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Hyperbaric Oxygen Therapy for Diabetic Foot Ulcers in Sub-Saharan Africa: A Critical Review of Clinical Evidence, Health-System Feasibility and Public Health Implications

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ABSTRACT

Diabetic foot ulcers are an important cause of morbidity, amputation, disability and healthcare expenditure in sub-Saharan Africa, where limitations in preventive foot care, referral pathways, vascular services, multidisciplinary wound care and financial protection may contribute to poor outcomes. This critical narrative review evaluates the potential role of systemic hyperbaric oxygen therapy as an adjunct to standard diabetic foot ulcer care in sub-Saharan Africa by integrating evidence on clinical effectiveness and safety with health-system, economic, equity and implementation considerations. Evidence was drawn from clinical studies, systematic reviews, clinical guidelines, economic evaluations and literature relevant to diabetic foot care and health-system capacity in the region. Global evidence suggests that systemic hyperbaric oxygen therapy may improve wound healing in selected patients whose ulcers fail to heal with best standard care, but findings remain heterogeneous; evidence for reducing amputation is uncertain, and direct regional evidence is sparse. Implementation in sub-Saharan Africa would require reliable oxygen, electricity, trained staff, safe maintenance systems, multidisciplinary care, referral pathways, sustainable financing and feasible treatment completion. The therapy should therefore not be considered routine or first-line treatment. Where appropriate infrastructure exists, carefully monitored referral-centre pilots should assess clinical outcomes, safety, treatment completion, affordability, budget impact and equity before wider implementation.

1 | Introduction

Diabetic foot ulcers (DFUs) are among the most serious and resource-intensive complications of diabetes mellitus, contributing to infection, prolonged hospitalisation, lower-extremity amputation, reduced quality of life, premature mortality and substantial healthcare expenditure [1]. In sub-Saharan Africa (SSA), the burden of DFUs is intensified by

Abbreviations: ATA, atmospheres absolute; CFIR, consolidated framework for implementation research; CNS, central nervous system; DFU, diabetic foot ulcer; FDA, US Food and Drug Administration; HBOT, hyperbaric oxygen therapy; IWGDF, International Working Group on the Diabetic Foot; PAD, peripheral arterial disease; PRISMA, Preferred Reporting Items for Systematic Reviews and Meta-Analyses; PRISMA-S, PRISMA extension for reporting literature searches; RCT, randomised controlled trial; RE-AIM, reach effectiveness adoption implementation and maintenance; ROS, reactive oxygen species; SSA, sub-Saharan Africa; VEGF, vascular endothelial growth factor; WHO, World Health Organization.

Key Points

- HBOT may aid selected non-healing diabetic foot ulcers.
- Evidence remains mixed, with limited data from sub-Saharan Africa.
- Use should depend on health-system readiness and optimized standard care.
- Local pilot evaluation should precede wider implementation.

rising diabetes prevalence, delayed diagnosis, limited routine foot screening, weak referral systems, inadequate access to multidisciplinary wound care and high out-of-pocket healthcare costs [2]. These challenges often result in late presentation with advanced infection, ischemia or gangrene, increasing the likelihood of preventable amputations and long-term disability. For many SSA health systems, DFUs therefore represent not only a clinical complication of diabetes but also a marker of wider gaps in chronic disease prevention, early detection, surgical access, rehabilitation and financial protection.

Hyperbaric oxygen therapy (HBOT) has been investigated as an adjunctive intervention for DFUs because it can increase tissue oxygen tension and may support oxygen-dependent processes involved in wound repair, including angiogenesis, fibroblast activity, collagen synthesis, leukocyte function and infection control [3, 4]. These mechanisms provide a plausible therapeutic rationale, particularly for chronic, ischemic, infected or non-healing ulcers [5]. However, the clinical evidence remains heterogeneous [6–8]. Some trials and meta-analyses suggest improved healing or reduced major amputation risk in selected patients [4, 9], whereas other controlled studies have reported limited or no additional benefit compared with sham therapy or optimised standard care [8]. As a result, HBOT should not be framed as a universal, first-line or stand-alone treatment for DFUs, but as a selective adjunctive therapy whose value depends on patient selection, ulcer severity, ischemia status, treatment completion and the quality of concurrent standard wound care [10, 11].

This uncertainty is especially important for SSA, where direct clinical evidence on systemic HBOT for DFUs remains limited and where the conditions required for safe delivery may be unevenly available. HBOT is resource-intensive and depends on reliable medical-grade oxygen, uninterrupted electricity, specialised chambers, trained personnel, safety protocols, equipment maintenance, referral pathways and sustainable financing [12, 13]. These requirements intersect with existing constraints in oxygen infrastructure, vascular assessment, podiatry, specialist wound care, rehabilitation, biomedical engineering and public financing [13]. Broad adoption without local feasibility, safety, cost-effectiveness and equity assessment could divert scarce resources from higher-impact DFU interventions, including prevention, foot screening, offloading, debridement, infection control, vascular referral, glycaemic optimisation, patient education and rehabilitation [10, 11].

The central question for SSA is therefore not simply whether HBOT can improve wound healing under controlled conditions, but whether it can be responsibly integrated into real-world DFU care pathways without worsening inequity or weakening essential services [11, 14]. Although HBOT for DFUs has been reviewed in relation to wound healing, amputation prevention and treatment safety, most existing discussions are dominated by clinical evidence from high-income settings and do not sufficiently address implementation feasibility in resource-constrained health systems [4, 6, 15]. Far less attention has been given to whether HBOT can be implemented responsibly in SSA, where health-system constraints may determine clinical value as much as biological efficacy [16–18]. In particular, previous reviews have not sufficiently integrated HBOT evidence with SSA-specific realities such as limited oxygen infrastructure, unreliable electricity, shortages of specialist wound-care and vascular services, weak referral systems, high out-of-pocket expenditure, rural–urban inequities and the absence of local cost-effectiveness data [11, 16, 17]. This creates an important evidence-to-policy gap: even if HBOT benefits selected DFU patients under controlled conditions, its public health value in SSA remains uncertain unless implementation readiness, safety, cost-effectiveness and opportunity costs are assessed locally.

This review addresses that gap by reframing HBOT as a complex, oxygen-dependent, referral-level health-system intervention, rather than simply an adjunctive wound-healing therapy. This review is positioned as a policy-oriented critical review of HBOT. Accordingly, this review critically synthesises global evidence on systemic HBOT for DFUs and evaluates its relevance to SSA through the lenses of clinical selection, implementation readiness, safety, cost-effectiveness, financing, equity and policy decision-making. Specifically, the review contributes by:

1. separating global evidence on HBOT effectiveness from SSA-specific implementation realities;
2. identifying the clinical, infrastructural, workforce, safety, financing and equity conditions required for responsible HBOT delivery in SSA;
3. proposing a cautious pilot-based pathway for evaluating HBOT before scale-up, including local assessment of treatment completion, adverse events, affordability, budget impact, cost-effectiveness and equitable access.

By integrating clinical evidence with health-system feasibility and policy considerations, this review provides a decision-oriented framework for determining whether, where, and under what conditions HBOT could be incorporated into DFU care pathways in SSA. This review focuses on systemic HBOT delivered in a pressurised chamber. It does not evaluate topical oxygen therapy, which differs in mechanism, equipment requirements, cost, evidence base and implementation implications.

