

WHITE PAPER

A Wound that Won't Heal

The Global Call for
Robust Chronic Wound Care

Aethl Bio

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Executive Summary

Health is the utmost priority for every human being.

Yet, treatment for common chronic wounds, which can have mortality rates comparable to cancer¹, has long gone neglected by modern healthcare systems. While nations spend billions each year trying to mitigate its public health burden, chronic wound prevalence is projected to only increase with time. There is a clear global demand for a transformation in delivery of chronic wound care to fit the economic and clinical needs of a changing landscape.

Where is the need?

As OECD nations observe a rapidly growing elderly population, the primary demographic for chronic wound patients, so does the market demand for targeted research and treatment. In addition, the increased prevalence of chronic disease across the globe heightens the need for advancements in wound healing.

What can we do?

- **Promote a patient-centered approach** to treatment
- **Emphasize complete healing** of wounds to prevent infection and/or amputation
- **Reduce healing time** using biomaterials and technological advancements
- **Update clinical regulatory policy** to match patient need

The following paper delves into primary challenges for chronic wound patients and promising solutions to create happier, healthier communities.

Understanding the Chronic Wound Burden

The label “chronic wounds” describes a range of long-term nonhealing wounds including diabetic foot ulcer (DFUs), pressure ulcers (PUs), venous ulcers (VUs), and surgical infections. These often arise due to health complications from a combination of preexisting chronic disease, such as diabetes, sensory neuropathies, or cardiovascular disorders, making it difficult to attribute wounds to a root cause. Healthcare providers, researchers, and policymakers face the immense challenge of adopting a streamlined method to identify and address the burden chronic wounds pose on public health.

In the US, the gap between a rising demand for chronic wound treatment and limited resource allocation creates what has been likened to a “silent epidemic”².

Key factors that contribute to the ongoing chronic wound public health burden are shown in Figure 1.

A Vulnerable Aging Population

As people age, wound healing capability weakens, and prevalence of chronic wounds increases³. Predictably, most chronic wound patients are elderly. Modern healthcare institutions face the challenge of meeting the wound care needs of a rapidly growing elderly population. The EU projects that by 2050, over 28% of people living in EU countries will be aged ≥ 65 ⁴. The US Census Bureau projects the elderly population to nearly double in size by 2060, with adults 65+ growing from 17% to 23% of the national population⁵. This is especially a concern in the Asian continent, where the older population is projected to nearly triple in size by 2060, with the most growth concentrated in Eastern and Southern Asia⁶.

FIGURE 1

5 Key Factors Driving the Chronic Wound Care Public Health Burden

- 1 Growing Elderly Population
- 2 Widespread Diabetes (diabetic foot)
- 3 Disruptions to Patient Daily Life
- 4 Overwhelmed Healthcare Institutions
- 5 Ineffective Clinical Policy

Dangers of Diabetic Foot

Every year, approximately 18.6 million people worldwide experience diabetic foot, a common complication from diabetes⁷. DFUs are the leading global cause of nontraumatic limb amputation, and in the Western hemisphere, the leading cause for amputations for lower extremities^{8,9}.

Despite mortality rates comparable to cancer, and about 1 in 5 DFU patients requiring amputation, there lacks a clear clinical pathway for diagnosis and treatment. Rather, it is likely for patients to only receive treatment once the wound has progressed to the point where amputation is necessary¹⁰.

There is a severe public health need for advancements in accessible, cost-effective DFU screening and treatment technology.

Disruption to Quality of Life

Reduced mobility, financial strain, chronic pain, and experiencing social isolation are common challenges for patients with chronic wounds¹¹. A cross-sectional study on chronic wound patients in Germany found that only 9% of patients were employed¹². Chronic wounds create large, prolonged disruptions to patient quality of life and ability to participate in society.

Caregivers, a role often fulfilled by family or friends, fulfill an essential role for patients during the lengthy healing process. A correlational study on DFU caregivers in Turkey found that transportation services and specialized wound care training posed the strongest burden on caregivers¹³.

To protect our communities, it is vital to allocate resources to support everyone involved in treatment.

Economic Burden on Healthcare Institutions

Chronic wounds tend to have prolonged healing time due to not only duration of recovery, but the likelihood of widespread infection while the body's immune system is compromised, which increases the risk for rehospitalization¹⁴. Hospital bed occupancy, amputations, and surgical interventions add to high treatment costs. The long-term specialized care required for chronic wound treatment creates a significant economic burden on healthcare institutions.

