



7-Oct-2008

ASX RELEASE

Article on Effective Ways of Managing Lymphedema publishes in the 'Breast Center Bulletin' in the US

ImpediMed attaches for the information of shareholders a newsletter from the National Consortium of Breast Centers, Inc, in the United States. The newsletter includes an article by Dr Steven Schonholz on 'Effective Ways of Managing Lymphedema'. It discusses how Dr Schonholz has incorporated the use of ImpediMed devices, and the L-Dex™ reading, in the clinical assessment and management of breast cancer patients for aiding in the prevention of Lymphedema progression to irreversible stages.

Dr Schonholz concludes in this article that "With this new technology not only will we be able to identify sub-clinical lymphedema, but also we will be able to prevent the chronic sequelae of the disease process, and may be able to identify the risk factors associated with lymphoedema".

For shareholders the article is a good description of the value proposition of ImpediMed's L-Dex™ products in a clinical application in the US market.

ImpediMed is going direct to market with a sales force now of 8 people to place L-Dex™ products with Breast Surgeons, Oncologists and Therapists throughout the United States.

For more information:

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About ImpediMed

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The Breast Center Bulletin



No. 102 September 2008
21SNN0896-6677

Published by the National
Consortium of Breast
Centers, Inc.

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Upcoming Events

**19th Annual National
Interdisciplinary Breast
Center Conference**
March 14-18, 2009

**Saturday, March 14
Specialized Pre-Conference
Courses:**

- Genetics Course
- Digital Mammography
Course
- Surgical Course
- CBE Certification Course
- Breast Cancer Navigator
Course

**Wednesday, March 18
Specialized Post-Conference
Courses:**

- Grant Writing Course
- BSE Certification Course

 This symbol identifies a "spotlight article" featuring a specific breast center's unique program(s). If you would like to see your center featured in a spotlight article please email Emily McAllister at EmilyM@breastcare.org

This newsletter is an opportunity for members to discuss programs and products, but does not represent an endorsement by the NCBC.



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visit www.breastcare.org for more
conference details!**

Collaboration Resulting in Providing Centralized Quality Care to Patients

With Marcy Parsons, RN, RT(R), CRN Breast Health Services, MultiCare Health System
Tacoma, WA

Three leading healthcare organizations, Franciscan Health System, MultiCare Health System, and TRA Medical Imaging are joining forces to create a state-of-the-art breast center for residents of Tacoma and the entire Puget Sound region in Washington state. These organizations are also partnering with the Gary E. Milgard Family Foundation, a private charitable organization. The not-for-profit Carol Milgard Breast Center will open in Tacoma, WA during the first part of 2009. Dr. Khai Tran, medical director of mammography and women's imaging at TRA Medical Imaging in Tacoma, refers to the new center as the realization of a dream that these healthcare organizations have been working toward for years. The center is a solution to a very real problem the residents of Washington have: long wait times for results after screening procedures, due to the lack of a centralized breast center. The center will combine a comfortable, caring environment with the newest technology and highly trained and specialized staff with the goal of focusing on helping women through the stressful process of a breast cancer diagnosis. Currently, only a few mammography and breast imaging experts work in the immediate Tacoma area. Not to mention, many facilities are still using film mammography for screening. The combination of these, and other factors, results in a real problem of getting a patient's films in front of the few local doctors available who can read them. By consolidating breast screening and diagnostic services, the center will change the current dynamic and make the process of getting screening results to each patient more efficient.



Exterior Rendering of the new breast center

The healthcare organizations' view is that even though they compete with each other on many fronts, the field of breast care is one in which they can collaborate to benefit everyone, most importantly the women in the Tacoma area. By working together, combining funding, staff and other efforts, the healthcare organizations can do a much better job of providing coordinated quality care than they could ever do as three separate entities. Though Franciscan and

MultiCare have worked together before to provide other services to the community, The Carol Milgard Breast Center represents a new venture: the first time three healthcare systems have collaborated to open a brand new medical imaging facility.