2 | Methodology

2.1 | Review Design

This article was designed as a critical narrative review examining the clinical evidence, biological rationale, safety profile, economic implications and health-system feasibility of

HBOT as an adjunctive treatment for DFUs in SSA. A narrative review approach was considered appropriate because the topic involves heterogeneous evidence from randomised trials, systematic reviews, clinical guidelines, health-system reports, economic analyses and implementation-related literature. The aim was not to generate a pooled effect estimate, but to synthesise available evidence, identify knowledge gaps and critically assess whether HBOT could be responsibly integrated into DFU care pathways in resource-constrained SSA settings. The review was guided by principles for high-quality narrative reviews, including justification of scope, transparent search description, critical interpretation and balanced presentation of evidence [19]. This review focused on systemic HBOT, defined as administration of 100% oxygen to the whole patient inside a pressurised chamber. Topical oxygen therapy was not reviewed in depth because it differs from systemic HBOT in mechanism, delivery method, equipment requirements, cost, safety profile, evidence base and implementation implications. Therefore, evidence on topical oxygen therapy was not treated as interchangeable with evidence on systemic HBOT. Although this article was designed as a critical narrative review rather than a systematic review, reporting of the literature search was informed by the Preferred Reporting Items for Systematic Reviews and Meta-Analyses extension for reporting literature searches (PRISMA-S), while the overall review design and critical narrative synthesis were guided by methodological principles for high-quality narrative reviews [20, 21]. The review does not claim compliance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 statement and was not designed to provide exhaustive systematic screening, formal risk-of-bias assessment, certainty-of-evidence grading, meta-analysis or a PRISMA study-selection flow diagram.

2.2 | Literature Search Strategy

A structured literature search was conducted using PubMed/MEDLINE, Scopus, Web of Science and Google Scholar. Additional sources included clinical guidelines and policy documents from relevant international and regional organizations, including the World Health Organization (WHO), the International Diabetes Federation, and diabetic foot or hyperbaric medicine guideline bodies. Electronic searches prioritised literature published from 1 January 2011 to 16 August 2026. Older publications were retained when they were landmark randomised trials, foundational mechanistic studies or historically important sources needed to interpret the development of HBOT for diabetes-related foot disease. Reference lists of pivotal trials, systematic reviews and guidelines were also examined to reduce the likelihood that influential supportive or contradictory evidence was omitted.

Search terms included combinations of the following: 'hyperbaric oxygen therapy', 'HBOT', 'diabetic foot ulcer', 'diabetes-related foot ulcer', 'wound healing', 'amputation', 'sub-Saharan Africa', 'low-resource settings', 'cost-effectiveness', 'health systems', 'oxygen infrastructure', 'medical oxygen', 'implementation', and 'public health policy'. Searches were limited mainly to English-language publications. All schematic figures presented in this review were created using BioRender (https://BioRender.com).

2.3 | Eligibility Criteria

Eligible clinical evidence included randomised or controlled clinical studies evaluating systemic HBOT in people with diabetes-related foot ulcers and reporting wound healing, amputation, safety, treatment completion or related clinical outcomes. Systematic reviews, meta-analyses and evidence-based clinical guidelines were eligible when they directly evaluated or made recommendations concerning systemic HBOT for DFUs. Economic evaluations were eligible when they assessed costs, cost-effectiveness, resource use or budgetary consequences of HBOT or advanced DFU care. For the SSA implementation component, peer-reviewed studies and authoritative health-system reports were eligible when they addressed DFU burden or care, medical oxygen systems, workforce capacity, referral pathways, financing, accessibility, equity or other factors directly relevant to HBOT implementation. Publications focused exclusively on topical oxygen therapy, non-diabetic wounds without direct relevance to DFU management, HBOT for unrelated indications, duplicate reports and publications without sufficient methodological or contextual information were excluded. Systemic HBOT and topical oxygen therapy were treated as distinct interventions. Studies from high-income countries were included when they provided relevant evidence on HBOT efficacy, safety, treatment protocols or economic evaluation, but their findings were interpreted cautiously because health-system conditions may differ substantially from those in SSA.

2.4 | Evidence Selection and Synthesis

Titles and abstracts were screened for relevance to the review questions. Full texts were reviewed when publications appeared to address HBOT effectiveness, safety, patient selection, DFU burden, SSA implementation constraints, oxygen infrastructure, health-system readiness, financing or cost-effectiveness. Because this was a critical narrative review, formal meta-analysis and pooled effect estimation were not performed. However, evidence selection prioritised sources with clear relevance, methodological quality and direct contribution to the review questions. Evidence was synthesised thematically across six domains: DFU burden and pathophysiology, biological rationale for HBOT, clinical evidence and conflicting findings, safety and contraindications, health-system readiness in SSA and economic or policy considerations.

Greater interpretive weight was given to randomised controlled trials, systematic reviews, meta-analyses, clinical practice guidelines and high-quality regional studies. Observational studies, implementation reports and policy documents were included when they provided relevant contextual evidence for SSA. Where evidence was conflicting, findings were interpreted in relation to patient selection, ulcer severity, ischemia status, quality of standard wound care, treatment protocol, number of HBOT sessions completed and follow-up duration.

2.5 | Critical Appraisal Approach

A formal risk-of-bias assessment was not conducted because the review was not designed as a systematic review. However, included literature was critically appraised narratively by considering study design, population characteristics, intervention protocol, comparator, outcome measures, sample size, follow-up duration and relevance to SSA health systems. Particular caution was applied when interpreting evidence from high-income settings because HBOT availability, vascular services, wound-care infrastructure, reimbursement mechanisms, oxygen systems and multidisciplinary care capacity may not be directly comparable to SSA settings.

3 | Burden and Pathophysiology of DFUs in SSA

DFUs are a major cause of diabetes-related morbidity in SSA, where they contribute to infection, prolonged hospitalisation, lower-extremity amputation, disability, loss of productivity and premature mortality. The burden of DFUs reflects both biological mechanisms of impaired wound healing and health-system factors that delay prevention, diagnosis and treatment. Understanding this dual burden is essential before considering advanced adjunctive therapies such as HBOT because most DFU outcomes depend first on timely screening, standard wound care, infection control, vascular assessment, glycaemic optimisation, offloading and referral.

3.1 | Pathophysiology of DFUs

DFUs usually arise from the interaction of peripheral neuropathy, peripheral arterial disease (PAD), impaired immunity, repetitive trauma and delayed wound repair [22]. Chronic hyperglycaemia contributes to endothelial dysfunction, oxidative stress, inflammation and microvascular impairment, reducing tissue perfusion and delaying normal healing processes [23, 24]. Peripheral neuropathy leads to loss of protective sensation, making patients less likely to detect minor trauma, pressure injury, burns or footwear-related lesions [10, 22]. Motor neuropathy can also contribute to foot deformity and abnormal pressure distribution, while autonomic neuropathy may cause dry skin and fissuring, creating portals for infection [25].

PAD further worsens DFU risk by reducing blood flow and oxygen delivery to injured tissue [26]. In ischemic or neuroischemic ulcers, reduced perfusion limits the delivery of oxygen, nutrients, immune cells and antibiotics to the wound bed [22, 26]. Tissue hypoxia impairs fibroblast proliferation, collagen synthesis, angiogenesis, epithelialisation and leukocyte bactericidal activity [27]. As a result, wounds may remain chronic, become infected or progress to gangrene if not promptly treated [11]. Infection is often polymicrobial in advanced ulcers and may involve superficial soft tissue, deep tissue, bone or systemic spread [28].

