

DIABETES AND RECREATIONAL DIVING: GUIDELINES FOR THE FUTURE

Workshop Proceedings



Jointly Sponsored by the
Undersea and Hyperbaric Medical Society
and
Divers Alert Network

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June 19, 2005

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Undersea and Hyperbaric Medical Society
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Pollock NW, Uguccioni DM, Dear GdeL, eds. Diabetes and recreational diving: guidelines for the future. Proceedings of the Undersea and Hyperbaric Medical Society/Divers Alert Network 2005 June 19 Workshop. Durham, NC: Divers Alert Network; 2005.

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Durham, NC 27705

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This diving safety workshop and the publication of this document were jointly sponsored by the Undersea and Hyperbaric Medical Society and Divers Alert Network.

Opinions and data presented at the Workshop and in these Proceedings are those of the contributors, and do not necessarily reflect those of the Undersea and Hyperbaric Medical Society or Divers Alert Network.

Cover design by Rick Melvin, DAN Communications.

ISBN 978-0-09673066-9-8

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UNDERSEA AND HYPERBARIC MEDICAL SOCIETY

www.uhms.org

The UHMS is an international, nonprofit organization serving over 2,500 members from more than 50 countries. Most UHMS members are diving or hyperbaric scientists and physicians. Associate members are nurses, technicians, respiratory therapists and others who work in the field of diving and hyperbaric medicine.

The Undersea and Hyperbaric Medical Society (UHMS) is the primary source of information for diving and hyperbaric medicine physiology worldwide. It was founded as the Undersea Medical Society in 1967 but in 1986 changed the name to Undersea and Hyperbaric Medical Society. The name change reflects the rapidly growing interest in hyperbaric oxygen physiology and therapy. The UHMS's purpose is to provide scientific information to protect the health of sport, military and commercial divers and to improve the scientific basis of hyperbaric oxygen therapy, promote sound treatment protocols and standards of practice and provide CME accreditation.

DIVERS ALERT NETWORK

www.diversalertnetwork.org

Divers Alert Network (DAN[®]) is a 501(c)(3) nonprofit dive safety organization associated with Duke University Health Systems in Durham, N.C. Since 1980, DAN has served as a lifeline for the scuba industry by operating the industry's only 24-Hour Diving Emergency Hotline, a lifesaving service for injured scuba divers. Additionally, DAN operates a Dive Safety and Medical Information Line, conducts vital dive-related medical research and develops and provides a number of educational programs for everyone, from beginning divers to medical professionals.

DAN is supported through membership dues and donations. In return, members receive a number of benefits, including access to emergency medical evacuation, travel and personal assistance for both diving and non-diving needs, DAN educational publications, a subscription to *Alert Diver* magazine and access to diving's premier dive accident insurance coverage. DAN currently has well more than 200,000 members worldwide.

The DAN Vision

Striving to make every dive, accident- and injury-free.

The DAN Mission Statement

DAN helps divers in need with medical emergency assistance and promotes diving safety through research, education, products and services.

ACKNOWLEDGMENTS

Thanks are due to UHMS and DAN for co-sponsoring the workshop, to all those who participated in the workshop and, particularly, to those who made presentations and prepared written papers. Special appreciation is extended to Dr. Simon Mitchell for presenting the “straw man,” which provided structure for the workshop discussion; and to all who contributed comments and suggestions during the iterative drafting of the final document.

Additional thanks to Cindi Easterling and Lisa Wasdin for their skillful logistics management; Jaime Adams, Jessica Adams, Kayla Donnawell and Sheila Modi for their proofreading assistance; and Rick Melvin for cover art.

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UNIT CONVERSIONS

$$1.0 \text{ m} = 3.28084 \text{ ft}$$

$$1.0 \text{ ft} = 0.3048 \text{ m}$$

$$1.0 \text{ mmol}\cdot\text{L}^{-1} = 17.98561 \text{ mg}\cdot\text{dL}^{-1}$$

$$1.0 \text{ mg}\cdot\text{dL}^{-1} = 0.0556 \text{ mmol}\cdot\text{L}^{-1}$$

$$1.0 \text{ kcal} = 0.0041868 \text{ MJ}$$

$$1.0 \text{ MJ} = 238.8459 \text{ kcal}$$

GUIDELINES FOR DIABETES AND RECREATIONAL DIVING

A workshop addressing issues of diabetes and recreational diving was jointly sponsored by the Undersea and Hyperbaric Medical Society (UHMS) and Divers Alert Network (DAN) to bring together experts and interested parties from within and beyond the international diving community. The meeting was held on June 19, 2005 in Las Vegas, Nevada, USA, following the UHMS annual scientific meeting. The objectives of the workshop were to review the existing data and, as warranted by participant support, to develop consensus guidelines to address diabetes and recreational diving. More than 50 individuals from seven nations, mostly clinicians and researchers, participated in the discussions.

Limitations: 1) The discussion was restricted to recreational diving. The issues concerning professional diving require future, separate deliberations. 2) This is a set of guidelines, not rules. The participants agreed that appropriate and justifiable differences in acceptable procedures may exist and that interest groups must have the flexibility to use the guidelines as they best serve their community's needs.

The guidelines were divided into three sections: 1) selection and surveillance of people with diabetes in scuba diving; 2) scope of diving by people with diabetes; and 3) glucose management on the day of diving. Individual divers must bear responsibility for their health and safety and for adherence to established guidelines developed to improve their protection and that of their dive partners. Divers with diabetes are encouraged to participate in relevant research studies to expand the data available concerning diving with diabetes. Anyone with questions should consult with physicians knowledgeable in both diving medicine and diabetes care.

Section 1. Selection and Surveillance

Those evaluating persons with diabetes for medical fitness to dive must first ensure that no other exclusionary conditions (e.g., epilepsy, pulmonary disease) exist. The physiological demands of diving must then be considered. Coronary artery disease is a leading cause of death in the largely non-diabetic diving population. Immersion may result in increased myocardial wall stress. There may also be a reduced awareness of ischemic symptoms. People with diabetes are at higher risk of medical complications such as myocardial infarction, angina and hypoglycemia than the general diving population. Such risks are exacerbated by the fact that many dive sites are quite isolated from medical aid. While only some medications increase the risk of hypoglycemia, all persons with diabetes are at risk of secondary complications of the disease.

Recreational scuba diving may be undertaken by candidates otherwise qualified to dive who use medication (oral hypoglycemic agents [OHAs] or insulin) to treat diabetes provided the following criteria are met.

1.1. Age 18 years and over (limit may be lowered to 16 years if special training* is available)

*special training will include dive training programs designed specifically to meet the education needs of individuals with diabetes and, desirably, to include participation by parents and/or responsible family members or guardians.

1.2. For a new diver at least three months have passed since the initiation or alteration of treatment* with OHAs or one year since the initiation of treatment with insulin. An established diver using OHAs who is started on insulin should wait at least six months before resuming diving.

*“alteration of treatment” is defined as a change in medication(s) or dosage(s) that could result in significant deviations from current status (changes likely to include only moderate change from current status would be described as “adjustment of treatment”).

1.3. There should have been no episodes of hypoglycemia or hyperglycemia requiring intervention from a third party for at least one year, and no history of hypoglycemia unawareness. Note: certain OHAs (e.g., metformin, acarbose), when used on their own, do not predispose to hypoglycemia.

1.4. Glycosylated hemoglobin (HbA_{1c} - a measure of plasma glucose stability over the past two to three months) should be $\leq 9\%$ when measured no more than one month prior to initial assessment and at each annual review. If HbA_{1c} $>9\%$ the diver should contact his/her diabetes specialist for further evaluation and modification of therapy.

1.5. There should be no: retinopathy worse than nonproliferative; significant autonomic or peripheral neuropathy; nephropathy causing proteinuria; coronary artery disease or significant peripheral vascular disease. Patients with retinopathy, peripheral vascular disease and/or neuropathy have a higher risk of sudden death due to coronary artery disease. Retinal hemorrhage could be precipitated by small changes in mask pressure during descent and ascent or equalizing maneuvers. Patients with neuropathy may experience exaggerated hypotension when exiting the water. Peripheral vascular disease may alter inert gas washout and predispose an individual to limb decompression sickness.

1.6. No more than two months prior to the first diving medical assessment and at each annual evaluation, a review is conducted by the candidate’s primary care physician (knowledgeable in treating diabetes) who must confirm that: criteria 1.3 – 1.6 are fulfilled; the candidate demonstrates accurate use of a personal blood glucose monitoring device; and that the candidate has a good understanding of the relationship between diet, exercise, stress, temperature, and blood glucose levels.

1.7. No more than two months prior to commencing diving for the first time and at each annual review, a diving medical examination is completed, preferably by (or in consultation with) a doctor who has completed an accredited post-graduate diving medical examiner’s course*. The review report completed by the primary care physician must be available. It is strongly recommended that formal evaluation for silent ischemia be undertaken for candidates over 40 years in accordance with U.S. American Heart Association/American College of Cardiology or equivalent guidelines.

*Any accredited course (one certified as fulfilling certain standards by a national and/or regional professional association) in diving medicine is acceptable

1.8. At the diving medical examination, the candidate acknowledges in writing the receipt of and intention to use the diabetic diving protocol; the need to seek further guidance if there is any material that is incompletely understood; and the need to cease diving and seek review if there are any adverse events associated with diving suspected to be related to diabetes.

1.9. Steps 1.1 – 1.8 must be completed annually, using the same physicians where possible. After the initial evaluation, periodic surveillance for silent ischemia can be in accordance with accepted guidelines for evaluation of diabetics.

Section 2. Scope of Diving

Persons with diabetes selected according to Section 1 of this document who satisfactorily complete a recognized diver training course are considered suitable for recreational diving. The following stipulations and strong recommendations regarding diving activity and methods apply.

