

The Veteran Diabetic Foot Ulcer (DFU) Epidemic: A U.S. Department of Veterans Health Administration (VHA) Hyperbaric Oxygen Therapy (HBOT) Services Review



CARE FOR HIM WHO SHALL HAVE BORNE THE BATTLE

Abraham Lincoln

Prepared for the US Congress and the American People

**by
Eric W. Koleda**

October 2022



Heal brains. Stop suicides. Restore lives.

In Memoriam, and with HOPE

This report is published in memory of all the Diabetic Foot Ulcer (DFU) Veterans who have suffered the consequences of “*Diabetic Foot Wounds*” and for those who will follow. Lower Leg Amputation (LLA) is not the final answer when properly diagnosed in time and acted upon immediately with FDA, CMS, and Tricare approved comprehensive Wound Care and Hyperbaric Oxygen Therapy (HBOT) treatments.

NOTE: The author and reviewers recognize that the numbers and statistics contained herein are dependent on published data, some of which are not current and have been adjusted over twenty years. We expect to be challenged on the data, as it should be. We have no conflicts of interest with respect to our motivation: we seek to significantly reduce service member diabetic foot ulcers and change medicine with respect to how DFU wounds are treated– or not treated using ineffective current standards of care. This report represents a collective effort by a pro bono Veteran and non-Veteran Coalition working to restore Quality of Life to the Veteran with DFU wounds and their families. We in society expect medicine to provide treatments that do no harm while providing safety, efficacy, and compassion at low cost and as quickly as humanly possible. We hope the US Congress and the entire community of Care Givers read the data objectively, and transition to a sense of urgency to provide approved HBOT treatment to fight the epidemics of DFU Lower Limb Amputations and eventual death.

The data presented in this report represent a summary of HBOT services not provided to Veterans and the access to FDA, CMS and Tricare approved Hyperbaric Oxygen Therapy (HBOT) treatment to which Veterans are legally, medically, ethically, and morally entitled. The VHA data is not consistent and with several cases conflicting. The VHA data is provided as conveyed versus interpreting the meaning of the conflicting data points.

About the Author

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RECOGNITION

This report has been reviewed by individuals chosen for their diverse perspectives and technical expertise. The purpose of this independent report is to provide candid and critical comments that will assist the U.S. Congress and government in making sound medical and financial decisions related to the treatment of Diabetic Foot Ulcers (DFU) Veterans. The report development is designed to meet objective scientific standards. The following individuals conducted a peer review and lent a substantial contribution to the design, and interpretation of results, draft document preparation and revisions, and approval of the final version on behalf of all the DFU Veterans across America. Neither the authors nor the editors have a conflict of interest; all work is pro bono.

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Extensive new material and updated data are in keeping with the scientific method: discovering the truth by building on previous discoveries. The data on safety and efficacy of HBOT for "Diabetic Foot Ulcers" are medically and financially compelling. HBOT for DFUs was approved by the Centers for Medicare and Medicaid Services in 2002, Tricare approved coverages in 2008 and the FDA followed in 2010 (Appendix 2) Two decades of industry HBOT medical data were compiled reflecting on the benefits to patients suffering from the DFUs.

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Keywords: Diabetic Foot Ulcers, DFU, Humana Military (HM, Tricare East), Veterans Affairs, VA, Veterans Health Administration, VHA, Hyperbaric, Hyperbaric Oxygen Therapy, HBOT, oxygen, Veterans

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Executive Summary

The increase in the Worldwide Diabetic Patient population at risk for Lower Limb Amputation (LLA) is growing exponentially. The Diabetic Foot Ulcer (DFU) epidemic increase in US Veteran Diabetes population due to poor clinical management is substantially greater than the civilian Medicare population resulting in an alarming LLA rate which is largely unnecessary.

The following data brings transparency to the existing VHA DFU LLA epidemic:

- More than **796,340 Veterans have died from Diabetic Foot Ulcer (DFU) Lower Limb Amputation (LLA)** in 22-years (Table 7) than all Veterans KIA (623,982) since WWI
- **The VHA DFU LLA mortality rate is 64-71 percent** within 3-years post-LLA surgery as compared to a 74 percent DFU heal rate with timely HBOT treatments (Table 3 and 6)
- The 20-year average annual VHA DFU LLA's is 8,624 of which **6,123 die on average post 3-year LLA** (Table 6)
- The 20-year average annual DFU Veterans **NOT receiving HBOT is 93.7 percent** of the VHA 2.2 million diabetic population (Table 8)
- The VHA **only contracts to 31.5 percent of existing HBOT hospitals** in the U.S. (Table 10)

The US Veteran's Administration continues to mismanage the clinical evaluation and timely care of the estimated 2.2 million diabetic Veteran population at risk for Diabetic Foot Ulcer limb amputation. This failure on the part of the VHA has resulted in substantially higher Lifetime costs, morbidity, mortality and a tragic reduction in Veteran length and quality of life that is well below that of the Medicare civilian population statistical comparators as reflected in this report.

The underlying tragedy is that the VHA is arbitrarily withholding services to conserve contract expenditures when expending six times the cost in treatments, amputations, surgical, and after care cost. HBOT contract services will provide fewer capital expenditures long-term by including existing hospital-based civilian Community Care Providers in the Diabetic Foot Ulcer Veteran population. This will reduce the Veteran morbidity and mortality statistics to realign with the comparable U.S. civilian Medicare population.

A full 74 percent of the high amputation-risk civilian population did not experience lower leg amputation due largely to the timely and aggressive use of Hyperbaric Oxygen Therapy and Wound Care in their Amputation Prevention Clinical Care Plan.¹ The Veteran Administration's national tragedy of 172, 470 Lower Limb Amputations (LLAs) procedures has resulted in a 70.9 % mortality (Table 3/6) through a three-year cycle.

To compile the data, the author has forwarded duplicate letters requesting historic data on the treatment of Veteran Diabetic Foot Ulcers (DFUs) to the CEO of Health Net Federal Services (HNFS-Tricare West) and Humana Military (HM-Tricare East) on March 9, 2022. HNFS provided a written response on April 12, 2022. Humana Military has not provided a detailed data response as of this writing after numerous Congressional requests. Dr. Lieberman of the Veterans Health Administration was sent a similar letter on March 28, 2022. The VHA provided their data response

¹ Advances in Wound Care, Volume 7, Number 12, DOI: 10.1089/2018.0855. Impact of Hyperbaric Oxygen on More Advanced Wagner Grades 3 and 4 Diabetic Foot Ulcers: Matching Therapy to Specific Wound Conditions, Ennis, Huand, Gordon

on July 22, 2022. This report is a data summary of the Hyperbaric Oxygen Therapy (HBOT) provided or available to Veterans within the Veterans Health Administration (VHA) network, the societal economic impact, and the correlation to industry standards.

Hyperbaric Oxygen Therapy (HBOT) is an on-label, FDA, CMS, and Tricare-approved (Appendix 3) treatment for Diabetic Foot Ulcers that has been proven safe and effective in helping prevent LLAs. It is a standard of care worldwide, *but not in the VHA. It is estimated the VHA Diabetic Foot Ulcer (DFU) LLAs will have a \$2.7 billion annual economic impact on America in 2022 (Table 1)*. The 2021 9,542 DFU LLA Veterans listed in Table 4 could have been treated with HBOT for \$115.3 million or 4.2 percent of the current annual \$2.7 billion DFU spend. Reducing and sustaining a 74 percent reduction of LLAs by treating with HBOT will have significant quality of life and financial benefit for Veterans and reducing the economic impact to US taxpayers (Table 1).

The surgical cost estimate of over \$628.8 million, inpatient care of \$607.2 million, and the cost of care after surgery estimate of \$904.3 million accounts for approximately 78 percent of the total amputation cost in 2022 (Table 1). The cost escalation for surgical procedures and after-care will not be sustainable long-term based on current financial trends. Diabetes and diabetes-related lower extremity complications combined account for the third most costly disease burden.² (Figure 5)

A review of 14 studies (768 participants) provided evidence that hyperbaric oxygen therapy is effective as an adjunct treatment measure for DFUs.³ Based on the VHA provided data, approximately 94 percent of diabetic Veterans infected with DFUs are not provided HBOT treatments (Table 8). As a result, approximately 64-71 percent of these Veterans are dying within three-years post LLAs (Table 3 and 6). The VHA delays or refusals to provide HBOT to DFU Veterans for outside treatment referrals is essentially sentencing DFU LLA Veterans to early deaths. In addition, the VHA currently does not provide “Informed Consent” to Veterans concerning HBOT treatments or services (Appendix 15) as required under the current medical Code of Medical Ethics Opinion 2.1.1.

With an estimate of over 2.2 million diabetics in the VA, the projection for the next ten years will be for DFU LLAs to increase substantially from the current VA annualized 20-year average of 8,624 amputations per year (Table 6). The cost escalation for surgical and after-care procedures *will not* be sustainable long-term by the VHA or Tricare insurance providers based on current projected trends.

The VHA does not operate hyperbaric oxygen chambers within the VHA healthcare network requiring the services to be contracted to outside hospital Community Care Wound Care Centers. There are approximately 1,156 hospital Wound Care facilities with HBOT chambers across America as of a 2018 report.⁴ “As per SPCO knowledge, there are no HBO units currently used in VHA facilities for clinical or non-research purposes. Due to the complexity of keeping the competence, the cost and maintenance of the chambers, maintaining the competence and certifications of physicians and tenders, and the fact that was more cost effective to send patients to community

² Lazzarini, P.A., Pacella, R. E., Armstrong, D. G., & van Netten, J. J. (2018). Diabetes-related lower-extremity complications are a leading cause of the global burden of disability. *Diabetic Medicine*, 35(9), 1297-1299. <https://doi.org/10.1111/dm>

³ Ncbi.nlm.nih.gov, Efficacy of hyperbaric oxygen therapy for diabetic foot ulcer, a systematic review and meta-analysis of controlled clinical trials, doi: 10.1038/s41598-021-81886-1, January 26, 2021

⁴ American Hospital Directory, 2018 Report provided by the CEO for this report writing

chambers, we stopped providing the care in house, and established contracts with Department of Defense, academic affiliates, the private sector Chambers, and using Community Care.”⁵ The VHA currently sub-contracts for HBOT services through 365 facilities in 42 states and the District of Columbia. The VHA contract facilities represent approximately 31.5 percent of available HBOT facilities in America (Table 10). This is grossly under contracted based on the number of VHA Veteran DFUs and LLAs per year.

The VHA data provides an insight into the lack of referrals of VHA DFU Veterans for Hyperbaric Oxygen Therapy (HBOT) across the entire U.S. Veteran LLAs have surpassed 8,624 on average per year since 2002 (172,470/20 years) to date. The VHA data reflects 63 percent (Table 6) to 70 percent (Table 3) of the Veteran amputees die within three-years from related diabetic post-surgery complications. The VHA provided data indicates 796,340 DFU LLA Veterans have died since 2001 or on average 36,197 per year (Table 7) The two VHA data averages of 8,624 LLA’s per year and 36,197 DFU LLA deaths per year are conflicting data points we could not resolve or validate.

In retrospect, potentially more Veterans have died from DFU LLA’s than all of WWI (116,516), WWII (405,399), Korea (36,516), Vietnam (58,209), Iraq and Afghanistan (7,342) combat operations combined (623,982).⁶ ***Transparency of this avoidable national DFU epidemic based on the VHA denial and or delays of HBOT referrals for basic FDA, CMS, and Tricare approved medical treatment which results in Veteran deaths must be brought before the American people and resolved immediately.***

HBOT has been medically proven to prevent LLAs in 74 percent of cases when treated with FDA/CMS/Tricare-approved HBOT in a ***timely manner***.⁷ The VHA data indicates approximately 94 percent of DFU Veterans are routinely denied access to, not provided “Informed Consent”, or refused referral to HBOT treatments for the past two-decades resulting in the likelihood of their demise within three-years. The VA system and Tricare should be able to realize significant cost savings over the short and long-term with the use of HBOT services for many of the FDA, CMS, and Tricare-approved indications while saving thousands of Veterans lives.

The VHA numbers based on industry data appear to be extremely low; the number of diabetic Veterans within the VHA is estimated to be 25 percent. The 2022 VA population is 18,204,166 (Appendix 1) and 49% estimated enrolled in the VA or 8,920,041. Twenty-five-percent of 8.9 million equates to an estimated 2,230,010 diabetic Veterans. The VHA numbers may also be obscured as approximately 51 percent of Veterans are not enrolled in the VHA network.

There is an overlap between diabetes and “stroke belt states.” Fifteen states comprise the diabetic belt and 10 of the 11 stroke belt states reside within the diabetic belt. An estimated 1.1 million Veterans are impacted in the diabetic and stroke belt (Tricare East) or approximately 50 percent of the total 2.2 million estimated diabetic Veterans in the VA system.⁸ The Humana Military DFU data cries out for thorough analysis to understand the overall national Veteran DFU epidemic.

⁵ Department of Veteran Affairs, Under Secretary of Health, Letter by Steven L. Lieberman, MD, Deputy Under Secretary of Health letter to Congressman Gregory F. Murphy, July 22, 2022

⁶ Statista.com Number of military fatalities in all major wars involving the US from 1775 to 2022, June 21, 2022

⁷ Advances in Wound Care, Volume 7, Number 12, DOI: 10.1089/Wound.2018.0855. Impact of Hyperbaric Oxygen on More Advanced Wagner Grade 3 and 4 Diabetic Foot Ulcers: Matching Therapy to Specific Wound Conditions

⁸ This Report, Page 14, Paragraph One and Table 2, Page 15

The U.S. Diabetic and Stroke Belts reside entirely within the Humana Military Tricare East geographic region and its cohorts may generate the most Veteran DFUs and Lower Limb Amputations for the entire national Tricare network (Figure 1 and Table 2). Health experts have identified a "diabetes belt" that includes 644 counties in 15 states across the southern and southeastern United States. Additionally, these same health experts have identified a "stroke belt" that covers 11 states within the "diabetic belt" (Figure 1 and Table 2). **North Carolina is in the middle of both the diabetic and stroke belts and accounts for 8 percent of 2019 CDC-reported diabetic deaths (3,124/38,599) in the diabetic state belt.⁹ Approximately 40.7 percent (7,400,081/18,204,166, Table 2 and Appendix 1) of all US Veterans are in this Diabetic Belt and North Carolina accounts for approximately 7.5 percent (83,767/1,115,456) of the total diabetics in the belt (Table 2).**

The 2020 cdc.gov diabetes mortality rate for patients is 25.2 per 100,000 (Appendix 4) or 102,015 in total across America. Over the last 22-years, 796,340 VHA Veteran DFU LLA diabetics have died, (Table 7) or on average 36,197 per year. The VHA data conflicts with the total annual DFU LLA deaths within its own data. The VHA LLA average annual deaths is 35.5 percent of the national total deaths (36,197/102,015) and Veterans only represent 7 percent of the total population.¹⁰ The 5-year national average mortality rate for DFU LLA's is 56.6 percent.¹¹ The current VHA DFU LLA mortality rate is 63.8 (Table 6) to 70.9 percent (Table 3) or 7.2 to 14.3 percent higher than the national average. The higher mortality rate can be directly correlated to the denial and limited access to HBOT treatments for Veterans with DFUs.

