



July 19, 2017

American Diabetes Association
Board of Directors
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An open letter to the American Diabetes Association board of directors

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Dear ADA board of directors:

The Undersea and Hyperbaric Medical Society (UHMS), American College of Hyperbaric Medicine (ACHM), Canadian Undersea and Hyperbaric Medical Association (CUHMA), European Undersea and Baromedical Society (EUBS), European Committee on Hyperbaric Medicine (ECHM), the Societa Italiana di Medicina Subacquea ed Iperbarica (SIMSI), the Sociedade Brasileira de Medicina Hiperbárica (SBMH), Southern African Underwater and Hyperbaric Medical Association (SAUHMA), the Hyperbaric Society of India (HSI), the Swedish Wound Healing Society (SHWS) and the South Pacific Underwater Medical Society (SPUMS) have been made aware of the following position statement from the ADA that is to be released in the upcoming year.

The American Diabetes Association's annual Standards of Medical Care in Diabetes provides comprehensive guidelines for clinicians caring for people with diabetes. The Standards are developed by the Professional Practice Committee (PPC), a multi-disciplinary team of 12 leading experts in the field of diabetes care. On an annual basis, the PPC conducts a comprehensive review of all areas of diabetes care, including foot and wound care. The PPC reviewed the available data on the use of hyperbaric oxygen therapy in 2016 and did not identify enough supporting data on the efficacy of this treatment to recommend its use. The PPC continues to review all treatment options available for people with diabetes with evidence-based criteria for potential inclusion the Association's Standards of Medical Care, a resource for providers and people with diabetes to guide diagnosis and treatment.

William T. Cefalu, MD, Chief Scientific, Medical & Mission Officer of the American Diabetes Association

We take issue with the conclusions of the statement – especially without the benefit of any references or analysis which one would hope would accompany the statement – and would like the opportunity to address our concerns with the members of the PPC in charge of the comprehensive review of the hyperbaric medicine literature, as well as members of the ADA board of directors.

As the leading scientific and medical specialty organizations in our respective countries, we bear the responsibility of objectively analyzing the existing literature in order to provide the most reasonable recommendations to patients and providers. There are several randomized controlled trials [1-9], a plethora of observational studies[9-22], and an abundance of meta-analyses and systematic reviews of the hyperbaric medicine literature with regard to treatment of diabetic foot ulcers[23-35]. It is beyond the scope of this letter to conduct yet another meta-analysis of the literature, but the statement that “there is not enough supporting data” to recommend the use of hyperbaric oxygen therapy for diabetic foot wounds belies the fact that the majority of the research is positive. The negative results are largely based on two recently published studies[3, 36] that have either corrupt data[37-39] or poor design[40-44]. We strongly believe that the statement by the ADA is based on fundamentally flawed research and will serve as a detriment to the millions of people worldwide who currently live with a diagnosis of diabetes.

Based on the existing reliable evidence [1-35], the question that we should be asking is not *whether* hyperbaric oxygen is effective for DFU, but *for which DFU* is HBO₂ an effective adjunctive therapy. This has been recently addressed in Europe[45, 46], and the UHMS and ACHM, with the input of the international scientific societies in the field of hyperbaric medicine, commit to developing appropriate use standards based on sound scientific research.

In conclusion, we request a meeting with Dr. Cefalu and the PPC to discuss our concerns about the ADA’s interpretation of the literature, petition the ADA board of directors and the PPC to consider amending or revising the ADA position statement, demand a list of scientific references and/or analyses that has led the PPC to their current negative position on the use of adjunctive HBO₂ therapy for the treatment of select DFUs, and ask for a public comment period before making the ADA position final. Anything short of this demonstrates a lack of both transparency and scientific discourse.

Sincerely,



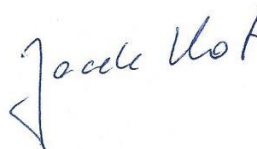
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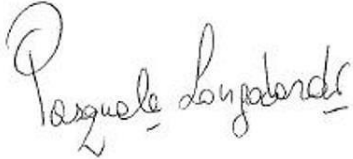
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