In SSA, these biological risks are often compounded by delayed presentation, limited routine foot examination, poor access to diagnostic imaging or vascular assessment, inadequate offloading, inconsistent availability of wound-care supplies and restricted access to specialist teams [17, 29]. Consequently, many patients present with advanced ulcers, severe infection or established tissue necrosis. This makes DFU management more complex and increases the likelihood of hospitalisation, surgery, amputation and long-term disability.

3.2 | Epidemiology and Burden of DFUs in SSA

The burden of DFUs in SSA is increasing alongside the rising prevalence of diabetes, urbanisation, lifestyle changes, population aging and persistent gaps in chronic disease care [30, 31]. Many people with diabetes in SSA remain undiagnosed or are diagnosed late, reducing opportunities for early risk stratification, neuropathy screening, patient education, glycaemic optimisation and preventive foot care. For those already living with diabetes, regular foot assessment is often unavailable or inconsistently provided, particularly in rural and lower-level health facilities [5, 17].

Recent pooled evidence provides a stronger regional estimate than isolated hospital-based studies. A systematic review and meta-analysis of observational studies in SSA reported a pooled DFU prevalence of 13.35% among people with diabetes, with associated factors including rural residence, peripheral neuropathy, poor foot self-care, longer duration of diabetes, previous ulcer history, physical inactivity, foot callus and limited access to diabetes self-monitoring resources [32]. These findings show that DFUs in SSA are strongly linked to preventable or modifiable factors, many of which can be addressed through strengthened primary and secondary diabetes care [10, 11].

Country-level studies support this pattern. Evidence from Ethiopia, Somalia, Uganda and other SSA settings indicates that DFUs are frequently associated with poor glycaemic control, longer diabetes duration, peripheral neuropathy, inadequate foot-care practices, delayed care-seeking and limited access to screening [5, 31, 33, 34]. Many patients reach referral facilities only after ulcers have become infected, ischemic or deep [29, 32]. Such delays increase the risk of minor or major amputation and place substantial pressure on surgical, rehabilitation and prosthetic services, which are already limited in many settings [5].

The socioeconomic burden is also substantial. DFUs can lead to prolonged hospitalisation, repeated clinic visits, wound dressings, antibiotics, surgical procedures, transport costs, caregiver burden, lost income and long-term disability [17, 29]. Because out-of-pocket payment remains common in many SSA health systems, DFU care can be financially catastrophic for patients and households [2]. Amputation may further reduce mobility, employment, social participation and quality of life, especially where prosthetic and rehabilitation services are inaccessible or unaffordable [5].

The high burden of DFUs in SSA supports urgent investment in diabetic foot prevention and care pathways. However, this burden should not be interpreted as direct justification for broad HBOT implementation. The strongest population-level

gains are likely to come first from routine foot screening, patient education, early ulcer detection, pressure offloading, debridement, infection control, vascular assessment, glycaemic management, referral systems and rehabilitation [10, 11]. HBOT should therefore be considered only as a selective adjunctive therapy for advanced, ischemic, infected or non-healing DFUs after standard care has been optimised and where the necessary health-system conditions for safe delivery are present.

4 | HBOT: Biological Rationale, Patient Selection and Treatment Protocols

HBOT involves the inhalation of 100% oxygen in a pressurised chamber, usually at pressures greater than 1 atmosphere absolute (ATA) and commonly between 2.0 and 3.0 ATA [35, 36]. Under hyperbaric conditions, the amount of oxygen dissolved in plasma increases substantially, allowing oxygen to diffuse into hypoxic tissues even when local blood flow is impaired [37]. In DFUs, this provides a biological rationale for adjunctive treatment, particularly where impaired perfusion, tissue hypoxia, infection and delayed healing coexist. However, HBOT does not correct inadequate macrovascular blood flow and should not replace debridement, infection management, offloading, vascular assessment or revascularisation where indicated, glycaemic management and other components of comprehensive DFU care.

4.1 | Historical Development and Biological Rationale for HBOT in DFU Healing

Clinical investigation of HBOT in diabetes-related foot disease predates many contemporary trials. Early studies included work on diabetic gangrene in the 1980s, followed by the randomised study of Faglia et al. [38] in 1996 and the double-blind randomised trial of Abidia et al. [39] in 2003. These studies helped establish the clinical rationale for evaluating HBOT as an adjunct to conventional diabetic foot care and were followed by later randomised and sham-controlled trials that more directly examined wound healing and limb outcomes.

The biological rationale for HBOT is based on its ability to temporarily increase tissue oxygen tension in hypoxic wound environments. Oxygen availability supports important processes involved in wound repair, including fibroblast activity, collagen deposition, angiogenesis, epithelialisation and leukocyte-mediated bacterial killing. Human mechanistic evidence in patients with diabetes also indicates that HBOT can stimulate vasculogenic stem/progenitor-cell mobilisation from bone marrow and increase recruitment of these cells to wound tissue [40]. In chronic DFUs, these processes may be impaired by peripheral arterial disease, microvascular dysfunction, oedema, infection and sustained inflammation [41]. By increasing oxygen availability, HBOT may support wound repair in carefully selected patients whose ulcers remain hypoxic despite standard care [37, 42]. These mechanisms are most relevant in chronic, ischemic, infected or non-healing ulcers where tissue oxygen delivery is impaired. However, biological plausibility should not be interpreted as proof of clinical effectiveness. The clinical response to HBOT depends on ulcer phenotype, vascular supply, infection control, offloading, glycaemic management, treatment completion and the quality of concurrent standard care. Figure 1 summarises these proposed mechanisms.

4.2 | Patient Selection

Appropriate patient selection is central to the responsible use of HBOT in DFU management. HBOT is generally considered for selected patients with advanced, ischemic, infected or non-healing DFUs that have failed to improve despite optimised standard care [5]. It is not recommended as routine treatment for all DFUs or as first-line therapy for superficial, uncomplicated ulcers [11].

Guideline-based use commonly emphasises patients with Wagner grade 3 or higher ulcers, especially where there is deep infection, abscess, osteomyelitis, gangrene or failure to improve after approximately 30 days of standard care [5]. Patients with ischemic or neuro-ischemic ulcers may be considered if vascular assessment has been performed and revascularisation has been addressed where feasible [43]. The International Working Group on the Diabetic Foot (IWGDF) guidance similarly limits consideration of HBOT to neuro-ischemic or ischemic diabetes-related foot ulcers where standard care has failed and where resources already exist to support the intervention [44]. Assessment of tissue oxygenation, such as transcutaneous oxygen pressure where available, may help identify patients whose wounds are hypoxic but potentially responsive to oxygen-based therapy [6, 45].

Before HBOT is initiated, patients should undergo comprehensive DFU assessment. This should include ulcer classification, infection assessment, vascular evaluation, glycaemic review, medication review, offloading assessment and screening for contraindications [10, 11, 43]. Standard care should be optimised first, including debridement, wound dressing, infection control, offloading, vascular referral when indicated and patient education. HBOT is most defensible when used as part of a multidisciplinary care pathway rather than as an isolated intervention [10, 11].

In SSA, patient selection must also consider feasibility and equity. Even eligible patients may not complete HBOT if they face high transport costs, long travel distances, treatment fees, work disruption or limited caregiver support [2, 17]. Therefore, eligibility criteria should include not only clinical suitability but also a realistic assessment of treatment completion, follow-up capacity and financial protection.