Pressure Ulcers (PU)

At any given time, 1 out of 10 hospitalized patients in the United States experiences a PU¹⁵. Each PU can amount to an individual patient cost from \$20,900-\$151,700. In the US, PUs are estimated to cost the healthcare system over \$28.6 billion annually¹⁶.

Venous Ulcers (VU)

VUs are the most common lower extremity chronic wound, reflected by an exceptionally high recurrence rate at approximately 50-76%¹⁷. Contributors to this recurrence rate include comorbidities such as obesity, hypertension, and diabetes. An estimated 3-5% of people aged ≥ 65 will experience a VU. In a US-based case control study, leg VUs treatment costs ranged from \$11,088 to \$27,408.

Gaps in Diagnostic Procedures

A chronic wound, as nominally implied, is a long-term disruption to the human skin that cannot return to working capacity. Yet, the definition of a healed wound from a clinical standpoint does not prioritize restoration of function, only restoring the wound surface.

This “surface level” definition ignores the common case where chronic wounds reoccur, welcoming further costly health complications and rehospitalization.

Studies have repeatedly shown patients have a higher chance of recurrence if they are cleared on the basis of structural closure despite still having a compromised skin barrier, particularly for DFUs^{18,19}.

Even the ability for healthcare providers to judge a patient's condition is limited in scope for chronic wound patients. In a review evaluating venous disease outcome measures, only 2 out of 8 questionnaires were of robust quality, and of them, only one was appropriate for patients with venous ulcers²⁰.

Challenges for Regulatory Policy

Flaws in the current clinical understanding of wound care is mirrored in regulatory policy.

A 2022 review of the U.S. Food and Drug Administration (FDA) found that out of 70+ products approved for wound care, only three of them were intended for nonhealing chronic wounds²¹.

The availability of products for chronic wound care vastly underscores the existing need. One in six Medicare beneficiaries suffer from chronic wounds, costing the nation about \$22.5 billion dollars a year¹⁵.

Recommendations for the Future of Wound Care

RECOMMENDATION #1

Adopt Patient-centered Assessments and Diagnostics

Limited time, access to medical resources, and varied range of expertise may limit a provider's ability to adequately care for a chronic wound. However, healthcare institutions that adopt a holistic, multi-disciplinary approach to wound care have observed strides in patient health outcomes⁸.

It is critical to integrate clinical, psychosocial, and environmental factors to develop a more comprehensive understanding of the patient's needs. Simple but effective accommodations include offering telehealth options, which increases access to long-term care for rural communities. Tailoring treatment to patient's individual priorities encourages engagement in their recovery process and effective communication between patient and provider²¹.

RECOMMENDATION #2

Utilize Biotechnology Advancements

Newer technologies integrated into chronic wound care, such as stem-cell skin grafting, often require costly materials, making it difficult to distribute to large populations^{22,15}. In the case of Hyperbaric Oxygen Therapy (HBOT), which has been used to treat chronic DFUs for the past 20 years, recent meta-analysis on its efficacy has been found inconclusive, highlighting a need for further research²³.

A growing chronic wound market has prompted the development of cost-effective methods to target specific biomarkers that promote restoration of function and faster healing rates than current standard of care²². Early stage studies observing wound area reduction and decreasing amputation rates suggest the potential for alternatives to conventional treatment^{24,25,26}. More research needs to be done to understand the best way to integrate new technologies into standard of care.

Described below are recent directions in technological advancement that show promise to shape the future of chronic wound care.

- **Bioactive dressings:** Bioactive dressings incorporate a range of materials to prevent water loss in wounds, a major cause of healing complications, and overall accelerate the healing process. Primary targets include reducing hypoxia (lack of oxygen supply), preventing infection, promoting angiogenesis (blood vessel reformation), or tissue repair.
- **Pharmacological treatments:** Pharmacological treatments targeting proteins involved in skin healing.

RECOMMENDATION #3

Update Clinical Regulations

Patients require comprehensive wound care assessments that emphasize wound prevention and restoration of function to the wound site. Policymakers and providers should consider revising the wound care endpoint for a healed patient to emphasize restoration of skin barrier function, and as well as what services are considered medically necessary and reimbursable care.

Conclusions

Chronic wounds — such as, but not limited to, DFUs, PUs, and VLUs — are a growing threat to our communities. Despite the evident human and material cost, global healthcare institutions struggle to meet burgeoning demands for reliable care. Fortunately, a growing base of new therapies and diagnostic measures provide a glimpse into how the future of chronic wound care can transform. Clinical policy that emphasizes patient-centered healthcare based on thorough, evidence-based research is essential to address the current burden on public health.

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