Proposed Project Title: Part 2: *A bridge to hope.* A clinical study evaluating new options for the early treatment of chronic Lymphorrhea. Empowering patients and caregivers to self-manage dressing changes and safe compression in the early days of symptom onset using the nurse-developed Disposable Leg Wrap.

Problem Statement:

Patients experiencing intermittent lower extremity lymphorrhea, often referred to as weeping edema, encounter numerous challenges and significant unmet needs (10). When this symptom manifests, individuals frequently struggle to protect their often-blistered skin while managing the persistent drainage that seeps from their lower limbs (1,2,3,4). At the same time, patients and their caregivers often face frustration and anxiety due to potentially waiting several days to weeks to access primary or specialized healthcare for evaluation and treatment. A retrospective study involving 197 patients seeking wound care in 2016 revealed that the median waiting period to consult a physician from the onset of symptoms was eight days, with a range extending from one to thirty-two days (22).

During this often-prolonged interval, patients and their caregivers resort to various self-management strategies. These can include using materials found at home, such as towels positioned over and under the legs or taped around the legs. In some cases, individuals may even confine a foot and leg within a plastic bag to capture fluid. This latter practice is particularly concerning, as plastic bags simply trap the fluid, submerging the skin in exudate and creating a humid, warm environment. This condition significantly increases the risk of skin maceration, the development of new wounds, and infection—issues that already threaten those experiencing lymphorrhea. Patients and caregivers often adopt these measures simply to cope, best that they can, with daily challenges associated with this difficult symptom (23).

Once patients can consult with their physicians and, in the absence of infection, they typically receive conservative recommendations. These may include leg elevation, adherence to a low-sodium diet, and, if appropriate, treatment with diuretics. Many patients are then referred to a wound clinic for further evaluation, which may involve fitting them with an inelastic layered absorptive dressing, commonly known as an "Unna Boot"(13,15), if they meet the necessary criteria following a comprehensive assessment. However, this standard process often results in additional delays, exacerbating complications arising from inadequately managed exudative fluid (22).

In the case of Lymphorrhea, one problem leads to another problem. The first problem is the inability of patients and/or caregivers to safely and adequately manage weeping fluid, prevent maceration, and keep fluid contained without strikethrough issues, which soil the environment. The second issue is the lack of means to provide safe, light compression at the onset of symptoms, which could be the most helpful and practical approach before symptoms have escalated and caused secondary damage. Is it possible that the adage "a small symptom is easier to treat than a big symptom" applies here? Lastly, the time it takes to access needed care is often delayed due to a burdened healthcare system as well as escalating prevalence of lymphorrhea and other often PVD-related wound issues, as the underlying causative comorbidities are often associated with the sequelae of diabetes, which worldwide is increasing at alarming rates (25). This recurring cycle underscores the urgent need for more efficient and effective healthcare solutions designed to address the unique struggles faced by those suffering from the distressing and debilitating issue of Lymphorrhea (6, 8).

P: For six patients identified to be in the first 72 hours of a chronic Lymphorrhea weeping episode

O: does the early initiation of both frequent dressing changes and leg care, accompanied by safe Level 2 medical compression stocking (MCS) enabled by the Disposable Leg Wrap

C: suggest that in comparison to patients who do not receive early exudate management and compression

O: have objectively or subjectively (pt report) better outcomes in the form of lessened skin maceration and inflammation, and either resolution of or shortened course of a weeping episode

T: and will involve the provision of fourteen individual disposable leg wraps to each participant, facilitating two dressing changes and leg cleansing per 24 hours. This will occur alongside the use of a carefully measured level II MCS, which has been established as safe even for patients with an Ankle-Brachial Index (ABI) of 0.5 or lower (14, 20). Additionally, two MSC's will be provided to each participant. Following a seven-day duration, the condition of the leg will be assessed, focusing on any changes in exudate production, the overall condition of the skin, and the patient's reported comfort experienced before, during, and after this initial treatment phase. These patients will be contacted daily by phone for updates and to provide support as needed.

Summary of PICOT question This pilot study, referred to as Study #2, investigates the option of using the Disposable Leg Wrap, with a focus on the innovative capacity for initiating early, safe home wound care management in conjunction with safe, level 2

compression MCS (20) treatment at the onset of an exudative event such as lymphorrhea - preferably within the initial 72 hours. Historically, the delivery of such timely care has been hindered by various factors, including delays in patients seeking assistance, challenges in accessing medical care, and the absence of an appropriate product in the current wound care market that enables non-professional caregivers to safely, quickly, and easily apply the DLW absorbent dressing, allowing twice daily dressing changes on their own. This study is designed to assess if there are measurably improved clinical outcomes with BID dressing changes and leg hygiene, performed in conjunction with safe, relatively mild compression VIA the use of a level 2 MCS when in the early stage of an exudative event. Because the DLW has been shown to be simple and safe to apply, non-professional caregivers can be delegated to perform this care, which has not been possible due to the limitations associated with both the use of difficult-to-apply bulky gauze wraps and delays in accessing wound care.