4.3 | Treatment Protocols

HBOT protocols vary across studies and clinical settings, but DFU treatment commonly involves daily sessions at 2.0–3.0 ATA, often around 2.4 ATA, for 90–120 min per session [6, 46]. Treatment is typically delivered 5 days per week, although some protocols use five to seven sessions weekly [4, 9]. A full course often includes 20–40 sessions, with some severe or chronic

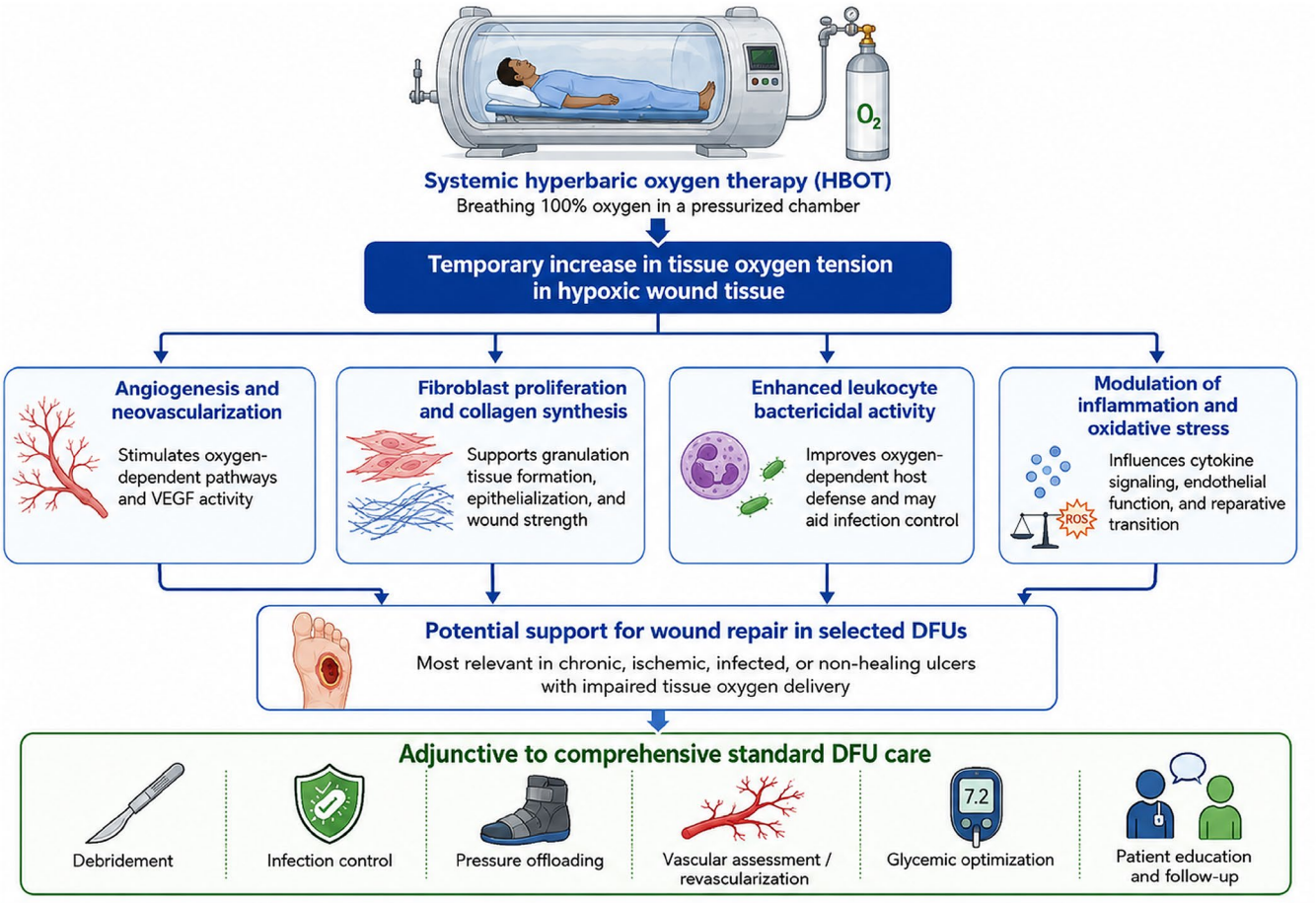

FIGURE 1 | Biological rationale for systemic hyperbaric oxygen therapy in diabetic foot ulcer healing. Systemic HBOT increases dissolved plasma oxygen and can temporarily increase oxygen tension in hypoxic wound tissue. Increased oxygen availability may support angiogenesis, fibroblast activity, collagen synthesis, epithelialisation, leukocyte-mediated bacterial killing and modulation of inflammatory and oxidative-stress pathways. These mechanisms provide biological plausibility for HBOT but do not establish clinical benefit in all DFUs. HBOT should be used only as an adjunct to comprehensive DFU care, including appropriate debridement, infection management, offloading, vascular assessment or revascularisation where indicated and glycaemic management. DFU, diabetic foot ulcer; HBOT, hyperbaric oxygen therapy; ROS, reactive oxygen species; VEGF, vascular endothelial growth factor.

ulcers requiring more sessions depending on clinical response, wound severity and facility protocols [6, 46].

Treatment response should be monitored throughout therapy. Monitoring may include serial wound measurements, wound photography, infection markers, pain and functional status, glycaemic control, adverse-event surveillance and reassessment of vascular status where indicated [11, 43]. HBOT should be discontinued or reconsidered if there is no meaningful clinical response after an adequate trial, if adverse effects occur or if the patient is unable to complete treatment safely [5, 11].

In SSA, protocol design should be adapted to local infrastructure without compromising safety. Facilities offering HBOT should have trained operators, emergency protocols, reliable oxygen supply, backup power, chamber maintenance systems, fire safety procedures and clear referral criteria. Treatment protocols should also be linked to multidisciplinary DFU care so that HBOT does not delay debridement, antibiotics, offloading, vascular intervention or surgical management when these are needed [10, 11, 43]. Table 1 summarises HBOT treatment parameters and patient-selection considerations for diabetic foot ulcers.

5 | Clinical Evidence: Benefit, Uncertainty and Sources of Conflicting Findings

5.1 | Pivotal Randomised and Sham-Controlled Trials

The randomised evidence does not support a simple conclusion that systemic HBOT is either uniformly effective or ineffective for diabetes-related foot ulcers. Rather, individual trials have evaluated clinically different populations under different background-care conditions and have used different endpoints, treatment schedules and comparators. The most defensible interpretation is therefore that any treatment effect is likely to depend on patient and ulcer phenotype, while the available evidence remains insufficient to define a precise responder population.

Early supportive evidence came from patients with relatively severe or ischemic disease. Faglia et al. [38] randomised people hospitalised with severe, predominantly ischemic foot ulcers to comprehensive treatment with or without systemic HBOT. Among the 68 participants completing the protocol, major

TABLE 1 | Evidence-informed patient-selection considerations and systemic HBOT parameters reported in diabetic foot ulcer studies.

