Towards An Evidence Base For Our Practice

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Despite the large number of people affected by primary or secondary lymphedema, general consensus and research evidence are lacking to support many of the clinical recommendations to reduce the risk of lymphedema or prevent its progression to more advanced and permanent stages (Poage et al., 2008; Ridner, 2002). Economic and healthcare delivery-system forces; increasing awareness and advocacy by patients, families, and advocates; findings from increasingly rigorous, sophisticated, and longer-term research studies; and technological developments in assessment and treatment in the field of lymphology are coming together with synergistic momentum to support identification of evidence-based interventions for best practices in treating and preventing lymphedema. Particularly in this past decade, increasing emphasis on evidence-based practice in LE risk reduction and management has been the legacy of five key organizations which will be discussed here: International Lymphoedema Framework, National Lymphedema Network, Oncology Nursing Society, Lymphatic Research Foundation, and American Lymphedema Framework Project.

Following is an introduction to the terms used. Also, see Table 1 on page 2 (Permission request from ONS is pending).

Evidence-Based Practice

As defined by the Oncology Nursing Society, Evidence-Based Practice (EBP) aims to make clinical decisions

Table 1 — Definitions and Distinctions

EVIDENCE-BASED PRACTICE
Evidence-based practice is “a total process beginning with knowing what clinical questions to ask, how to find the best practice, and how to critically appraise the evidence for validity and applicability to the particular care situation. The best evidence then must be applied by a clinician with expertise in considering patient’s unique values and needs. The final aspect of the process is evaluation of the effectiveness of care and the continual improvement of the process” (DePalma, 2000; from http://onsopcontent.ons.org/toolkits/evidence/definitions.shtml).

RESEARCH UTILIZATION
“A process of using findings from conducting research to guide practice” (Ti- tler, Mentes, Rake, Abbott and Baumler, 1999).
“The process by which scientifically produced knowledge is transferred to practice” (Brown, 1999. (From http://onsopcontent.ons.org/toolkits/evidence/defi- nitions.shtml).

DIFFERENCES BETWEEN EVIDENCE-BASED PRACTICE AND RESEARCH UTILIZATION

While research utilization (RU) overlaps with some of the same philosophic thread-works of EBP, EBP goes beyond just the rigorous scientific research steps.
Research Utilization refers to the review and critique of scientific research, and then the application of the findings to clinical practice.
Evidence-Based Practice (EBP) represents a broader concept. When clinicians use the EBP approach, they go beyond the expertise of clinicians and researchers, and consider the patient's preferences and values to guide patient care.

FACTORS IN THE EVIDENCE SOURCE EQUATION

Clinician Experience + Patient Preferences + Scientific Findings = Evidence-Based Guidelines

Combining the strongest evidence from all three sources for a specific health problem improves the care of current and future patients who share that problem.
- Clinician Experience: A clinician who makes trustworthy observations, carefully analyzes care situations, knows individual patients' preferences, applies pertinent learnings from previous clinical situations to the current one, and has relevant knowledge can offer insights that improve patient care (Wakefield et al. 1998).
- Patient Preferences: When clinicians solicit and respect the treatment-related desires of patients, the most appropriate health care decisions can be made. Patient preferences are influenced by values, beliefs, culture, and previous personal or family experiences.
- Scientific Findings: Rigorous, credible, clinically relevant research that, when applied to a specific health situation, contributes to improved care. (From http://onsopcontent.ons.org/toolkits/evidence/definitions.shtml).
based on best evidence, either from the research literature or clinical expertise. EBP considers the preferences and values of the patient and family in the process of delivering care. While the clinician may utilize the best evidence available, application and outcomes in lymphedema care will differ based upon the patients’ values, preferences, concerns, and/or expectations (http://onsopcontent.ons.org/toolkits/evidence/definitions.shtml).

