

ALFP TO UPDATE THE BEST PRACTICE DOCUMENT

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The Best Practice for the Management of Lymphoedema document (Lymphoedema Framework, 2006) has made a significant impact on the quality of lymphoedema care in the United Kingdom and worldwide. The International Lymphoedema Framework (ILF) has partnered with the American Lymphedema Framework Project (ALFP) to update and expand the 2006 edition to incorporate recent advancements and updated understanding. The goal of this manuscript is to provide an overview of the continued partnership of the ILF and the ALFP and to outline the methodology used for this important update.

Key words

Lymphoedema
Best Practice
Literature search
Expert review
Consensus

Interest in lymphoedema research and in its clinical management has increased dramatically in recent

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years. Indeed, in the last five years alone, the number of retrieved articles from a PubMed keyword search on lymphoedema has increased nearly 10% per year, resulting in a 42% increase in the number of publications returned from 2004 to 2008, as compared to the relatively modest body of literature of the prior two decades (Figure 1). During that timeframe, organisations such as the American Cancer Society (ACS), the National Lymphedema Network (NLN), the Lymphology Association of North America[®] (LANA[®]), the International Lymphoedema Framework (ILF), and the American Lymphedema Framework Project (ALFP) have emerged and served as important collaborative platforms for investigators' accelerating interest and awareness of lymphoedema in the medical community. These organisations have also been instrumental in initiating consensus within the field, however, fragmented guidelines remain for the evaluation, treatment, and follow-up care of patients with lymphoedema. For example, the ACS consensus and reference document on lymphoedema care is one of the most cited in the field of lymphology to date (ACS, 1998).

In 2006, the UK-based Lymphoedema Framework (now the ILF) released the *Best Practice for the Management of Lymphoedema* (Lymphoedema Framework, 2006). This document was the culmination of a substantial review of

the lymphoedema-based literature and a UK national consensus on standards of practice (Morgan et al, 2006). Initially launched in 2002, the Best Practice document project was driven by the Lymphoedema Framework with input from patients with lymphoedema, national patient support groups, national professional lymphoedema groups, clinical experts, and stakeholders from industry. Subsequently, an international panel of experts (including the second and final authors on this manuscript) along with key national and international lymphoedema organisations reviewed and endorsed the document before its final release. Sponsored in part by an educational grant from Sigvaris[®], the Best Practices document (Lymphoedema Framework, 2006) was distributed in the UK to all primary care trusts identified as key stakeholders in the field of lymphoedema. It has subsequently been distributed to over 15 countries worldwide.

National and international experts are in agreement that the Best Practice document was successful in raising awareness of lymphoedema in the UK and globally. The effect on health policy in the UK is equally noteworthy, as the Best Practice document dramatically changed national lymphoedema reimbursement practices and access to care. Despite epidemiologic studies that estimated the prevalence of lymphoedema at 1 000 000

patients in the UK (Moffatt et al, 2003), health policy makers had been reluctant to address the problem due to a lack of available evidence in Cochrane systematic reviews. The document also led to a new classification for lymphoedema-related supplies (e.g. garments and devices) by the Department of Health (DH), with subsequent reimbursement by the drug tariff. Ongoing research in the UK is currently focused on defining lymphoedema metrics that will be applied to organisations in the National Health Service to measure stage or severity, treatment efficacy, effectiveness, outcomes, and costs. Outside the UK, practices outlined in the document are currently being applied in the course of lymphoedema management in clinics throughout the world. The document has been translated into Japanese for distribution by the Japanese Lymphoedema Framework. The document has been endorsed by the international lymphoedema community as a new 'standard' and has been referred to as the 'bible' for lymphoedema management by clinical specialists.

A key initiative for the ALFP is to provide an update to the Best Practice document. At the initial ALFP ad hoc Steering Committee Meeting in October of 2008, an ALFP Best Practice Committee was created and charged with the task of reviewing and updating the Best Practice document (Figure 2).

