

# International Lymphoedema Framework Chronic Oedema/Lymphoedema Outcome Measures Project: American Lymphedema Framework Project Stakeholders Report

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## Key words

Chronic oedema, lymphoedema, outcome measures project

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## Abstract

**Introduction:** Research demonstrates the negative impact of lymphoedema on all aspects of life. Ongoing issues in building evidence-based treatment consensus guidelines create therapy challenges. **Aim:** To explore healthcare professional characteristics in the US, perceptions of lymphoedema outcome priorities and outcome measurements. **Method:** A survey was launched by the International Lymphoedema Framework (ILF) in 2018. Data were analysed addressing stakeholder characteristics and perspectives from healthcare professionals, patients, educators and industry. **Results:** Data from 341 USA healthcare professionals were analysed. Most respondents were occupational (42%) and physical (39%) therapists. Sixty-five percent of respondents reported measuring treatment outcomes. Forty-six percent of respondents reported not knowing if international or regional guidelines existed. Top treatment outcomes measures reported were arm circumference (84%) and mobility (65%). Stable limb volume (54%) and improved quality of life (54%) were the top success measures. **Conclusions:** The American Lymphedema Framework Project recommends increasing awareness of national and international standards for lymphoedema care/outcomes.

Lymphoedema is a chronic condition resulting from a dysfunction of the lymphatic system. This dysfunction, caused by the movement of protein-rich fluid from the vascular system to interstitial tissue spaces, can result from genetic abnormalities (primary lymphoedema) or conditions such as lymphatic filariasis and cancer (secondary lymphoedema) (Finnane et al, 2015; Armer et al, 2020).

Characterised by physical symptoms, such as pain, swelling, compromised function, altered skin integrity and decreased mobility, as well as psychosocial effects, such as depression, anxiety and altered body image, lymphoedema management requires expert assessment and diagnosis, consistent decongestive treatment and a lifetime adherence to self-management activities (Finnane et al, 2015; Armer et al, 2020;

International Society of Lymphology, 2020). Healthcare professionals engage in the work of treating and managing lymphoedema to minimise symptom exacerbation and optimise quality of life.

In order to manage this challenging condition, healthcare professionals rely on the accumulated body of research for valid assessment tools, clinical treatment guidance and outcome measures capable of demonstrating treatment effectiveness. For over two decades, the lymphoedema research community has worked to reach consensus on assessment, treatment guidelines and outcome measures to support these professionals (Paskett et al, 2007; Fu et al, 2014; Armer, 2020).

During this time, multiple studies have highlighted the challenges faced by healthcare professionals worldwide to

care for the lymphoedema community without consensus on these care issues. At the foundation of care, researchers have demonstrated the challenge of measuring incidence and prevalence presented by the use of multiple reporting mechanisms and assessment tools (Paskett et al, 2007; McLaughlin et al, 2008; Pereira et al, 2017; Sierla et al, 2018; Armer, 2020; Torgbenu et al, 2020).

Lack of consensus on which measurement tools provide optimal assessment complicates development of clinical trials, limits the applicability of results and impairs the ability of professionals to accurately screen for lymphoedema risk (Armer and Stewart, 2005; Ahmed et al, 2008; Nielsen et al, 2008; Schmitz et al, 2009; Bernas, 2013; Naoum et al, 2020). Inconsistencies of measurement, assessment and treatment

