Inadequate peripheral lymphedema screening is a persistent gap in the provision of quality survivorship care at many breast cancer centers. Lymphedema should be identified and treated during the subclinical stage, when it is more likely reversible. The purpose of this project was to integrate a screening process for patients with breast cancer at risk for lymphedema, using bioimpedance spectroscopy via the L-Dex®, in a breast cancer center. A protocol was developed that included specific criteria for early patient referral to physical therapy.

**AT A GLANCE**
- For breast cancer survivors, a screening protocol should be established that uses bioimpedance spectroscopy to identify subclinical lymphedema.
- Advanced practice nurses should provide lymphedema education to patients.
- Early identification and referral to physical therapy based on the screening protocol could reduce the incidence of clinical lymphedema and the associated effects.

### Lymphedema Screening

A process is needed to ensure that patients at risk for upper-extremity lymphadenopathy receive the prescribed treatment and return for follow-up care, including measurements, management, and risk reduction (American College of Surgeons, 2014). The National Lymphedema Network recommended a written protocol in breast cancer treatment centers for arm measurements and a referral process for patients who qualify for a certified lymphedema therapist. Moreover, preoperative and postoperative measurements should be the standard of care throughout survivorship, and patients with a 10-point increase in L-Dex® U400 scores should be referred to physical therapy (PT) for conditioning and compression sleeve use (National Lymphedema Network Medical Advisory Committee, 2013).

Bioimpedance spectroscopy (BIS) is an effective, evidence-based screening method for subclinical lymphedema (Soran et al., 2014) using the L-Dex. In one study, BIS-based detection and early subclinical lymphedema treatment in at-risk breast cancer survivors reduced clinical lymphedema incidence (36.4% to 4.4%) over five years (Soran et al., 2014). BIS was highly reliable for detecting subclinical lymphedema in another cross-sectional study (Fu et al., 2013). In a multi-institutional study, BIS detected changed L-Dex scores within six months postoperatively, before the onset of lymphedema-related clinical changes (Vicini et al., 2013). The L-Dex generates a measurement using a low frequency electrical signal that is transmitted from the device to the patient via skin surface electrodes; it is noninvasive, and the patient does not experience any sensation during the measurement (Soran et al., 2014).

### Challenging the Standard of Care

At the University of Cincinnati Cancer Institute (UCCI) Breast Cancer Center, the advanced practice nurse (APN) team recognized that patients were referred to PT only after reporting symptoms consistent with clinical lymphedema. No standard screening process existed for detecting subclinical lymphedema or making appropriate referrals for early identification and intervention. A protocol was developed that included specific criteria for early patient referral to physical therapy.
FIGURE 1.
PROTOCOL FOR THE USE OF BIOIMPEDANCE SPECTROSCOPY IN THE EARLY DETECTION OF UPPER-EXTREMITY LYMPHEDEMA

PREOPERATIVE MEASUREMENT AND EDUCATION
- Perform a preoperative L-Dex® measurement at the time of surgery or port placement.
- Obtain a baseline L-Dex measurement prior to neoadjuvant chemotherapy.
- Provide lymphedema education, including the purpose of L-Dex measurement.

L-DEX MEASUREMENT PROCEDURE
- Preparation
  - Obtain measurements prior to any lymphedema physical therapy treatment.
  - Patients should not exercise two hours prior to the measurement.
  - Perform equipment precheck.
- Measurement steps
  - Measure the at-risk side:
    - The side that has had sentinel node or axillary node dissection OR
    - The side of cancer for bilateral sentinel or axillary node dissection OR
    - The dominant arm for prophylactic bilateral mastectomy with bilateral sentinel node dissection
  - Provide a copy of the L-Dex score at the preoperative and postoperative measurements.
  - Document the L-Dex score and discuss with an advanced practice nurse or surgeon to determine if a physical therapy referral is needed.
  - Do not dismiss the patient from the visit until after a provider reviews the L-Dex report.
- Ensure a follow-up appointment is made:
  - 3-month postoperative appointment
  - 6-month postoperative appointment
  - 12-month postoperative appointment
  - Every 6 months for years 1–5
  - Annually beginning at year 6

CRITERIA FOR PHYSICAL THERAPY REFERRAL
- If the L-Dex score increases by 10 or more above baseline, do the following:
  - Discontinue scheduled measurements for any patient under care of physical therapy.
  - Resume scheduled measurements after the patient has been released from physical therapy.