**Best Evidence**

With so much information literally at our fingertips in this age of internet access, it is sometimes difficult for therapists, clinicians and patients to know what is the best evidence for lymphedema treatment. Best evidence can be found in both research and non-research sources (http://onsopcontent.ons.org/toolkits/evidence/definitions.shtml).

For example, research evidence can include (and not be limited to): meta-analyses, integrated research reviews, and research with human subjects. Non-research sources may include (and not be limited to): clinical expertise, quality improvement data; infection control data; cost effectiveness analysis; retrospective or concurrent chart reviews; and patient preferences (http://onsopcontent.ons.org/toolkits/evidence/definitions.shtml).

**International Lymphoedema Framework**

In 2002, the International Lymphoedema Framework (ILF; http://intlf.org/) was launched under the direction of Clinical Director Dr. Christine Moffatt, a nurse researcher/clinician expert in lymphedema and wound healing. The aims of the ILF are to provide evidence of the magnitude of lymphedema and lymphedema-related disorders as a health problem, to determine the level of need, and to provide international guidance on service development and care of patients. The ILF is focused on supporting the development and evaluation of integrated primary care-based LE services. An essential feature of the ILF is the partnership that has been established to enable the many different lymphedema stakeholder groups around the world to be represented in reaching a consensus about the appropriate treatment for patients with primary and secondary lymphedema. A major achievement of the ILF has been the publication of the International Consensus Document, Best Practices for the Management of Lymphoedema in 2006 (http://intlf.org/), providing best-evidence practice guidelines based on an extensive literature review. The UK Best Practices document has already impacted patient access to specialist care in Great Britain. It has become a model for other countries. To ensure international outreach to the lymphedema community, the ILF is now promoting and supporting collaborative relationships with worldwide lymphedema organizations and the development of national partnerships around the world.

**National Lymphedema Network**

Since 2005, in an effort to bring organization and consensus to the field of LE management and training, the National Lymphedema Network (NLN) Medical Advisory Committee (MAC) has developed and periodically revised position papers based on consensus expert opinion and the current scientific literature. The authors include members of the NLN MAC, a group which is composed of therapists, physicians, and nurses expert in the field of LE.

Position papers include:
- **Training** http://www.lymphnet.org/pdfDocs/nlntraining.pdf, 2005,
- **Air Travel** http://www.lymphnet.org/pdfDocs/nlnairtravel.pdf, 2008,
- **Exercise** http://www.lymphnet.org/pdfDocs/nlnexercise.pdf, 2008,

**Table 2 — What interventions are effective in reducing the risk for and treating secondary lymphedema?**

**Selected ONS PEP Card Recommendations Based on Weight of the Evidence***

**RECOMMENDED FOR PRACTICE**
- Complete Decongestive Therapy

**LIKELY TO BE EFFECTIVE**
- Maintaining Optimal Body Weight

**BENEFITS BALANCED WITH HARMS**
- Prophylactic Antibiotics for Recurrent Infections

**EFFECTIVENESS NOT ESTABLISHED**
- Hyperbaric Oxygen

**NOT RECOMMENDED FOR PRACTICE**
- Drug Therapy: Diuretics

**EXPERT OPINION**
- Air Travel Precautions

*See ONS PEP card and Poage et al. 2008, for details of evidence base for categorization of interventions. Consensus on categorization based on level of evidence in the literature will be re-evaluated as additional evidence becomes available.


**Oncology Nursing Society**

In 2007-2008, an Oncology Nursing Society (ONS) Lymphedema Putting Evidence into Practice (PEP) team consisting of advanced practice nurses, staff nurses, and a nurse researcher
undertook a thorough review of current literature to identify effective interventions for the treatment of lymphedema following cancer treatment. The specific task of the ONS PEP card team was to develop a resource for oncology nurses that provides evidence-based nursing interventions for reducing risk for and treating secondary lymphedema. This would enable:

1) Staff nurses to recommend prompt and effective interventions for patients with or at risk of lymphedema following cancer treatment; and

2) Advance Practice Nurses who are Certified Lymphedema Therapists to treat the patient, both according to consensus evidenced-based practice guidelines.