- 2.1. It is recommended that dives do not involve depths greater than 30 meters of sea water (100 fsw), durations longer than one hour, compulsory decompression stops, or take place in overhead environments. The depth limit is to avoid situations in which narcosis could be confused with hypoglycemia. The time limit is to moderate the time blood glucose would remain unmonitored. The decompression and overhead environment limits are to avoid situations in which direct and immediate access to the surface is not available.
- 2.2. Divers with diabetes should dive with a buddy/leader who is informed of their condition and is aware of the appropriate response in the event of a hypoglycemic episode. It is recommended the buddy does not have diabetes.
- 2.3. It is recommended that divers with diabetes avoid combinations of circumstances that might be provocative for hypoglycemic episodes such as prolonged cold and arduous dives.

Section 3. Glucose Management on the Day of Diving

Divers with diabetes who are selected according to Section 1 of this document, and who participate in appropriate diving activity as specified in Section 2, should use a protocol to manage their health on the day of diving. Note: the blood glucose monitoring protocols are applicable to people with diabetes whose medication may put them at risk of hypoglycemia.

- 3.1. For every day on which diving is contemplated, the diver should assess him or herself in a general sense. If he or she is uncomfortable, unduly anxious, unwell in any way (including seasickness), or blood glucose control is not in its normal stable pattern, DIVING SHOULD NOT BE UNDERTAKEN.
- 3.2. The suggested goal for the diabetic approaching any dive is to establish a blood glucose level of at least $150 \text{ mg}\cdot\text{dL}^{-1}$ ($8.3 \text{ mmol}\cdot\text{L}^{-1}$), and to ensure that this level is either stable or rising before entering the water. The workshop recommends that this be determined by three measurements of blood glucose, ideally taken 60 minutes, 30 minutes and immediately prior to diving. Diving should be postponed if blood glucose is $<150 \text{ mg}\cdot\text{dL}^{-1}$ ($8.3 \text{ mmol}\cdot\text{L}^{-1}$), or there is a fall between any two measurements.
 - a. Where relevant, strategic and individually tailored reductions in dosages of OHA medication or insulin on the evening prior or on the day of diving may assist in meeting these goals. Initial testing of individual protocols should be conducted under very controlled circumstances.
 - b. Where relevant, a regimen of incremental glucose intake to correct inappropriate pre-dive levels or trends may assist in meeting these goals.
- 3.3. It is recommended that diving should be postponed or cancelled if blood glucose levels are higher than $300 \text{ mg}\cdot\text{dL}^{-1}$ ($16.7 \text{ mmol}\cdot\text{L}^{-1}$).

- 3.4. Divers with diabetes should carry oral glucose in a readily accessible and ingestible form at the surface and during all dives. It is strongly recommended that parenteral glucagon is available at the surface. The dive buddy or other person at the surface should be knowledgeable in the use of glucagon. If symptoms or indications of hypoglycemia are noticed underwater, the diver should surface, establish positive buoyancy, ingest glucose and leave the water. An informed buddy should be in a position to assist throughout this process. Use of an “L” signal with the thumb and index finger of either hand is recommended as a signal for suspected hypoglycemia.
- 3.5. Blood glucose levels should be checked at the end of every dive. Appropriate response to the measured level can be determined by the individual mindful of his or her plans for the rest of the day. It should be noted that the requirements for blood glucose status outlined in 3.2 remain the same for any subsequent dive. In view of the recognized potential for late decrements in blood glucose levels following diving it is strongly recommended that the level is checked frequently for 12-15 hours after diving.
- 3.6. Divers with diabetes are strongly recommended to pay particular attention to adequate hydration on days of diving. Elevated blood glucose will lead to increased diuresis. While the data are limited, there is some evidence from divers with diabetes that an increase in hematocrit observed post-dive (suggesting dehydration) can be avoided by deliberate ingestion of fluid.
- 3.7. Divers with diabetes should log all dives, associated diabetic interventions and results of all blood glucose level tests conducted in association with diving. This log can be used to refine future planning in relation to diving.

2005 DIABETES AND RECREATIONAL DIVING WORKSHOP: EXECUTIVE SUMMARY

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Historically, the diving medicine community has maintained a conservative position and concluded that insulin-requiring diabetes mellitus (IRDM) should be an absolute contraindication for participation in scuba diving. Dissent for this view has grown over the last 20 years. Recognizing that a substantial number of divers are diving successfully with diabetes – either openly or surreptitiously – has lead many to believe that it is time to acknowledge this fact and reexamine the position concerning diabetes and diving.

This diabetes and diving workshop was jointly sponsored by the Undersea and Hyperbaric Medical Society (UHMS) and Divers Alert Network (DAN) to bring together experts and interested parties from within and beyond the international diving community. Co-organizers were Dr. Guy Dear, Dr. Neal Pollock and Ms. Donna Uguccioni. The meeting was held on June 19, 2005 in Las Vegas, Nevada, USA, following the UHMS annual scientific meeting. The objectives of the workshop were to review the existing data and, if deemed appropriate by discussants, to produce consensus guidelines addressing diabetes and recreational diving. More than 50 individuals from seven nations, mostly clinicians and researchers, participated in the discussions. The list of participants and their affiliations are found at the end of the proceedings document.

Nine invited speakers described data and experience gathered from around the world. Dr. Guy Dear (USA) provided the opening remarks. Mr. Steve Prosterman (USVI) provided an invaluable description of his personal experience both with diabetes and with diabetes and diving. Dr. Eugenio Cersosimo (USA) presented an overview of the current state of the art in clinical management of diabetes mellitus. Dr. Chris Edge (UK) reviewed 14 years of data, totaling approximately 14,000 dives, from United Kingdom divers diving with diabetes. Dr. Dan Lorber (USA) represented the American Diabetes Association and presented an overview of discrimination and legal advocacy issues pertinent to persons with diabetes. The final paper appearing in this document was edited and approved by the ADA advocacy group. Ms. Donna Uguccioni (USA) reviewed 12 years of data gathered through DAN-affiliated efforts, including surveys, workshops and observational studies. Dr. Duke Scott (USA), the medical director for the YMCA SCUBA program, described the American YMCA program that has been used to train persons with diabetes to dive for the past 10 years. Dr. Alexis Tabah (France) shared research data from two field studies on divers with diabetes conducted in France and reviewed the recently developed national regulations allowing recreational diving by persons with diabetes. Dr. Warren Silberman (USA) described the U.S. Federal Aviation Administration's nine-year-old policy allowing special issuance of medical certificates to individuals with diabetes for third-class (noncommercial) aviation licenses. Dr. Simon Mitchell (NZ) closed the presentation portion of the meeting by delivering a draft list of guidelines for diving with diabetes developed from the published literature.

The edited transcript of the workshop reveals the depth of discussions and controversy surrounding each of the guidelines presented below. Some points were easily settled and others more contentious, but all were finally decided through compromise and consensus. The general level of agreement for each point is indicated in this summary.

The workshop participants agreed that the available data supported the position that at least some individuals with diabetes might reasonably be allowed to dive. There was no open dissent on this fundamental issue. The discussion focused on the specifics of who and how.

Two important issues were raised at the start of the discussion. The first concerned the scope of the deliberations. It was agreed that the discussion was to be limited to recreational diving. The issues concerning professional diving require future, separate deliberations. The second issue concerned the nature of the product that would be produced by the group effort. It was agreed that a set of guidelines, not rules, would be generated. The participants agreed that appropriate and justifiable differences in acceptable procedures may exist and that interest groups must have the flexibility to use the guidelines as they best serve their community's needs.

The draft list delivered by Dr. Mitchell served as a "straw man" to guide the discussion. The consensus guidelines, like the draft form, were grouped under three sections: selection and surveillance, scope of diving, and glucose management on the day of diving.

The **selection and surveillance** section began with general text indicating the importance of screening for other exclusionary conditions (e.g., epilepsy, pulmonary disease) and careful consideration of the context in which diving might be conducted. This includes immersion, the potential for extremely remote diving locations, and the high normal risk of cardiac involvement in diving fatalities. The section then addressed limits on age (18 years or older with the possibility of lowering to 16 years with special training), frequency of medical evaluation (at least annually), minimum periods of time from point of initiation or alteration of treatment to start or return to diving (three months from initiation or alteration of treatment with oral hypoglycemic agents and one year since the initiation of treatment with insulin), allowable history of hypoglycemic or hyperglycemic events requiring third party intervention (none within past year), hypoglycemia unawareness (no history allowed), recent glycosylated hemoglobin ($\text{HbA}_{1\text{c}}$) scores (further evaluation and possibly modification of therapy recommended for values >9 percent), and secondary complications (none can be significant). The section also addressed the importance of having candidates demonstrate a good understanding of diet, exercise, stress, temperature and blood glucose levels and the need for silent ischemia screening. Finally, the section addressed the need to have candidates agree to follow diabetic diving protocols and to stop diving and seek review for any adverse events that may be related to diabetes.

Several aspects pertaining to the minimum age for training were discussed. The merits of involving family members in training and in providing positive reinforcements to persons with diabetes were recognized. The need to be consistent with applicable public rules was also discussed.

The selection of appropriate minimum durations between initiation or alteration of treatment was contentious. Discussants favored a variety of intervals. The final wording reflected the more conservative position.

The importance of disqualification based on recent history of extreme hypoglycemia, hyperglycemia or hypoglycemia unawareness were widely accepted. Similarly, the importance of a solid understanding of the disease, personal responsibility and a willingness/ability to conduct appropriate self-monitoring

were all widely accepted. The option to recommend disqualification based on a history of emergency visits to hospital for any condition related to the diabetes was discussed and rejected.