Parameter	Suggested approach	Supporting evidence
Patient selection	Selected ischemic/neuro-ischemic or advanced non-healing DFUs after optimised care.	Chen et al. [44]; Huang et al. [5]
Pre-treatment assessment	Ulcer severity, infection, perfusion/ischemia, offloading, glycaemic status and contraindications.	Schaper et al. [47]; Huang et al. [5]
Treatment pressure	DFU trials have commonly used approximately 2.4–2.5 ATA; broader chronic-wound studies have used varying pressures, commonly around 2.0–2.5 ATA.	Löndahl et al. [9]; Fedorko et al. [48]; Santema et al. [49]; Kranke et al. [46]
Session duration	Major DFU RCTs used approximately 85–90 min at therapeutic pressure; treatment durations vary across the wider evidence base.	Löndahl et al. [9]; Fedorko et al. [48]; Santema et al. [49]
Frequency	Once-daily treatment approximately 5 days per week has been used in major DFU trials; individual protocols vary.	Löndahl et al. [9]; Santema et al. [49]
Number of sessions	Major modern DFU trials have used approximately 30–40 sessions; the prescribed course should follow the protocol and clinical context rather than a universal fixed regimen.	Löndahl et al. [9]; Fedorko et al. [48]; Santema et al. [49]
Concurrent standard care	Debridement, infection control, offloading, vascular care and glycaemic management	Chen et al. [44]; Schaper et al. [47]; Huang et al. [5]
Monitoring	Monitor wound response, adverse events, blood glucose and treatment completion.	Zhang et al. [50]; Baitule et al. [51]
Reassessment	Continued therapy should be reviewed according to clinical response, safety, treatment tolerance and the predefined treatment protocol.	Huang et al. [5]; Chen et al. [44]

Note: HBOT should remain an adjunctive therapy for cautiously selected DFU patients. Protocols vary across guidelines, facilities and patient-specific circumstances. Treatment should be delivered only where appropriate safety systems, trained personnel, oxygen supply, emergency procedures and multidisciplinary DFU care are available.
Abbreviations: ATA = atmospheres absolute; DFU = diabetic foot ulcer; HBOT = hyperbaric oxygen therapy; RCT = randomised controlled trial.

amputation occurred in 3/35 receiving HBOT compared with 11/33 controls. This trial provided an important early efficacy signal, but it preceded contemporary standards of vascular assessment and multidisciplinary wound care and did not use a sham intervention, limiting direct comparison with modern trials.

Abidia et al. [39] subsequently conducted a double-blind randomised trial in people with ischemic, non-healing lower-extremity ulcers. HBOT was delivered at 2.4 ATA for 90 min over 30 treatments. Complete epithelialisation was reported in 5/8 HBOT-treated ulcers compared with 1/8 controls. Although the sham-controlled design strengthens causal interpretation, the very small sample means that the effect estimate is imprecise and should be regarded as supportive rather than definitive.

The randomised, double-blind, placebo-controlled trial by Löndahl et al. [9] provides one of the stronger supportive contemporary trials. Ninety-four participants with Wagner grade 2–4 ulcers of more than 3 months' duration were studied. Complete healing at 1 year occurred in 52% of the HBOT group compared with 29% of the placebo group. A larger difference was observed among participants completing more than 35 treatment sessions, suggesting that treatment completion may influence observed effectiveness; however, analyses based on treatment completion are post-randomisation and cannot by themselves establish a causal dose–response relationship.

By contrast, the sham-controlled trial by Fedorko et al. [48] randomised 107 people with Wagner grade 2–4 lesions to 30 sessions of HBOT or sham treatment in addition to comprehensive wound care. At 12 weeks, neither criteria for amputation nor wound healing differed significantly between groups. This negative result is important because the use of sham treatment and structured multidisciplinary wound care reduced several sources of bias that can affect open trials.

The multicentre randomised trial by Santema et al. [49] further illustrates why ischemia alone does not guarantee benefit. Among 120 people with diabetes and ischemic lower-extremity wounds, adjunctive HBOT did not significantly improve overall complete wound healing or limb salvage at 12 months. Importantly, 21 of 60 patients allocated to HBOT (35%) were unable to complete the planned treatment protocol. Outcomes were better among those who completed treatment, but this secondary comparison is susceptible to selection bias because people capable of completing a demanding treatment course may differ systematically from those who cannot.

5.2 | Why the Trials Disagree

The conflicting findings are therefore unlikely to be explained by treatment pressure alone, since many contemporary trials used broadly similar pressures around 2.4–2.5 ATA. More

important differences include ischemic phenotype and severity, eligibility for or timing of revascularisation, infection and ulcer classification, quality of background multidisciplinary care, sham versus non-sham comparison, outcome definition, duration of follow-up and ability to complete 30–40 treatment sessions. The Löndahl et al. [9] and Santema et al. [49] trials particularly illustrate the potential importance and interpretive difficulty of treatment completion.

Systematic reviews consequently produce different estimates depending on which populations and study designs are combined. The 2015 Cochrane review found evidence of improved short-term healing in diabetes-related foot ulcers but not a persisting healing benefit at 1 year and emphasised weaknesses in trial design and reporting [46]. A later meta-analysis restricted to ulcers with arterial insufficiency found fewer major amputations with HBOT but no consistent improvement in complete wound healing [6]. These apparently discordant results reinforce the problem of combining clinically heterogeneous populations rather than establishing a universal treatment effect.

Contemporary guideline interpretation is therefore appropriately cautious. The 2023 IWGDF guideline gives only a conditional recommendation based on low-certainty evidence to consider systemic HBOT for neuro-ischemic or ischemic diabetes-related foot ulcers when best standard care has failed and resources already exist to support treatment. The guideline does not support routine HBOT for all diabetes-related foot ulcers [44].

5.3 | What Can Reasonably Be Concluded

The evidence is most consistent with a possible selective adjunctive role, rather than routine effectiveness across all DFUs. Ischemic or neuro-ischemic ulcers that remain unhealed despite high-quality standard care represent the population with the strongest current guideline rationale, but even within this phenotype the Santema et al. [49] trial demonstrates substantial uncertainty. Evidence for non-ischemic uncomplicated ulcers is substantially less persuasive [52]. HBOT should therefore be considered only after vascular assessment and optimisation of established diabetic foot care and the magnitude of benefit for an individual patient remains uncertain. Before implementation decisions are made, the clinical question should therefore be framed as 'which patients, under which background-care conditions, are likely to derive enough benefit to justify a resource-intensive treatment?' rather than simply 'does HBOT work?'. Clinical efficacy and health-system feasibility are distinct questions. Evidence that systemic HBOT may improve outcomes in selected patients does not establish that the intervention will be effective, affordable or equitable when transferred to SSA health systems. Most pivotal HBOT trials were conducted in settings with established multidisciplinary wound care, vascular assessment, reliable oxygen and electricity, trained hyperbaric personnel and mechanisms supporting repeated treatment attendance. Accordingly, the remainder of this review considers safety and SSA implementation separately from the question of biological or clinical efficacy.

Table 2 summarises the pivotal randomised trials, systematic reviews and guideline evidence informing the current interpretation of systemic HBOT for DFUs, highlighting the main findings and key methodological considerations.

6 | Safety, Contraindications and Risk Mitigation

HBOT is generally considered safe when delivered by trained personnel using appropriate protocols, equipment maintenance and safety systems. However, it is not risk-free. Patients with DFUs often have multiple comorbidities, including cardiovascular disease, peripheral arterial disease, renal impairment, chronic lung disease, infection and poor glycaemic control, which may increase treatment complexity. Therefore, HBOT should be delivered only after careful patient assessment, screening for contraindications and integration with comprehensive DFU care [53, 54]. The need for integration with standard DFU care is also emphasised by IWGDF guidance, which frames HBOT as an adjunctive intervention rather than a substitute for debridement, infection control, offloading, vascular assessment and other core components of care [44].