The team reviewed current clinical practice guidelines, systematic reviews, and research studies undertaken between 1997-2007. The 2006 UK Best Practices document and NLN MAC Position Papers were highly useful in order to insure critical domestic and international literature was not overlooked and in some cases as validation of consensus decisions. Some 218 articles were initially extracted, reviewed, and categorized using the ONS PEP Weight of the Evidence Classification System (Recommended for Practice, Likely to be Effective, Benefits Balanced with Harms, Effectiveness not Established, Effectiveness Unlikely (not used in this case), and Not Recommended for Practice). Only those studies that met these criteria were reviewed and included in final recommendations for practice by consensus of the team. Where evidence was limited, expert opinion consistent with sound clinical practice was utilized.

A timely evaluation of current knowledge regarding cancer-related secondary LE, including identification of gaps in research and recommendations for future directions for clinicians and researchers, was prepared (Poage et al., 2008). The product of nine months of intensive task force effort and external expert review led to the May 2008 release of the ONS LE PEP Card (http://resource.ons.org/ProductDetails.aspx?sku=INPEPV04; Poage et al., 2008). Revision of the May 2008 PEP card in December 2008 is evidence of the ongoing need to continually evaluate literature for the latest evidence and reassessment of expert opinion (Table 2).

Many intervention studies reviewed were limited by small sample size, lack of control groups, and/or short-term follow-ups. The rigors of current therapies, even evidence-based, may also pose considerable challenges for patients and clinicians as they are dependent on access to specially trained therapists. Thus, as few would deny, the team concluded that on-going research is needed.

**Lymphatic Research Foundation**

The Lymphatic Research Foundation (LRF) has long recognized the need to establish scientific evidence upon which to base possible prevention and treatment strategies for lymphatic diseases and lymphedema. In 2008, development of a patient registry and biorepository (blood and tissue collection) was authorized by the board and the first phase of this project, the patient registry is under development. When both phases of this project are complete, patients and their healthcare providers will be able to place information in the registry. Eventually, patients will also be able to donate blood or tissue samples (from sources such as tissues removed during surgical procedures) to be “banked” or stored. The long term goal of this project is to contribute to the field of scientific knowledge about lymphatic diseases and lymphedema. The Lymphatic Research Foundation expects, with appropriate approvals, to make data from both the registry and the tissue/blood bank available for qualified scientists to use in research studies.

**American Lymphedema Framework Project**

The American Lymphedema Framework Project (ALFP) was launched in 2008 as a national collaborative initiative in partnership with the ILF. A core group of multidisciplinary clinicians including physicians, nurses, therapists, and investigators with a demonstrated expertise in lymphedema serve as the ALFP’s leadership steering committee. This project involves a partnership with patients, advocates, lymphedema therapists, expert clinicians, researchers, organizations, educators/trainers, third-party payers, and industry as stakeholders to develop and implement nationally-endorsed standard of evidence-based best practices for lymphedema within the different service models in the U.S. The mission of the ALFP is to improve clinical outcomes in patients with and at risk for lymphedema and related disorders. This mission will be accomplished by attainment of two key goals:

1) establishing and disseminating evidence-based and expert consensus on the highest quality standards of care as a Best Practices Document for patients with and at risk for lymphedema in the United States, and

2) developing and disseminating the ALFP minimum dataset (MDS).

The ALFP will provide an organized forum for stakeholders to develop and evaluate a set of consensus evidence-based Best Practices in the United States. The development of the MDS is aimed at the collection of common data elements by therapists about patient encounters for improved evaluation of patient-based outcome measures. The implementation of the Best Practices document and the lymphedema minimum data set will provide a comprehensive evaluation of the size and complexity of lymphedema.
as a health care problem in the United States and demonstrate the clinical, psychosocial, and economic benefits of adopting best practices.