The committee is made up of a diverse group of lymphoedema specialists, including physicians, nurses, physical therapists, occupational therapists, massage therapists, researchers, patient advocates, caregivers, and industry experts. Specifically, the ALFP sought to:

- ▶ Identify and integrate US-based health policies and lymphoedema practices in order to create a document to guide contemporary and optimal lymphoedema care
- ▶ Update and extend the Best Practice document with evidence dating from 2005 through to 2009 based on a professional, rigorous literature review and national/international consensus process
- ▶ Identify broad practice standards applicable to the international lymphoedema community for future

review, consensus building, and translations.

The challenge to creating a current US and global Best Practice document from the foundations of the 2006 UK Best Practices document with updated literature is primarily related to the paucity of randomised clinical trials in the field of lymphoedema – an obstacle that has remained since the creation of the original document. Randomised clinical trials (RCTs) are considered central to the development of clinical practice guidelines and foundational to a true Cochrane review (West and Newton, 1997). However, for conditions in which randomised clinical trials are not widely available, other sources of evidence, such as the expert opinion of professionals and patients (Rycroft-Malone, 2001; Smith and Pell, 2003) and consensus methods are considered valid approaches for developing best practice guidelines (Frances et al, 1998; Black et al, 1999; Hawryluck and Crippen, 2002; Michie et al, 2005). For the ALFP-updated Best Practice document, this process of incorporating new information pertaining to lymphoedema treatment will involve an extensive updated literature review followed by expert review and consensus.

Literature search

A literature search of the following

databases is currently underway by an experienced search librarian: Cumulative Index to Nursing & Allied Health Literature (CINAHL), PubMed, PubMed Clinical Queries (including Complementary Medicine), EBM Reviews — Cochrane Central Register of Controlled Trials, Cochrane Database of Systematic Reviews (CDSR), American College of Physicians (ACP) Journal Club, Database of Abstracts of Reviews of Effects (DARE), Physiotherapy Evidence Database (PEDro), WorldCat, Papers First, Proceedings, and the National Guidelines Clearing House. The literature review search strategy was adapted from the Cochrane Review for physical therapies for reducing and controlling lymphoedema of the limbs, the UK Best Practice document, and the outline of the American Best Practice document update.

The general terms used for all of these search engines include: lymphedema/lymphodema/lymphoedema, oedema/edema, elephantiasis and swelling. These were then combined with the following term sets: therapy, manual lymph drainage (MLD), compression, pumps, movement, risk, and care. These terms were exploded and modified according to the database being searched

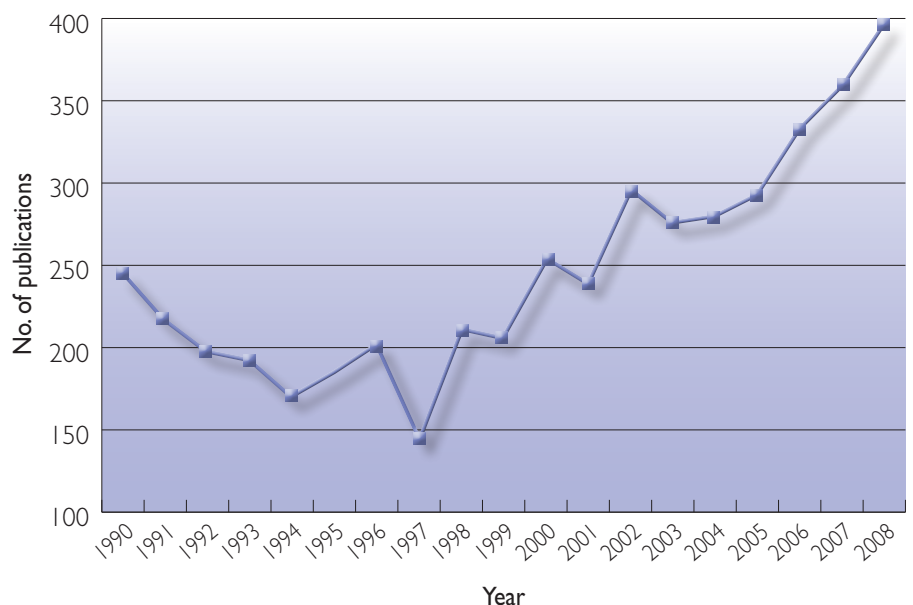


Figure 1. PUBMed cited literature using search term 'lymphedema' (1990–2008).