6.1 | Contraindications and Pre-Treatment Assessment

The most important absolute contraindication to HBOT is untreated pneumothorax, because pressure changes during treatment may worsen trapped intrathoracic air and precipitate life-threatening tension pneumothorax. Other conditions require careful risk–benefit assessment rather than automatic exclusion. These include severe chronic obstructive pulmonary disease, emphysema with air trapping, recent thoracic surgery, uncontrolled seizure disorder, severe claustrophobia, active upper respiratory tract infection, chronic sinus disease and inability to equalise middle-ear pressure [54].

Certain medications may also require caution. Some chemotherapeutic agents, including doxorubicin, bleomycin and cisplatin, have been described as potentially problematic in relation to HBOT because of concerns about toxicity or adverse interaction [55]. Medication history should therefore be reviewed before treatment. Pregnancy is not always an absolute contraindication, but HBOT in pregnant patients should be considered only where potential benefits clearly outweigh risks and where appropriate specialist input is available [56, 57].

Pre-treatment assessment should include respiratory history, ear and sinus assessment, cardiovascular review, medication review, blood glucose assessment, infection status, vascular status and evaluation of the patient's ability to tolerate chamber treatment. In DFU patients, HBOT should not begin until standard wound care has been optimised, including debridement, infection control, offloading, glycaemic management and vascular assessment where indicated [44].

6.2 | Adverse Effects

The most common adverse effect of HBOT is barotrauma, particularly involving the middle ear and sinuses. Middle-ear barotrauma may cause ear pain, pressure, temporary hearing

TABLE 2 | Key clinical evidence informing systemic HBOT use in diabetes-related foot ulcers.

Study	Population/design	HBOT/ comparator	Main finding	Critical interpretation
Chen et al. (IWGDF) (2024)—International [44]	Evidence-based international guideline on interventions to enhance healing of diabetes-related foot ulcers.	Not a protocol study.	Conditional consideration of systemic HBOT in selected ischemic/neuro-ischemic ulcers after failure of best standard care.	Low-certainty evidence; supports selective rather than routine use.
Brouwer et al. (2020)—Netherlands [6]	Systematic review and meta-analysis focused on DFUs with arterial insufficiency.	Varied.	Possible reduction in major amputation; complete-healing results were inconsistent.	Definitions of ischemia, revascularisation and standard care varied among studies.
Santema et al. (2018)—Netherlands [49]	Multicentre RCT; $n = 120$; ischemic lower-extremity wounds in people with diabetes.	Standard care plus HBOT versus standard care.	No significant overall improvement in complete healing or limb salvage.	Thirty-five percent of the HBOT arm did not complete the protocol, highlighting feasibility and adherence.
Fedorko et al. (2016)—Canada [48]	Double-blind, sham-controlled RCT; $n = 107$; non-healing Wagner grade 2–4 ulcers.	244 kPa, 90 min, 30 sessions versus sham treatment.	No significant improvement in healing or indication for amputation.	Strong negative trial conducted with comprehensive background wound care.
Kranke et al. (2015)—International [46]	Cochrane review of chronic-wound trials including DFU studies.	Varied.	Short-term healing signal, with uncertainty in longer-term outcomes.	Study quality, small samples and heterogeneity reduce certainty.
Londahl et al. (2010)—Sweden [9]	Double-blind, sham-controlled RCT; $n = 94$; chronic Wagner grade 2–4 ulcers.	2.5 ATA, 85 min, 5 days/ week, up to 40 sessions versus hyperbaric air.	Healing at 1 year: 52% versus 29%.	One of the stronger supportive trials; single-centre study; completion analyses were post-randomisation.
Abidia et al. (2003)—United Kingdom [39]	Double-blind randomised trial; 18 participants recruited; ischemic, non-healing ulcers.	2.4 ATA, 90 min, 30 sessions versus hyperbaric air.	Complete epithelialisation: 5/8 versus 1/8 evaluable ulcers.	Sham-controlled supportive evidence, but the sample was very small and the effect estimate imprecise.

(Continues)

TABLE 2 | (Continued)

Study	Population/design	HBOT/ comparator	Main finding	Critical interpretation
Faglia et al. (1996)—Italy [38]	Randomised trial; severe, predominantly ischemic Wagner grade 2–4 ulcers; 68 participants completed the protocol.	HBOT plus comprehensive care versus comprehensive care; mean 38.8 HBOT sessions.	Major amputation: 3/35 versus 11/33.	Important early supportive signal; no sham comparator; predates contemporary vascular and multidisciplinary care.

Note: Table 2 prioritises pivotal trials and evidence syntheses rather than attempting an exhaustive inventory.
Abbreviations: ATA, atmospheres absolute; DFU, diabetic foot ulcer; HBOT, hyperbaric oxygen therapy; IWGDF, International Working Group on the Diabetic Foot; RCT, randomised controlled trial.

symptoms or tympanic membrane injury. The risk is higher in patients with upper respiratory tract infection, sinus disease, poor Eustachian tube function or inability to perform pressure-equalisation techniques [58]. Pulmonary barotrauma is rare but potentially serious, particularly in patients with air trapping or underlying lung disease.

Oxygen toxicity is another recognised risk. Central nervous system oxygen toxicity may present with visual disturbance, nausea, dizziness, twitching, confusion or seizure, although seizures are uncommon when standard treatment pressures and durations are used. A systematic review and meta-analysis of HBOT adverse effects found that ear discomfort and ocular effects were among the main reported adverse events, and that adverse reactions were more likely when chamber pressure exceeded 2.0 ATA or when treatment involved more than 10 sessions [50]. Pulmonary oxygen toxicity is also uncommon during typical DFU protocols because individual sessions are relatively short, but risk may increase with prolonged or repeated exposure [59].

Hypoglycaemia may occur in patients with diabetes during or after treatment, particularly among those using insulin or insulin secretagogues. HBOT can contribute to treatment-associated hypoglycaemia, although point-of-care glucose monitoring and close nursing observation are usually sufficient to deliver treatment safely in diabetic patients [51]. Blood glucose should be checked before treatment, and patients should not enter the chamber if glucose is too low or if they are clinically unstable. Facilities should have protocols for glucose supplementation and post-treatment monitoring.

Other adverse effects include reversible myopia, fatigue, anxiety, claustrophobia and rare fire-related hazards. Reversible myopia is usually associated with repeated sessions and often improves after treatment ends. Claustrophobia or anxiety may affect treatment completion and should be addressed through patient counselling, reassurance, chamber familiarisation, and, where available, use of more tolerable chamber designs [50].

6.3 | Risk Mitigation in SSA

In SSA, safety planning is particularly important because HBOT delivery depends on infrastructure that may be unevenly available. Facilities should have reliable oxygen supply, uninterrupted electricity or backup power, trained chamber operators, emergency response protocols, fire safety systems, equipment maintenance schedules and clear referral pathways. HBOT should not be introduced into facilities that cannot meet basic safety and monitoring requirements. This is consistent with US Food and Drug Administration (FDA) safety advice emphasising manufacturer instructions, fire-prevention measures, staff training, patient monitoring during treatment, cleaning procedures, maintenance intervals, safety checks, and control of prohibited items in HBOT chambers [12]. Medical oxygen infrastructure is also a major implementation issue in low-resource settings, where uninterrupted access to adequate oxygen volumes is not always available [60, 61].