One of the most comprehensive studies of DFU LLAs was completed in 2018. "During the study time frame, 2,651,878 wounds were evaluated. The population-level healing rate was 74.2 percent, which is consistent with the previously reported 74.6 percent based on 1,006,690 wounds at the same time of that publication."¹² This is one of the largest published studies on the efficacy of HBOT healing DFUs ever completed. It is a 4.2 percent cost to treat and heal DFUs based on current VHA provided cost data versus an estimated \$2.7 billion annual cost of Lower Limb Amputation (LLA) and all the associated after-care costs (Table 1). The number of VHA Veteran LLAs (Table 3 and 4) conducted, and the resulting loss of life could be considered acceptable medical practice based on the existing acceptable medical treatment standards. One might ask if a medical investigation would provide the profession a passing grade for performance. Whatever the cost of treatment, it should not be a determining factor whether a Veteran does or does not receive adequate medical care.

An *inewsourc*e investigation in partnership with USA TODAY found veterans across the country are caught in the crossfire of the VA's battle to retain patients and funding since the passage of a landmark health care law known as The VA Mission Act.¹³ A review of thousands of pages of department manuals and medical records, along with interviews with dozens of patients, advocates, and providers, shows that VA administrators are overruling doctors' judgments and preventing them

⁹ CDC.gov, Diabetes Mortality Rate by State

¹⁰ Census.gov/topics/population/veterans

¹¹ Ncbi.nlm.nih.gov, Five year mortality and direct costs of care for people with DFU complications are comparable to cancer, March 24, 2020, Doi: [10.1186/s13047-020-00383-2](https://doi.org/10.1186/s13047-020-00383-2)

¹² Advances in Wound Care, Volume 7, Number 12, DOI: 10.1089/Wound.2018.0855. Impact of Hyperbaric Oxygen on More Advanced Wagner Grade 3 and 4 Diabetic Foot Ulcers: Matching Therapy to Specific Wound Conditions

¹³ Inewsourc

from sending their patients outside the VA health care system.¹⁴ Suicidal patients were cut off from what they considered “life-saving” mental health treatments by employees overwhelmed with paperwork—against the advice of the VA’s own psychiatrists.¹⁵ The most contentious — and some argue, most critical — a reason to send veterans outside the VA is when it’s in their “best medical interest.” That decision must be made by the Veteran and their “referring clinician,” the law says, and can help address a patient’s unique needs. VA manuals say veterans can receive an unlimited number of outsourced treatments, but only if reviewers deem them “clinically appropriate.”¹⁶ Patients described their anguish when they suddenly faced denials of care and letters demanding they return to veterans’ hospitals. Veterans indicate they have waited months or years for the VA to set up or renew appointments with private doctors.¹⁷ ***DFUs for Veterans in the VHA has become a potential death sentence when FDA/CMS/Tricare-approved treatments are widely available and the fundamental medical right of “Informed Consent”, let alone treatment, is being denied Veterans.***¹⁸ ***Informed Consent for medical treatment is fundamental in both medical ethics and law.***

“They can’t say, ‘No, you don’t get the care,’ and they can’t say, ‘Yes, you will get the care,’” she said. “They’ll just say, ‘It is processing.’”¹⁹ **As a result of these delays and denials, DFU Veterans who normally would receive limb-saving treatments are instead having amputations and 70.9 percent are dying within 3 years post-surgery. This report is created to request the US Congress to act and mandate the VA and DoD to legally provide “Informed Consent” of HBOT treatments for every single Veteran for on and off label HBOT treatments, and ensure the treatments are provided in a timely manner to eliminate LLAs for DFU Veterans. DFU Veterans can be treated and healed (on average 74 percent) with HBOT for less than 4.17 percent (Table 1, \$115,324,612/\$2,762,525,238) of the total DFU cost, a significant cost savings to the US taxpayer while being a significant lifesaving approved treatment protocol.**

The average HBOT treatment cost of \$12,086 per DFU Veteran in 2022 is actual VHA cost to treat (Table 5 and Page 25). Lifetime healthcare costs for people with limb loss is \$509,275 as compared to \$361,200 for people without limb lost.²⁰ Hospital charges for patients who underwent an amputation totaled \$8.7 billion in 2013.²¹ The estimated cost to American private and public insurance agencies is \$12 billion annually.²² HBOT is a proven, safe, and an approved treatment which every Veteran is entitled. There is ethical, moral, medical, financial, and a legal basis for all DFU Veterans to be provided HBOT for their injuries. The VHA data reflects 93.6 percent are simply not getting HBOT and in 74 percent of cases, it’s a limb and life-saving treatment.

¹⁴ Ibid.

¹⁵ Ibid.

¹⁶ Ibid.

¹⁷ Ibid.

¹⁸ Ama-assn.org, Chapter 2: Opinions on Consent, Communication and Decision Making, 2.1.1, Informed Consent

¹⁹ Inewsourc.org VA Doctors are being overruled on Veterans’ treatment plans. Here’s why. November 21,2021, Jill Castellano

²⁰ Infor@AccessProsthetics.com; 15 Limb Loss Statistics that May Surprise You, October 18,2017

²¹ Ibid.

²² Ibid.

Estimated Veteran Cost and Savings Treating DFUs with HBOT

DFU Cost Element	2022 Estimated Total Annual Cost
Total Estimated Annual Amputation	\$628,883,455
Surgical Cost \$12,577,699,119/20 Yrs= (Table 6)	
Total Estimated Average Inpatient Hospital Stays Cost (11 Days) (Appendix 11)	\$607,281,506
Total Estimated Three-Year Wheelchair Costs (Appendix 6)	\$355,470,999
Total Estimated VA After LLA Cost of Care of DFU Patients (Appendix 7)	\$904,314,424
Total Estimated Prosthesis Costs (Appendix 8)	\$89,418,082
Estimated VA and Social Security Disability Payments (Appendix 12)	\$177,156,772
Total Estimated Annual DFU & LLA Costs	\$2,762,525,238
DFU Cost Element (Based on 2021 Actual 9,542 Wagner Grade III or Higher Veterans Treated with HBOT	2022 Estimated Total Treatment Cost
Based on 9,542 DFU Veterans Receiving HBOT or \$12,086 per Veteran	\$115,324,612

Table 1

Introduction

"All that a man hath he will give his life for his country ... the soldier puts his life at stake, and often yields it up in his country's cause. The highest merit, then, is due the soldier"
(Abraham Lincoln March 1864).

NOTE: This partial report contains information from the data repository provided by The Veterans Health Administration and the healthcare industry. A comprehensive final report will be provided should Humana Military (Tricare East) respond and provide the DFU data requested.

Among the overall US population, 2018 estimates were 34.2 million people of all ages, or 10.5 percent of the population, had diabetes. An additional 34.1 million adults 18 years or older or 13 percent of all US adults, and 7.3 million adults were not aware or did not report having diabetes.³ Seniors over 65 years of age account for 26.8 percent of the US population with diabetes.⁴ Approximately 25 percent of the Veterans enrolled in the Veteran Administration Health network are diabetic. Approximately 25 percent of diabetics will develop a DFU in their lifetime, 56 percent of DFUs will become infected and one in five of those will require an amputation.⁵ Approximately 85 percent of lower limb amputations are preceded by a foot ulcer.⁶ Following Lower Limb Amputation (LLA), 50 percent will undergo contralateral amputation within two-five years. Patients undergoing a bilateral amputation due to a DFU, have a five-year mortality rate higher than rates for breast cancer, colon cancer, and prostate cancer combined.⁷ *Amputation is not just a life-altering event, it has become a potential death sentence worse than cancer for Veterans.*

Hyperbaric Oxygen Therapy (HBOT) has been approved for Diabetic Foot Ulcers (DFUs) by CMS since 2002, Tricare since 2008, and FDA since 2010 (Appendix 3). It makes the medical treatment widely adopted, accepted, practiced, and covered since 2002 or later. Based on patient testimonies, Veterans within the Department of Veteran Affairs (VA) healthcare system are not routinely provided "Informed Consent" regarding the availability of HBOT as an approved treatment option for DFUs Wagner Grade III or higher (Appendix 15). This is required under the Code of Medical Ethics Opinion 2.1.1. Routine access to HBOT for DFUs is a legal right for Veterans. If Informed Consent is not provided, there is a potential violation of federal law. The Community Care Choice Act was passed by Congress in 2014 and the VA Mission Act in 2018 which allows for access to HBOT treatments outside the VA as a fundamental medical right when the VHA cannot provide the service. This includes HBOT treatment for DFU, an approved, on-label, covered intervention. There are currently over 1,156 Wound Care Centers and hospitals equipped with HBOT chambers with trained and certified medical staff widely available across the entire U.S. to provide life-saving treatments routinely.

How is it that only 3 percent of Tricare West and 6 percent of VHA DFU Veterans are referred for treatments outside the VA? The 63.78 percent (Table 6) to 70.9 percent (Table 3) of those amputees die within three- years from related diabetic post-surgery complications or 796,340 since 2001. (The VHA provided data is conflicting based on annual averages). HBOT has been medically proven to prevent LLAs in 74 percent of cases when treated with FDA/CMS/Tricare-approved HBOT and is administered in a timely manner.²³ The VA does not operate hyperbaric oxygen chambers within the VA healthcare network requiring these services to be contracted to outside hospital Wound Care

²³ Advances in Wound Care, Volume 7, Number 12, DOI: 10 1089/2018.0855. Impact of Hyperbaric Oxygen on More Advanced Wagner Grades 3 and 4 Diabetic Foot Ulcers: Matching Therapy to Specific Wound Conditions, Ennis, Huand, Gordon

Centers. Veterans are simply not being informed about, nor being provided access to HBOT treatment by the VHA and it is costing Veterans their lives. There are Community Care Providers on the VHA approved listing who have attempted for years to treat VHA DFU patients but there are seldom and far between any referrals for the services.

The soaring diabetes rates, and the associated lower limb amputations, across the globe have fueled prosthetics and wheelchair industries. There are **2.1 million people** living with limb loss in the USA, and that number is *expected to double* by 2050.²⁴ Our Veteran population is not immune to this reality. Diabetes is one of the most widespread chronic diseases in the United States yet is also one of the most ignored and underdiagnosed. The civilian population has relatively easy access to limb-saving treatments including hyperbaric oxygen through commercial payers, Tricare, Medicare, and Medicaid. Hyperbaric Oxygen Therapy (HBOT) is a therapy proven to reduce amputations in patients with diabetic foot ulcers (DFUs) and is an approved indication by the FDA, CMS, and Tricare.²⁵ Our Veterans deserve the same ease of access to this life-saving care, which is not the current situation.

Despite recent efforts by the VA to improve access to community care, the referral and reimbursement process continues to be overly burdensome and limits access.²⁶ Providing routine HBOT services to diabetic DFU patients in both the VA, DoD and civilian communities is a proven treatment modality to improve DFU outcomes and reduce or prevent amputations. A standard course of HBOT has been shown to improve outcomes and reduce the need for amputations while proving more cost-effective than amputation surgery and associated after-care (rehab, home health, physical therapy, durable medical equipment, and prosthetics).²⁷ The VA system and Tricare should be able to realize significant cost savings over the short and long-term with the use of HBOT services for many of the FDA-approved indications, but especially with DFU as the financial analysis reflects. HBOT treatments are estimated to be less than 13 percent of the cost of surgical, inpatient hospital stay, and cost of care expenses for DFU amputations (Appendices 8-14). That is the financial reality. Perhaps a more important reality is the decline in quality and length of life associated with the loss of Veteran limbs.

In 2022, it is estimated the VA Diabetic Foot Ulcer (DFU) Lower Limb Amputations (LLAs) will have a \$2.7 billion annual economic impact (Table 1). The surgical cost estimate of over \$628.8 million, inpatient care of \$607.2 million, and the cost of care after surgery estimate of \$904.3 million accounts for approximately 78 percent of the total amputation cost in 2022 (Table 1). With an estimate of over 2.2 million diabetics in the VA, the projection for the next ten years will be for DFU LLAs to increase substantially from the current VA twenty-year average of 8,624 amputations per year (Table 11). The cost escalation for surgical procedures and after-care will not be sustainable long-term by

²⁴ Infor@AccessProsthetics.com; 15 Limb Loss Statistics that May Surprise You, October 18, 2017

²⁵ CMS.gov, Hyperbaric Oxygen Therapy for Hypoxic Wounds and Diabetic Wounds of the Lower Extremities, CAG-00060N, August 30, 2002

²⁶ Inewssource.org VA Doctors are being overruled on Veterans' treatment plans. Here's why. November 21, 2021, Jill Castellano

²⁷ Advances in Wound Care, Volume 7, Number 12, DOI: 10.1089/2018.0855. Impact of Hyperbaric Oxygen on More Advanced Wagner Grades 3 and 4 Diabetic Foot Ulcers: Matching Therapy to Specific Wound Conditions, Ennis, Huand, Gordon

insurance providers or the VHA without significant tax escalations to the US taxpayer. Diabetes and diabetes-related lower extremity complications combined account for the third most costly disease burden.² Reducing and sustaining a 74 percent reduction of the amputations by treating with HBOT will have significant quality of life and financial benefit.²⁸

Health experts have identified a "diabetes belt" that includes 644 counties in 15 states across the southern and southeastern United States, according to a new study from the Centers for Disease Control and Prevention (CDC).²⁹ The diabetes belt includes counties in Alabama, Arkansas, Florida, Georgia, Kentucky, Louisiana, North Carolina, Ohio, Pennsylvania, South Carolina, Tennessee, Texas, Virginia, and West Virginia. The entire state of Mississippi is also contained within the belt.³⁰ Nearly 12 percent of people who live in this region have [diabetes](#), compared with 8.5 percent of people in the rest of the United States. In the United States, nearly [26 million people have diabetes](#) and 79 million have prediabetes, according to a report published in January 2011 by the CDC.³¹ The latest reports on Veterans indicate that 25 percent of Veterans in the Veterans Health Administration are diabetic. With a 2022 Veteran population estimated at 18.2 million (Appendix 1), 49 percent in the VA system or 8.9 million, 25 percent with diabetes equates to an estimated 2.2 million diabetic Veterans.