PT intervention. As a result, the APN team sought to implement a lymphedema screening protocol and evaluate the protocol’s ease, adherence, and integration into the clinical setting. In addition, the team examined APN confidence in performing L-Dex measurements and the efficiency of the decision-making process for providing PT referrals. Moreover, this project aimed to determine the percentage of at-risk breast cancer survivors with postoperative measurements who had subclinical lymphedema and received a protocol-based PT referral.

Methods
The UCCI institutional review board approved exempt status. No conflict of interest existed. The setting was the surgical oncology clinic at the UCCI Breast Cancer Center in downtown Cincinnati. UCCI treats an estimated 1,411 new patients with cancer each year (Association of Community Cancer Centers, n.d.). A surgical oncologist, an APN, an oncology nurse, two medical assistants (MAs), and a certified lymphedema physical therapist piloted the protocol. Patients who were diagnosed with breast cancer and underwent an SLNB or axillary dissection were eligible. This pilot was performed for six months with data collected during three quarters. Formative evaluations were performed at the end of each quarter, allowing the identification of specific challenges, including workflow issues, protocol adherence, or other factors that had yet to be identified.

Procedure
The Plan, Do, Study, Act model was used to develop and implement the pilot protocol. During the Plan phase, the project coordinator collaborated with UCCI’s breast cancer surgical oncologist and an APN to develop an evidence-based protocol, including patient eligibility criteria, preoperative measurement and education, the L-Dex measurement procedure, postoperative schedule for follow-up L-Dex measurements, and criteria for referral to PT (see Figure 1).

The project coordinator collaborated with the certified lymphedema physical therapist regarding the protocol and referral process, and developed an evaluation rating scale and interview tool for evaluation purposes. The evaluation rating scale tool included whether the measurement was preoperative or postoperative, length of time needed for each measurement, and requirement for a PT referral. It also included 11 items measured using a 10-point Likert-type scale, which addressed the ease of using the protocol, confidence in determining the measurement, and knowledge of when to refer the patient to PT. APNs underwent an evaluation interview of the protocol at two-month intervals (quarters) during the pilot project (see Figure 2).

The surgical oncologist and APN were trained to use the L-Dex device and protocol. The APN was responsible for uploading data from the device to the computer software, as well as for completing the evaluation rating scale for each measurement and client-specific EPIC® documentation. The Do phase consisted of protocol implementation during the six-month pilot project. Patients underwent a baseline L-Dex measurement and received education regarding lymphedema and the purpose of the L-Dex screenings. Timing of measurements varied according to time since surgery. Patients were referred to a certified lymphedema physical therapist if they experienced a 10-point increase or more in L-Dex score from their preoperative baseline measurement.

Analyses
To evaluate temporal trends in the time to perform and confidence ratings with the L-Dex measurement, the evaluation rating scale tool information was divided
into three categories: time frame (three quarters), staff member who performed the L-Dex measurement (APN, nurse, or MA), and measurement points (preoperative baseline or postoperative follow-up). In addition, the percentage of patients who underwent a postoperative L-Dex measurement and were referred to PT was calculated.

The data were entered into Microsoft Excel for analysis of the following measures: average time to perform the L-Dex measurements each quarter, ease and confidence ratings of using the protocol each quarter, and number of postoperative patients referred to PT based on their L-Dex score.

**FIGURE 2.** BIOIMPEDANCE SPECTROSCOPY OF PATIENTS AT RISK FOR LYMPHEDEMA: USING THE L-DEX® PROTOCOL (LDP) EVALUATION TOOL

**INSTRUCTIONS**
Please complete the LDP Evaluation Tool following each use of the L-Dex to measure patients at risk for lymphedema.

**PREOPERATIVE MEASUREMENT?**
- Yes
- No

**POSTOPERATIVE MEASUREMENT?**
- Yes
- No

If yes, specify the postoperative measurement:
- 3 months
- 6 months
- 12 months

**Length of time to perform L-Dex measurement:**

Start time: ___________ End time: ___________

Was patient referred to physical therapy based on the score?
- Yes
- No

**Note.** Please place an X in the box that indicates the degree to which you agree or disagree with the following statements.