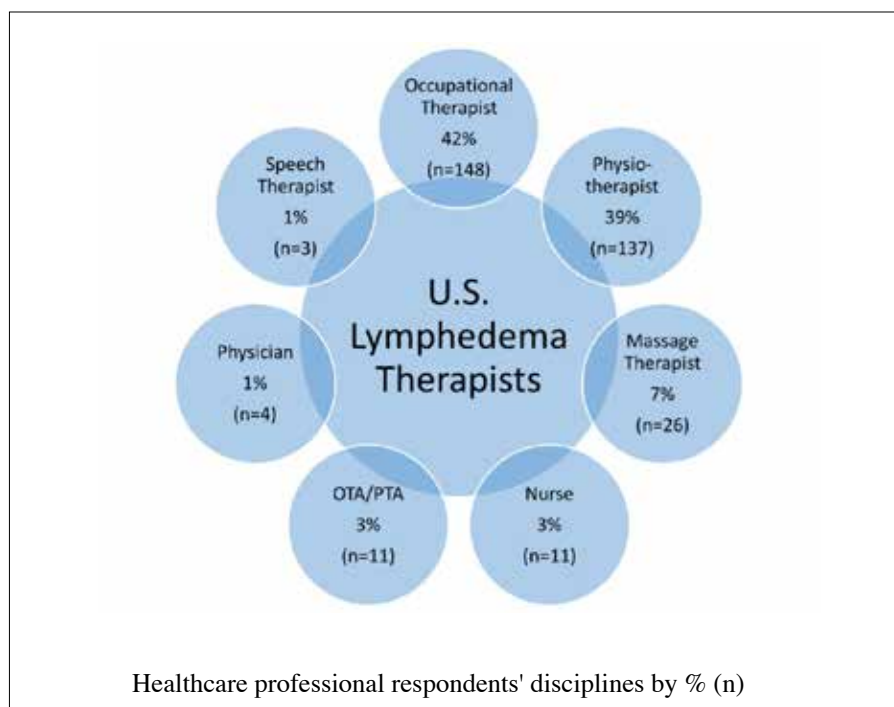


Figure 1. Professional demographics of respondents.

modalities across research reports hinder systematic reviews, limiting their ability to provide clear guidance to healthcare professionals at the bedside (Armer, 2020; Fu et al, 2014; McCaulley and Smith, 2014; Rogan et al, 2016; Sierla et al, 2018). Variations across studies in measuring treatment impact and patient outcomes are also a result of lack of consensus (Nielsen et al, 2008; Finnane et al, 2015; Ridner et al, 2018; Tidhar and Armer, 2018; Armer et al, 2020; Naoum et al, 2020). These variations can create confusion for organisations working to develop treatment policies or implement prevention measures and negative impact reimbursement for therapy and the tools needed by patients to successfully manage lymphoedema.

Despite these challenges, the lymphoedema care community has continued the effort to achieve consensus in lymphoedema management. This effort has moved out across healthcare disciplines and around the world. In 2012, experts proposed a research trajectory for compression therapy in lower-extremity lymphoedema with the goal of optimising patient outcomes (Stout et al, 2012). Advancements in technology and imaging ability have provided new insight into the physiology of the lymphatic system and supported the development of microsurgery to repair lymphatic damage. The Australian Lymphoedema Education,

Research, and Treatment Program (ALERT) has developed a multidisciplinary care model for patients undergoing microsurgery, using indocyanine green (ICG) imaging to make treatment decisions (Boyages et al, 2019).

The researchers have used ICG imaging to gain new understanding of how manual lymphatic drainage (MLD), part of the 'gold standard' of lymphoedema management, moves lymphatic fluid, fundamentally altering our understanding of this process and initiating a change in therapy practice (Koelmeyer et al, 2021). In 2018, the Oncology Nursing Society convened a panel of experts to synthesise available research and develop breast cancer-related lymphoedema guidelines (Armer et al, 2020). In addition to these multinational and multidisciplinary consensus efforts, the International Lymphoedema Framework (ILF) has recognised the continued pressing need for treatment standards consensus and carried out studies to move the effort forward.

## Background

The ILF recognised challenges with international variation in chronic oedema/lymphoedema outcome measurements. Based on their research, it was determined that there was a lack of agreed-upon standards, validated measurement methods, and consistent assessment methods (Sierla

et al, 2018; Armer, 2020; Armer et al, 2020; International Society of Lymphology, 2020). Additional difficulties associated with the challenges in developing standard recognised outcome measurements included a lack of: (1) evidence or low awareness of standard outcome measurement; (2) outcome consensus to guide healthcare providers; (3) definition for effective versus ineffective treatment outcomes; and (4) understanding of patient versus professional perceptions of outcome priorities (Pereira et al, 2017; Armer, 2020; Armer et al, 2020; International Society of Lymphology, 2020). Through an international study, LIMPRINT (Lymphoedema IMPact PRevalence – INTernational Lymphoedema Framework), nine countries with 40 sites conducted research to provide data to work toward an international outcome measure standard, providing a foundation with robust validation to facilitate awareness, understanding and increased insurance coverage of lymphoedema treatment (Moffatt et al, 2019).

In 2018-19, the ILF designed and led a multinational, multi-sponsored project to address lack of consistency and clarity in chronic oedema outcome measures (COM) (Moffatt and Norregaard, 2018). The objectives of the ILF-COM were to: 1) develop a foundation for an international outcome measure standard; and 2) form the foundation for robust validation of identified outcome measures. The ILF-COM study goal-driven actions included: scoping systematic review assessment methods, doing qualitative interviews with medical device industry stakeholders to explore reimbursement issues, and conducting national surveys to focus on patients and healthcare professionals. The American Lymphoedema Framework Project (ALFP) was one of 14 national frameworks that participated in conducting a national survey to focus on perspectives of patients and healthcare professionals on chronic oedema/lymphoedema outcome measures.

