

Narrative Time-Line
On Submission of Diabetic Foot Ulcers
For New CMS Hyperbaric Oxygen Indication
First New Indication in 18 years

Timeline of IHMA's original submission and subsequent actions to get Diabetic Foot Ulcers approved. This landmark decision was important because this is the first new indication to be added by Medicare for HBOT in over 18 years. This means more hyperbaric clinics opening across the nation, needless amputations have been significantly lowered, and is an important building block for other hyperbaric indications to be recognized and added for treatment and insurance reimbursements.

The then interim IHMA Vice-President, Dr. Paul Harch, compiled and presented over 125+ articles, with the Argument that the submission was based on science regarding reduction of amputation rate and cost effectiveness before the CMS committee.

June 2001 Attend UHMS meeting in San Antonio, TX and make presentation to the Hyperbaric Oxygen Committee on approval of acute traumatic brain injury as an accepted indication. At the last minute I learned that my appearance was nearly blocked by individuals on the Executive Committee who did not want to allow my presentation because I was a non-member. Decision, however, was granted in my favor due to the fact that I was presenting a scientific argument that should override political issues.

The application was disgracefully rejected and no explanation given; however, accounts of the meeting after I was ushered from the room and not allowed to defend the argument revolved around the proposition of Dr. Michael Bennett that the approval process needed to be revised and until new rules could be instituted my application should be rejected. Interestingly, my application, according to the scoring systems of both Gottlieb and the American Heart, scored amongst the highest of any accepted indications. (See actual scoring and argument in this Folder).

Immediate consultations were secured with a variety of individuals, including Dr. William Duncan and Ken Locklear. For some time I had had discussions about forming a new medical society to circumvent the arbitrary nature of the UHMS and the non-scientific approach to hyperbaric oxygen therapy for neurological applications. The impetus to do so was the strong encouragement of Dr. Duncan.

Specifically, there seemed to be a double standard that was rooted in political bias and personal hatred of Dr. Richard Neubauer. The IHMA was formed in the final weeks of June and officers were identified. Originally Dr. Bill Maxfield was to be the president of the IHMA and I was to be the vice-president. Meetings were immediately scheduled with the FDA, CMS, and representatives from the NIH through Dr. Duncan.

Narrative Time-Line
On Submission of Diabetic Foot Ulcers
For New CMS Hyperbaric Oxygen Indication
First New Indication in 18 years

- June 29, 2001 Meetings with the FDA occurred and a meeting with Dr. John Whyte, the deputy director of CMS. Ken Locklear, the new executive director of the IHMA and Dr. William Duncan were in attendance. Two major issues were discussed:
- 1) I was asking for the methodology required for submission of new hyperbaric indications for CMS coverage.
 - 2) In addition, we wanted to address the onerous physician attendance interpretation that had proliferated at the fiscal intermediary state level. Dr. Whyte informed us that the approval process required solid clinical data. I had originally wanted to present as many as four new indications but after hearing his requirements it became obvious that we likely had data for only two. He referred me to Kate Tillman of CMS for submission of this application. Regarding the physician attendance, he acknowledged the problems and vowed to help correct the process.
- 1st wk. July '01 I make e-mail and phone contact with Kate Tillman and discuss submission of new indications by the IHMA. She notifies me that they currently wanted to address all of the hyperbaric issues in this coming year and so there was some urgency to quickly submit my requests such that they could proceed expeditiously. She said that the UHMS had recently submitted a request for hypoxic wound. I told her that I don't believe we would be endorsing that; however, I would get back with her. We end up trading some e-mails.
- Jul-Aug '01 I notify Dr. Keith Van Meter of the IHMA's intent to submit request for indications to CMS. He notified me that the UHMS had submitted a request on hypoxic wound or was in the process of submitting one and that possibly we could join together and have a common submission. I informed him that my knowledge of the science was that it was insufficient and inadequate to obtain an indication, based on Dr. Whyte's recommendations to me. He asked that I call Carolyn Fife, which I promptly did and we again discussed this issue. I asked if she had any new data which I was unaware of and she referred me to Dr. Paul Sheffield. The conversation with Dr. Sheffield ensued and he indirectly confirmed my impression that we had no new data and that the data we did have was fairly sparse and weak.
- Late July '01 I decide that the IHMA will not submit a request for hypoxic wound to CMS. I then table my efforts temporarily to make my presentation to the Neubauer 2001 symposium in late July.
- August 2001 Upon return from Neubauer's conference I quickly contact Kate Tillman and tell her that I am still going to submit this, to please allow me sufficient time. I then

Narrative Time-Line
On Submission of Diabetic Foot Ulcers
For New CMS Hyperbaric Oxygen Indication
First New Indication in 18 years

asked her for a deadline and she said that she needed this within the next few months. Again, she said that CMS will only be considering all the hyperbaric issues this year and then after that will probably not re-evaluate hyperbaric medicine for five years.