Mary Madison, RN – [redacted] Hospice will provide individually packaged Dressing for Leg Wounds (DLWs) at no cost. This product is fully patented. Any inquiries regarding manufacturing processes, sterilization testing, materials utilized, or other concerns may be addressed upon request. The [redacted] Hospice department is well-equipped to identify patients at the onset of a weeping leg edema episode, owing to the frequent interactions among multi-disciplinary staff, as well as the capacity for patients or their caregivers to contact Hospice at any time, 24/7. An MD will be consulted and, if appropriate, an order received to allow each patient to participate I this study if they so desire and agree to the terms of participation.

For this study, 84 individually packaged dressings will be supplied, with an allocation of 14 dressings per participant. It is advisable to obtain photographs of the affected leg(s) both prior to and following the 7-day treatment period to facilitate the evaluation of patient outcomes. The patient and/or their caregiver will evaluate their experience during the 7-day period concerning dressing changes and compression treatment, including their assessment of outcomes in relation to prior treatments received, if applicable.

A liability waiver has been prepared in advance of the product trials; however, it will be necessary to consult with the [redacted] Research Committee to determine the appropriate liability language essential for ensuring that patients and/or their medical representatives can provide informed consent for participation in this research trial involving a new Class 1 (lowest risk) wound care product.

Data Collection and Analysis Plan:

a. **Setting for Data Collection:** Data will be collected through the utilization of before-and-after photographs, as well as a Survey Monkey link that will be easily accessible via a QR code affixed to the exterior of the DLW packaging. Caregivers will be prompted to complete this survey following a period of seven days of twice-daily (BID) dressing changes and compression treatment. It is preferable for the Survey Monkey assessment to be finalized within two days after the completion of wrap application. A follow-up telephone call may be necessary to ensure that the survey is completed.

b. **Description of Outcome and Measurement Plan:** The caregiver responsible for administering the dressing changes and compression stocking applications will complete an electronic questionnaire designed to capture their experience using the DLW for the early compression treatment of the affected leg, as well as their impressions regarding the outcomes achieved after this care regimen. A Likert scale will be employed for this assessment. Should this research project receive approval, additional inquiries concerning the benefits and features of the product may be incorporated, alongside a section for narrative feedback.

c. **Evaluation Plan (If Not Measuring an Outcome):** [Please specify your approach here, if applicable.]

d. **Data Collection Method:** Patient privacy will be safeguarded through a variety of measures. Each set of wraps will feature a unique four-digit identifier attached to the exterior. This identifier will be entered into the Survey Monkey platform to accurately identify the corresponding case. Both the four-digit identifier and the patient's name, along with their medical record number (MR#), will be securely maintained in an electronic record to facilitate retrospective tracking of the patient, the DLW, and the associated product lot number.

e. **List all data points (including PHI) that will be extracted from a patient's medical record: Please note: *ALL PHI MUST* remain within [redacted] and cannot be taken off-site. Identified data cannot be stored on personal computers, emailed, or stored on thumb drives. Failure to adequately protect**

[redacted] **patient data is considered a non-compliance with the HIPAA law and** [redacted] **policy which may result in corrective action including but not limited to termination of this project.**

Discuss how the patient's/participants' privacy will be reported:

Must include: 1) Identify where data will be stored. 2) How data will be secured and/or deidentified. 3) How/when data will be destroyed. 4) Who will have access to the information.

a. *Expected month to present to Professional Practice Council your Project Findings (60 days from Project end date): December 2025*

All projects done at [redacted] **require you to present the results of the project to** [redacted] **You will need to provide them to** nursingresearch@[redacted].org **at the end of your project.**

Does your intent include sharing the results of your project with an audience outside of [redacted]**? Check yes or now. If you checked yes, then check all that will apply:**

__**x**___YES

_____ No

_____ Yes, to share information VIA academic institute

__x___ Yes, to share information VIA publication

_____ Yes, to share information VIA poster submission

__ x___ Yes, to share information VIA conference presentation

_____ Yes, to share information VIA other format: please identify

_____ Other, explain:

**

Notes:

[redacted] **Use Only**

Approved Denied

Name:_____Signature:_____Date: ___/___/___