## Methodology

The ILF-COM national framework survey was developed by ILF and distributed by Survey Monkey via various social media methods and platforms to be completed by patients and healthcare professionals. The ILF database accepted responses from December 2018–February 2019 and data were analysed by the ILF in collaboration

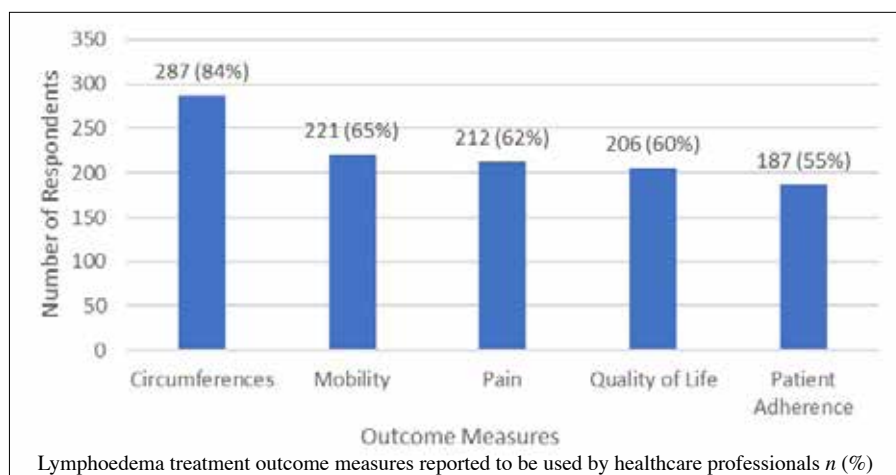


Figure 2. Reported outcome measures.

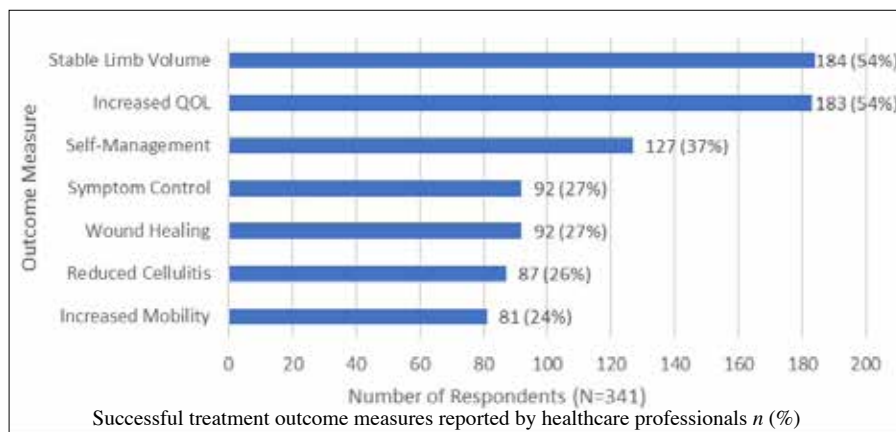


Figure 3. Successful treatment outcomes.

with the national frameworks from March –May 2019. National reports were prepared by June 2019 and initial findings were presented in an ILF-COM poster session at the 2019 ILF-ALFP Conference in Chicago, US (Armer et al, 2019a; 2019b).

In the implementation of the survey in the United States (US), ALFP received valid responses from 726 individuals. Initial analysis included data obtained from patients, healthcare professionals, and other stakeholders including industry representatives and educators. The following data analysis includes responses from 354 healthcare professionals in the US. Patient responses have been excluded from this report and will be reported elsewhere.

### Results

As Figure 1 demonstrates, most healthcare professional respondents were occupational therapists (42%; n=148) and physiotherapists (39%; n=137), followed by massage therapists (7%; n=26), nurses (3%; n=11), occupational/physical therapy

assistants (3%; n=11), physicians (1%; n=4) and speech therapists (1%; n=3). Fourteen (4%) respondents reported being healthcare professionals, but did not specify their discipline.

Thirteen respondents reported their discipline, but did not finish 80% of the survey, so from this point on, these respondents are excluded from the denominator, resulting in data analysed from 341 healthcare professionals. The authors also note that some survey items allowed multiple responses by an individual respondent.

Two-thirds of respondents worked in a public venue (67%; n=227), 31% (n=107) worked in a private venue, and 2% (n=7) worked in both public and private facilities. Of all healthcare professionals, 46% (n=156) reported working in a hospital, 9% (n=32) reported working in a community setting and another 9% (n=32) reported working in a lymphoedema specialist centre.

Sixty-five percent of the survey respondents indicated that they do

measure treatment outcomes (n=221), while 19% indicated they sometimes measure treatment outcomes (n=65) and 8% said they do not measure treatment outcomes (n=26). Twelve percent (n=42) of respondents said they did not know if treatment outcomes were measured (n=15) or did not respond (n=27).