- Sept-Oct '01 I assemble the scientific argument for what I consider the strongest indication, diabetic foot wounds. I construct an argument that includes 129 references. (See bibliography in this Folder).
- Nov. 1, 2001 The argument is submitted to Kate Tillman on behalf of the IHMA.
- Mid-Nov. '01 Kate Tillman responds that they will temporarily hold my application while they fully consider hypoxic wounds since they were not going to consider diagnosis-specific indications yet. Once the hypoxic wound decision is made, they will then accept diagnosis indications.
- Late Dec. '01 The hyperbaric community is informed that hypoxic wounds have been rejected by CMS.
- Jan. 2002 I inquire about the progress of my diabetic foot wound application. Kate Tillman informs me that the UHMS submitted an application in early January for diabetic foot wounds and that was the current application they were acting upon. I then reminded her of our e-mails and my submission to her in November, her response, and the fact that I had this application in and we wanted it considered as well. She then incorporates my scientific argument into the application and proceeds accordingly. She also notified me at the very end of January that they had been waiting for over thirty days for the criteria for inclusion from the UHMS. She said that they had not been able to get response from any of the individuals. Within 48 hours I submitted criteria on behalf of the IHMA.
- Feb. 2002 Kate Tillman attempts to schedule a meeting with all interested parties, i.e., the UHMS and the IHMA. The only weekend that could be accommodated was the end of March/very early April due to multiple UHMS representatives attending a conference in Baltimore and their convenience demanded for an extended weekend on the tail end of the conference. When I informed her that I was the original one who submitted the application she acknowledged such but said that she wanted to try to accommodate all parties. As a result, I made the accommodation to fly in on their weekend.
- Early April '02 A meeting is held between all interested parties, which include representatives from the UHMS and myself representing the IHMA. All parties were situated

Narrative Time-Line
On Submission of Diabetic Foot Ulcers
For New CMS Hyperbaric Oxygen Indication
First New Indication in 18 years

around tables that were set up in a rectangular format. On one long side of the room were the CMS officials including Kate Tillman, Dr. Ronald Deicas – an M.D., Ph.D., ophthalmologist – and Dr. Jeffrey Suren – the director of the division – who is a neurologist. I was seated to the left of those individuals and a lengthy discussion ensued on the diabetic foot submission. Multiple contributions were made by a number of individuals including some very impassioned statements and one outburst, demanding from the CMS people: “What do you people need to get an approval, we have submitted a phenomenal amount of data and you now have rejected hypoxic wound!”.

CMS officials then asked for summary statements from everybody and proceeded counterclockwise. Since I was on the far left-hand side, I was the last to give a summary statement. Since none of the previous arguments had addressed the scientific argument that I had submitted to CMS, I had withheld a significant comment until the very end. I then addressed the CMS representatives and told them that this entire submission was based on the argument that hyperbaric oxygen therapy could reduce major amputations in diabetic foot wounds.

I then asked them if they could deny to us today that the scientific evidence showed that hyperbaric oxygen reduced such amputations. Dr. Deicas came out of his chair to state that: well, yes, they agreed – and as he started to say *agree*, he stopped short and they all smiled, at which time they said, well, that is the argument of the submission and that is what we’ll be reviewing and we will give you a decision within a few short months. The obvious conclusion to this meeting was that the scientific argument upon which the submission was based was, in fact, solid and that they could not deny that the evidence showed a reduction in major amputation.

I left this meeting convinced that we had an excellent chance at approval of the first new indication in 18 years, based purely on the science and the level of evidence Dr. Whyte instructed me to present for a new indication.

Ensuing months CMS is contacted by Representative Istook’s office and information presented by both them in support of the diabetic foot wound indication and the Amputee Coalition.

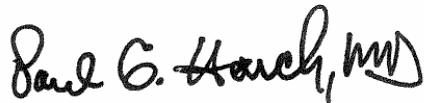
Summer 2002 Decision memorandums are issued by CMS stating that they will be approving diabetic foot wounds for hyperbaric oxygen therapy. The rules are then issued and the effective date for beginning this is stated as April 1, 2003.

Narrative Time-Line
On Submission of Diabetic Foot Ulcers
For New CMS Hyperbaric Oxygen Indication
First New Indication in 18 years

In summary, the IHMA submitted an application for approval of diabetic foot wounds for hyperbaric oxygen therapy to CMS in November of 2001, based on meetings with the deputy director of CMS, who instructed the interim vice-president of the IHMA, Dr. Paul Harch, on the levels of scientific evidence necessary for approval of a new indication.

Decision was made by the IHMA vice-president to take the most solid shot at approval with the strongest evidence rather than to face a near-certain rejection with hypoxic wounds. While hypoxic wound was being rejected, the IHMA submitted this application.

The argument upon which the application was based became the foundation argument that CMS acknowledged and upon which they based approval of diabetic foot. In his summary statement at the meeting in April of 2002 with the CMS officials, Dr. Harch, again, restated the scientific argument and asked if this argument could be refuted. The CMS officials essentially acknowledged the strength of this and subsequently approved diabetic foot wounds.

A handwritten signature in black ink that reads "Paul G. Harch, M.D." with a stylized flourish at the end.

Paul G. Harch, M.D.
August 2004

PGH/pr