The United States Diabetic Belt



Figure 1

²⁸ ncbi.nlm.nih.gov, Jan 26, 2021, Efficacy of hyperbaric oxygen therapy for diabetic foot ulcer, a systematic review and meta-analysis of controlled clinical trials

²⁹ Livescience.com, 15 US States Make Up Newly Identified 'Diabetes Bel', Cmanda Chan, March 9, 2011

³⁰ Ibid.

³¹ Ibid

This geographic overlay represents the area of the country where type 2 diabetes (the most common form of diabetes, which tends to occur later in life and accounts for over 90% of all diabetes cases) is the most prevalent. While there is [no one specific cause of diabetes](#), the CDC does note that the diabetes belt has a higher rate of obesity and a lower rate of leisure-time physical activity compared to other areas in the United States. North Carolina is in the middle of this belt and accounts for 8 percent of CDC-reported diabetic deaths. Approximately 40.6 percent (7,400,081/18,204,166, Appendix 1) of all US Veterans are in this Diabetic Belt and North Carolina accounts for approximately 3.6 percent (659,584/18,204,166) of the total.

The Stroke and the Diabetic Belt States

(A) US 2022 Diabetes State Rank	(B) US 2022 Stroke State Rank	(B) State	(C) Diabetes Rate	(D) 2022 State Veteran Population	(E) Estimated Diabetic Veterans Per State (C X D)
1	48	West Virginia	15.7%	130,536	20,494
2	1	Alabama	15.0%	330,207	49,531
3	24	Mississippi	14.6%	165,538	24,169
4	18	Louisiana	14.3%	243,335	34,797
5	42	Tennessee	14.2%	431,274	61,241
6	40	South Carolina	13.6%	365,139	49,659
7	4	Arkansas	13.2%	197,138	26,022
8	17	Kentucky	13.1%	267,594	35055
9	43	Texas	13.0%	1,453,450	188,949
11	33	North Carolina	12.7%	659,584	83,767
13	35	Ohio	12.5%	709,287	90,079
17	10	Georgia	11.8%	629,302	74,258
16	14	Indiana	12.0%	380,690	45,683
23	46	Virginia	11.1%	677,533	75,206
17	9	Florida	11.8%	1,440,338	169,960
19	38	Pennsylvania	11.4%	759,474	86,580
Total			13.6%	7,400,081	1,115,450

Table 2

- Note 1: Diabetes rates from stateofchildhoodobesity.org, Diabetes in the US, September 2021
- Note 2: State stroke rankings from ncbi.nlm.nih.gov and cdc.gov
- Note 3: All diabetic and stroke belt states reside in **Tricare East Region (Humana Military)**
- Note 4: The yellow represents the diabetic belt states and the green the stroke belt states
- Note 5: Veteran populations from Appendix 1

There is an overlap between diabetes and stroke belt states. There are 15 states comprising the diabetic belt and 10 of 11 stroke belt states reside within the diabetic belt. An estimated 1.1 million Veterans impacted in the diabetic and stroke belt (Tricare East) or approximately 50 percent of the total 2.2 million estimated diabetic Veterans in the VA system.

The Diabetic Lower Limb Amputation Epidemic and Treatments

Diabetes is the leading cause of nontraumatic amputations in the United States.³² The International Diabetes Federation has anticipated the numbers of diabetes patients will increase to 700 million by 2045.³³ Globally, every 30 seconds, a lower limb is lost, which is a major sequela of diabetes.³⁴ “Incidence rate of DFU in diabetes patient is 2%, (9.26 million) and this risk increases 17–60% with a previous history of DFU in next three years; also, among them, half (4.63 million) of diabetes patients undergo lower limb amputation at some stage of their life. Additionally, 28–51% DFU patients after the first amputation will have a higher probability of the second amputation within five years.”³⁵ DFUs have been studied for decades. There was a total of 14 studies (768) patients which included (384 in HBOT and 384 in study group) including twelve Random Controlled Trials (RCT’s) and two Controlled Clinical Trials (CCTs). Out of the 14 studies, eleven trials reported complete healed DFUs in their results.³⁶ It is conclusive evidence HBOT heals DFU’s in the majority (11/14 RCT/CCT/ 78.5%) of clinical patients and avoids amputations if treated timely.

The HBOT amputation groups showed significant differences in lower amputations versus the non-HBOT treated groups. The authors noted that the rate of major amputations was significantly greater in the non-HBO patients.³⁷ The CMS report supports HBOT not only heals DFUs in most cases, but significantly reduces Lower Limb Amputations (LLAs). The high incidence rate of post DFU LLAs death with Veterans is troubling considering the data. Five-year mortality for Charcot, DFU, minor and major amputations were 29.0, 30.5, 46.2 and 56.6%, respectively.³⁸ This is 34.0 percent (29.0%) to 14.3 (56.6%) percent below the VA mortality rate of 63.8 percent to 70.9 percent (Table 6 and Table 3). Compare that to the five-year pooled mortality for all reported cancer is 31 percent.

The data reflects 94 percent of diabetic Veterans in the VA healthcare network are not receiving HBOT (Table 8) (we could not discover how many of DFU patients had been informed that HBOT treatments were available and that it would have probable allowed those patients to avoid amputation) and approximately 64-71 percent (Table 6 and Table 3) are dying post LLA surgery within 3 years. Diabetic DFU patients outside the VA conversely are receiving HBOT and on average 74 percent of their DFU’s are healed and LLAs avoided, significantly extending their life expectancy, and greatly reducing the economic impact to the US taxpayers.³⁹

“Data for 27,878 matched pairs of Medicare and 4,536 matched pairs of privately insured patients were analyzed. During the 12-month follow-up period, DFU patients had more days hospitalized (+138.2% Medicare, +173.5% private, days requiring home health care (+85.4% Medicare, +230.0% private), emergency department visits (+40.6% Medicare, +109.0% private), and outpatient and

³² Hyperbaric Treatment of Diabetic Foot Ulcer, Mary E. Hanley, Biagio Manna, July 18, 2022

³³ ncbi.nlm.nih.gov, Jan 26, 2021, Efficacy of hyperbaric oxygen therapy for diabetic foot ulcer, a systematic review and meta-analysis of controlled clinical trials

³⁴ Ibid.

³⁵ Ibid.

³⁶ ncbi.nlm.nih.gov, Jan 26, 2021, Efficacy of hyperbaric oxygen therapy for diabetic foot ulcer, a systematic review and meta-analysis of controlled clinical trials

³⁷ CMS.gov, Hyperbaric Oxygen Therapy for Hypoxic Wounds and Diabetic Wounds of the Lower Extremities, CAG-00060N, August 30, 2002

³⁸ Pubmed.ncbi.nlm.nih.gov, Five-year mortality and direct costs of care for people with diabetic foot complications are comparable to cancer, Mar 24, 2020, DOI:10.1186/s13047-020-00383-2

³⁹ Advances in Wound Care, Volume 7, Number 12, DOI: 10.1089/2018.0855. Impact of Hyperbaric Oxygen on More Advanced Wagner Grades 3 and 4 Diabetic Foot Ulcers: Matching Therapy to Specific Wound Conditions, Ennis, Huand, Gordon

physician office visits (+35.1% Medicare, +42.5% private) than matched controls.”⁴⁰Diabetes increases the chances of having a stroke, which can damage brain tissue and cause disability or even death. People with diabetes are 1.5 times more likely to have a stroke than people without diabetes. In 2015, the global prevalence of diabetes was estimated to be 415 million adults, with 12% of global expenditure (US \$673 billion) on health spent for diabetes care alone.⁴¹ The incidence of stroke and its sequelae are on the rise. Patients with diabetes are particularly at a significantly higher risk of stroke and have higher mortality.⁴²

Diabetic lower extremity amputation complications remain enormously burdensome for Veterans. Most notably, DFU and LLAs appear to be more than just a marker of poor health. They are independent risk factors associated with premature death for Veterans. While advances continue to improve outcomes of care for people with DFU and amputation, efforts should be directed at primary prevention with timely HBOT to maximize ulcer-free, hospital-free, and activity-rich days. Diabetes is more prevalent among US veterans, who make up 9% of the civilian US population, than among the general population and affects nearly 25% of US Department of Veterans Affairs (VA) patients.⁴³

How Does Hyperbaric Oxygen Therapy Heal DFUs?

Hyperbaric Oxygen Therapy (HBOT) is a therapy proven to reduce amputations in patients with diabetic foot ulcers (DFUs) and is an approved indication by the FDA, CMS, and Tricare.⁴⁴ “Hyperbaric oxygen therapy is the treatment of a disease or medical condition by the inhalation of near-100% (at least 95%) medical grade oxygen at pressures greater than one atmosphere absolute (ATA) (101.3 kilopascals (kPa)) in a pressure vessel constructed for that purpose. Most clinical HBOT DFU treatments are conducted at 2.0 to 2.5 ATA. However, in certain instances at chamber treatment pressures for diving or post-surgical gas embolus above 3.0 ATA, oxygen levels are intermittently reduced below 100% oxygen by using mask air to achieve a partial pressure of oxygen below 1.2 ATA to help avoid oxygen toxicity. Medical grade oxygen should meet USP (US Pharmacopeia) or national equivalent standard for purity.”⁴⁵

The Undersea & Hyperbaric Medical Society (UHMS), the nation’s premier experts on hyperbaric oxygenation, speaks directly to the use of HBOT used to heal “arterial insufficiency” and selected problem wounds...Although the underlying physiology and basis science support the contention that HBO2T is likely to be used in a variety of problem wounds, the best evidence exists for treatment of ischemic, infected (Wagner Grade III or higher) diabetic foot ulcers. “Normal wound healing proceeds through an orderly sequence of steps involving control of contamination and infection, resolution of inflammation, regeneration of the connective tissue matrix, angiogenesis, and resurfacing. Several of these steps are critically dependent upon adequate perfusion and oxygen availability. The result of this process is sustained restoration of anatomical continuity and functional integrity. Problem or

⁴⁰ Pubmed.ncbi.nlm.nih.gov, Burden of diabetic foot ulcers for Medicare and private insurers, September 2014, <https://doi.org/10.2337/dc13-2176>

⁴¹ Ncbi.nlm.nih.gov, Diabetes Mellitus and Stroke: A clinical update. World J Diabetes. 2017 Jun 15; 8(6): 235–248.

⁴² Ibid.

⁴³ US Department of Veterans Affairs. Veterans Health Administration: close to 25 percent of VA patients have diabetes. <https://www.va.gov/health/NewsFeatures/20111115a.asp>. Updated April 17, 2015.

⁴⁴ For an in-depth exposition of how HBOT works on DFUs, see UHMS Indication 06b. Arterial Inefficiencies: Enhancement of Healing in Selected Problem Wounds. <https://www.uhms.org/resources/hbo-indications.html>

⁴⁵ UHMS.org, Indications for Hyperbaric Oxygen Therapy, Definition of Hyperbaric Oxygen Therapy, 13th Edition

chronic wounds are wounds that have failed to proceed through this orderly sequence of events and have failed to establish a sustained anatomic and functional result”

Debridement, Offloading, or Total Contact Casts (TCC), Negative Pressure Wound Therapy and Hyperbaric Oxygen Therapy (HBOT) are a few of the leading-edge treatments considered standard of care worldwide. While it is common to find doctors in the VHA and elsewhere who are ignorant about the use of HBOT for DFUs, to include endocrinologists. It is therefore a failure of the medical system overall to ensure that anyone dealing with DFUs is cognizant of all interventions to heal wounds of all types with a scientifically validated on-label, safe, effective, and economical treatment. Veterans are entitled to fully informed consent on all treatment options.

Veterans deserve the same ease of access to this life-saving care as civilians, which is not the current situation based on 93.64 percent of Veterans not getting access to HBOT treatment (Table 8). Despite recent efforts by the VA to improve access to community care, the referral and reimbursement process continues to be overly burdensome and because of this, limits access. Providing routine HBOT services, a proven treatment modality, to diabetic DFU patients in both the VHA and DoD will improve DFU outcomes and reduce or prevent amputations. A standard course of HBOT has been shown to improve outcomes and reduce the need for amputations while proving more cost-effective than amputation surgery and associated after-care (rehab, home health, physical therapy, durable medical equipment, and prosthetics).⁴⁶ The VHA system and Tricare should be able to realize significant cost savings over the short and long-term with the use of HBOT services for many of the FDA-approved indications, but especially with DFUs. The reality is the decline in quality and length of life associated with LLAs for DFU Veterans.