Many healthcare professionals working in lymphoedema are unaware of treatment outcome guidelines. Sixty-three (18%) reported there were no international, national, or regional guidelines, while 157 (46%) reported that they did not know of such guidelines. Some respondents, however, were aware of some combination of international (n=23; 7%), national (n=86; 25%), and/or regional (n=15; 4%) treatment outcome guidelines.

Seventy-eight percent (n=267) of respondents indicated that some or all aspects of their treatments are covered by insurance, while 9% (n=30) did not know what was covered and 5% (n=17) said that there was no insurance coverage of lymphoedema treatments. An additional 27 respondents did not answer this question.

Data analysis yielded the five most-frequently used lymphoedema treatment outcome measures, as shown in Figure 2. Arm circumference was assessed by 287 respondents (84%) and mobility was assessed by 221 respondents (65%). Rounding out the top-five outcome measures reported included pain (62%; n=212), quality of life (60%, n=206) and patient treatment adherence (55%; n=187).

Figure 3 shows the top outcome measures for successful lymphoedema treatment outcomes, as reported by healthcare professionals. Stable limb volume (54%; n=184), improved quality of life (54%; n=183) and self-management ability (37%; n=127) were each identified as one of the three most important measures of successful treatment. Respondents also reported symptom control (27%; n=92), wound healing (27%; n=92), reduced cellulitis (26%; n=87) and increased mobility (24%; n=81) as important measures of successful outcomes.

### Conclusion and recommendations

It is worth reiterating that a substantial number of healthcare professionals treating chronic oedema and lymphoedema in the US are uncertain of or not using validated

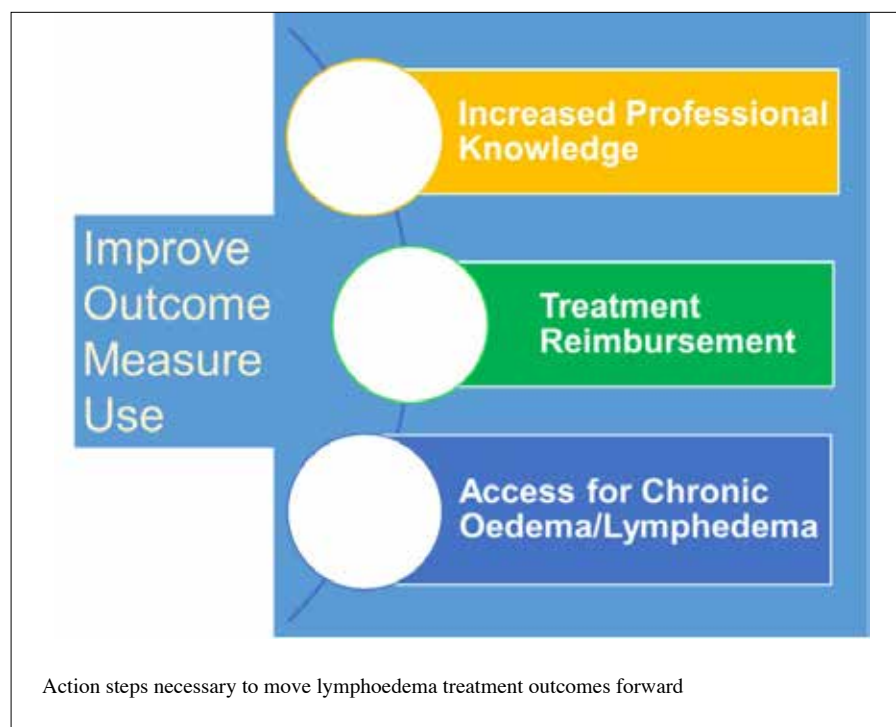


Figure 4. Model to move lymphoedema treatment outcomes forward.

outcome measures for successful treatment, nor aware of regional, national, or international guidelines. Healthcare professionals trained in chronic oedema and lymphoedema care are the bedrock of optimal individualised care for patients based on consensus guidelines.

Based on the results of the survey, the ALFP recommends working to increase awareness of national and international standards for lymphoedema care/outcomes with an opportunity to improve lymphoedema care guided by an action plan (Figure 4). The action plan to improve outcome measures relies on: 1) increasing professional education to facilitate awareness and understanding of lymphoedema; and 2) providing insurance reimbursement to increase treatment access for chronic lymphoedema.

Using the results of the research from all the national framework participants, the ILF is developing recommendations for international outcome measurement standards for chronic oedema and lymphoedema and identifying similarities and variations in ILF-COM study findings among countries.

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