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- It was easy to determine if the patient was eligible for the L-Dex measurement preoperatively.
- Using the L-Dex patient education brochure was helpful in teaching my patient about lymphedema and the purpose of the L-Dex measurement.
- Running a "test cell" on the L-Dex each day prior to use was easy.
- Inputting patient information into the L-Dex was easy.
- Following the measurement steps to prepare the patient for the L-Dex measurement was easy.
- Placing the electrodes on the patient according to the protocol was easy.
- Providing the patient with a copy of his or her L-Dex score was easy.
- Determining if the patient should be referred to physical therapy based from the protocol was easy.
- The protocol was easy to follow and assisted with efficiency in performing the L-Dex measurement.
- I am confident that I can determine if the patient required a postoperative measurement according to the follow-up criteria.
- I am confident that I can get an accurate measurement using the L-Dex and can determine if the patient should be referred to physical therapy according to the protocol.

Please answer the following:

- Were there any characteristics about this patient that made the protocol difficult to follow?

Please provide any additional comments you think would be helpful in evaluating the protocol.
Results

Formative Evaluations
During the first quarter, workflow was impeded because measurements could not be completed for the number of eligible patients by the APN. Therefore, L-Dex training was provided to additional oncology staff to increase those performing measurements and decrease demands on the APN.

During the second quarter, protocol adherence was addressed because L-Dex scores were not being routinely reported to the surgical oncologist or APN prior to the patient leaving the center, which impeded a decision regarding a PT referral. Therefore, UCCI’s technology department uploaded the L-Dex software onto the physician computers, allowing the surgeon or APN to view the L-Dex score on entering the patient’s room. Additional staff training regarding the L-Dex score review by the surgeon or APN for patient care decisions was performed.

Staff Utilization
During the study phase in the pilot project, 33 evaluation rating scale tools were collected and categorized (10 in quarter 1, 12 in quarter 2, and 11 in quarter 3). Of the 26 preoperative baseline and 7 postoperative (three-month) measurements, the APN performed 27 and the nurse or MA performed 6. The APN’s L-Dex measurement time decreased during the pilot from 42 minutes per measurement in quarter 1 to 28 minutes in quarter 3.

Lymphedema Measurements
The mean level of agreement for the 11 items in Figure 2 increased from 8.2 in quarter 1 to 9.8 in quarter 3, indicating greater satisfaction and confidence. Of the 7 patients with postoperative L-Dex measurements, two were referred to PT based on their L-Dex score. The protocol identified 28% of postoperative patients with subclinical lymphedema who would not have been found through standard-of-care clinical parameters.

All at-risk breast cancer survivors were agreeable and compliant with the L-Dex measurement screenings. Because the standard of care did not include lymphedema education, those receiving protocol measurements reported being well informed about lymphedema risks and the importance of measurements postoperatively and as part of their long-term survivorship care.

Discussion
Integrating the protocol into the clinical setting became more efficient. The APN’s ease and confidence in using the protocol and decision-making process improved. The protocol captured 28% of postoperative patients with subclinical lymphedema, consistent with reported contemporary rates (Soran et al., 2014).

The project aims were met. The protocol could be fully implemented and integrated into the clinical setting. Significant lessons were learned during the pilot, which involved the training of more staff and protocol fidelity to avoid missing patients who qualify for a PT referral.

During the Act phase, the team determined that the protocol did not need further revision. The quality improvement project allowed for a standard screening process to detect subclinical lymphedema and provide early treatment. This is a vital, previously unaddressed component of breast cancer survivorship. The detailed protocol ensured consistency and workflow efficiency when using the L-Dex U400 device.

Recommendations for the future include evaluating the effectiveness of early treatment in the prevention of clinical lymphedema by following those patients referred to PT based on their L-Dex score to determine if the combination of detection and early treatment of subclinical lymphedema improves patient outcomes. In addition, the protocol should be expanded to feature an additional breast surgical oncologist at the other UCCI Breast Cancer Center in the Cincinnati area. Also, a controlled research study should be conducted at UCCI to determine the effectiveness of detecting and treating subclinical lymphedema using the established L-Dex protocol.

Conclusion
A protocol for BIS via the L-Dex device should be established in clinical practice; this provides APNs with a consistent, objective approach to detect subclinical lymphedema, assists the APN with evidence-based decision making for PT referral, and provides improved lymphedema education from the APN for at-risk survivors. The protocol could decrease clinical lymphedema incidence, improving functional ability and quality of life among survivors by decreasing arm edema and reducing joint and muscle aches, limb tightness, infection rates, and overall medical costs for chronic lymphedema treatment.

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The author takes full responsibility for this content and did not receive honoraria or disclose any relevant financial relationships.
REFERENCES

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