The necessity for an HbA_{1c} criterion was contentious. Some felt that it was not an appropriate criterion; others preferred a range of high and low cutoff values. Key considerations included recognition that the tightest control might be associated with a greater frequency of hypoglycemic events and the utility of the measure for counseling purposes. The final wording reflected a relatively inclusive limit.

The discussion of secondary complications of diabetes reflected the importance of monitoring and protecting the long term health of persons with diabetes. The relatively high frequency of cardiac involvement in diving incidents and the potential for accelerated development of coronary artery disease in persons with diabetes was addressed with a strong recommendation for silent ischemia screening for candidates over 40 years of age. The guideline text regarding secondary complications and silent ischemia screening was kept general in recognition of the limitations of available research data and potential regional/national differences in screening and evaluation standards. This section is expected to evolve as additional data become available.

The value of annual medical evaluation and the importance of the diver taking personal responsibility in managing his or her disease were generally accepted. There was discussion regarding the appropriate recommendations for physician training. While the abilities of fully trained diabetologists and diving medical officers were appreciated, practical limitations on the availability of specialty-trained physicians were also recognized. It was decided that accepting physicians knowledgeable in treating diabetes and physicians who had completed any post-graduate course in diving medicine was appropriate at this time.

The **scope of diving** section addressed limits on dive depth (100 fsw [30 msw]), decompression obligation and overhead environments, dive time (<60 min), the need to inform dive partners of their condition and the appropriate response to adverse events, the diabetic status of the buddy diver (recommended to not have diabetes), and recommendations on avoiding situations that may promote or exacerbate hypoglycemic events.

The discussants widely agreed that divers with diabetes should avoid situations which restrict direct access to the surface (notably dives with obligatory decompression or in overhead environments), those that could create conditions potentially confused with hypoglycemic symptoms (specifically nitrogen narcosis), and those expected to increase the likelihood of hypoglycemic events (e.g., prolonged cold and arduous dives).

There was more debate regarding maximum dive times. Positions favored a variety of recommended maximums and the discretion of the individual. The final wording on the dive time reflects a compromise between the extreme views. Options to include guidelines on a maximum number of dives to be carried out in a given day and/or a minimum surface interval between dives were discussed and rejected.

The discussants widely agreed that it is important for divers with diabetes inform their dive partners of their condition. There was more debate regarding the propriety of two divers with diabetes diving together. A comment was made that two divers with diabetes may be diving in a larger group. The final wording of the recommendation favored a conservative position.

The **glucose management on the day of diving** section began by noting that the blood glucose monitoring protocols are applicable to people with diabetes whose medication may put them at risk of hypoglycemia. The section then addressed the importance of self-assessment to ensure readiness to dive, as recommended for all divers, and several procedures specific to diabetes management. Advance preparation included individually tailored pre-dive modification of oral hypoglycemic agents or insulin and carbohydrate ingestion, attention to hydration, and critical health self-assessment prior to diving. Measurement standards included minimum pre-dive blood glucose levels ($150 \text{ mg}\cdot\text{dL}^{-1}$ [$8.3 \text{ mmol}\cdot\text{L}^{-1}$]), repeated pre-dive blood glucose measures to ensure a stable or rising trend (nominal planned monitoring at approximately 60 min, 30 min and immediately pre-dive), maximum pre-dive blood glucose levels ($300 \text{ mg}\cdot\text{dL}^{-1}$ [$16.7 \text{ mmol}\cdot\text{L}^{-1}$]), and post-dive blood glucose testing (repeated throughout a 12-15 hour post-dive period). Intervention supplies to have available included ingestible oral glucose and parenteral glucagon. Record keeping addressed logging dives, blood glucose test results and diabetic interventions associated with diving.

The discussants widely agreed on the importance of most elements in this section: a self-assessment of health preceding diving; both divers and buddies carrying a readily accessible and ingestible form of oral glucose; divers surfacing before ingesting glucose if needed; the availability of parenteral glucagon at the surface; the strategic tailoring of medication regimens in conjunction with diving (worked out in advance of diving or under highly controlled circumstances); serial pre- and post-dive blood glucose checks; incremental correction of sub-optimal blood glucose levels; adequate hydration; and the logging of dives and all information pertinent to diabetes management.

Controversy surrounded the reasonable frequency of pre-dive blood glucose measures, the need to specify pre-dive blood glucose ranges, the optimal and acceptable ranges of pre-dive blood glucose, and the appropriate duration of post-dive blood glucose monitoring. Arguments for recommending minimal obligatory monitoring and greater freedom for the diver were largely based on the record of relatively trouble-free diving by minimally monitored persons with diabetes registered in the United Kingdom. Arguments for greater obligatory monitoring and tighter controls favor the potential for the guidelines to be more useful to persons, both divers with diabetes and medical professionals, who may have less experience with diabetes management and/or diving. The final wording of the recommendations reflected the conservative position of requiring repeated blood glucose tests and definitive minimum and maximum values.

The draft text of the guidelines was completed by the end of the workshop. The draft text was refined after the meeting by the workshop planners. The refined text and an edited transcript of the discussion were then distributed to participants electronically. Each was invited to provide comment. Changes were circulated to stimulate further electronic discussion. The guidelines provided at the beginning of this proceedings document represent the final text produced after integration of all input received. An abbreviated version of the final guidelines appears in Table 1.

The participants in this workshop viewed the guidelines as a work in progress. We fully expect further refinements or even substantial modifications as our understanding of the issues involved in diving with diabetes evolves. It is important that any individual who has questions should consult with physicians knowledgeable in both diving medicine and diabetes care.

Future progress will be facilitated by efforts in two directions. The first is continued support and promotion of initiatives to collect data relevant to diabetes and diving. The second is development of programs and relationships to educate individuals with diabetes who are diving or interested in diving and those who might be professionally involved with divers with diabetes. The latter group includes certifying agencies, dive professionals, medical monitors addressing qualification issues and emergent needs, and the general diving public.

Table 1: Guidelines for Recreational Diving with Diabetes - Summary Form¹

Selection and Surveillance
<ul style="list-style-type: none"> ▪ Age ≥ 18 years (≥ 16 years if in special training program) ▪ Delay diving after start/change in medication <ul style="list-style-type: none"> ○ 3 months with oral hypoglycemic agents (OHA) ○ 1 year after initiation of insulin therapy ▪ No episodes of hypoglycemia or hyperglycemia requiring intervention from a third party for at least one year ▪ No history of hypoglycemia unawareness ▪ HbA_{1c} $\leq 9\%$ no more than one month prior to initial assessment and at each annual review <ul style="list-style-type: none"> ○ values $>9\%$ indicate the need for further evaluation and possible modification of therapy ▪ No significant secondary complications from diabetes ▪ Physician/Diabetologist should carry out annual review and determine that diver has good understanding of disease and effect of exercise <ul style="list-style-type: none"> ○ in consultation with an expert in diving medicine, as required ▪ Evaluation for silent ischemia for candidates >40 years of age <ul style="list-style-type: none"> ○ after initial evaluation, periodic surveillance for silent ischemia can be in accordance with accepted local/national guidelines for the evaluation of diabetics ▪ Candidate documents intent to follow protocol for divers with diabetes and to cease diving and seek medical review for any adverse events during diving possibly related to diabetes
Scope of Diving
<ul style="list-style-type: none"> ▪ Diving should be planned to avoid <ul style="list-style-type: none"> ○ depths >100 fsw (30 msw) ○ durations >60 min ○ compulsory decompression stops ○ overhead environments (e.g., cave, wreck penetration) ○ situations that may exacerbate hypoglycemia (e.g., prolonged cold and arduous dives) ▪ Dive buddy/leader informed of diver's condition and steps to follow in case of problem ▪ Dive buddy should not have diabetes
Glucose Management on the Day of Diving
<ul style="list-style-type: none"> ▪ General self-assessment of fitness to dive ▪ Blood glucose (BG) ≥ 150 mg·dL⁻¹ (8.3 mmol·L⁻¹), stable or rising, before entering the water <ul style="list-style-type: none"> ○ complete a minimum of three pre-dive BG tests to evaluate trends <ul style="list-style-type: none"> ▪ 60 min, 30 min and immediately prior to diving ○ alterations in dosage of OHA or insulin on evening prior or day of diving may help ▪ Delay dive if BG <ul style="list-style-type: none"> ○ <150 mg·dL⁻¹ (8.3 mmol·L⁻¹) ○ >300 mg·dL⁻¹ (16.7 mmol·L⁻¹) ▪ Rescue medications <ul style="list-style-type: none"> ○ carry readily accessible oral glucose during all dives ○ have parenteral glucagon available at the surface ▪ If hypoglycemia noticed underwater, the diver should surface (with buddy), establish positive buoyancy, ingest glucose and leave the water ▪ Check blood sugar frequently for 12-15 hours after diving ▪ Ensure adequate hydration on days of diving ▪ Log all dives (include BG test results and all information pertinent to diabetes management)

¹ For full text see: Pollock NW, Uguccioni DM, Dear GdeL, eds. Diabetes and recreational diving: guidelines for the future. Proceedings of the UHMS/DAN 2005 June 19 Workshop. Durham, NC: DAN; 2005.

OPENING REMARKS

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Good morning, ladies and gentlemen. I would like to welcome you to the “Diabetes and Recreational Diving: Guidelines for the Future” workshop. The most important aspect is that we get all of you involved today.

This is the first Divers Alert Network-Undersea and Hyperbaric Medical Society workshop on diabetes and diving. We hope to produce guidelines that can be used by recreational divers with diabetes, their caregivers, and dive professionals to allow this small but important group to take part in the sport that most of us know, love and enjoy. Diabetes, as you know, has long been banned in diving, along with other diseases that have been classified as relative or absolute contraindications to diving. The suggested reason, of course, is that we think the diabetes might cause loss of consciousness underwater. Whether or not this is likely has yet to be determined.