Figure 2 illustrates how highly concentrated oxygenation helps accelerate cell and tissue growth over short periods of time, usually 2-3 months. The on-label approved treatment requires a Wagner Grade III or higher to be insurance covered. The essential element is beginning treatments immediately prior to or following Grade III diagnosis. If there are lengthy delays in diagnosis and or scheduling of treatments outside the VA, it can mean **a matter of life or death for DFU Veterans**. Once gangrene sets in, the typical option is Lower Limb Amputation (LLA). “The effect of HBOT on diabetic foot ulcers, Wagner Grades III and IV, was evaluated using a retrospective observational real-world data set. The study reported on the overall healing rate of 74.2 percent at the population level for 2.6 million wounds.”⁴⁷

⁴⁶ Advances in Wound Care, Volume 7, Number 12, DOI: 10 1089/2018.0855. Impact of Hyperbaric Oxygen on More Advanced Wagner Grades 3 and 4 Diabetic Foot Ulcers: Matching Therapy to Specific Wound Conditions, Ennis, Huand, Gordon

⁴⁷ Advances in Wound Care, Volume 7, Number 12, DOI: 10 1089/2018.0855. Impact of Hyperbaric Oxygen on More Advanced Wagner Grades 3 and 4 Diabetic Foot Ulcers: Matching Therapy to Specific Wound Conditions, Ennis, Huand, Gordon

A Typical DFU Treated Foot with HBOT



Day 1 Prior to Scheduled Amputation, Wagner Grade III was present for one year and unresponsive to conventional therapy



After 26 HBOT treatments



After 50 HBOT treatments

Figure 2

SINBAD scores are used to evaluate DFU characteristics and the severity of the ulcers. A simplistic explanation of SINBAD scores follows; SINBAD <3 is less severe, SINBAD >3 is severe ulcer. The simplistic analysis is *“Time is Tissue: The longer the referral times equates to more tissue loss, which equates infection and amputation.”*⁴⁸ The acronym SINBAD is defined as:

Site-where is the ulcer, front or rear of the foot

Ischemia-problems with blood circulation due to damaged blood vessels, fragile skin results

Neuropathy-damage to nerves which results in loss of sensation

Bacterial infection-whether there is infection in the ulcer

Area-the size and shape of the ulcer

Depth-how deep the wound may be

Findings from 173 varying foot care clinics provided data to the National Diabetes Footcare Audit (NDFA) in 2014-2016. “The report found almost half (46%) of most ulcers were associated with neuropathy or loss of sensation.⁴⁹ The report goes on to report 66 percent of people with diabetes who self-referred had less severe ulcers. The longer the referral time, 2 months or more, 58 percent result in severe ulcers.”⁵⁰

⁴⁸ DF Blog, <https://linkd.in/gFhygvFE@diabetesUK>

⁴⁹ Diabetes.org.uk, Diabetes Foot Care: Are services in England and Wales putting your feet first? National Diabetes Footcare Audit (NDFA), 2014-2016 in England and Wales, March 2017

⁵⁰ Ibid.

The NDFA found that people with diabetes who had less severe ulcers were almost twice as likely to be alive and ulcer free at the 12-week follow-up than people who had severe ulcers. Timely treatment is therefore an essential element. It appears DFU Veterans are not getting timely referrals based on the VHA data provided.

The results with pooled analysis have shown that HBOT was significantly effective in the complete healing of diabetic foot ulcers (OR = 0.29; 95% CI 0.14–0.61; I² = 62%) and reduction of major amputation (RR = 0.60; 95% CI 0.39–0.92; I² = 24%).⁵¹ Figure 2 is an illustration of a typical DFU foot prior to scheduled amputation that received HBOT treatments over a two-month period. The obvious point is **the delays and denials within the VHA referral process for outside HBOT treatments is costing Veterans their lives for DFUs in which 74 percent are curable.**

Severity of DFU Initial Diagnosis and Treatment Based on SINBAD Rating

Figure 10. Ulcer severity by time to first assessment by multi-disciplinary foot team, England and Wales, 2014-2015 (Source: NDFA³⁹)

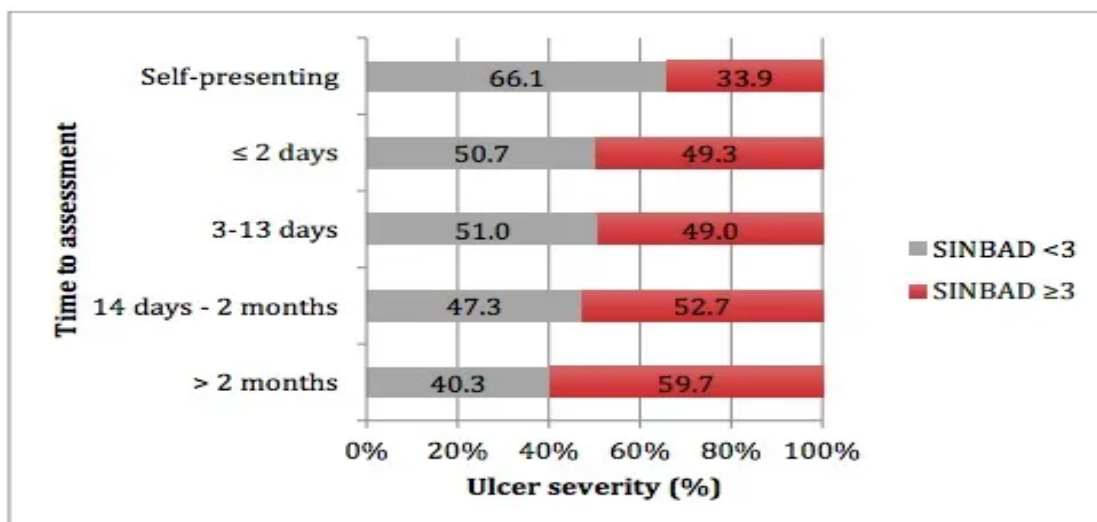


Figure 3

"The estimate in the US in 2007 was \$18.9 billion spent on the care of diabetic foot ulcers and \$11.7 billion on lower extremity amputations. It becomes a death sentence for 70.9 percent of DFU Veterans who are told amputation is the only option remaining. It is estimated lifetime healthcare costs for each person with limb loss is \$509,275 compared to \$361,200 for people without limb loss."⁵² Escalating this 15-year-old cost at the historic 3.24 percent average inflation rate per year (Appendix 14) equates to an estimated \$30.5 billion in 2022 spent on diabetic foot ulcers and \$19.5 billion on lower extremity amputations across America.

⁵¹ nebi.nim.nih.gov, Efficacy of Hyperbaric Oxygen Therapy for Diabetic Foot Ulcer, a systematic review and meta-analysis of controlled clinical trials, Published online 2021 Jan 26. Doi: [10.1038/s41598-021-81886-1](https://doi.org/10.1038/s41598-021-81886-1)

⁵² infor@AccessProsthetics.com: 15 Limb Loss Statistics That May Surprise You, October 18, 2017

Global Mortality Rates of Diabetic Foot Ulcer

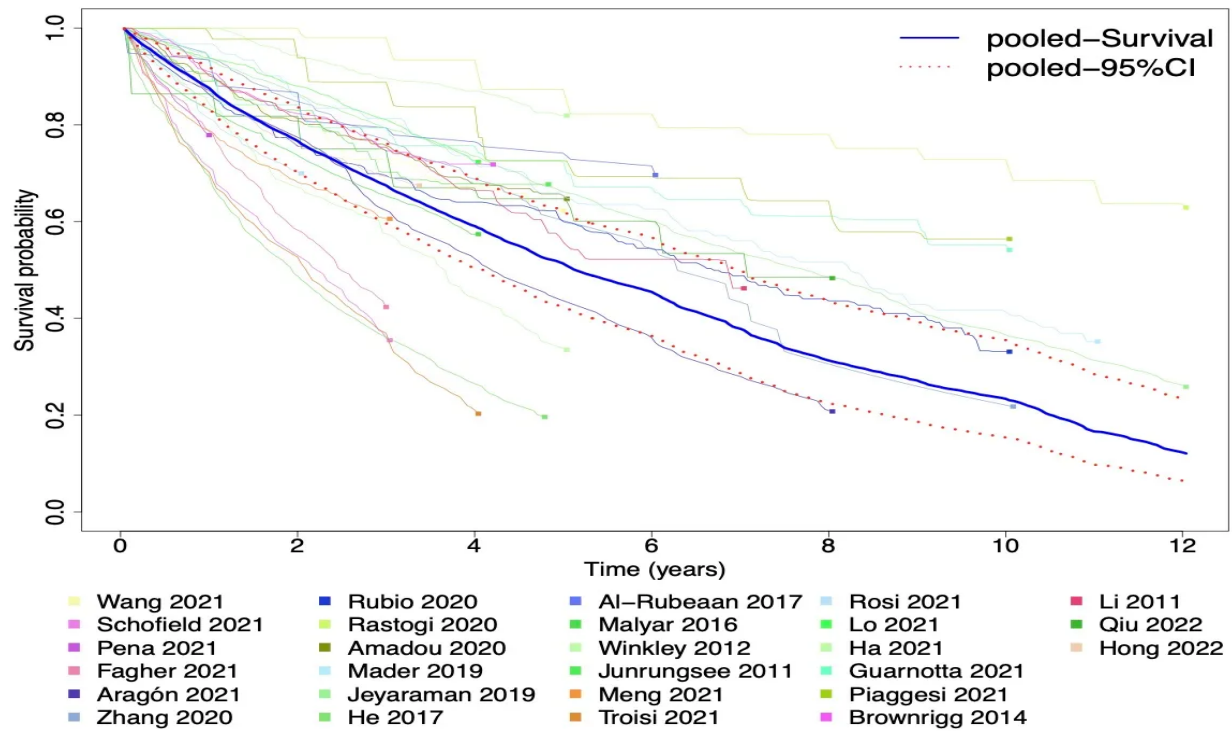


Figure 4

Note 1: Figure 4 source is diabeticfootonline.com, Global Mortality of diabetic foot ulcer: a systematic review and meta-analysis of observational studies-nearly 50% 5-year mortality @alpslimb#ActAgainstAmputation

Leading 5-Year Mortality of DFU Complications and Cancer in the US

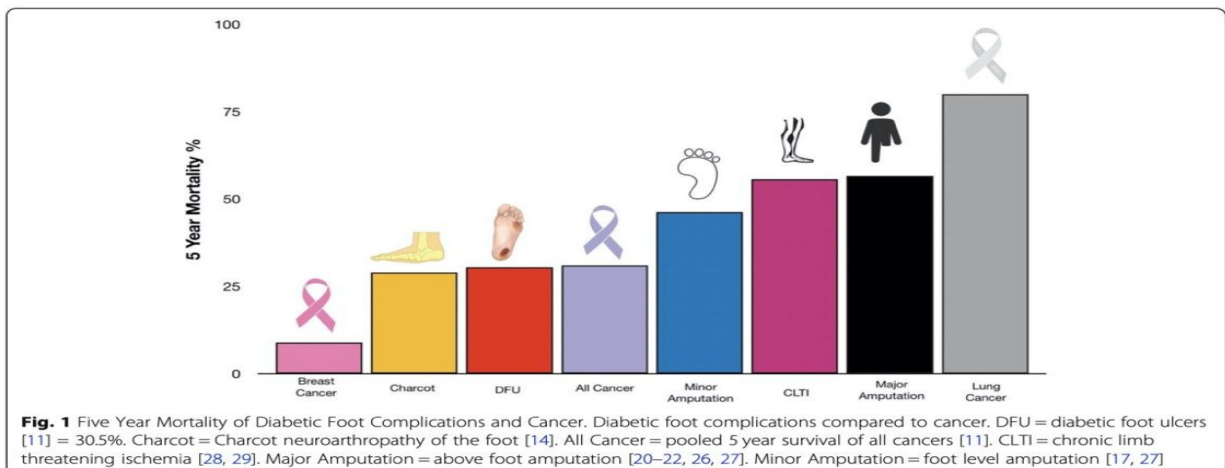


Figure 5

Note 1: Source is apexheartandvascular.com, APEX Heart and Vascular Care Vein Clinic, Peripheral Arterial Disease (PAD) and Amputation Prevention, July 2, 2020, Dr. Anuj Shah

“There were 34 studies, with 124,376 participants representing 16 countries, among whom there were 51,386 deaths. Of these, 27 studies with 21,171 patients were included in the Kaplan-Meier-based meta-analysis. This meta-analysis found that the overall mortality of DFU was high, with nearly 50% mortality within 5 years. Cardiovascular disease and infection were the leading two causes of death.”⁵³ The above extensive global analysis of DFUs is a key indicator as the VHA data reflects a death rate 63.78 percent (Table 6) to 70.9 percent (Table 3) within three-years. DFU LLA Veterans in the VHA healthcare network will die at a rate 14-21 percent higher than the global average. This is another indication that HBOT, when administered in a timely manner and effectively to DFU patients is extending life for patients.

Since September 2002, a total of 8,880 to 8,896 VHA Veterans have received HBOT or an average of 444 per year or 37 DFU Veterans per month.⁵⁴ The VHA average of 8,624 DFU LLA Veterans annually or 719 per month. This equates to 95% percent of VHA Veterans suffering from DFUs are in all likelihood NOT receiving the benefits of HBOT; it is not clear that they have been provided the option to receive HBOT treatments. However, the VHA data reflects that Veterans had not received HBOT.

1989-1998 History of VHA Lower Limb Amputations, Cost, Deaths (VA.gov)

(A)Year	(B) Number of Veteran Lower Limb Amputations (LLA'S) Note 1	(C) Average Cost Per Veteran LLA Surgery Note 3	(D) Total Estimated Veteran Surgery Cost for LLA's (B X C)	(E)Mortality Rate Expected 30 days After LLA 13.5% (B X 13.5%) Note 4	(F) Mortality Rate Expected 1 Year After LLA 48.3% (B X 48.3%) Note 4	(G) Mortality Rate Expected 3 Year After LLA 70.9% (BX 70.9%) Note 4
1989	6585	\$44,750.00	\$294,678,750.00	889	3181	4669
1990	6576	\$44,750.00	\$294,276,000.00	888	3176	4662
1991	6021	\$44,750.00	\$269,439,750.00	813	2908	4269
1992	5794	\$44,750.00	\$259,281,500.00	782	2799	4108
1993	6130	\$44,750.00	\$274,317,500.00	828	2961	4346
1994	6096	\$44,750.00	\$272,796,000.00	823	2944	4322
1995	6097	\$44,750.00	\$272,840,750.00	823	2945	4323
1996	6052	\$44,750.00	\$270,827,000.00	817	2923	4291
1997	5644	\$44,750.00	\$252,569,000.00	762	2726	4002
1998	5329	\$44,750.00	\$238,472,750.00	719	2574	3778
Total	60324		\$2,699,499,000.00	8144	29136	42770
Average Per Yr	6,032					

Table 3

⁵³ diabeticfootonline.com, Global Mortality of diabetic foot ulcer: a systematic review and meta-analysis of observational studies-nearly 50% 5-year mortality @alpslimb#ActAgainstAmputation

⁵⁴ Department of Veteran Affairs, Under Secretary of Health, Letter by Steven L. Lieberman, MD, Deputy Under Secretary of Health letter to Congressman Gregory F. Murphy, July 22, 2022

Note 1: Table 3 data extracted from Department of Veteran Affairs, Journal of Rehabilitation Research and Development Vol. 37 No 1, January/February 2000, Trends in Lower Limb Amputations in the Veteran Health Administration, 1989-1998, Table 1.