The center will be named to honor the spirit of a woman who was a long-time Tacoma resident, philanthropist, and breast cancer

survivor. The breast center will offer screening and diagnostic services including digital mammography, breast ultrasound, breast MRI, and breast biopsy, including stereotactic, ultrasound-guided and MRI-guided biopsy, and bone density services. With a singular focus on breast screening and diagnosis, the center will employ board certified radiology physicians specially trained in breast imaging and will comply with best practices for care established by the Mammography Quality Standards Act, as well as voluntary guidelines recommended by the American Cancer Society. By adopting these high standards and maintaining a focus on breast care, the healthcare organization believe the center will make incredible strides toward improving breast care for all women in the region. *For more information about The Carol Milgard Breast Center, please contact Marcy Parsons via email at mparsons@carolmilgardbreastcenter.org.* ■

Effective Ways of Managing Lymphedema

By Steve Schonholz, MD, Clinical Coordinator Mercy Medical Center Springfield, MA

Lymphedema is a topic that many physicians know about but experience difficulty in managing effectively. There is the stigma that the surgical procedures necessary for primary control of the disease, contribute to this post-operative impairment. There are multiple risk factors for lymphedema but none that have proven definitive. Additionally there are different modalities of treatment but unfortunately, only after the lymphedema becomes clinically evident and irreversible skin and tissue changes begin to occur. At the Breast Care Center at Mercy Medical Center in Springfield, MA, we have become proactive in the care of our patients regarding lymphedema. Current literature shows that with early detection we can prevent the long term disability associated with lymphedema. We have implemented a program using the L-Dex™ score and physical therapy both preoperatively and postoperatively.



The American Cancer Society (ACS) has projected 1.5 million new cancer cases in 2008 and the overall cost of this care has been estimated by the National Institutes of Health (NIH) to be \$206.3 billion annually. This figure includes the cost of lost productivity due to illness, and lost productivity due to premature death. The relative 5 years survival rate for all cancers is 66%. An estimated 10.5 million Americans have been identified as having a past history of cancer. (1)

Unfortunately, many of these survivors have developed life-long physical impairments secondary to the effects of their primary medical treatment (surgery, chemotherapy and radiation therapy) designed to ablate local, regional and systemic disease. One such common impairment is secondary lymphedema seen in patients with breast, colorectal, pelvic and skin (melanoma) cancers. Incidence rates for lymphedema range from 24-49% (2) for breast cancer and 5-67% for pelvic cancers (3-6).

This impairment is often chronic and impacts function of survivors in the home and work environment and contributes to secondary issues related to cosmetics and quality of remaining life.

The clinical diagnosis of lymphedema by primary health care providers (surgeons, medical and radiation oncologists) is often not established until

the condition is visibly apparent or until the degree of dysfunction and impairment is so severe that patients are unable to function within their given work or home environment.

One example of a new prospective paradigm of cancer care and its potential impact on severity of impairment was demonstrated in a recent clinical trial conducted by the NIH between 2001-2006 investigating comorbidities in a cohort of 196 newly diagnosed breast cancer patients. Results of the study indicated the importance of a prospective model of care in the reduction of lymphedema severity and a positive therapeutic effect of early intervention and were recently published in *Cancer* (Gergich, et al, "Preoperative Assessment Enables the Early Diagnosis and Successful Treatment of Lymphedema", *Cancer*, June 15 2008, Vol 112, pp 2809-2819).

In 2007, the U.S. Food and Drug Administration cleared the first of ImpediMed Limited's medical devices for clinical assessment and monitoring of lymphedema. The technology employs a low-frequency current that passes through the patient via gel-backed electrodes placed on the skin. The procedure is painless, imperceptible to the patient and is simple to perform. The low-frequency current produced travels only through extra cellular space, due to the high capacitance of lipids contained in the cellular membranes, thus preventing the current from traveling through intracellular space.

The first ImpediMed device has been designed to compare impedance, or resistance to the flow of that current, through the patient's at-risk limb with that of his or her contralateral uninvolved limb. The results of that ratio are reported by the device as the Lymphedema Index, or L-Dex™ value. The more extra cellular fluid contained in the arm, the higher the L-Dex value. In a study of healthy women, Cornish et al. established normative ranges, which have been standardized into an L-Dex range from -10 to +10. An abnormal L-Dex score can assist physicians in their diagnosis of sub-clinical lymphedema up to 10 months prior to clinical presentation (7).

"...we have become proactive in the care of our patients regarding lymphedema."

L-Dex measurements can be used to prospectively manage the risk

Continued on Pg. 3

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NCBC to Offer Breast Health Navigator Certification Program at 2009 Conference

By Emily McAllister, Public Relations and Project Manager, National Consortium of Breast Centers, Inc. Warsaw, IN

In the recent history of quality patient care, the breast health patient educator and navigator has become a vital component in many breast centers across the country. This position is sometimes referred to as the case manager, breast services manager or care coordinator, Nurse Navigator or Patient Navigator. For several years NCBC members have asked to share the job descriptions of navigators. These have been collected by the NCBC and are contained in a library accessible to members. Based upon the diversity in job descriptions reflecting various roles and responsibilities from center to center, it was determined that a coordinated approach to clarifying this position would be welcomed by both the breast health professionals filling this role as well as the administrators who have set expectations of the position.