Diabetes is becoming more common. While the rate of diagnosis is increasing, there is also a true increase in prevalence. Around 10 to 12 percent of the current U.S. population is afflicted, with variable rates across age groups. We are going to hear more about current trends from our speakers.

Is the ban reasonable? A complete ban, that currently exists, is certainly unreasonable without convincing research evidence. There are some formal studies that have examined the issue of diving with diabetes, and we will hear about those from our speakers. Diabetes is a continuous spectrum of disease with those requiring insulin at the peak. But we need to address all of the patients with diabetes in this spectrum. If we erect hurdles to control that population with diabetes, we can say that those with minor disease would pass over any hurdle but those with severe symptoms may fall at the first hurdle. The guidelines that we produce need to be concise, simple and effective.

The plan is to set the stage with the presentations of Steve Prosterman and Eugenio Cersosimo. We will then take a short break. Chris Edge, Dan Lorber, Donna Uguccioni, Duke Scott and Alexis Tabah will follow to complete the morning session.

Warren Silberman will present the first afternoon presentation and Simon Mitchell from New Zealand will close the presentation with a “straw man” set of guidelines that we will then attack, debate, and deliberate.

The floor will be open through the discussion period, and we want full participation from everybody here. If feasible, we would like to produce a final set of guidelines by day’s end. It is going to be the summer solstice on June 21 so we should have plenty of daylight, although I hope we do not run on and on.

I want to briefly introduce the faculty. The first speaker is Stephen Prosterman. He is the diving supervisor and captain at Camp DAVI (Diabetes Association of the Virgin Islands). He is the founder and director of that program. Many individuals with diabetes have had fun diving in the Virgin Islands under his guidance.

Our keynote speaker is Eugenio Cersosimo, Associate Professor of Medicine and Medical Director of clinical research at the very prestigious Texas Diabetes Institute. He is world-renowned in diabetes research and we are looking forward to his exposition.

We will then hear from Chris Edge, an anaesthetist and old friend of mine from Cambridge days, and a diving physician based in Oxford and London. He is also on the BSAC (British Sub-Aqua Club) Medical Council.

Dan Lorber is a Clinical Assistant Professor at the Weill Medical College of Cornell and a member of the American Diabetes Association National Board, Advocacy Committee and Legal Advocacy Subcommittee.

Donna Uguccioni has been involved in DAN research projects for many years and with the DAN diabetes projects from the first field study.

Duke Scott has been the Medical Director of YMCA Scuba for a number of years. He authored the YSCUBA Protocol for Divers with Diabetes. The SSI SCUBA program also adopted this program a few years ago to allow those with diabetes to dive.

Alexis Tabah is joining us from Paris, where he works at St. Joseph Hospital. Those of you who were at the UHMS meeting heard a very interesting presentation he made on the French experience. He also presented at the European Underwater Baromedical Society meeting in Corsica last year.

Ole Hyldegaard from Denmark intended to present additional data from Europe but was unable to join us due to a family emergency.

Warren Silberman is the manager of aerospace medical certification for the U.S. Federal Aviation Authority (FAA). We will get a view from the cockpit from him as we consider the effects below sea level.

Finally, Simon Mitchell is a diving and hyperbaric physician based in Auckland, New Zealand. He is widely published in the diving literature. Parenthetically, he holds the world record for the deepest wreck dive - to a shipwreck at 600 feet [183 m] off Brisbane.

I do want to thank the other members of the crew who helped put this all together. Neal Pollock has been indefatigable in getting everything organized. Cindi Easterling has been our continuing medical education (CME) coordinator and has kept us on track. Thanks to you all. Of course, I could not leave without mentioning Mike Curley of DAN, who has been very supportive of the whole mission, as well as the UHMS staff, Don Chandler and Lisa Wasdin.

So, let's go diving. One comment from the Kings Regiment of the UK, "nec aspera terrent" – difficulties be damned!

Thank you.

INSIGHTS OF A DIVING INSTRUCTOR TEACHING AND MANAGING DIABETES

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I am currently the diving officer at the University of the Virgin Islands (UVI). I also ran the hyperbaric chamber at Roy Schneider Hospital in the eighties and started doing it again a few years ago. I have held my U.S. Coast Guard captain's license since 1984 and was a paramedic from 1983 to 1989, after training with the Miami-Dade Fire Department.

I have had Type 1 diabetes since 1966 with no complications. My glycosylated hemoglobin (HbA_{1c}) levels have always reflected excellent control, from 5.9 to 6.2 percent, at the top end of the normal range for healthy persons without diabetes. I attribute that primarily to being physically active my whole life. I think that regular exercise is one of the most important aspects in good diabetes control.

Insulin therapy is a huge part of diabetes control. I have used fast-acting insulins along with a long-lasting basal type insulin as long as these products have been available. I now use Humalog (insulin lispro), similar to Novolog (insulin aspart), both fast acting insulins, with Lantis as a basal rate insulin. This has been called the poor person's pump, employing basal long-lasting insulin plus additional doses of fast-acting insulin around mealtimes to cover food intake. I take about eight units of Lantis in the morning and eight units at night as my basal dose. I take about 5-6 units of Humalog at each meal. This can change depending on my blood glucose, activity level before or after the meal, and/or meal size and carbohydrate content of the meal.

Normally, I check blood glucose six to eight times a day. On particularly active days, if, for example, I am diving a lot, this may increase to 10 to 12 times or more per day. This is my formula for keeping diabetes under control - exercise, good insulin therapy and frequent blood glucose testing. Insulin is simply a tool to keep blood glucose under control.

I am active in many sports, water sports such as wind surfing, sea kayaking, ocean swimming and other sports that also warrant good blood glucose control such as climbing, biking, basketball, juggling and unicycling.

I have been diving since 1979 and an instructor since 1982. I have made well over 6,000 dives, most of them as an instructor, and have had no problems diving.

I became a dive instructor at a time when the agencies were just starting to consider putting restrictions on individuals with diabetes. Over the course of my diving career, I have learned that there are many individuals with diabetes who dive, including dive shop owners and instructors. The majority have not gone public. I am one of the few who have come out of the closet. The numbers are definitely underreported.

Some of the diabetics I have met have had great control of their disease, including professional triathletes competing in the Hawaii Iron Man triathlon (2.4 mile [3.86 km] swim, 112 mile [180 km] bike, 26.2 mile [42.2 km] run). You need to know yourself and your disease to complete a nine to fifteen hour (or longer) Iron Man race. Conversely, there are others who are not in control or very smart about their diabetes, particularly in combination with diving. Most have been lucky, but I believe education is needed to take the necessity for luck out of the process.

Meeting some of these individuals has made me realize how easy it can be to hide your diabetes from others. It is not visible or obvious. Diabetics can even mislead doctors for a while. It is possible to bring your blood glucose into the 120 to 112 mg·dL⁻¹ (6.7 to 6.2 mmol·L⁻¹) range just prior to an appointment.

I came to realize the dangers of hiding the disease. In addition to not having anyone prepared to help in the event of an emergency, the isolation keeps the person from learning as much as he or she can about diving with diabetes.

The organization that was most helpful in my early education was the International Diabetes Athletic Association (IDAA), later renamed the Diabetes Exercise and Sports Association (DESA). Attending meetings made me appreciate that there are more people out there like me - with diabetes but also very active, who know how to handle their activities. Prepared to do whatever is required to safely participate in activities; not wanting to be restricted unnecessarily.

Diabetes Camps

Diabetes camps have probably been the biggest part of my diabetes education. Working in camps provides the opportunity for regular exposure to the latest techniques and medications. All my major alterations in treatment have come at the camps; starting in the early 1980s when I went from one shot per day to multiple injections after I decided that I really wanted to control my diabetes.

One of the things I realized was that despite the value of group camps, there were few for kids beyond 16 years of age. Recognizing the potential for having health issues to take on a lesser priority without the proper peer influence, a program to target this underrepresented group seemed like a great idea.

I started and ran Camp DAVI, Diabetes Association of the Virgin Islands, from 1989 to 1998. Based in St. John, Virgin Islands, it became a great all around water sports camp. The property was an old research station that the university controlled after taking it over from the U.S. military. The location is isolated and the facilities are fairly rustic. I was able to act like a drill sergeant and have people exercise a lot, usually far in excess of their normal patterns. Between the exercise and the good diet, we frequently saw great reductions in insulin needs. Seeing positive gains while being able to participate in hiking, trail running, snorkeling, sea kayaking, small boat sailing, swimming and scuba diving offered excellent positive reinforcement.

The camp started with college age participants and was then opened up to anyone 16 years or older. Younger kids are allowed if one of their parents plays an active role and also participated in the camp. The youngest camper I had was 14 years of age, accompanied by his father. Everyone learns and benefits. The program is very active, offering numerous learning opportunities and putting the responsibility for control on the camper.

Starting in 1991 I decided to open up the camp to people older than college age. While most campers were young adults, we did have some “full” adults. My oldest camper was 64. We had just as good camaraderie across age spans as within age groups.

The first year of the camp, 1989, we made a total of about 70 person-dives. We had 10 people who dived once per day for seven days. One dive was aborted when a diver developed symptomatic hypoglycemia while underwater. We decided that the easiest way to signal a sense of low blood glucose was to give an "L" sign with thumb and index finger (forefinger). It is simple and not easily mistaken for any other standard diving signal.

We typically average around 15 blood tests per day per person; sometimes only 10 or 12; sometimes 20. If we are getting ready to dive and someone has a blood glucose out of range, it is managed and retested until it gets to where we want it. This can require a lot of tests in a short period.

Divers all have to carry a glucose source in a waterproof package. We have tried many variations. The original homemade versions have now been replaced by a variety of commercially available options. Insta-glucose is quite popular; providing good packaging and a reasonable snack/bolus with 22 grams of carbohydrates.