Risk mitigation should begin before treatment. Patients should receive education on the purpose of HBOT, expected session duration, ear-pressure equalisation, symptoms to report, glucose monitoring and the importance of completing standard DFU care alongside HBOT. Clinical teams should use standardised checklists before each session to assess blood glucose, respiratory symptoms, ear or sinus problems, wound status, infection signs and treatment tolerance. The IWGDF practical guideline emphasises structured patient and staff education, standardised assessment, multidisciplinary treatment and close monitoring as core strategies for reducing the burden of diabetes-related foot disease [26].

Staff training is essential. Clinicians, nurses, chamber operators and biomedical technicians should be trained to recognise and manage barotrauma, oxygen toxicity, hypoglycaemia, anxiety, chamber malfunction and fire hazards. Fire safety is especially important because HBOT involves oxygen at high concentration, which increases fire risk. Facilities should prohibit flammable materials and unauthorised electronic devices inside chambers, conduct routine safety drills and maintain equipment according to manufacturer and regulatory standards [12].

Safety monitoring should be linked to quality improvement. HBOT programs should record adverse events, treatment interruptions, missed sessions, chamber downtime, oxygen supply failures and emergency responses. These data are necessary to determine whether HBOT can be delivered safely and sustainably in SSA referral settings [26]. Table 3 summarises key adverse effects of HBOT and mitigation strategies for DFU care in SSA.

7 | Health-System Implementation and Policy Implications for Sub-Saharan Africa

Clinical efficacy and health-system feasibility are distinct questions. Evidence that HBOT may improve outcomes in selected patients does not establish that the intervention will be effective, affordable or equitable when transferred to SSA. Most pivotal trials were conducted in settings with established multidisciplinary wound care, vascular assessment, reliable utilities, trained hyperbaric personnel and mechanisms that supported repeated treatment attendance. Implementation in SSA should therefore be considered only as a selective, referral-level intervention and should be evaluated locally before broader adoption.

7.1 | Minimum Readiness and Integration With Standard DFU Care

Systemic HBOT is an infrastructure-dependent intervention. Safe and consistent delivery requires a functional hyperbaric chamber, a reliable supply of medical-grade oxygen, stable electricity with appropriate backup power, monitoring and emergency equipment, fire-safety systems, trained personnel, biomedical engineering support and sustainable maintenance arrangements. These requirements are particularly important in settings where oxygen systems may already face power interruptions, equipment failure, limited technical expertise, maintenance barriers and supply-chain constraints [12, 61, 62]. Introduction of HBOT should therefore be preceded by assessment of whether these requirements can be sustained without compromising oxygen availability for essential services such as emergency care, surgery, obstetrics, neonatal care and critical care.

A chamber purchase alone does not create a functioning HBOT program. Recurrent maintenance, safety governance, trained staff, reliable utilities, emergency preparedness and access to replacement parts determine whether treatment can be delivered safely over time. For this reason, initial evaluation is most defensible in tertiary or referral centres where hyperbaric infrastructure and multidisciplinary diabetic foot services already exist or can be supported without weakening essential services.

HBOT should not function as an isolated technical service. Appropriate use requires coordination among clinicians responsible for diabetes and wound care, surgical teams, vascular services where available, nurses, hyperbaric personnel and biomedical technicians. Multidisciplinary DFU care should therefore be functional before HBOT is introduced. Patients should have access to wound assessment, debridement, infection management, pressure offloading, glycaemic management, vascular assessment or referral where indicated, and patient education [10, 11, 44, 47]. HBOT cannot compensate for untreated infection, inadequate pressure relief or unaddressed macrovascular ischemia.

7.2 | Economic, Access, Treatment-Completion and Equity Considerations

The economic implications of HBOT extend beyond chamber acquisition. Health-system costs include equipment purchase and installation, facility modification, oxygen, electricity, staffing, training, maintenance, safety inspections, consumables, emergency preparedness and equipment downtime. A technically available chamber may therefore remain unsustainable if oxygen, maintenance, staffing or replacement parts cannot be financed consistently.

Appropriate referral is central because the clinical evidence does not support indiscriminate use. Referral pathways should document ulcer severity and duration, infection, ischemia, prior offloading and debridement, vascular assessment and revascularisation options, glycaemic management and response to standard care [10, 44, 47]. Where vascular assessment or revascularisation is unavailable, it becomes difficult to distinguish a potentially oxygen-responsive wound from one in which uncorrected macrovascular ischemia is the dominant problem.

Regional literature describes limited access to specialised foot care, delayed presentation, treatment cost and gaps in multidisciplinary services [63, 64]. These weaknesses may reduce the real-world effect of HBOT even if a biological treatment effect exists because the intervention depends on timely selection and concurrent high-quality wound care.

TABLE 3 | Adverse effects of HBOT and mitigation strategies for DFU care in SSA.

Adverse effect	Description	Risk considerations	Mitigation strategies
Middle-ear or sinus barotrauma	Pressure-related injury affecting the middle ear or sinuses. Symptoms may include ear pain, pressure, hearing changes or sinus discomfort.	More likely in patients with upper respiratory tract infection, chronic sinus disease, poor Eustachian tube function or inability to equalise pressure.	Screen ear/sinus symptoms; teach pressure equalisation; use controlled compression/decompression.
Pulmonary barotrauma	Rare pressure-related lung injury that may occur during compression or decompression.	Higher risk in patients with severe chronic obstructive pulmonary disease, emphysema, air trapping or untreated pneumothorax.	Screen for respiratory disease; obtain specialist input for high-risk lung disease; follow decompression protocols; ensure emergency response readiness.
Oxygen toxicity	Toxicity from exposure to high oxygen concentrations under pressure; may affect the central nervous system or lungs.	Central nervous system (CNS) toxicity may rarely cause seizures; pulmonary toxicity is uncommon with standard DFU treatment durations but may occur with prolonged exposure.	Use established pressure/time protocols; continuous observation; trained emergency response.
Hypoglycaemia	Low blood glucose during or after HBOT sessions.	More likely in patients using insulin or insulin secretagogues, those with poor oral intake or unstable glycaemic control.	Check glucose according to local protocol and clinical risk; treat low glucose before chamber entry.
Claustrophobia or anxiety	Psychological distress caused by the chamber environment.	May lead to treatment refusal, interruption or non-completion.	Provide pre-treatment counselling, chamber familiarisation, symptom monitoring.
Reversible myopia or visual changes	Temporary refractive changes associated with repeated HBOT sessions.	More likely after multiple sessions; usually improves after treatment ends.	Inform patients before treatment; monitor symptoms; refer for ophthalmologic evaluation if symptoms persist.
Fire hazard	Oxygen-rich environments increase combustion risk if safety rules are not followed.	Risk increases with poor chamber maintenance, flammable materials, unsafe clothing, oils, electronic devices or inadequate staff training.	Control ignition sources/materials; staff competency; maintenance, drills and emergency procedures.
Treatment non-completion	Failure to complete the prescribed HBOT course.	May result from cost, transport burden, anxiety, adverse effects, distance from facility or competing work/family demands.	Assess feasibility before initiation; support transport planning where possible; monitor attendance; address adverse effects early.

Note: Risk mitigation should be adapted to local facility capacity, but safety standards should not be compromised. HBOT should be delivered only where trained personnel, oxygen supply, equipment maintenance, emergency response and fire safety procedures are available.
Abbreviations: CNS, central nervous system; DFU, diabetic foot ulcer; HBOT, hyperbaric oxygen therapy; SSA, sub-Saharan Africa.

