

Nursing Research Project Submission Form

Proposed Project Title: ****Part 1 of 2:** Addressing Unmet Needs: A Solution for Managing Highly Exudative Leg Conditions.** This clinical study evaluates the efficacy of a new nurse-developed product, the Disposable Leg Wrap (DLW), designed to address the 7 main challenges associated with traditional bulky gauze wraps used for managing highly exudative conditions such as lymphorrhea (also known as weeping edema).

Problem Statement: Managing fluid associated with highly exudative leg conditions, such as lymphorrhea, commonly referred to as weeping leg edema, presents significant challenges that can substantially diminish the quality of life for affected individuals (4,5,6.) This complexity also places considerable strain on healthcare systems, which often struggle to meet the needs of patients requiring frequent nursing interventions for dressing changes involving complex gauze wraps (23). Patient and family feedback frequently indicates that, despite daily care, their needs remain inadequately addressed, primarily due to intrinsic limitations of bulky gauze wraps.

First: The cumbersome nature of these wraps necessitates nursing visits every 1 to 2 days for dressing changes, raising concerns about delegating such tasks to non-professional caregivers due to care and safety issues. In practice, it is considered neither appropriate nor safe and is rarely performed.

Second: The absorbent capacity of gauze materials is inherently limited, often resulting in saturation before the next scheduled visit.

Third: Cotton fiber-based gauze is ineffective in wicking fluid away from the skin, which can result in maceration and an increased risk of new wounds and infections (16,17,18,19).

Fourth: The lack of adjustability in these wraps can lead to either excessive looseness, causing the wrap to slip down the leg, or excessive tightness, which may induce pain and create potential ischemic conditions as fluid dynamics evolve.

Fifth: Gauze wraps hinder visual assessment of the wound or skin without necessitating a complete dressing change.

Sixth: There is inadequate protection against fluid leakage through the dressing, leading to soiling of patients' clothing, furniture, bedding, and other personal items.

Seventh: The inability to apply a medical compression stocking over a bulky gauze wrap further complicates the application of potentially beneficial compression treatments.

Additionally, the emotional impact of ongoing fluid leakage can be profound, with patients often expressing feelings of uncleanliness, anxiety, and shame. Family members and caregivers frequently experience frustration, sadness, and helplessness as they witness their loved ones enduring this persistent challenge (3,4,6,7)

P: For patients needing frequent RN visits to provide difficult, bulky, gauze wrap dressing changes for weeping edema or chronic draining wounds

I: are non-professional caregivers able to manage their own dressing changes independently using the disposable leg wrap

C: when compared to various caregivers' ability or willingness to safely provide dressing changes using the current traditional bulky gauze wraps

O: which many family caregivers, or other non-licensed caregivers find too difficult to manage, necessitating daily RN visits for this care. Will the DLW be viewed more as simply "a diaper for the leg"

T: which would be determined by providing 4 wraps for CGs with a "teach, show, teach back" training to the caregiver, who will then decide if they are willing to provide the next 4 dressing changes with an evaluation of their experience after this is completed.

Summary of PICOT question: The DLW was originally conceptualized in 2013 as an innovative solution to enhance the protection, absorption, and overall quality of life for patients experiencing weeping lower leg edema. It has now evolved into a safety-manufactured product, ready for clinical trial. This pilot study will primarily assess the willingness and capability of an average caregiver to perform dressing changes safely, efficiently, and independently, utilizing four wraps for a total of four dressing changes on one leg. Additionally, the study will encompass essential aspects of wound care, including skin cleansing and the application of barrier creams. This information will be provided through tailored instruction from a nurse assisting with the study, which will also encompass guidance on the proper application of the DLW to ensure an optimal fit around the leg.