In addition, websites of health institutions and online lymphatic/lymphoedema societies and organisations are being searched. The biennial congress proceedings of the International Society of Lymphology (ISL) (1977–2009) *Lymphology*, *Lymphatic Research and Biology*, and the *Journal of Lymphoedema* are being searched by hand. Primary authors will be contacted when publications are not available. Foreign language publications will be searched and translated as resources are available. Levels of evidence will be documented in the process of publication review using a system based on the Health Technology Assessment Model (Murphy et al, 1998).

Expert review

To ensure a comprehensive and well-rounded review of the document, the ALFP Best Practice Committee and advisors include several members of the international advisory board of the original UK Best Practice document, in addition to a national and international multidisciplinary group of lymphoedema experts and patient representatives. The document will be reviewed in detail, focusing on key areas of optimal contemporary lymphoedema practice supported by the literature, systematic reviews, and national and international guidelines (where they exist). A total of five face-to-face working meetings have been scheduled over a two-year period

in addition to telephone and electronic group meetings to enable further exploration, clarification, and dispute resolution.

Consensus

Following the literature update and expert review, consensus building will be the final element before the release of the Best Practice document. The consensus approach to the development of best practice guidance has been recommended for measuring expert opinion where clinical trial literature is scant, conflicting, or unclear (Kane et al, 2003; Morgan et al, 2006). Consensus will enhance the credibility of the document and promote its widespread adoption (Murphy et al, 1998). This first step in national consensus has been taken with the engagement of experts in lymphoedema from all disciplines treating persons with lymphoedema in the US, as well as educators, advocates, industry, organisations, and, most importantly, patients. Members of the ALFP and ILF Advisory Boards have also been invited to participate on the Consensus Panel. The international perspective is a key element, as it will not only extend the document's scope and relevance, but also enrich its content, perspective, and influence.

The multinational panel will be invited to score various aspects of care

and management to be considered for inclusion in the updated Best Practice document using a web-based scoring and editorial system. This web-based system was initially developed to process editorial management of evidence-based answers of clinical inquiries for the Family Physicians Inquiries Network and recently repurposed to provide a cyber platform for ALFP's consensus-building. As with the initial Best Practice document consensus process, each statement will be rated on a four-point Likert scale: strongly agree, agree, disagree, or strongly disagree (Morgan et al, 2006). The online process ensures private and independent consideration and individual time for reflection of issues and mitigates 'the effects of status and dominance by more vocal members' (Murphy et al, 1998). An 80% agreement for each item will be considered an acceptable level for inclusion into the updated document, and formal disagreement will require a suggested alternative to facilitate dispute resolution and document revision.

Conclusions

Due to the paucity of empirical evidence to support many aspects of clinical practice in managing lymphoedema, the use of a three-tiered approach including literature review, expert opinion, and consensus is central to the development of the updated Best Practice document. This approach is also critical to building