The next, and most important step in our evolution was recognizing the importance of following the trends in blood glucose. We found that home glucose monitoring devices gave us great power. We could make sure that the levels were stable or moving in the appropriate direction.

We started requiring multiple pre-dive blood measures in 1990. We would usually do tests one hour before, 20 to 30 minutes before, and then immediately before the dive. We also required post-dive testing. That was quite educational. The drops were sometimes surprising. A diver might go in with a blood glucose of $250 \text{ mg}\cdot\text{dL}^{-1}$ ($13.9 \text{ mmol}\cdot\text{L}^{-1}$) and would come out with a value of $120 \text{ mg}\cdot\text{dL}^{-1}$ ($6.7 \text{ mmol}\cdot\text{L}^{-1}$). That was initially unexpected. Some of this could be attributed to inexperience, but similar large drops reported by other researchers (Dear et al., 2004) confirm that vigilance is required.

Being in a group of divers that were all diabetic meant that it was not a problem to delay the dive to accommodate blood glucose adjustment. This is very different from the experience one might expect with a typical dive operation. Everyone understood the situation in our case and could learn from each controlled event.

Our goal was to elevate stable blood glucose slightly above the normal range pre-dive, typically to $150\text{-}180 \text{ mg}\cdot\text{dL}^{-1}$ ($8.3\text{-}10.0 \text{ mmol}\cdot\text{L}^{-1}$). The exact target is an individual decision. Each person learns to regulate his or her blood glucose for optimal effectiveness. If the blood glucose is falling it must be adjusted through carbohydrate snacks until rising or stable before diving. It is very important for the diver not to dive if the blood glucose is falling. If it is rising the dive can start when it is in the $130\text{-}150 \text{ mg}\cdot\text{dL}^{-1}$ ($7.2\text{-}8.3 \text{ mmol}\cdot\text{L}^{-1}$) range.

I must clarify that the targets are not always met. Pre-dive values can be quite high, particularly when the person is first adapting his or her control to the diving activity. It is my position that a temporary spike in blood glucose in someone who is generally under good control is not a problem. The fact that they do normally have good control motivates them to master the new circumstances. This was demonstrated in an observational study that we recently completed (Pollock et al., *in press*).

Over the next eight years we had approximately 80 divers complete a total of 600 dives. Other than the single case in the first year (before we were conducting multiple pre-dive blood tests), no dive had to be interrupted. Additionally, we did not have any cases of symptomatic hypoglycemia despite seeing fairly large glucose drops in some cases.

The American Diabetes Association (ADA) established a subcommittee to look at diving in 1994. Dr. Burghen, Dr. Lorber and other doctors represented the ADA; Tom Neuman represented the Undersea and Hyperbaric Medical Society (UHMS); and Joel Dovenbarger represented Divers Alert Network (DAN). This was also when DAN's interest increased and we put together a formal protocol based on the Camp DAVI protocol that was used in the three year DAN study (Dear et al., 2004). These were essentially the same guidelines that the ADA approved. These protocols were approved for no-decompression sport diving and have been informally adopted and used widely in the diving world by those diving with diabetes. The main component making these guidelines unique is the use of multiple tests to determine direction of the blood glucose.

Camp DAVI/ADA Protocol

The Camp DAVI/ADA protocol is summarized in Table 1.

Table 1: Camp DAVI/ADA Protocol for Divers with Diabetes

- HbA_{1c} must be <9.0% to show understanding of diabetes control
- Diabetes must be under good control with no severe hypoglycemic events within the past year
- Must be able to recognize and quickly treat hypoglycemia
- Must not have secondary complications of diabetes or other medical problems. These include major vessel disease of the lower limbs, kidney disease, serious retinal disease, and other complications that may put the diver at more risk for diving, such as heart disease, which is by itself contraindicated in diving.
- Buddy/Instructor should also be familiar with diabetes and treatment of hypoglycemia
- Person must understand the relationship between diabetes and exercise
- Both diver and buddy/instructor must always carry rapidly absorbable glucose in a waterproof package
- Minimum of three tests of blood glucose (BG) must be completed before every dive
 - 60 min, 20-30 min, and immediately pre-dive
- If BG is stable it should be at least slightly elevated before dive
 - 150-180 mg·dL⁻¹ (8.3-10.0 mmol·L⁻¹)
 - A rapidly absorbable carbohydrate snack must be eaten if BG falls in the pre-dive monitoring period
 - BG is to be re-checked 10-15 min later
- Divers are not to dive if the BG is falling
- If BG is rising, the dive can begin when the range of 130-150 mg·dL⁻¹ (7.2-8.3 mmol·L⁻¹) is reached
- If BG is "extremely high" or there are ketones present in urine, dive should be aborted until diabetes is under better control
- If diver feels hypoglycemic on dive he or she is to give "L" sign with thumb and index finger to buddy
 - diver and buddy will then slowly surface, inflate buoyancy compensator and ingest glucose; the dive is then aborted
- All diving should be no-decompression to allow for direct ascent to surface
- BG test should be completed post-dive to understand effect of diving

Participants were required to demonstrate that their diabetes was under at least moderate control. We decided that HbA_{1c} scores below nine percent indicated a good understanding of diabetes control. A lower value might now be appropriate. The nine percent limit was adopted before many of the modern insulins were available and before studies confirmed the long-term health benefits of keeping diabetes under very tight control. I expect that most of the diabetologists around the country are encouraging their patients to maintain much lower levels.

Participants must not have experienced severe hypoglycemic events within the past year. Of course, low blood glucose is the primary event we seek to avoid. It is especially important that they can recognize early and quickly treat hypoglycemia. It is not uncommon to see children still running around who, when checked, have blood glucose levels of 45 mg·dL⁻¹ (2.5 mmol·L⁻¹). Others will begin to feel symptoms of hypoglycemia between 100 and 120 mg·dL⁻¹ (5.6 and 6.7 mmol·L⁻¹). It is critical for the individual to understand his or her own patterns, to be able to recognize hypoglycemia, and treat it before it becomes problematic.

Candidates must not have any secondary complications of the disease or other medical problems that might further compromise the safety of diving.

It is imperative that the buddy and/or instructor be familiar with diabetes and the treatment of hypoglycemia. This was a practical benefit of involving family members in the camps. It was reassuring to have a trained buddy at the camp that I knew would continue to support the camper's diving. Well trained and prepared backup is important any time a person might need help.

Candidates for diving must understand the relationship between their diabetes and exercise. Diving does not normally involve intense exercise but the effort is equivalent to a walk or a hike. Sustaining this effort for 45 minutes can produce some substantial blood glucose drops. The effect can be exacerbated by diet, thermal stress or nervous stress.

The availability of fast-acting glucose is important, particularly if a dive ends up being more physically demanding than anticipated. Both the diver and his or her buddy (or instructor if that is the nature of the partnership) should carry at least one package of this glucose on every dive.

The minimum of three pre-dive blood tests is important to get a clear picture of the trend in blood glucose levels. Falling blood glucose can be easily corrected with a carbohydrate snack, normally 15 to 30 grams carbohydrates, depending on the person. Much will depend on the individual insulin therapies. If pre-dive blood glucose is stable, it should be slightly elevated before the dive to provide a bit of cushion. If the levels are extremely high (with the definition of 'extremely' being open to interpretation), or if there are ketones present in the urine, the dive should be aborted until the diabetes is under better control. We do not regularly conduct urine monitoring unless there is persistent high blood glucose or if an individual is ill. We did it every morning the first few years of the camp but later got away from that.

A diver who feels hypoglycemic at any point during the dive can easily communicate this with the "L" sign. The signal can be made with either hand. The response is simple; a quick okay and signal to ascend and the diver and buddy/instructor slowly surface, inflate their buoyancy compensators to establish positive buoyancy, ingest the glucose and then swim out or be picked up from the aborted dive.

Some divers might be tempted to take the glucose underwater. The additional hazards associated with self-administration underwater – pulling out and opening packages, potentially removing the regulator, and controlling delivery and volume – make this strategy less desirable, particularly for

novice divers. Training and guideline standards must take the conservative position and have divers ascend and establish positive buoyancy before ingesting glucose. Having said this, there have been products made to deliver liquid into the regulator at depth which could be incorporated into treatment using juice or some other high carbohydrate liquid. A high degree of in water experience and comfort and training with these products is required if they are to be used underwater.

Maximum depth and obligatory decompression are issues for the diver with diabetes. Diving should be limited to 100 feet (30 m) to avoid confusing hypoglycemia symptoms with nitrogen narcosis. No-decompression diving is important so the divers can ascend directly to the surface at any time without fear of additional complications.

Post-dive blood glucose testing is important for divers with diabetes to understand the impact of a given set of dive conditions on their blood glucose levels. This will enable them to refine their control. The choice of management techniques has a great impact on control and the ability to incorporate activities such as diving. I believe that it is important to use modern insulin therapies and multiple injections. I have seen most problems with the long-lasting insulin isophane (NPH) group of insulins that have predictable action in normal circumstances but less predictable action under less typical circumstances. The modern therapies integrating basal, long-lasting insulins with meal-time boluses provide more stable and predictable control.

The Closet Diabetic

I teach a lot of diving students at UVI who wish to augment their studies of marine biology. I often mention that I have diabetes and am happy to discuss my experience with those who are interested. I had one student who seemed to take more interest than most when he started his course. I believed that he had a brother with diabetes. One of our discussions included him saying that his brother did not like Humalog insulin and me saying how important it was to use modern insulin therapies and multiple injections.

I noticed during the first dive that this student was not following my instructions. He seemed to be ignoring me. You learn as an instructor that you must address such issues quickly. It is much easier to deal with problems before they escalate.

I brought him up to the surface to find that he was not fully lucid. At that point, I realized that all the diabetes discussions had been about himself. Fortunately, I had Insta-glucose in a pocket and was able to open the package quickly and squirt the contents into his mouth. Fortunately, the student suffered no harm.