Note 2: The mortality rates Colum E, F, and G were estimates and added to the chart.

Note 3: Columns E, F, and G are based on Mortality rates from the VA/DoD Clinical Practice Guide for Rehabilitation of Individuals with Lower Limbe Amputation, Version 2.0, Page 9, 2017

Note 4: Column C Cost based on Imperial College of London, High Cost of Healthcare for UK Military Amputees from Afghan Conflict, May 31, 2015, Science Daily 2001-2014. 40-year single amputee base cost is estimated at \$1.34M for transtibial or below the knee (\$33,500 per year), \$1.79M for through-the-knee amputee and above the knee (\$44,750 per year). The higher surgical cost estimate was used based on 15% of the discharges recorded two or more amputations during the hospitalization

Note 5: Table 3, Column C surgical cost was NOT escalated 3.24% annually based on historical inflation rate in Appendix 15 to reflect a conservate cost estimation

Table 3 reflects over 60,000 Lowe Limb Amputations (LLA's) with an average of 6,032 DFU LLAs conducted per year over the 10-year period at an estimated cost of \$2.7 billion. The average cost per surgical procedure for 60,324 DFU LLA Veterans is \$44,750 (\$2,699,499,000/60,324) over the ten-year period. The cost of surgeries coupled with the estimated 42,770 lives lost within three years post-LLAs is both a moral and sound economic argument to treat DFUs with HBOT.

Table 4 represents the most recent provided VHA DFU LLA data. It shows a 44.9 percent increase in the average number of annual Veteran DFU's LLAs from 1989 to 2022 (6,585 to 9,542). The last five years from 2017 through 2021, the average Veteran LLAs is a five-year average of 9,253 per year. Over the entire twenty-year period, the average LLAs equate to 8,201 per year. The last five-year average of 9,253 versus the 1989-1998 average of 6,032 represents a 35 percent increase in the number of LLAs the VA is performing annually. The average number of DFU Veterans treated with HBOT per year is 548 (Table 5) which equates to 5.9%. Hyperbaric Oxygen Therapy is FDA, CMS and Tricare approved DFU treatment and on average 74 percent effective in healing DFUs. *Why then are approximately 95 percent of the VHA DFU Veterans not receiving the treatment resulting in 70 percent dying within three-years?*

If the cost to treat DFUs with HBOT is a fraction of the LLA annual cost, how can cost be a factor? "If they have a problem with the budget, they need to come and talk to Congress," said Rep. Mike Bost, R-IL, ranking member of the House Committee on Veterans' Affairs. "They don't need to go ahead and try to figure out how to take services away from our veterans."⁵⁵ Under department policy, VHA doctors usually don't send their patients outside the health care system on their own, records show. They can make recommendations that go through reviews by other staff — such as administrators, clerical workers or clinicians trained by hospital leadership — who can cancel treatment requests and insist patients come to the VA instead.⁵⁶

⁵⁵ Inewssource.org news story, November 21, 2021, Jill Castellano, VA doctors are being overruled on veterans' treatment plans. Here's why.

⁵⁶ Inewssource.org news story, November 21, 2021, Jill Castellano, VA doctors are being overruled on veterans' treatment plans. Here's why.

For veterans ultimately approved for treatments elsewhere, the VA can require checkups at its hospitals anyway that includes veterans facing severe disabilities, burdensome drives, or long wait times for VA appointments. “It basically defeats the whole purpose of the Mission Act,” said Darin Selnick, senior advisor to Concerned Veterans for America, an organization pushing for Veterans to have more access to private health care.⁵⁷

20-Year VHA Historic DFU Lower Leg Amputations (LLA) Per Year

01. Daily Procedures and Demographics by FY						
FY	Daily Procedures	Procedure Codes	Amputees	Amputees Age Average	Amputees Diabetes	Amputees Diabetes %
2002	6,977	7,157	5,315	65.9	3,951	74.34
2003	7,123	7,364	5,357	66	4,060	75.79
2004	7,125	7,361	5,357	65.2	4,076	76.09
2005	7,410	7,787	5,414	65.2	4,222	77.98
2006	7,741	8,332	5,504	64.8	4,233	76.91
2007	7,946	8,537	5,530	64.8	4,259	77.02
2008	7,697	8,294	5,571	65.1	4,270	76.65
2009	7,598	8,136	5,524	65.2	4,233	76.63
2010	8,198	8,782	5,909	65.2	4,588	77.64
2011	8,444	8,952	6,172	65.1	4,786	77.54
2012	8,643	9,227	6,156	65.5	4,833	78.51
2013	8,799	9,390	6,401	65.7	5,107	79.78
2014	8,913	9,514	6,542	66	5,175	79.1
2015	8,675	9,341	6,386	66.2	5,141	80.5
2016	9,166	11,977	6,596	66.6	5,415	82.1
2017	9,225	12,279	6,693	67.1	5,517	82.43
2018	9,901	13,339	7,151	67.5	5,957	83.3
2019	10,073	13,632	7,283	67.9	6,069	83.33
2020	9,521	13,239	6,784	68.3	5,741	84.63
2021	9,542	15,150	6,953	68.4	5,846	84.08
2022	3,753	5,309	2,960	68.4	2,468	83.38
Total	172,470		125,558	66.2	99,947	79.4

Table 4

Note 1: Data provided by the VHA via letter date July 22, 2022, from Deputy Under Secretary of Health to Congressman Greg Murphy, MD (R-NC)

The average age for VHA DFU LLA’s Veterans is 66 and 79 percent are diabetic as shown in Table 4. The VHA did not provide an explanation of the Daily DFU LLA Procedures versus the

⁵⁷ Ibid.

Amputees categories in Table 4. The amputee to daily LLA procedure is 72.8 percent (125,558/172,470). We use the higher number of 172,470 in our analysis of LLA’s performed daily as the basis for determining overall DFU LLA Veteran surgical exposure.

20 Year VHA Cost of Treating Total DFU Veterans with HBOT

Date of Service (DOS) FY	Total Paid	Unique Veterans
2002	\$149,832.60	34
2003	\$1,785,379.53	192
2004	\$3,043,182.93	246
2005	\$3,374,842.15	248
2006	\$4,112,758.05	261
2007	\$5,656,839.70	324
2008	\$6,242,005.80	352
2009	\$7,933,852.40	369
2010	\$11,211,238.52	452
2011	\$8,249,179.32	462
2012	\$5,997,450.62	450
2013	\$6,238,623.04	556
2014	\$6,350,100.95	586
2015	\$7,156,620.68	634
2016	\$5,393,913.04	558
2017	\$4,745,531.19	684
2018	\$9,890,853.26	987
2019	\$9,149,673.28	1,009
2020	\$6,413,709.68	996
2021	\$14,271,721.93	1,097
2022	\$5,090,450.38	466
Total	\$132,457,759.05	10963
Aveg Per Year	\$6,622,888	548

Table 5

Note 1: Data provided by the VHA via letter date July 22, 2022, from Deputy Under Secretary of Health to Congressman Greg Murphy, MD (R-NC)

Note 2: The VHA data indicates a total of 10,963 DFU Veterans with HBOT over a twenty-year period, or on average of 548 per year, or 46 per month. The electronic calculations for the VHA provided data in

Table 5 above equate to 10,963 total and was the number used in the average calculations.

The VA average annual cost to treat DFUs with HBOT is \$6,622,888 (\$132,457,759/20) or \$12,085 per Veteran (\$6,622,888/548). The cost to conduct VA LLA amputations over the past

twenty-years is estimated at \$12.5 billion (Table 6). This equates to a twenty-year average cost per surgical procedure cost for 8,624 (172,470/20) average LLAs at cost of \$628,883,456 per year (\$12,577,669,119/172,470, Table 6), or \$72,926 per procedure. The surgical cost is six (6) times greater than treating with HBOT to save the lower limbs. *The financial analysis supports DFU treatment with HBOT versus amputation by an overwhelming 6 to 1 cost ratio. This is assuming timely referrals by the VA of DFU Veterans as even a 30 delay or denial in the referral process can mean life or death for Veterans.*

“Direct costs of care for diabetes in general was \$237 billion in 2017. This is compared to \$80 billion for cancer in 2015. As up to one-third of the direct costs of care for diabetes may be attributed to the lower extremity, these are also readily comparable.”⁵⁸

VHA Estimated Annual DFU LLA Surgical Cost and VHA Mortality Rate

(A)Year	(B) Number of DFU Veterans Note 2	(C) Average Cost Per Veteran LLA Surgery Note 3	(E) Total Estimated Veteran Surgery Cost for LLAs (B X C)	(F)Mortality Rate Expected 30 days After LLA 13.5% (C X 13.5%) Note 5	(G) Mortality Rate Expected 1 Year After LLA 48.3% (C X 48.3%) Note 5	(H) Mortality Rate Expected 3 Year After LLA 63.78% (C X 63.8%) Note 5
2002	6,977	\$51,614.00	\$360,110,878.00	942	3370	4451
2003	7,123	\$53,286.00	\$379,556,178.00	962	3440	4544
2004	7,125	\$55,013.00	\$391,967,625.00	962	3441	4546
2005	7,410	\$56,795.00	\$420,850,950.00	1000	3579	4728
2006	7,741	\$58,635.00	\$453,893,535.00	1045	3739	4939
2007	7,946	\$60,535.00	\$481,011,110.00	1073	3838	5070
2008	7,697	\$62,496.00	\$481,031,712.00	1039	3718	4911
2009	7,598	\$64,521.00	\$490,230,558.00	1026	3670	4848
2010	8,198	\$66,612.00	\$546,085,176.00	1107	3960	5230
2011	8,444	\$68,770.00	\$580,693,880.00	1140	4078	5387
2012	8,643	\$70,998.00	\$600,856,074.00	1167	4175	5514
2013	8,799	\$73,299.00	\$644,957,901.00	1188	4250	5614
2014	8,913	\$75,673.00	\$674,473,449.00	1203	4305	5686
2015	8,675	\$78,125.00	\$677,734,375.00	1171	4190	5535
2016	9,166	\$80,657.00	\$739,302,062.00	1237	4427	5848
2017	9,225	\$83,270.00	\$768,165,750.00	1245	4456	5886
2018	9,901	\$85,968.00	\$851,169,168.00	1337	4782	6317
2019	10,073	\$88,753.00	\$894,008,969.00	1360	4865	6880
2020	9,521	\$91,629.00	\$872,399,709.00	1285	4599	6074
2021	9,542	\$94,597.00	\$902,644,574.00	1288	4609	6088
2022	3,753	\$97,662.00	\$366,525,486.00	507	1813	2394
Total	172470		\$12,577,669,119.00	23284	83304	110490

Table 6

⁵⁸ Ibid.

Note 1: All numbers were rounded to the nearest whole number

Note 2: Data provided by the VHA via letter date July 22, 2022, from Deputy Under Secretary of Health to Congressman Greg Murphy, MD (R-NC)

Note 3: Source: Imperial College o London, High Cost of Healthcare for UK Military Amputees from Afghan Conflict, May 31, 2015, Science Daily 2001-2014, 40-year single amputee base cost is estimated \$1.3M for transtibial or below the knee (\$33,500 per patient year), \$1.79 million for through the knee amputee and \$1.79 million above the knee amputee (\$44,750 per patient year). The \$44,750 per surgical operation in 1998 was escalated at 3.24 percent per year annual average inflation rate per year (Appendix 14) to arrive at \$97,662 per surgical procedure cost in 2022

Note 4: 60-70% of hospitalized Veterans in the US have diabetes (stat.com, Diabetic Foot Ulcers: Silent Killer of Veterans, November 11, 2019)

Note 5: Mortality rates from VA/DoD Clinical Practice Guide for Rehabilitation of Individuals with Lower Limb Amputation, Version 2.0, Page 9, 2017

Table 3 VHA data represents estimated cost and mortality rates based on VHA 70.9 percent who die 3-years post LLA surgery. The VHA data reflects a 63.8 percent mortality rate as reflected in Table 7 below. The actual number of deceased DFU LLA Veterans over 22 years of 796,340 equates to an annual average of 36,197 DFU Veteran deaths per year. There is conflict with the total VHA 796,340 deaths versus the annual DFU LLA average deaths per year our analysis could not rectify based on the provided VHA data. HBOT DFU treatments save on average 74 percent of lower limbs which equates to 26,786 of the 36,197 yearly averages of Veteran lives which could have been saved if treated timely with HBOT. ***The 7.12% variation in mortality rate of 70.9 percent in Table 3 and 63.78 percent in Table 7 are both VHA sited data references.***

“The VA does not have Wagner 1-5 Classification data within 3 years since initial LLAs. The below data in Table 7 provides the number of deceased patients from FY2001 since initial LLAs.”⁵⁹ The Table 7 VA data reflects on average of ***36, 197 (796,340/22 yrs.) DFU Veterans post LLAs dying each year for the past 22 years within the VA healthcare network.***

Industry HBOT average DFU HBOT heal rate is 74 percent. Essentially, 26,786 (36,197 x 74%) deceased LLA Veterans potentially should have been saved had HBOT treatments been provided in a timely manner to these Veterans. What is not included in this analysis this analysis are comorbidities that contribute to Veteran mortality. A more thorough analysis than we have undertaken using other date sets will be required. We assumed there were not any other medical conditions outside the 79 percent of DFU Veterans inflicted with diabetes as reflected in Table 4.

