capitation (fixed prices for a given medical problem). Models of the later used in Sweden reduce the costs of some procedures to a third of those in the U.S.—and the physicians did not get paid less, Porter said.

He concluded, like Kellerman, by reminding the audience of their role in making the changes necessary: "Is your organization on this journey? Have you started down the path to add value?"

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'Model Needed, But This Isn't It'

Cheville acknowledged that in many areas of supportive care—for example, physical functioning, pain management, treating psychosocial morbidit—breast cancer patients' problems are not being detected and adequately addressed in a timely fashion. There does need to be improvement in current strategies for detection and monitoring of treatment sequelae, and she said she is in favor of some type of prospective surveillance model (PSM).

But she argued that this particular model is vague, while at the same time "aspires to address virtually all sequelae attributed to cancer treatment in the survivorship cohort—psychological morbidity, fatigue, sleep deprivation, chemotherapy-induced peripheral neuropathy, boney metabolic disease, etc.—a very ambitious and broad umbrella."

> "It's not good enough to wait for problems to develop."

This prospective surveillance model fails to distinguish itself from much more structured and elaborately formulated survivorship plans that already exist—all of which endorse screening activities, education, and proactive treatment of sequelae.

"In fact, this is clinical practice—do we need to call it something different?" she said. "A basic tenet of good medicine is to risk-stratify patients, identify their vulnerabilities, screen in an evidence-based fashion, and modulate our monitoring and treatment responses over time. This is good medicine."

One of Cheville's complaints was the lack of outcomes data to support the model. "At every talk about breast cancer survivorship that I've been to we see numbers from different cohorts, and, with the exception of quality-of-life data, they all lack population norms," she said. Other than for lymphedema, "we don't know what is the risk of shoulder range of motion, musculoskeletal dysfunction, upper quadrant neuropathic pain syndromes, that are attributable to breast cancer treatment."

And the prospective surveillance model requires integrated activity across multiple disciplines and specialties, without acknowledging the formidable logistical challenges involved in that. "Who does the therapy, who prescribes the medication?"

Cheville said she would not consider the model a guideline, since it has not undergone the critiques and rigorous scrutiny of a guidelines, and lacks evidence-based, validated algorithms. "These things should be evidence-based. In attempting to be all things to all survivors while ignoring the costs, infrastructural requirements, and shaky evidence base, the PSM is a vague and frustrating road map for stakeholders."

A near-term investment to prevent chronic morbidity is appealing but unproven she said. "Most importantly, there is no empirical or theoretical basis to suspect that the prospective surveillance model impacts the natural history of lymphedema. There are cheaper screening models available."

Rebuttal

Rather than rebut Cheville's arguments, Stout actually thanked her for laying out a template for development and validation of the model. She did not dispute that evidence is lacking, but said that patients cannot wait until all the evidence is in. And, the model was created to be broad, rather than vague, so it could be tailored to the patient's stratifiable risk.

"We move forward in medicine with far more invasive, far more costly procedures with far less data," Stout said. We cannot risk missing the earliest onset of lymphedema—if we miss the earliest diagnosis and wait until we have a visible condition we have fibrosis and a lifelong chronic condition."

No Perfect Consensus

In an e-mail exchange after the meeting, Cheville said the final prospective surveillance model described in the *Cancer* supplement "did not reflect a perfect consensus of all the authors," and that she wrote a separate piece in the supplement on the cost implications.

"I do think we need to improve our current strategies for detection and monitoring of treatment sequelae, so I am in favor of some type of prospective surveillance model," Cheville said. However, given the current level of supportive evidence and cost implications, it is premature to advocate for all the recommendations called for in the model. "We will not have the payers' ear forever, and if we annoy them or squander their interest on untenable versions of the [model], we will get nowhere."

> "There is no empirical or theoretical basis to suspect that the prospective surveillance model impacts the natural history of lymphedema. There are cheaper screening models available."