This kind of situation could arise for many of us. The outcome could have been much worse, however, if it involved an instructor who did not recognize what was going on or did not have the means to quickly resolve the problem.

The fact that people may feel compelled to hide their disease is frightening. It leaves everyone unprepared and at much greater risk. The diving public needs to be educated - both those with diabetes and those who do not have diabetes. Understanding management techniques, learning to recognize early signs and symptoms of hypoglycemia, and following well tested protocols to be able to dive with greater confidence and safety are all critical elements. There are a lot of divers with diabetes; more so than most of us will ever know. A blanket ban has not proven to be reasonable and it is certainly difficult to enforce.

Education and research are the best strategies to minimize acute risk and promote long-term health. Given the appropriate tools, divers with diabetes will be more effective in taking responsibility for their disease, their safety, and the preparedness of their dive partners. We have a responsibility as dive educators and deciders of policy to make this a reality.

ACKNOWLEDGMENTS

Most of my knowledge of diabetes comes from practical experience and learning mainly through camping situations. I would like to thank Dr. George Burghen for his invaluable teaching of diabetes management and Mr. Robert Trouy who helped get me to become involved in diabetes camps and education.

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INSULIN THERAPY IN THE MANAGEMENT OF DIABETES MELLITUS

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This article will provide a review of the current principles and practice of the insulin treatment of individuals with diabetes mellitus, and provide background that will enable practitioners to promote safe and efficacious use of insulin replacement therapy in otherwise healthy, physically active people with diabetes who have an interest in diving.

Current Classification of Diabetes Mellitus

Diabetes mellitus is a condition characterized by elevations in blood sugar due to either an absolute deficiency or inappropriate action of the hormone insulin. In the absence of insulin, sugar cannot be utilized and stored properly in the body and, thus, it accumulates in the blood. As sugar spills into the urine people urinate frequently and develop tremendous thirst. Because calories are lost in the urine, these individuals are always hungry and they lose weight fast. Most diabetic patients, however, have a relative, not absolute, deficiency of the hormone insulin. In these cases, a high insulin demand by the abundant fat mass cannot be compensated for by the limited pancreatic production of insulin. As a result, storage and utilization of sugar and fat cannot be regulated normally, and circulating levels of sugar and fat are elevated. Having either absolute or relative insulin deficiency leads to chronic hyperglycemia with undistinguishable signs and symptoms and to both acute and chronic complications.

According to the American Diabetes Association (Expert Committee, 1997) there are essentially four types of diabetes mellitus. Type 1 diabetes with two subcategories: Type 1A with a definite autoimmune component and Type 1B with no evidence for an autoimmune process. Type 2 diabetes mellitus is the most prevalent type of diabetes worldwide and responsible for 90% of all diagnosis. Secondary diabetes is a category that lumps together everything else that does not fit into the other three categories; including diseases of the pancreas such as pancreatitis (alcoholic or chronic pancreatitis following pancreatic necrosis), streptozotocin-induced diabetes, post-pancreatectomy, and some other rare forms such as insulin and insulin receptor genetic defects, all of which can lead to hyperglycemia. Gestational diabetes mellitus is a state of glucose intolerance diagnosed during pregnancy, which often precedes the appearance of Type 2 diabetes mellitus. We will spend more time with the two most common forms of diabetes, Type 1 and 2.

Type 1 diabetes mellitus (T1DM) used to be called juvenile-onset diabetes or insulin-dependent diabetes mellitus (IDDM), but these terms are no longer appropriate. There are patients with Type 1 diabetes diagnosed in the adult life, and we are seeing more and more of Type 2 diabetes in young individuals. Although all patients with Type 1 diabetes do require insulin therapy for survival, approximately 50% of Type 2 diabetic patients are also expected to require insulin therapy as the

disease progresses. The absolute insulin deficiency is secondary to beta-cell destruction by an autoimmune process that can be detected in nearly 90% of all patients at the time of diagnosis (Type 1A). The remaining 10% of patients will develop absolute insulin deficiency by a currently unknown mechanism (Type 1B). Although there is no defined genetic transmission, some families have a predisposition for the disease, which probably reflects a contribution of the environment both *in utero* and after birth. Most patients with Type 1 diabetes are lean, young (<35 years of age) and are typically diagnosed during an episode of sudden illness. The presence of diabetic ketoacidosis (DKA) confirms the absolute lack of insulin, which is most frequently associated with Type 1 diabetes mellitus.

Type 1 diabetes mellitus represents about 10% of all diabetic patients, and it is estimated to affect nearly 1.5 million Americans. These are very relevant numbers, particularly if one considers that the majority of those afflicted are young and athletic individuals who have the most gain in terms of quality of life from adequate and safe insulin replacement regimens.

Type 2 Diabetes Mellitus (T2DM) used to be called adult-onset diabetes and non-insulin dependent diabetes (NIDDM), but for reasons mentioned above, these terms are inappropriate. Type 2 diabetes develops in individuals who have a combination of insulin resistance and relative insulin deficiency. Unlike Type 1 diabetes, there is often a strong positive family history in patients with Type 2 diabetes. Type 2 diabetes is believed to be a polygenic disorder and because there is nearly 100% concordance between homozygotic twins, the presence of diabetes in an immediate family member is essential for the diagnosis of Type 2 diabetes to be unquestionable. Type 2 diabetes affects primarily obese adult individuals above 35 years age, and is usually asymptomatic, or it may have a slow onset with mild hyperglycemia at diagnosis. The latter contrasts with the sudden illness typical of Type 1 diabetes mellitus.

The diagnosis is confirmed with fasting plasma glucose above $126 \text{ mg}\cdot\text{dL}^{-1}$ ($7.0 \text{ mmol}\cdot\text{L}^{-1}$) or a postprandial glucose value above $200 \text{ mg}\cdot\text{dL}^{-1}$ ($11.1 \text{ mmol}\cdot\text{L}^{-1}$). It is estimated that there are approximately 15 million Type 2 diabetic patients in the U.S. and 150 million worldwide. Simultaneous with the epidemic proportions of obesity, the number of Type 2 diabetic patients diagnosed and undiagnosed is growing considerably in the entire world.

Why Patients with Diabetes Require Insulin Therapy

It is easy to understand why patients with Type 1 diabetes require insulin for survival. Because they have an absolute deficiency, there is a need for insulin replacement. Without insulin, these individuals develop hyperglycemia with severe dehydration and DKA, acute complications that are associated with greater than 50% mortality. Insulin therapy has saved and prolonged many lives. The evolution of this therapy over the past 75 years has led us to recognize the importance of maintaining near-normoglycemia. This is necessary in order to reduce the appearance and the progression of diabetic chronic complications, namely the microvascular diseases, retinopathy, nephropathy, neuropathy, and the macrovascular diseases, myocardial infarction, stroke, and peripheral vascular diseases. There is overwhelming evidence to indicate that these chronic diabetic complications can be prevented or delayed with adequate glycemic control, resulting in a substantial decline in morbidity and mortality. In addition, modern insulin therapy improves in-hospital survival and long-term outcome after acute myocardial infarction, and enables pregnancy to term with uncomplicated delivery of healthy infants.

Results of the Diabetes Control and Complications Trial (DCCT) are summarized in Figure 1 (DCCT, 1993).

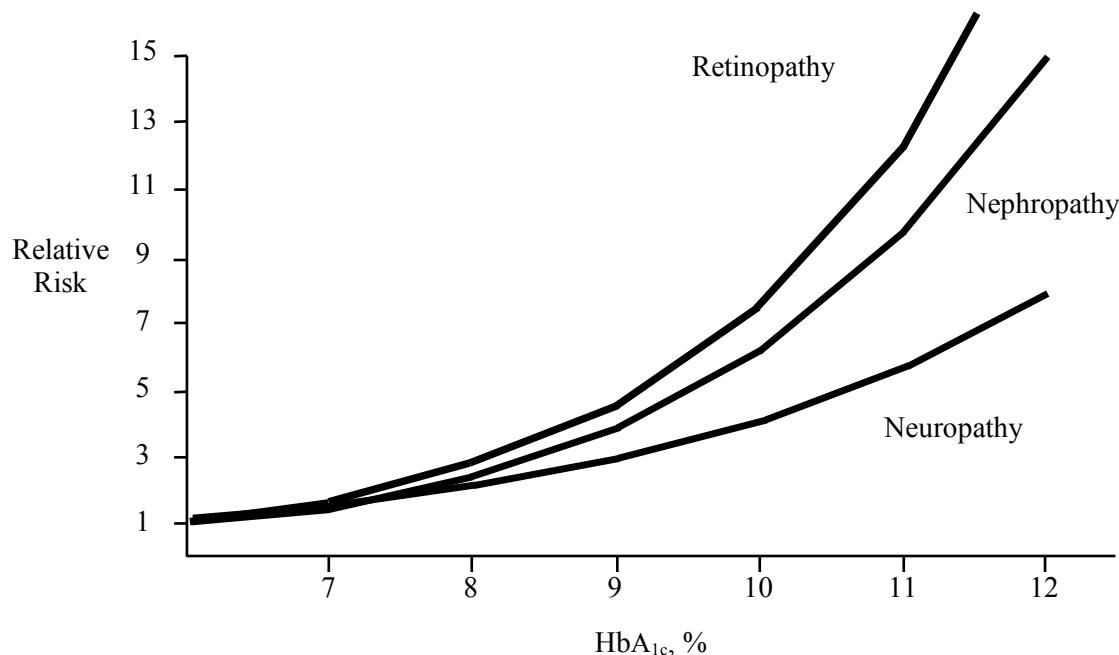


Figure 1: Diabetes control and complications trial: HbA_{1c} and microvascular complications (adapted from *N Engl J Med* 1993; 329[14]: 977-986).