⁵⁹ Department of Veteran Affairs, Under Secretary of Health, Letter by Steven L. Lieberman, MD, Deputy Under Secretary of Health letter to Congressman Gregory F. Murphy, July 22, 2022

22 Year VHA DFU LLA Veteran Mortality Rate

FY	Living	Deceased	Grand Total	Percent Mortality
2001	4,308	39,565	43,873	90.18%
2002	5,865	43,670	49,535	88.16%
2003	6,110	43,676	49,786	87.73%
2004	6,739	43,592	50,331	86.61%
2005	8,490	47,297	55,787	84.78%
2006	9,308	46,277	55,585	83.25%
2007	10,112	43,981	54,093	81.31%
2008	11,072	42,923	53,995	79.49%
2009	11,982	40,299	52,281	77.08%
2010	13,715	39,725	53,440	74.34%
2011	15,425	38,772	54,197	71.54%
2012	17,317	38,140	55,457	68.77%
2013	19,426	37,264	56,690	65.73%
2014	23,969	39,337	63,306	62.14%
2015	28,230	39,161	67,391	58.11%
2016	31,783	38,481	70,264	54.77%
2017	35,268	36,203	71,471	50.65%
2018	40,227	32,550	72,777	44.73%
2019	46,822	28,448	75,270	37.79%
2020	48,001	21,128	69,129	30.56%
2021	56,978	13,253	70,231	18.87%
2022	36,812	2,598	39,410	6.59%
Total	487,959	796,340	1,284,299	63.78%

Table 7

Note 1: Table 7 data provided by the 14-page letter date July 22, 2022, from VHA Deputy Under Secretary of Health to Congressman Greg Murphy, MD (R-NC)

The 2001 to 2017 average mortality rate equate to 74.4 and the 2001 to 2019 rate is 70.9 percent. We did not include the 2020-2022 rates in this short summary as they have not completed their 3-year post LLA time cycles and 2022 was a partial year. The 2020-2022 VA provided data was included in the overall 20+-year average reflected in Table 7. The 70.9 percent post LLA mortality rate coincides with the previous VA reported numbers in Table 3. The 796, 340 DFU LLA deaths represent on average 36,197 DFU LLA deaths (796,340/22yrs) per year. This is substantially above the 110,490 estimated deaths reported in Table 6 which is based on 63.8% death rate over 3-year time. The actual mortality deaths reported in Table 7 is seven times that of actual deaths reported in Table 6 VHA data repository. The VHA data in this paragraph is conveyed as provided versus interpreting the meaning of the conflicting data points.

Table 8 reflects the percentage of DFU LLA Veterans who received HBOT treatments. The past twenty-year period indicates 6 percent of DFU LLA Veterans have received HBOT treatments and approximately 94 percent have not received HBOT treatments. The VA Hyperbaric Oxygen Treatment for Wound Care Consent Form (Appendix 15) does not provide “Informed Consent” on the availability of HBOT as a treatment option for DFU Veteran patients which is a

contributing factor on why Veterans are not receiving the treatments, they are not informed of the treatment availability.

VHA Historic Percentage of DFU LLA Veterans Receiving HBOT Treatments

(A) FY	(B) Daily VHA LLA Procedures	(C) Unique Veterans Receiving HBOT	(D) Percent of DFU LLA Veterans Receiving HBOT	(E) Total DFU/LLA Veterans Not Receiving HBOT
2002	6,977	34	0.48%	99.52%
2003	7,123	192	2.69%	97.31%
2004	7,125	246	3.45%	96.55%
2005	7,410	248	3.35%	96.65%
2006	7,741	261	3.37%	96.63%
2007	7,946	324	4.07%	95.93%
2008	7,697	352	4.57%	95.43%
2009	7,598	369	4.86%	95.14%
2010	8,198	452	5.51%	94.49%
2011	8,444	462	5.47%	94.53%
2012	8,643	450	5.20%	94.80%
2013	8,799	556	6.32%	93.68%
2014	8,913	586	6.57%	93.43%
2015	8,675	634	7.31%	92.69%
2016	9,166	558	6.09%	93.91%
2017	9,225	684	7.41%	92.59%
2018	9,901	987	9.97%	90.03%
2019	10,073	1,009	10.01%	89.99%
2020	9,521	996	10.46%	89.54%
2021	9,542	1,097	11.50%	88.50%
2022	3,753	466	12.42%	87.58%
Total	172,470	10963	6.36%	93.64%

Table 8

Note 1: Data provided by the VHA via letter date July 22, 2022, from Deputy Under Secretary of Health to Congressman Greg Murphy, MD (R-NC). Column B individual Veterans may have had multiple LLA procedures and may be included in this number count.

Note 2: The VHA written responses to questions 5-9 provided conflicting data on the total annual number of Lower Limb Amputations (LLA) over the 20-year data period from 164,016 to 172,470. This total variation equates to 8,454 over the 20-year data period or an average deviation of 422.7 per year ($8,454/20 \text{ Yr.} = 422.7$) which is a 4.9% deviation ($8,454/172,470 \times 100$)

Note 3: The report used the 172, 470 total VA LLA procedures conducted per year as the basis for the analysis.

Note 4: The VA provided the total number of Veterans treated with HBOT and expenditures that is NOT all inclusive of Veterans with DFUs and LLAs. The VA indicated they could not provide specific numbers of Veterans by disease process during the twenty-year period. Consequently,

the DFU treated Veterans with HBOT may be lower than what is shared in the tables in this report.

2000 to 2022 VHA Mobility Devices and Prosthetics Ordered

Prosthetics	FY2000-2006	FY2007-2014	FY2015-2022	22 Yr Total	% Escalated
All Prosthetics	398,593	780,591	999,389	2,178,573	150.7%
New Prosthetics	268,370	571,819	777,480	1,617,669	189.7%
Prosthetics Lower Artificial	15,510	31,713	37,289	84,512	140.0%
Prosthetics Mobility	87,175	158,688	205,158	451,021	135.4%
Prosthetics Other	165,034	380,414	534,384	1,079,832	223.8%
Prosthetics Upper Artificial	651	1,004	649	2,304	0.4%
Total	1,065,556	2,133,001	2,776,258	5,974,815	160.6%

Table 9

Note 1: Data provided by the VA via letter date July 22, 2022, from Deputy Under Secretary of Health to Congressman Greg Murphy, MD (R-NC)

Note 2: The VHA data on the number of new prostheses and mobility devices including wheelchairs ordered by the VHA each year for those Veterans with a diagnosis of amputation involving an arm or leg

Note 3: Table 9 was consolidated from data provided by the VHA for each year of units into the consolidate chart above to simplify the reported numbers.

With the average life expectancy of just 3-years post LLAs, there is a significant cost associated with post LLA mobility devices (wheelchairs, scooters) and prosthesis for lower limbs. Table 9 reflects the VHA total purchases of prosthesis and mobility devices for the past 22 years in total number of units for each year. Appendix 6 chart reflects strictly estimated wheelchair cost. The VHA did not provide any cost related to new or used prosthesis, mobility devices, prosthesis repairs, or other prosthesis.

The wheelchair costs in Appendix 6 will be significant less than the total cost of purchased prosthesis and mobility devices list in Table 9 based on the complexity and cost of prosthesis devices. Consequently, the total cost estimate of 22-year wheelchairs of \$355,470, 999, or \$16,157,773 per year (\$355,470,999/22) is a fraction of the cost estimated paid for all prosthesis and mobility devices in total by the VHA related to DFU LLAs. Appendix 8 is an estimated cost to provide prosthesis to each of the 9,542 DFU LLA Veterans. The cost estimate for prosthesis for 9,542 Veterans is \$89.418,082. The analysis did not project out percentages of wheelchair users versus straight prosthesis fitted Veterans and calculated the full amount of 9,542 for both wheelchairs and prosthesis. The analysis used a reduced three-year wheelchair cost based on the

projected death rate of 70.9 percent after three years. The 2008 prosthesis cost was escalated at 3.24 percent average annual inflation rate to arrive at the 2022 estimated cost.

2022 VHA HBOT Contract Facilities by State

Number of States (Includes DC)	States	Number of HBOT Contract Facilities	States Without Contract HBOT Facilities	States with Facilities >10
1	AI	8		
2	AR	7	AK	
3	AZ	3		
4	CA	10		10
5	CO	3		
6	CT	4		
7	DC	1		
8	FL	37	DE	37
9	GA	12		12
10	HI	1		
11	IA	4		
12	IL	7	ID	
13	IN	8		
14	KS	5		
15	KY	9		
16	LA	11		11
17	MA	4		
18	MD	9		11
19	ME	4		
20	MI	10		10
21	MN	10		10
22	MO	15		15
23	MS	4		
24	NC	13	MT	13
25	ND	1		
26	NE	2		
27	NH	5		
28	NJ	6	NM	
29	NY	30	NV	30
30	OH	11		11
31	OK	6		
32	OR	2		
33	PA	28		28
34	RI	3		
35	SC	7	SD	
36	TN	4		
37	TX	26		26
38	UT	3		
39	VA	10		10
40	VT	1		
41	WA	1		
42	WI	18		18
43	WV	2	WY	
Total		365		252

Table 10

Note 1: Data provided by the VA via letter date July 22, 2022, from Deputy Under Secretary of Health to Congressman Greg Murphy, MD (R-NC)

Note 2: Washington DC is counted (#7) in the state count in Table 10 above

A total of 15 States with HBOT contract facilities account for 69 percent of all HBOT facilities in the VHA system (Table 10). Eight (8) states did not have any HBOT facilities listed and twenty (20) states or 46.5 percent of the 43 states had five or less HBOT facilities. The industry average of DFU patients treated with HBOT has a 74 percent heal rate and a 24 percent reduction in LLAs.⁶⁰ ***The VHA treatment referral ratio to outside HBOT services is extremely low (31%) considering the VA does not operate any hyperbaric oxygen chambers within the VHA national healthcare hospital network, the high level of annual LLA's performed, and over 1,156 hospital Wound Care Centers available to provide HBOT treatment services.***

Conclusion

When Veterans receive timely HBOT treatments for their Wagner Grade III or higher DFUs, there is a 74 percent DFU heal rate and 24 percent reduction in DFUs LLAs. It is estimated 127,627 (74%) DFUs LLAs may have been avoided if HBOT was made available to Veterans during the twenty-year period.

VHA Diabetic Foot Ulcers (DFUs) is an Epidemic with a considerable mortality rate of 70.9 percent and a significant expense for the VHA due to the high Lower Limb Amputations which appears based on the data are not treated in a clinically aggressive and timely manner with HBOT.

The VHA is spending substantially more capital and with substantially higher morbidity and mortality statistic that the comparable US civilian DFU Medicare population. Hyperbaric Oxygen Therapy (HBOT) is FDA, CMS, Tricare, and VHA approved for DFU treatments. HBOT has demonstrated to dramatically reduce 74 percent of lower extremity amputations in patients with DFUs. HBOT treatment also significantly reduces life-time costs (Table 1) while improving quality and length of life. Essentially, only approximately 6 percent of Veterans with at-risk DFUs are receiving HBOT treatment when compared to the present US civilian DFU population is inexcusable.

The VHA provided DFU and LLA data reflects self-incrimination and an abysmal transparency of how 94 percent of DFU Veterans are not receiving approved HBOT and time sensitive medical treatments. DFU Veterans are dying at a monthly average of over 3,000. On average 74 percent of the DFUs could be blunted with HBOT treatment and improve quality of life and extend life expectancy.

There is over 1,156 HBOT Wound Care Centers located in hospitals across the U.S. with qualified, trained, and certified personnel available to treat DFU Veterans. The VHA has only contracted with 31 percent of available facilities.

⁶⁰ ncbi.nlm.nih.gov, Efficacy of HBOT for DFU, a systemic review and meta-analysis of controlled clinical trials January 2021

Diabetes mellitus is one of the most prevalent conditions for which the VA pays compensation to Vietnam War-era Veterans.⁶¹ In 2020, diabetes represented roughly 6.5 percent of all service-related conditions for which these veterans received compensation, according to the VA.⁶² Diabetes is more prevalent among US Veterans, who make up 9 percent of the civilian US population, than among the general population and affects nearly 25 percent of the US Department of Veterans Affairs (VA) patients.⁶³ The disease is also the leading cause of blindness, end-stage renal disease, and amputation for VHA patients. It is reported on that the VHA provides health benefits to 1.45 million Veterans who have diabetes.⁶⁴ The Veterans Administration (VA) cares for more than 8 million US veterans, of whom approximately 25 percent have diabetes.⁶⁵ ⁶⁶ This equates to approximately 2,200,000 diabetic Veterans within the VHA healthcare network. The overall prevalence of diabetes was 20 percent for the general U.S. population but nearly 25 percent for Veterans, according to a recent study using data from the National Health and Nutrition Examination Survey (NHANES).⁶⁷ Twenty-five percent was the estimated average used in the report analysis.

Given the high number of VHA diabetic Veterans and the total number of Veteran impacted by this deadly disease, why is HBOT not widely prescribed by DFU Veterans across America? There are over two decades of proven safety, efficacy, and government approval for the treatment modality that is routinely not provided to 94 percent of DFU Veterans. ***It is costing Veterans' lives and crippling the VA Budget. The VHA does not operate hyperbaric oxygen chambers and the denial of routine access and treatment for Veterans is a violation of Federal law. The denial of "Informed Consent" for HBOT treatment options is likewise a violation of ethical and legal standards.*** The American public and their representatives in the US Congress should be shocked at these statistics and demand an investigation into the standard of care and a VA culture that may be immune to criticism of its medical practices. What this analysis did not consider is how many of the 14 FDA approved HBOT treatments are also not being provided to entitled Veterans and their outcomes.⁶⁸

Management students are taught that "***what gets measured gets managed***". As we could clearly document, the VHA has the data to measure success. By their own measurements, ***the VHA is failing yet yield to the status quo even at the loss of life.*** It will require the VA OIG and other outside agencies to conduct a deep and thorough investigation to migrate the VHA to manage back to first principles of medicine; ***first do no harm.***

⁶¹ GAO.gov, VA Disability: Vietnam Veteran's Claims for Type 1 Diabetes, GAO-22-105143, February 8, 2022

⁶² Ibid.

⁶³ US Department of Veterans Affairs. Veterans' Health Administration: close to 25 percent of VA patients have diabetes. <https://www.va.gov/health/NewsFeatures/20111115a.asp>. Updated April 17, 2015. Accessed February 23, 2017.

⁶⁴ Healthline.com, Not Your Granddaddy's VA-Changing Diabetes Care for Veterans, June 2018

⁶⁵ Veterans' Health Administration. *VA research on diabetes*, 2019. Google Scholar

⁶⁶ Liu Y, Sayam S, Shao X, *et al.* Prevalence of and trends in diabetes among Veterans, United States, 2005-2014. *Prev Chronic Dis* 2017;**14**: E135. [doi:10.5888/pcd14.170230](https://doi.org/10.5888/pcd14.170230) pmid: <http://www.ncbi.nlm.nih.gov/pubmed/29240552>

⁶⁷ USmedicine.com. Diabetes Prevalence Higher Among Veteran Than General Population. June 19, 2018

⁶⁸ Whether through ignorance or cultural predisposition, simplified denial, uneducated medical knowledge, there appears to be prevalence of the unknown about FDA, CMS, and Tricare approved HBOT indications within the VHA as reflected in the data and severe reduction in outside referrals, or there is a national policy for the same.