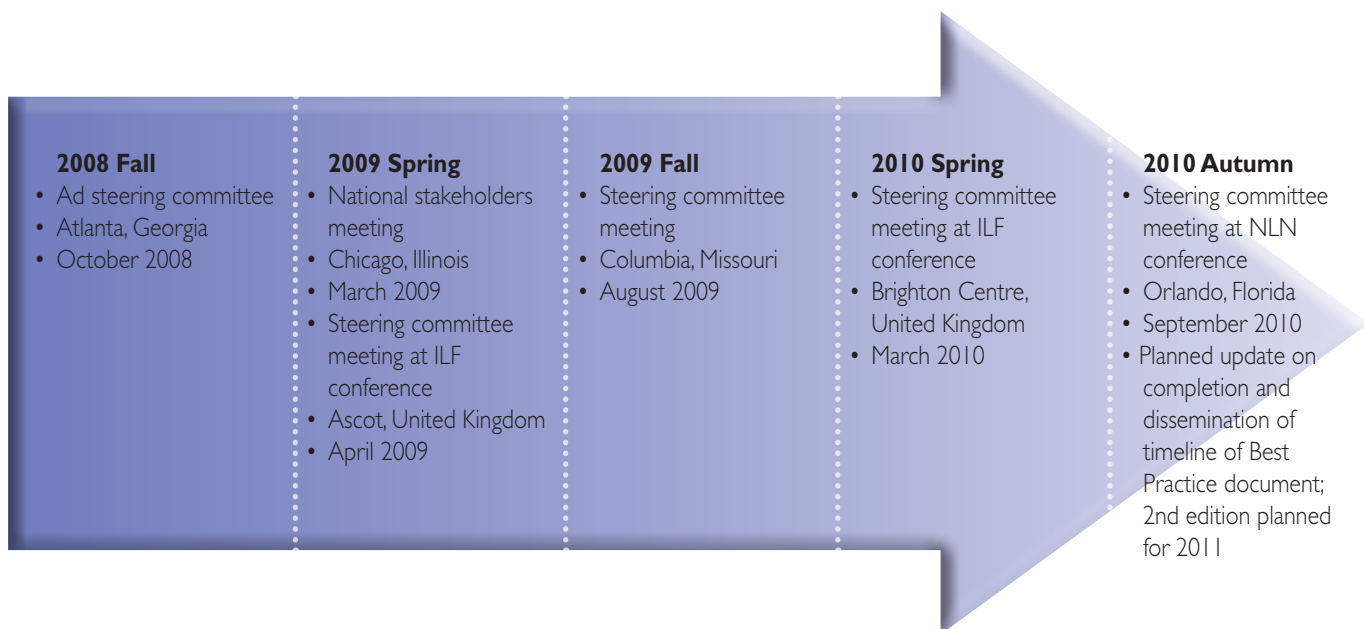


Figure 2. Timeline for development of updated Best Practice document.

consensus necessary for influencing health policy. The goal is to incorporate the most current research and collective knowledge and expertise of those contributing with a standardised process which can be used to update the Best Practice Document at regular intervals as new research emerges.

The inaugural Best Practice document continues to be successful in raising the profile of lymphoedema as a major health priority (Lymphoedema Framework, 2006). The goals of this manuscript are to provide an overview of the continued partnership between the ILF and the ALFP and to describe the methodology being applied in creating an updated and expanded Best Practice document. Partnership and consensus are fundamental principles to achieving progress in the field of lymphoedema. Publication of the updated Best Practice document is anticipated in 2011 before the third ILF annual conference in North America. In addition, supplements to the document in the form of position papers and care guidelines are now available, in process, and planned covering a variety of important topics, including children and adolescents (2010), risk reduction (tentatively 2011), obesity/bariatrics (tentatively 2011), and palliative care in lymphoedema populations (2010). JL

Acknowledgements

Support to the ALFP was provided in part by the American Cancer Society (ACS), through The Longaberger Company, a direct selling company offering home products including handcrafted baskets made in Ohio, and the Longaberger Horizon of Hope Campaign, which provided a grant to the American Cancer Society for breast cancer research and education. The Grantee's informational materials do not necessarily represent the views of ACS, ACS' staff, or its Board of Directors.

The views expressed in this paper solely represent those of the author(s) and are not the opinion of the US Government, the Department of Defense, or the Department of Navy, nor the respective institutions/employers.

The update of the Best Practice document is a good-faith effort to

summarise evidence-based practice guidelines and is not intended to be prescriptive for individual cases requiring medical treatment for lymphoedema. Rather, the individual assessment and development of an appropriate personalised plan of care under the guidance of a specially-trained lymphoedema therapist will draw from best practices guidelines as outlined in the Best Practice document.

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Key points

- ▶▶ National and international experts are in agreement that the Best Practice document has been successful in raising awareness of lymphoedema in the UK and globally.
- ▶▶ The ALFP has sought to identify US-based health policies and lymphoedema practices in order to update and extend the ILF Best Practice document.
- ▶▶ The updated Best Practice document will include information dating from 2005 through 2009 based on a literature review and national/international consensus process to identify broad practice standards.
- ▶▶ The challenge to creating a US Best Practice document with updated literature is primarily related to the paucity of randomised clinical trials in the field of lymphoedema – an obstacle that has remained since the creation of the original document.
- ▶▶ Following the literature update and expert review, consensus-building will be the final element before the release of the Best Practice document. The consensus approach to the development of best practice guidance has been recommended for measuring expert opinion where clinical trial literature is scant, conflicting, or unclear.