The DCCT was a large, long-term study of approximately 1,500 patients with Type 1 diabetes followed for a 10 year period. The study clearly demonstrated the beneficial effects of aggressive control of hyperglycemia on the rates of appearance and progression of retinopathy, nephropathy and neuropathy. An overall 50 to 75% reduction in these microvascular complications was achieved with a mean hemoglobin A_{1c} (HbA_{1c}) of 7.2% in the intensive insulin-treated group. Note, moreover, that there was no threshold for the beneficial effects; any reduction in HbA_{1c} was accompanied by a decline in the rate of complications. It has been estimated that there is a 10 to 50% reduction in complications for every 1% decline in HbA_{1c}. Three independent studies have demonstrated significant benefits of comparable magnitude with an average 60 to 70% reduction in complications with a decrease in HbA_{1c} levels of ~2%: the DCCT of Type 1 diabetes (DCCT, 1993), the Kumamoto of lean Type 2 diabetes (Ohkubo et al., 1995), and the United Kingdom Prospective Diabetes Study (UKPDS) primarily of obese Type 2 diabetes (UKPDS, 1998). Comparable reductions of 20 to 30% were also seen in Type 2 diabetes in the UKPDS with only 1% lower HbA_{1c} levels. In the DCCT study, when all major cardiovascular and peripheral vascular events were combined, intensive therapy reduced the risk of cardiovascular disease by 41%, although this reduction was not statistically significant. The relative youth of the patient cohort made the detection of a difference between treatments unlikely. Of interest, the 16% reduced risk in the incidence of coronary heart disease in the UKPDS cohort had a p=0.052, not quite reaching statistical significance despite considerable clinical importance.

The results obtained in The Diabetes Mellitus Insulin Glucose Infusion in Acute Myocardial Infarction (DIGAMI) study (Malmberg, 1997) indicate that intensive insulin therapy reduces morbidity and mortality in hospitalized diabetic patients. This group investigated whether the prognosis of patients with diabetes mellitus and an acute myocardial infarction was improved by

intensive metabolic treatment of the myocardial infarction with insulin-glucose infusion for 24 hours followed by multi-dose subcutaneous insulin treatment, in addition to standard treatment. All-cause mortality was followed for a mean of 3.4 (range 1.6–5.6) years for the 306 patients who were randomly assigned to receive the intensive treatment and the 314 patients (controls) who received standard treatment. The Kaplan-Meier cumulative mortality curves for the intensive treatment and control groups demonstrate that there were 102 deaths (33%) in the intensive treatment group and 138 in the control group (44%), for an 11% absolute reduction in risk compared with intensive treatment. The relative risk associated with insulin-intensive treatment compared with standard treatment was 0.72 (0.55 to 0.92; $p=0.011$). The author concluded that insulin glucose infusion followed by intensive subcutaneous insulin improved long-term survival in patients with diabetes who suffer an acute myocardial infarction, primarily through effects associated temporally with the acute episode.

The indications for insulin therapy in the management of patients with diabetes mellitus are summarized in Table 1.

Table 1: Indications for Insulin Therapy in the Management of Diabetes

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| <ol style="list-style-type: none">1. Absolute requirement for all T1DM2. In T2DM if:<ul style="list-style-type: none">- hyperglycemia above $300 \text{ mg}\cdot\text{dL}^{-1}$ ($16.7 \text{ mmol}\cdot\text{L}^{-1}$) at diagnosis- inter-current illness and hospitalization- alone or in combination with oral anti-diabetic agents to achieve target glycemic control |
|---|

Insulin therapy is an absolute requirement for all patients with Type 1 diabetes. In patients with Type 2 diabetes, insulin therapy must be initiated when there is hyperglycemia above $300 \text{ mg}\cdot\text{dL}^{-1}$ ($16.7 \text{ mmol}\cdot\text{L}^{-1}$), which often occurs at diagnosis. The insulin therapy in the latter case may be temporary and the patients may do well on oral agents prescribed after the condition is under control. Insulin therapy is also recommended in the presence of inter-current illness, respiratory tract or urinary infections, surgery or trauma, and during all hospitalizations. Finally, insulin is required alone or in combination with oral anti-diabetic agents to achieve target glycemic control in approximately one-half of all patients with Type 2 diabetes as the disease progresses.

Glucose-Insulin Physiology

Once the decision to treat the patient with insulin has been reached, then it becomes necessary to design a replacement regimen that reproduces the normal glucose-insulin physiology. Under normal conditions, insulin is secreted in a pattern with two components: the basal constant secretion and the postprandial spikes needed to cover the hyperglycemia that follows meals. Glucose concentration in the extracellular space (plasma) is closely regulated. Plasma glucose concentration generally averages between 80 and $100 \text{ mg}\cdot\text{dL}^{-1}$ (4.4 and $5.6 \text{ mmol}\cdot\text{L}^{-1}$) in the post-absorptive state (after an overnight fast), and it rarely exceeds $140 \text{ mg}\cdot\text{dL}^{-1}$ ($7.8 \text{ mmol}\cdot\text{L}^{-1}$) following meal ingestion. The pancreas is central to the maintenance of normoglycemia. Each increase in plasma glucose is accompanied by an increase in pancreatic insulin release. A decrease in glucose is accompanied by a decrease in insulin secretion and a concomitant increase in pancreatic glucagon secretion. Approximately 50% of the daily insulin found in the circulation is secreted independent of meals and it represents the basal insulin that is responsible for maintenance of normal fasting glucose values. This is accomplished primarily by suppression of endogenous glucose production. Thus, one must keep in mind that in

order to achieve adequate plasma glucose concentration, all diabetic patients will require basal insulin replacement, even in the absence of food intake.

Normoglycemia is maintained by a continuously changing match between the rates at which glucose enters and leaves the extracellular space (Figures 2 and 3).

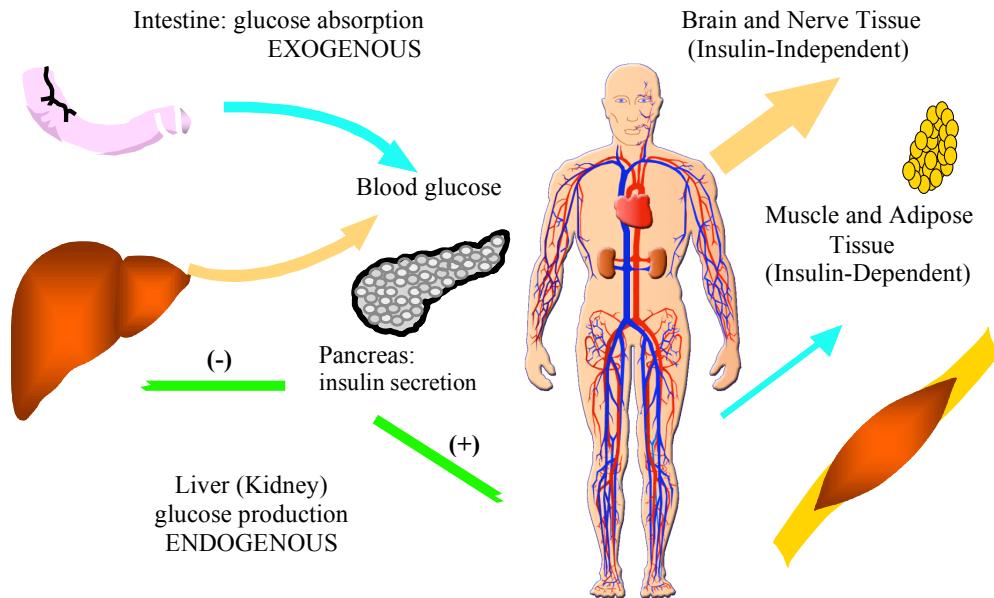


Figure 2: Glucose production equals utilization in the post-absorptive state

In the post-absorptive state glucose is produced predominantly by the liver (and to a lesser extent by the kidney). Glucose released into the circulation is derived from degradation of stored glycogen (glycogenolysis) in the liver and from glucose synthesis *de novo* (in liver and kidney) from precursors such as glycerol, lactate, alanine and glutamine (via gluconeogenesis). Most of the circulating glucose in the post-absorptive state is extracted by the brain and nerve tissues, via an insulin-independent mechanism.

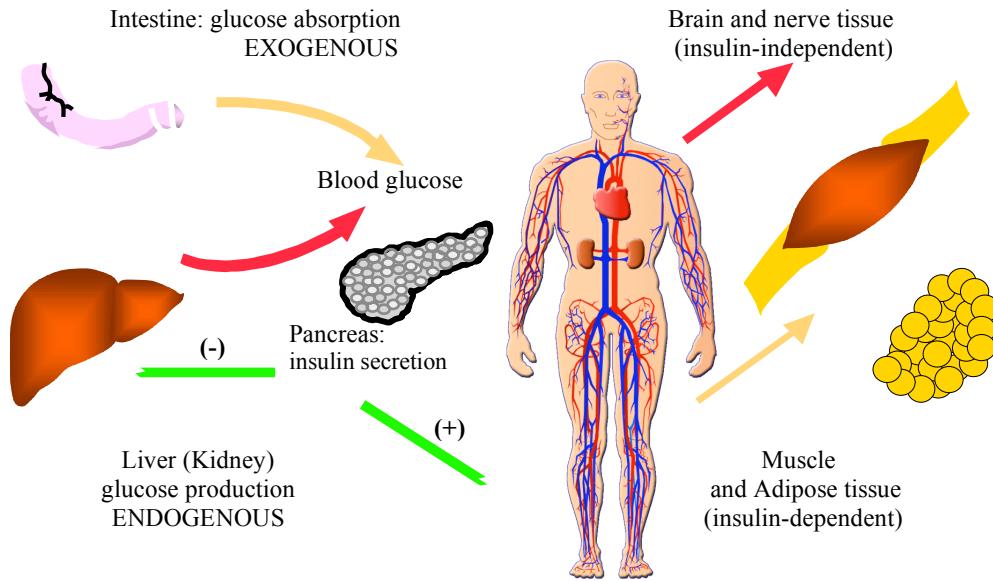


Figure 3: Glucose production does not equal utilization in the postprandial state