Summary of the key bullet points contained in this report on DFU Veterans include:

- Untimely HBOT diagnosis and the delays in treatment of Wagner Grade III or higher with HBOT results in LLAs and death within three years of 64-71 percent DFU LLA Veterans (Table 3 and 6). The VHA Veterans DFU LLA deaths total of 796,340 since 2001 (Table 7) or on average of 36,197 per year, or 3,016 per month. The industry average of 74 percent of DFU LLAs which may have been avoided with timely HBOT treatments.
- An estimated 93.7 percent of DFU Veterans in the current VHA health network are denied HBOT access through delays or administrative denials annually (Table 8).
- Epidemic DFU LLAs rates will increase with time as the estimated 2.2 million Veterans in the VHA with diabetes grows alongside the existing limited VHA 6.3% HBOT referral rate for DFU Veterans.
- FDA/CMS/Tricare approved HBOT is a legal, ethical, and medical treatment for DFU Veterans for which every Veteran is entitled under the Code of Medical Ethics Opinion 2.1.1 (Appendix 3).
- VHA does not operate any HBOT chambers thus requiring outsourcing. The 365 VHA current outsourced HBOT facilities are only 31.5 percent of the more than 1,156 Wound Care hospitals staffed and equipped with medical qualified HBOT chambers and experts. *“Shortages” of available HBOT capacity is a non-issue.*
- The VA Mission Act of 2018 federally mandates that FDA, CMS, and Tricare approved HBOT care be made available to DFU Veterans. The decision resides with the Veteran and healthcare provider to seek and attain treatments. The Veterans simply are not being provided “Informed Consent” or referred for treatment to an area HBOT Wound Care Community Service Provider ultimately resulting in reduced quality of life and potential death.
- An estimated 1.1 million diabetic Veterans reside in the Tricare East (Humana Military) Diabetic and Stroke Belts or 50 percent of the estimated 2.2 million in the VHA healthcare system (Table 2). As of this date, Humana Military as not provided any detailed DFU Veteran data.
- Since HBOT was approved by CMS in 2002 (Appendix 3), 172,470 DFU Veterans have undergone amputation procedures or on average of 8,624 per year, with an estimated annual average of 5,519 (64%) to 6,123 (71%) dying within each succeeding three-year cycle.

Recommendations

The recommendations brought forward in this document are medical, legal, and administrative. The US Congress in conjunction with the Department of Veteran Affairs Inspector General office is task with holding the VHA accountable for their failures leading to Veteran deaths. The following recommendations align the VHA accountability and necessary action steps.

1. The VA Mission Act of 2018 is federal law the VHA must adhere to. An immediate Senate, House and VHA Office of Inspector General (OIG) investigation is required to mandate the VHA immediately rectify and provide approved HBOT treatment protocols

and ancillary wound care to all Veterans requiring the immediate medical HBOT access and treatment.

2. Immediate implementation of DFU Management training program to all VHA medical staff on the FDA, CMS, and Tricare approved HBOT treatment protocols.
3. An immediate major expansion of the VHA national civilian Community Care Service Providers Wound and HBOT approved contract facilities for treatments within three months to include all 50 U.S. states.
4. Change the current VHA Consent Form to include a formal review by all medical staff to Veteran/patients on HBOT on the patient Informed Consent and disclosure as an approved FDA, CMS, and Tricare treatment protocol for those approved medical protocols.
5. An immediate review of all current VHA standard medical practices being followed for DFU Veterans diagnosis. All Wagner Grade II-III and above Veteran referrals for HBOT occur and are approved within 7-days or less of diagnosis based on the critical nature of the medical condition.
6. VHA OIG formal national investigation into why DFU Veterans have been routinely denied or delayed access to FDA, CMS, and Tricare approved (Appendix 3) medical treatment approved as a greater cost and with dismal Morbidity and Mortality statistics than the civilian Medicare comparator.
7. A Congressional investigation as to what financial compensation DFU and LLA Veterans and their families should be entitled based on the decades of VHA systemic medical malpractice which has occurred related to DFU care and LLAs.
8. The US must recognize the Global Diabetic Foot Ulcer (DFUs) is an Epidemic problem with a mortality rate of 70.9 percent within the VHA. We recommend that appropriate outside oversight and investigation be performed into the significant expense for the VHA due to the high rate of morbidity and mortality, to include “intangible” factors like Quality of Life and impact on families and society.
9. The GAO must investigate why the VHA is spending substantially more capital and with substantially higher morbidity and mortality statics than the comparable US civilian DFU Medicare population. Their analysis must also ask why Hyperbaric Oxygen Therapy (HBOT), an FDA, CMS, Tricare, and VHA approved DFU treatment is rarely prescribed. This includes attention to the question of why only 6 percent of Veterans at-risk of DFUs are receiving HBOT treatment when compared to present US civilian DFU population
10. There are over 1,156 HBOT Wound Care Centers located in hospital across the U.S. with qualified, trained, and certified staffing available to treat DFU Veterans. The VHA has only contracted with 31 percent of available facilities. We recommend that the HBOT infrastructure outside the VHA be brought into the fight against premature DFU LLA deaths of Veterans being delayed or denied access.

APPENDICES

Total 2022 Estimated US Veteran Population

Number	State	Veterans	Veterans (per 100k)
1	Alabama	330,207	6,671
2	Alaska	65,186	9,044
3	Arizona	488,061	6,388
4	Arkansas	197,138	6,481
5	California	1,574,531	3,970
6	Colorado	373,795	6,271
7	Connecticut	167,521	4,723
8	Delaware	65,438	6,553
9	Florida	1,440,338	6,494
10	Georgia	629,302	5,754
11	Hawaii	101,975	7,275
12	Idaho	116,157	6,124
13	Illinois	570,264	4,556
14	Indiana	380,690	5,564
15	Iowa	185,671	5,849
16	Kansas	176,444	6,044
17	Kentucky	267,594	5,963
18	Louisiana	243,335	5,271
19	Maine	103,776	7,632
20	Maryland	365,356	6,014
21	Massachusetts	303,534	4,385
22	Michigan	549,526	5,498
23	Minnesota	300,044	5,227
24	Mississippi	165,538	5,590
25	Missouri	401,779	6,496
26	Montana	85,350	7,808
27	Nebraska	117,466	5,991
28	Nevada	207,767	6,415
29	New Hampshire	96,098	6,971
30	New Jersey	321,991	3,630
31	New Mexico	144,977	6,874
32	New York	705,924	3,672
33	North Carolina	659,584	6,103
34	North Dakota	46,067	5,952
35	Ohio	709,287	6,048
36	Oklahoma	270,775	6,757
37	Oregon	283,045	6,544
38	Pennsylvania	759,474	5,931
39	Rhode Island	54,121	5,093
40	South Carolina	365,139	6,835
41	South Dakota	57,550	6,376
42	Tennessee	431,274	6,159
43	Texas	1,453,450	4,829
44	Utah	120,447	3,581
45	Vermont	36,988	5,938
46	Virginia	677,533	7,843
47	Washington	529,784	6,716
48	West Virginia	130,536	7,435
49	Wisconsin	331,340	5,647
50	Wyoming	44,999	7,729
Total		18,204,166	6,054

Appendix 1

Note 1: 2022 Veteran population data extracted from worldpopulationreview.com

15 CMS Approved HBOT Indications (CMS.gov)

Indications and Limitations of Coverage

A. Covered Conditions

Program reimbursement for HBO therapy will be limited to that which is administered in a chamber (including the one-man unit) and is limited to the following conditions:

1. Acute carbon monoxide intoxication,
2. Decompression illness,
3. Gas embolism,
4. Gas gangrene,
5. Acute traumatic peripheral ischemia. HBO therapy is a valuable adjunctive treatment to be used in combination with accepted standard therapeutic measures when loss of function, limb, or life is threatened.
6. Crush injuries and suturing of severed limbs. As in the previous conditions, HBO therapy would be an adjunctive treatment when loss of function, limb, or life is threatened.
7. Progressive necrotizing infections (necrotizing fasciitis),
8. Acute peripheral arterial insufficiency,
9. Preparation and preservation of compromised skin grafts (not for primary management of wounds),
10. Chronic refractory osteomyelitis, unresponsive to conventional medical and surgical management,
11. Osteoradionecrosis as an adjunct to conventional treatment,
12. Soft tissue radio necrosis as an adjunct to conventional treatment,
13. Cyanide poisoning,
14. Actinomycosis, only as an adjunct to conventional therapy when the disease process is refractory to antibiotics and surgical treatment,
15. Diabetic wounds of the lower extremities in patients who meet the following three criteria:
 - a. The patient has type I or type II diabetes and has a lower extremity wound that is due to diabetes.
 - b. The patient has a wound classified as Wagner grade III or higher; and
 - c. The patient has failed an adequate course of standard wound therapy

13 FDA Approved HBOT Indications (FDA.gov)

Conditions for which hyperbaric chambers are cleared for marketing by the FDA

FDA clearance of a medical device includes a determination that the device has the same intended use as, and is as safe and effective as, another legally U.S.-marketed device of that type. As of July 2021, the FDA has cleared hyperbaric chambers for the following disorders:

1. Air and gas bubbles in blood vessels
2. Anemia (severe anemia when blood transfusions cannot be used)
3. Burns (severe and large burns treated at a specialized burn center)

4. Carbon monoxide poisoning
5. Crush injury
6. Decompression sickness (diving risk)
7. Gas gangrene
8. Hearing loss (complete hearing loss that occurs suddenly and without any known cause)
9. Infection of the skin and bone (severe)
10. Radiation injury
11. Skin graft flap at risk of tissue death
12. Vision loss (when sudden and painless in one eye due to blockage of blood flow)
13. Wounds (non-healing, diabetic foot ulcers)

HBOT is being studied for other conditions, including TBI and COVID-19. However, at this time, the FDA has not cleared or authorized the use of any HBOT device to treat COVID-19 or any conditions beyond those listed above. The website, clinicaltrials.gov, has more information on HBOT clinical trials for COVID-19 and other conditions.

11 Tricare Approved HBOT Indications (Tricare.mil)

TRICARE covers hyperbaric oxygen therapy The medical use of oxygen at a level higher than atmospheric pressure. The patient breathes pure oxygen in a pressurized room or tube. when provided as treatment for:

1. Decompression sickness
2. Air or gas embolism
3. Carbon monoxide poisoning
4. Profound blood loss when transfusion can't be accomplished

Hyperbaric oxygen therapy must be provided by an approved institutional provider, such as a hospital or specialized treatment facility.

Hyperbaric oxygen therapy may be covered as an addition to standard therapy for:

5. Acute soft tissue injury (i.e., crush injury, compartment syndrome, acute traumatic peripheral ischemia, blast injury)
6. Clostridial myositis and myonecrosis
7. Compromised skin grafts and/or flaps
8. Chronic, severe, and/or gangrenous diabetic foot wounds
9. Osteoradionecrosis
10. Osteomyelitis refractory to standard medical management
11. Other indications when proven safe, effective, comparable, or superior to standard care.

Appendix 2

Approved Medical Indications for Hyperbaric Oxygen Therapy in the U.S.

Medical Condition	U.S. Food and Drug Administration (A)	Undersea and Hyperbaric Medical Society (B)	Centers for Medicare and Medicaid Services (C)	TRICARE (D)
1. Decompression Sickness	X	X	X	X
2. Air or Gas Embolism	X	X	X	X
3. Carbon Monoxide or Cyanide Poisoning	X	X	X	X
4. Crush Injury, Compartment Syndrome and other traumatic peripheral Ischemia's	X	X	X	X
5. Compressed Tissues and Flaps	X	X	X	X
6. Delayed Radiation Injury (Soft Tissue and Bone)	X	X	X	X
7. Acute thermal Burns	X	X		
8. Gas Gangrene (Clostridial Myositis and Myonecrosis)	X	X	X	X
9. Necrotizing Soft Tissue Infections	X	X	X	X
10. Enhanced Healing of Select Problem Wounds, Including Diabetic Ulcers	X	X	X	X
11. Refractory Osteomyelitis	X	X	X	X
12. Intracranial Abscess	X	X		
13. Exceptional Blood Loss Anemia	X	X		X
14. Central Retinal Artery Occlusion		X		
15. Acute Peripheral Arterial Ischemia			X	
16. Refractory Actinomycosis			X	

Appendix 3

Note 1: Column A based on FDA and CDRH Approval of Hyperbaric Oxygen Chamber label, K100268, April 2010, 13 indications

Note 2: Column B based on UHMS Hyperbaric Oxygen Therapy indications 12th ed. December 2008, 14 indications

Note 3: Column C based on CMS, Medicare Coverage Issues Manual Section 35-10, 2002, 12 indications

Note 4: Column D based on Tricare Policy Manual 6010-57-M, Chapter 7, Section 20, February 1, 2008, 11 indications

Note 5: The data contained in Appendix 3 was extracted from the Department of Defense Report to the US Congress on the use of Hyperbaric Oxygen for Medical Care and Research in Response to H.R. 3326, the Department of Defense Appropriations Act for Fiscal Year 2010, March 2011

CDC.gov Diabetes Mortality Rate (per 100,000) by State

YEAR	STATE	RATE	DEATHS
2020	AL	23.6	1450
2020	AK	24.8	174
2020	AZ	26.5	2566
2020	AR	33.8	1306
2020	CA	25.4	11642
2020	CO	18	1168
2020	CT	17.5	861
2020	DE	23.8	326
2020	FL	22.8	7528
2020	GA	23.9	2833
2020	HI	17	339
2020	ID	22.7	488
2020	IL	22.2	3485
2020	IN	29.6	2446
2020	IA	24.7	1047
2020	KS	28.5	1041
2020	KY	27.7	1549
2020	LA	33.1	1843
2020	ME	23.9	501
2020	MD	23.9	1784
2020	MA	17.2	1557
2020	MI	26	3399
2020	MN	21	1493
2020	MS	41	1460
2020	MO	23.1	1844
2020	MT	23.5	342
2020	NE	26.2	624
2020	NV	24.2	904
2020	NH	19.2	364
2020	NJ	21.2	2443
2020	NM	29.3	793
2020	NY	21.2	5410
2020	NC	26.9	3554
2020	ND	24.3	225
2020	OH	28.3	4382
2020	OK	32.8	1552
2020	OR	24.5	1364
2020	PA	23.6	4250
2020	RI	23.2	331
2020	SC	28.5	1943
2020	SD	29.2	329
2020	TN	30.1	2590
2020	TX	26.7	7900
2020	UT	27.3	778
2020	VT	17.5	153
2020	VA	24.7	2585
2020	WA	22.7	2072
2020	WV	41.3	1075
2020	WI	22	1684
2020	WY	20.7	148
50 States		25.2	102015