**Measurement and Evidence-Based Practice**

Evidence to support best practices can only be obtained when a researcher can accurately measure the effect of a risk-reduction activity or a method of treatment. For example, if we cannot measure whether pain, odd sensations in swollen areas, or limb size stay the same (as would be the case if we are trying to prevent LE) or change (as we hope would happen when LE is treated), we have no way of knowing if what we are doing is working. If researchers use different tools to measure these things, then we cannot compare the findings from different research studies. So, there is a need for reliable measurement method for patient symptoms and swelling.

- Patient registries and minimum (common) data sets are designed to make sure that all patients with similar problems and their healthcare providers who provide information for that database are asked/asking the same questions. Data from these sources can be used to measure many things, such as the number of treatments people with arm LE have when they undergo comprehensive decongestive therapy, or the kind of symptoms that accompany LE. Psychological problems, such as depression, can be measured using questionnaires that have been given to many people with and without depression. After initially testing the questionnaire in both groups, researchers can look at the difference in answers between the groups and assess if someone is depressed.

In the case of LE, physical measurement of the amount of swelling is difficult at times, especially in patients with swelling in places other than their arms and legs. Even when the swelling is in a limb, differing criteria and methods are used to determine if someone has LE, or if they are responding to treatment. These include water displacement, circumferences, perometry, electrical impedance, and self-reporting of symptoms. Thus, as there is no “perfect” way to measure some forms of LE or an agreed-upon way to measure limb volume, we struggle with understanding the effectiveness of some treatment modalities. This makes it difficult to establish the evidence base for our LE management. Because of these issues, when ONS was developing the PEP card, they also asked a nurse scientist to review all ways that are currently being used to measure LE and create a resource for healthcare professionals to use when deciding how to measure their patients. This review can be found at http://www-ons.org/outcomes/measures/lymphedema.shtml.

**Future Research**

Further investigation, with larger sample sizes, consistent measurement approaches, precisely defined and delivered, theoretically-sound interventions are required to advance the evidence basis for best practices in LE risk-reduction and management. In addition, longer follow-up time frames are needed before definitive conclusions can be reached regarding interventions for persons at risk of or those who have LE.

On-going research is needed to assess which interventions are most effective in reducing risk and preventing progression of LE. Only then can further research-based recommendations be made to improve evidence-based practice in LE risk-reduction and management.

**A Final Definition: Synergy**

Synergy is defined as:

> combined effort being greater than the sum of the parts: the working together of two or more people, organizations, or things, especially when the result is greater than the sum of their individual effects or capabilities

(Encarta Dictionary: English [North America]). In common language we talk about more heads (thinkers) being needed to help solve a complex problem. We speak of many hands making work light. Sometimes in special circumstances all of the cumulative efforts of a set of individuals yields even more than the sum of the individual efforts. That is synergy, when the whole is greater than the sum of the parts. We have a momentum, a synergy in our field as we make progress in bringing consensus to the evidence-based best practices for LE risk reduction and management among our diverse disciplines, our clinical experts, and investigators. It is indeed an exciting time to be involved in helping move our field forward.

**How Can You Help?**

There are several ways in which you can help to develop an evidence base for treatment of LE and related disorders, in addition to being actively involved in the NLN.

- Readers of this article concerned about increasing awareness, advocacy and access to best practices in LE, and establishing systems to evaluate progress in the field are invited to participate in the ALFP stakeholders activities. More information is available at www.alfp.org.
- Nurses who care for cancer patients with LE may want to join ONS and become a member of the Lymphedema Management Special Interest Group. Information is available at www.ons.org.
- Persons with lymphatic diseases and/or LE can be a part of LRF’s patient registry and Biorepository when they open. Stay tuned at www.lrf.org for future developments.
- Ongoing research studies need patient volunteers. Check crispcit.nih.gov or www.clinical trials.gov to find open studies which may be of interest to you or your patients.
Selected References


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