"...it was determined that a coordinated approach to clarifying this position would be welcomed..."

In recognition of this need, the NCBC formed a review team to identify the various navigation components in the breast health patient navigation process and assign skills and a knowledge base that will be needed by the breast health professional to perform the navigation components. This skill set as well as the knowledge base will be the basis of the Breast Health Navigator Certification.

There will be three classifications of navigators: the Breast Health Education Navigator, the Breast Health Imaging Education Navigator and the Breast Cancer Education Navigator. Each classification's skill set and knowledge base builds upon the previous. The Breast Health Education Navigator assists patients from the time they walk in the door to their scheduled mammogram. The Breast Health Imaging Education Navigator may work with the patient from the time of taking history through the results of their mammogram. And the Breast Cancer Education Navigator may work with the patient from intake through end-of-life.

The first year offering this certification will be 2009. Course attendees meeting minimum proficiency on the exam will receive certification for one year and be able to sit for the three-year certification in 2010 at no cost. This course will consist of instruction on the core competencies of navigation on Saturday, March 14 with a certification test on Sunday, March 15. The NCBC is excited to offer this program for the first time at the 19th Annual National Interdisciplinary Breast Center Conference March 14-18, 2009. Registration for the conference will be available online in October at www.breastcare.org and will include educational qualifications for registrants as well as a course curriculum outline. ■

Effective Ways of Managing Lymphedema...

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of lymphedema in patients with breast cancer and to monitor patients undergoing treatment for lymphedema. Clinical trials in the last decade by Armer, Box, and Johansson, investigated various impairments in patients diagnosed with breast cancer. (8-10)

These studies established the importance of early pre-operative baseline assessment of patients providing evidence-based rationale for this concept.

At the Breast Care Center all patients are evaluated using the L-Dex score to obtain a preoperative evaluation. With women undergoing lumpectomy and radiation, repeat measurements are obtained on the 1st visit postop (~1 week), again prior to initiation of radiation and with completion of radiation therapy. They then have repeat evaluation every 3 months for 2 years and then every 6 months thereafter. If chemotherapy is involved, measurements are obtained prior to chemotherapy and monthly throughout the course, and when completed. For women having mastectomy with or without reconstruction, they also have preoperative L-Dex score and in addition a PT consult for teaching and postoperative management. They follow the same routine as the women with lumpectomy and radiation regarding L-Dex evaluation but also receive PT management via our VNA postoperatively for the first 1-2 weeks.

If the L-Dex score continues to increase or stay elevated they are referred to the Lymphedema Clinic. They are evaluated and measured for a compressive sleeve. The sleeve will stay on for two-week intervals at which point the patient will be reevaluated. If the L-Dex score returns to normal, she is followed closely to watch for recurrent sub-clinical lymphedema. If continually elevated, the sleeve remains on until the L-Dex score returns to normal and then the patient is followed for progressive recurrence.

The physician sees the woman initially and the risk of lymphedema is discussed as well as detection and preventive therapy. This may be done at the initial consultation if it is dealing with an evaluation or management of a chronic process. It may also be done as a follow-up visit once a diagnosis of cancer is made and surgical options are being discussed. The testing is done by the Medical Assistant (MA) in our Center. The procedure is simple and involves data input, assessment and upload of results into tracking software. On repeat visits, the woman only sees the MA unless there is an elevation in the L-Dex score. A procedure note is dictated and submitted using a CPT billing code of 38999, Miscellaneous Lymphedema Study. At this time reimbursement has been between \$169 and \$240 per procedure.

We are not only using the L-Dex score for new patients but also to assist

with management of patients with chronic lymphedema. In some cases we have found individuals that have no longer required the compressive sleeve after years of wearing the sleeve and others who are able to be without the compressive sleeve for several weeks at a time. When a woman has this chronic problem and has required continual use of the compressive sleeve, even several weeks out of the year appears to be a significant advantage compared with continuous wear. With this new technology not only will we be able to identify sub-clinical lymphedema, but also we will be able to prevent the chronic sequelae of the disease process, and may be able to identify the risk factors associated with lymphedema.

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