2019 CDC.gov Diabetes Mortality Rate by State for the Diabetic Belt States

YEAR	STATE	RATE	DEATHS
2019	AL	19.8	1224
2019	AR	29.8	1144
2019	FL	19.3	6174
2019	GA	20.5	2375
2019	KY	29.1	1611
2019	LA	26.5	1458
2019	NC	24.1	3124
2019	OH	25.4	3873
2019	PA	20.4	3654
2019	SC	24.4	1610
2019	TN	25.9	2161
2019	TX	23.6	6889
2019	VA	22.8	2350
2019	WV	36.2	952
29 States		24.8	38599

Appendix 5

Note 1: States in yellow represent the top five diabetic deaths in the Diabetic Belt, Texas with 17.8%, Florida with 15.9%, Ohio with 10%, PA with 9.4%, and NC with 8% or a total of 61.1% of the 38,599 total

Estimated Total Veteran DFU LLA Prosthesis and Mobility Device (Including Wheelchair) Cost

(A)Year	(B) Number of Veteran Lower Limb Amputations (LLA'S)	(C)Mortality Rate Expected 30 days After LLA 13.5% (B X 13.5%)	(D) Mortality Rate Expected 1 Year After LLA 48.3% (B X 48.3%)	(E) Mortality Rate Expected 3 Year After LLA 70.9% (B X 70.9%)	(F) Estimated Cost Per Wheelchair Per Year (See Note 4)	(G) Year One Wheelchair Cost ((B - C) x F)	(H) Two Year Wheelchair Cost ((B - D) X F)	(I) Three Year Wheelchair Cost ((B - E) x F)	(J) Total Wheelchair 3-Year Cost (G+H+I)
2002	6,977	942	3,370	4,947	\$860.00	\$5,190,190	\$3,102,114	\$1,746,064	\$10,038,368
2003	7,123	962	3,440	5,050	\$889.00	\$5,477,480	\$3,273,823	\$1,842,713	\$10,594,017
2004	7,125	962	3,441	5,052	\$919.00	\$5,663,912	\$3,385,251	\$1,905,432	\$10,954,595
2005	7,410	1,000	3,579	5,254	\$950.00	\$6,089,168	\$3,639,422	\$2,048,495	\$11,777,084
2006	7,741	1,045	3,739	5,488	\$982.00	\$6,575,438	\$3,930,059	\$2,212,084	\$12,717,581
2007	7,946	1,073	3,838	5,634	\$1,015.00	\$6,976,389	\$4,169,703	\$2,346,970	\$13,493,063
2008	7,697	1,039	3,718	5,457	\$1,049.00	\$6,984,142	\$4,174,337	\$2,349,579	\$13,508,058
2009	7,598	1,026	3,670	5,387	\$1,084.00	\$7,124,341	\$4,258,132	\$2,396,744	\$13,779,216
2010	8,198	1,107	3,960	5,812	\$1,120.00	\$7,942,222	\$4,746,970	\$2,671,892	\$15,361,084
2011	8,444	1,140	4,078	5,987	\$1,158.00	\$8,458,101	\$5,055,305	\$2,845,442	\$16,358,848
10-Yr Total	76,259	10,295	36,833	54,068		\$66,481,384	\$39,735,116	\$22,365,413	\$128,581,913
2012	8,643	1,167	4,175	6,128	\$1,197.00	\$8,949,005	\$5,348,712	\$3,010,590	\$17,308,308
2013	8,799	1,188	4,250	6,238	\$1,237.00	\$9,414,974	\$5,627,216	\$3,167,350	\$18,209,539
2014	8,913	1,203	4,305	6,319	\$1,278.00	\$9,853,054	\$5,889,051	\$3,314,727	\$19,056,832
2015	8,675	1,171	4,190	6,151	\$1,321.00	\$9,912,619	\$5,924,652	\$3,334,765	\$19,172,036
2016	9,166	1,237	4,427	6,499	\$1,365.00	\$10,822,525	\$6,468,492	\$3,640,873	\$20,931,890
2017	9,225	1,245	4,456	6,541	\$1,411.00	\$11,259,251	\$6,729,518	\$3,787,794	\$21,776,563
2018	9,901	1,337	4,782	7,020	\$1,458.00	\$12,486,844	\$7,463,235	\$4,200,776	\$24,150,856
2019	10,073	1,360	4,865	7,142	\$1,507.00	\$13,130,710	\$7,848,066	\$4,417,383	\$25,396,158
2020	9,521	1,285	4,599	6,750	\$1,557.00	\$12,822,930	\$7,664,110	\$4,313,841	\$24,800,882
2021	9,542	1,288	4,609	6,765	\$1,607.00	\$13,264,178	\$7,927,331	\$4,462,639	\$25,654,148
10-Yr Total	92,458	12,482	44,657	65,552		\$111,916,091	\$66,890,382	\$37,650,739	\$216,457,212
2022	3,753	507	1,813	2,661	\$1,660.00	\$5,388,360.00	\$3,220,400	\$1,812,720	\$10,431,874
2002-2011	76,259	10,295	36,833	54,068		66,481,384	39,735,116	22,365,413	128,581,913
2012-2021	92,458	12,482	44,657	65,552		111,916,091	66,890,382	37,650,739	216,457,212
2022	3,753	507	1,813	2,661		5,388,360	3,220,400	1,812,720	10,431,874
21-Yr Totals	172,470.00	23,284.00	83,303.00	122,281.00		183,785,835	109,845,898	61,828,872	355,470,999

Appendix 6

Note 1: During the fiscal years 2000 to 2001, the VA provided Veterans with more than 131,000 wheelchairs and scooters at a cost of \$109,010,198 million (JRRD, Distribution and cost of wheelchairs and scooters provided by the VHA, Volume 44 Number 4, Pages 581-592, February 2007)

Note 2: Regionally, 71% to 86% of all wheelchairs provided were manual, 5-11% were powered, and 5-20% were scooters. The most frequently provided type of wheeled device during this 2-year period was the standard manual wheelchair (53%), followed by the lightweight rehabilitation manual wheelchair (17%), and then the scooter (13%) (JRRD, February 2007)

Note 3: Average cost for a manual wheelchair or scooter in 2001 was \$832.13 (\$109,010,198M/\$131K=\$832.13)

Note 4: Escalation of 2001 wheelchair costs of \$832.13 at 3.24% inflation per year is reflected in each year's estimated wheelchair cost in Appendix 6.

Note 5: Year one wheelchair cost is the actual estimated cost to purchase and provide to DFU LLA Veterans. Year two and three wheelchair costs are the reoccurring lost cost of wheelchairs belonging to Veterans who died, and the wheelchairs not recovered

Note 6: The JRRD February 2007 reported median cost for standard manual wheelchair cost (\$163), lightweight rehabilitation wheelchair cost (\$362), scooter (\$1,935) and powered standard and custom wheelchairs (\$3,804-\$4,504). Appendix 6 costs numbers were calculated using the mean total average for all associated cost for the financial analysis as shared in Note 4.

VA Estimated Cost of Care of Veterans with DFU LLAs

Year	AVG Care Cost Per Veteran Per Year	Total DFU LLA Veterans	Estiated Total Yearly Cost	Per Cent Escalation
2004 (1)	\$50,351.00	3,381	\$170,236,037.00	0.0%
2010 (1)	\$60,647.00	3,403	\$206,380,331.00	21.4%
2016 (2)	\$73,434.00	9,166	\$673,096,044.00	226.1%
2019(2)	\$88,917.00	10,073	\$895,660,941.00	33.0%
2021 (2)	\$94,772.00	9,542	\$904,314,424.00	1.0%

Appendix 7

Note 1: 2004 and 2010 cost per Veteran and total DFU LLA data extracted from pubmed.ncbi.nlm.nih.gov. Cost of LLA in US Veterans with diabetes using health services data in fiscal years 2004 and 20010, Volume 51, Number 8, 2014, Pages 1325-1330

Note 2: The 2010, 2016, 2019 and 2021 estimated costs were escalations of 2004 costs by 3.24% per year based on 114-year rolling inflation rate averages (Appendix 14)

Note 3: The 2004, 2010, 2016, 2019 and 2021 DFU LLAs are the actual number of DFU LLAs which were conducted within the VHA

Note 4: Average yearly cost escalation is 16.6% per year (281.5%/17) or doubling every 6 years

Estimated Average Annual Cost of Prosthesis

Year	Number of Prosthesis Made, Repaired, or LLAs	Cost of Prostheses	Average Cost Per Prostheses
2008 (1)	12,059	\$74,656,247.00	\$6,191.00
2021 (2)	9,542	\$89,418,082.00	\$9,371.00

Appendix 8

Note 1: VA Prosthetic and Sensory Aids Service is the largest provider of durable medical equipment in the world, servicing over 1.9 million Veterans with an annual budget of \$1.4 billion in 2008, the VA laboratories made or repaired approximately 12,059 prostheses for \$74.6 million

Note 2: 2008 data was escalated by 3.24% per year based on US annual average inflation rate for each year through 2021 (Appendix 14)

Note 3: The 12,059 is the number of prostheses made or repaired as reported in Note 1

Note 4: The 2008 average cost of prostheses of \$6,191 was escalated by 3.24% per year from 2008 to 2021 to arrive at the estimated \$9,371 per unit multiplied by 9,542 actual VHA LLAs which equates to \$89.4 million

Estimated Insurance Provider Cost for Total Wound Episode Per Patient

(A) Net Margin	(B) Medicare	(C) Medicaid	(D) Private or self-pay	(E) None
Overall, Inpatient and outpatient	\$4,758.00	\$824.00	\$4,593.00	\$8,351.00
Inpatient admissions	\$6,283.00	\$2,307.00	\$6,200.00	\$8,351.00
Outpatient procedures	\$3,030.00	\$5,670.00	\$3,744.00	

Appendix 9

Note 1: Data from Jvacurg.org/quantifying the cost and profitability of care for DFUs, October 13, 2018

Estimated Average VHA DFU LLA Inpatient Hospital Stay Cost Per Veteran

(A) Net Margin	(B) Medicare	(C) Medicaid	(D) Private or self-pay	(E) None	(F) Overall Average
Inpatient Admissions (Avg 11 days)	\$69,113.00	\$25,377.00	\$68,220.00	\$91,861.00	\$63,642.75

Appendix 10

Note 1: Data from Jvacsur.org/quantifying the cost and profitability of care for DFUs, October 13, 2018

Note 2: Average days in admission is 11 days for DFU LLA times inpatient admissions cost in Appendix 9 for each category to arrive at columns B-E cost (Data from Jvacsur.org/quantifying the cost and profitability of care for DFUs, October 13, 2018)

Note 3: Overall average takes the total addition of columns B-E and averages to \$63,642.75

Estimated VHA Total DFU LLA Inpatient Hospital Stay Cost for Veterans

(A) Net Margin	(B) Number of DFU LLA VA Patients Per Year	(C) Overall Average Cost Per Hospital Stay (11 Days)	(D) Estimated Annual Hospital Stay Cost for DFU LLA Veterans (B X C)
Inpatient Admissions (11 Days)	9,542	\$63,643.00	\$607,281,506.00

Appendix 11

Note 1: Data from Jvacsur.org/quantifying the cost and profitability of care for DFUs, October 13, 2018, which is included in Appendix 9 and 10.

VA DFU LLA Veteran Disability Payments

(A) 2021 DFU LLA Veterans	(B) 70% Monthly Disability Payment	(C) Annual Disability Payment (B X 12 Months)	(D) Estimated Total Disability Payments to DFU LLA Veteran (A X C)
9,542	\$1,547	\$18,566	\$177,156,772

Appendix 12

Note 1: VA and Social Security payments are tax-free in all states for disabled Americans. Disability cost per month extracted from 2020 VA.gov/benefits using 70 percent disability, with spouse and no parents or children as a conservative estimate based on the average age of DFU LLA Veterans is 66.2 years of age (Table 4).

Medicare Rates to Treat DFU Wagner Grade III or Higher Pre-LLA

(A) Average Number of HBOT Dive Hours for Wagner Grade III DFU	(B) 2021 Medicare (G0277) Rate Per Segment	(C) Average Number of 30 Minute Serments Per Dive (2-Hrs)	(D) Average Cost Per Dive Per Day (B X C)	(E) Average MD Cost Per Dive Session	(F) Total Estimated HBOT Dive Cost Peer Day Per Veteran (D+E)	(G) Average HBOT Cost Per Veteran to Heal DFU (1/2 of A X F)	(H) Total 2021 DFU LLA Veterans	(I) Estimated Cost to Treat 9,542 DFU Veterans Per Year (G X H)
50	\$119.00	4	\$476.00	\$125.00	\$601.00	\$15,025.00	9542	\$143,368,550.00

Appendix 13

Note 1: HBOT for DFU Wagner Grade III patients based upon 2.0-2.5 ATA pressure for 120 minutes per day (4 each Medicare segment)

Note 2: Medicare Rate cited is \$119 per 30-minute segment

Note 3: Medical doctor Medicare rate for hospital services is estimated at \$125 per visit

VHA Electronic Informed Consent Form

Please Click the “Document” tab to display the form



Practitioner Obtain in Consent (Locate name in box below. Click Add Button)

Add

Typing is allowed in the box below

Is the practitioner obtaining consent a trainee or under the supervisor of an attending physician?

Yes

No

Are there practitioner(s) performing or supervisors the treatment/procedure that are not list above?

Yes

No

Does the patient have decision-making capacity?

Yes

No

Will anesthesia or moderate sedation be used in the treatment procedure?

Yes

No

Describe the reason that this treatment/procedure is being performed, include ethe diagnosis, condition, or indication as appropriate

Description of Treatment/Procedure (Discuss the treatment/procedure in language that the patient/surrogate can understand

Appendix 15

Note 1: VHA’s consent program (IMED) includes only one specific HBO consent form for wound care. The screen shot of the IMED form is reflected in the Appendix above