Available evidence on the cost-effectiveness of adjunctive HBOT in diabetic foot disease is limited and heterogeneous and is derived predominantly from non-SSA settings [65]. Such estimates should not be transferred directly to SSA because equipment costs, oxygen supply, electricity reliability, staffing, reimbursement, baseline DFU care, transportation, rehabilitation and the costs associated with amputation differ substantially between health systems. HBOT should therefore not be described as cost-saving or cost-effective in SSA in the absence of locally generated evidence.

Opportunity cost is especially important in resource-constrained health systems. Investment in HBOT must be considered alongside competing priorities such as routine foot screening, wound-care supplies, offloading devices, antibiotics, vascular services, surgical capacity, glucose monitoring, rehabilitation, prosthetic services and patient education. Even if HBOT benefits selected individuals, its broader public-health value may be limited if the same resources could achieve greater population benefit by strengthening established DFU prevention and treatment services.

Treatment completion is a related clinical and implementation concern. HBOT commonly requires repeated attendance over several weeks, creating direct and indirect costs associated with transportation, accommodation, food, lost income, caregiver time and time away from work. Treatment non-completion was substantial even in one major European randomised trial [49], and the burden may be greater where patients travel long distances to tertiary facilities. A treatment that is technically available but cannot be completed is unlikely to reproduce outcomes observed in controlled trials.

Access and equity should therefore be assessed alongside economic efficiency. Concentrating HBOT in major urban referral centres may favour patients who live nearby, have insurance or greater financial resources or can afford repeated travel and treatment-related expenses. Without effective referral and financial-protection mechanisms, HBOT could widen existing rural–urban and socioeconomic disparities in access to advanced DFU care [2, 17, 63, 64]. Evaluation should therefore examine who is referred, who initiates treatment, who completes the prescribed course, and which clinical, geographic or socioeconomic barriers explain non-completion.

Within the literature identified for this review, SSA-focused studies primarily describe DFU burden, infection, access and broader health-system barriers rather than randomised evaluations of systemic HBOT. The clinical effectiveness, safety, treatment-completion rate, patient cost and cost-effectiveness of systemic HBOT in SSA therefore remain direct evidence gaps and should not be assumed from studies conducted in better-resourced settings.

7.3 | Priorities for Local Evaluation and Phased Implementation

Given the limited SSA-specific evidence, initial use of HBOT should occur through carefully monitored referral-centre pilot programs rather than immediate broad scale-up. Established implementation-science approaches, including the Consolidated Framework for Implementation Research (CFIR), the Reach, Effectiveness, Adoption, Implementation, and Maintenance (RE-AIM) framework and Proctor's implementation outcomes framework, may help structure such evaluations [66–68]. However, the central policy questions are whether HBOT produces meaningful local clinical benefit, can be delivered and completed safely, is affordable to patients and health systems, and can be implemented without worsening inequities.

Local evaluation should focus on six core domains. Clinical effectiveness should determine whether adjunctive HBOT improves clinically meaningful outcomes when added to optimised standard DFU care. Treatment completion should assess whether eligible patients can realistically complete the prescribed course despite transportation, financial, occupational and service-delivery barriers. Safety should include systematic recording of adverse events, treatment interruptions, oxygen-supply failures, chamber downtime and emergency responses. Patient costs should capture transportation, accommodation, out-of-pocket payments, caregiver costs and income lost through repeated attendance. Budget impact should determine whether the total recurrent cost of providing HBOT is affordable within available hospital, insurer or public-health resources. Equity should assess whether referral, initiation and treatment completion differ according to geographic location, socioeconomic circumstances or other factors that could systematically exclude otherwise eligible patients.

These outcomes should determine whether further investment is justified. Broader implementation should be considered only where locally generated evidence indicates that HBOT provides clinically meaningful benefit for appropriately selected patients, can be delivered and completed with acceptable safety, does not impose unreasonable financial burdens on patients or health systems, and does not worsen existing inequalities in access to DFU care. Where these conditions cannot be demonstrated, investment should remain focused on strengthening established components of comprehensive diabetic foot prevention and management.

8 | Limitations

This review has several limitations. First, it was designed as a critical narrative review rather than a systematic review or meta-analysis. Therefore, it does not provide pooled estimates of HBOT effectiveness, formal risk-of-bias scoring or certainty-of-evidence grading. Although a structured search strategy was used, study selection and synthesis involved interpretive judgement.

Second, the search was limited mainly to English-language publications, which may have introduced language bias and excluded relevant non-English studies, reports or regional evidence. Publication bias is also possible because studies with positive HBOT findings may be more likely to be published than studies showing limited or no benefit.

Third, direct SSA-specific clinical evidence on systemic HBOT for DFUs remains sparse. Most clinical evidence comes from

non-SSA settings with better access to vascular services, multidisciplinary wound care, hyperbaric infrastructure, reimbursement systems, reliable oxygen supply and rehabilitation services. Therefore, findings from these settings may not be directly transferable to SSA.

Fourth, the HBOT evidence base is heterogeneous. Studies vary in ulcer severity, ischemia status, Wagner grade, infection burden, revascularisation status, standard-care quality, treatment pressure, session frequency, number of completed sessions, sham comparators, outcome definitions and follow-up duration. This limits direct comparison across studies and makes it difficult to identify which patients are most likely to benefit.

Finally, the economic and implementation conclusions are policy-informing rather than definitive. Data on HBOT costs, affordability, patient transport burden, treatment completion, chamber utilisation, oxygen reliability and budget impact in SSA are limited. Therefore, recommendations for HBOT implementation should be interpreted as a framework for cautious pilot evaluation, not as evidence supporting immediate broad scale-up.

9 | Conclusion

HBOT may have a role as an adjunctive therapy for carefully selected patients with advanced, ischemic, neuro-ischemic, infected or non-healing DFUs after optimised standard care has failed. Its biological rationale is plausible, but clinical evidence remains heterogeneous, benefits are not consistent across all DFU populations, and direct SSA-specific clinical evidence remains sparse. Therefore, HBOT should not be promoted as a universal, first-line, stand-alone or automatically cost-saving intervention for DFUs in SSA.

In SSA, the responsible use of HBOT depends on health-system readiness as much as clinical eligibility. Safe implementation requires reliable medical-grade oxygen, stable electricity, trained personnel, functional chambers, maintenance capacity, emergency protocols, fire-safety systems, referral pathways, financing mechanisms and integration with multidisciplinary DFU care. Foundational DFU services, including prevention, routine foot screening, offloading, debridement, infection control, vascular assessment, glycaemic optimisation, rehabilitation and patient education, should be strengthened before HBOT is introduced.

Given the high cost of HBOT and limited SSA-specific evidence, implementation should proceed only through carefully monitored referral-centre pilot programs. These pilots should assess patient eligibility, treatment completion, wound healing, amputation outcomes, adverse events, patient costs, transport burden, chamber utilisation, cost-effectiveness, budget impact and equity of access. Until local evidence demonstrates clinical benefit, safety, affordability and sustainability, HBOT should remain a promising but selective adjunct rather than a substitute for comprehensive diabetic foot care.

Future research should determine which DFU patients in SSA are most likely to benefit from HBOT, whether the therapy is cost-effective in local health-system contexts, and how access can be expanded without worsening rural–urban and socioeconomic inequities.

The study contributes to global diabetic foot and health-system literature by shifting the HBOT debate from efficacy alone to responsible implementation in resource-constrained settings. Its central argument is that HBOT should be considered in SSA only where it strengthens, rather than diverts resources from, comprehensive DFU prevention and care.

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The authors have nothing to report.

Conflicts of Interest

The authors declare no conflicts of interest.

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