Glucose uptake by muscle and adipose tissue, which is insulin-dependent, is small in the post-absorptive state. During the transition period from the post-absorptive to the postprandial state, the primary site of glucose uptake shifts from the insulin-independent tissues (brain) to the insulin-dependent tissues (muscle and adipocytes). In the postprandial state, glucose extracted by muscle is either utilized to synthesize glycogen or it may enter the anaerobic glycolytic pathway. In adipocytes, glucose is converted to glycerol and utilized to synthesize triglycerides, the main form of fat storage. Following a meal, carbohydrates are digested in the gut to monosaccharide, primarily glucose (depending on the meal load), and taken up by the liver through the portal vein. Glucose derived from the meal load is either directed into hepatic glycogen synthesis (direct pathway) or released into the hepatic vein and systemic circulation. Hepatic glycogen also incorporates glucose derived from the process of gluconeogenesis (indirect pathway). Lactate generated in the postprandial period via anaerobic glycolysis in skeletal muscle becomes the most important precursor for hepatic glycogen synthesis via the indirect pathway.

In summary, a physiologic insulin replacement program should aim to: [i] correct and maintain fasting (post-absorptive) plasma glucose concentration between $70\text{-}110 \text{ mg}\cdot\text{dL}^{-1}$ ($3.9\text{-}6.1 \text{ mmol}\cdot\text{L}^{-1}$), [ii] to prevent elevations of plasma glucose above $140 \text{ mg}\cdot\text{dL}^{-1}$ ($7.8 \text{ mmol}\cdot\text{L}^{-1}$) in the postprandial period, and [iii] should be easily adjustable to extremes of hyperglycemia, such as during illness and of hypoglycemia as it may occur for instance, during physical exertion.

Principles and Practice of Intensive Insulin Therapy

There are five basic steps to implement an intensive insulin therapy program. The first is to establish a target glycemic goal range with the clear understanding that the patient's self-monitoring of capillary blood glucose must be performed frequently using proper technique. This is perhaps the most critical of all and perhaps the most difficult step for patients to follow. The second step is to estimate basal insulin requirements. The third step is to calculate pre-meal insulin boluses so as to mimic normal physiology. The fourth step is to design a supplemental scale that will attempt to correct some of the inaccuracies of the previous estimations and of other factors that interfere with plasma glucose, such as meals, physical activity, illness, etc.

Finally, the fifth step involves the patient directly, as one must decide about the most appropriate delivery system and insulin regimen for each person. In this very important step individual patient's capabilities, personal preferences and daily routine should always be taken into consideration.

The glycemic goal ranges may be either the standard, modified, or tailored to specific occasions such as hospitalization and pregnancy. One can emphasize fasting, pre-meal, post-meal (usually two hours afterwards) or bedtime capillary blood glucose values. The standard recommendation is to achieve blood glucose between 80 and 120 mg·dL⁻¹ (4.4 and 6.7 mmol·L⁻¹) before meals, below 140 mg·dL⁻¹ (7.8 mmol·L⁻¹) two hours after meals, and below 160 mg·dL⁻¹ (8.9 mmol·L⁻¹) at bedtime. Modified values are reserved for those patients at risk for the development of severe hypoglycemia or those with hypoglycemia unawareness. Individuals who have very little to gain from tight glycemic control such as frail elderly or terminally ill patients are not good candidates for tight glycemic control. In these patients, target blood glucose values range from 100 to 150 mg·dL⁻¹ (5.6 to 8.3 mmol·L⁻¹) before meals and should be below 180 mg·dL⁻¹ (10.0 mmol·L⁻¹) after meals and at bedtime, so as to avoid severe hyperglycemia and dehydration. During hospitalization the blood glucose must be maintained below 110 mg·dL⁻¹ (6.1 mmol·L⁻¹) all times, except when hospitalized patients are eating, and then blood glucose up to 180 mg·dL⁻¹ (10.0 mmol·L⁻¹) is tolerated. In normal pregnancy blood glucose concentrations in the fasting state and before meals should be between 60 and 90 mg·dL⁻¹ (3.3 and 5.0 mmol·L⁻¹). The two hour postprandial blood glucose values should be below 125 mg·dL⁻¹ (7.0 mmol·L⁻¹) and below 140 mg·dL⁻¹ (7.8 mmol·L⁻¹) at bedtime. These goals should be pursued vigorously for they have been associated with improved obstetrics and clinical outcomes.

Glucometers

There are several commercially available glucometers with a variety of features; but all of them require a "stick". Non-invasive devices are in development but improved accuracy is essential before they can be released to the public. The following is a short list of glucometers popular in the U.S.:

Glucometer Elite® XL (Bayer) – Test sites include forearm, palm, abdomen, thigh or finger. Test strip turns meter on when inserted; automatically draws in the correct amount of blood, needs a 3 µL blood sample. Up to 120 results can be stored in memory. Results can be downloaded electronically.

Glucometer DEX® (Bayer) – Test sites include forearm, palm, abdomen, thigh or finger. The 10-test cartridge eliminates need to open and handle individual test strips. Cartridge automatically calibrates meter for all 10 tests. Automatically draws 3-4 µL of blood into the test sensor for sampling. Up to 100 tests can be stored in memory. Results can be downloaded electronically.

OneTouch Ultra® (LifeScan) – Test sites are finger and arm. Plasma calibrated test strips provide results in five seconds. Needs a 1 µL blood sample. Up to 150 results can be stored in memory. Results can be downloaded electronically.

Accu-Chek® Voicemate (Roche) – Useful for visually impaired; available in Spanish and English. Works with the AccuChek Advantage blood glucose meter using the Comfort Curve Strip. Only Lilly insulin bottles can be read via barcode. The Voicemate will announce the type of insulin in the bottle.

FreeStyle® (Abbott) – Blood samples can be taken from fingertips, forearm, upper arm, thigh, calf, and fleshy part of the hand. Needs a 0.3 µL blood sample. Up to 250 results can be stored in memory. Results can be downloaded electronically.

There are a few continuous glucose monitoring systems currently available. These are capable of reading subcutaneous glucose concentration continuously over a period of three days or so and storing them in memory. The subcutaneous values are usually within 10% of the blood values but, more importantly, they are always changing in parallel to each other. The system encompasses a catheter tip with a glucose sensor and a wire connector to the monitor. The tip is introduced under the skin of the patient, usually in the abdominal skin area with the assistance of a needle. After the connection with the subcutaneous tissue is established and the meter is standardized against a few blood capillary readings, the monitor is placed either around the belt or inside a pocket. The sensor detects electrical activity proportional to glucose concentrations in the interstitial space and records a value every five minutes. The drawback of most available systems is that real-time readings are not displayed. Although this technology is available in some models in Europe, it is not yet approved for use in the U.S. The data are currently downloaded for later analyses.

The download usually summarizes data collected in the previous three days, though data up to seven days can be reported. Interstitial glucose values are typically plotted with different colors for each day, and the normal glucose range is highlighted. Event marks can be inserted by the patient to identify perceived hypoglycemia, meals, exercise, etc. After the sensor is removed the patient reviews the record with the physician or health care provider. Glycemic excursions, hypoglycemia and other inter-current events are discussed. This helps to direct more specific changes in lifestyle, exercise plans, diets, insulin dose and timing, etc., to achieve better glycemic control.

Another interesting development is the Glucowatch, an automatic, digital non-invasive subcutaneous glucose monitoring system approved for limited use. The device operates through the physical-chemical process of iontophoresis: a low electric current pulls the sugar outside from the subcutaneous interstitial space into the epidermis and into two gel discs where a chemical reaction determines the glucose concentration. The accuracy and precision of the entire system is not great but it gives fair and useful estimation of the trends in blood glucose concentration. The watch is set up to give a digital display of the average of two subcutaneous glucose values measured every 20 minutes. A chief limitation is that sweating interferes with the chemical process, making it useless to those who exercise regularly, and there is also a skin irritation at the site, which needs to be attended to. In addition, at least for now, the watch must be calibrated with frequent daily capillary blood glucose determinations.

Insulin Dosing

Implementing the intensive insulin therapy requires an estimate of basal insulin requirements. One can use the general formula of 0.5 to 1.0 units per kilogram body weight per day and determine the approximate total daily insulin and then use one-half of this value as the basal or meal-independent requirements. An alternative is to use basal insulin secretion rates in normal subjects, which is usually around 0.5 to 1.0 units per hour. It must be remembered that these are average values. Insulin doses should be reviewed every three to five days in relation to blood glucose patterns. This is particularly important in the early stages of implementation of the intensive insulin therapy program. As a rule of thumb, insulin doses should always be increased or decreased gently, by no more than 10% at one time.

Pre-meal insulin boluses can be calculated as approximately one-half of total daily insulin requirements. The boluses are usually divided into three unequal doses. Higher doses are frequently needed before breakfast because of the naturally occurring morning insulin resistance. Higher doses are also often needed before dinner since these meals are usually larger and richer in fat and carbohydrate content. Pre-lunch insulin doses are typically smallest, due to the smaller size of the meal and the fact that individuals tend to be more active during the daytime. If patients are able and willing to count calories, the rule of one unit of insulin for every 5-10 grams of carbohydrate during

breakfast and for every 10-15 grams of carbohydrate for all other meals works very well. Insulin boluses should not be given if a meal is skipped.

A supplemental insulin scale must be developed to quickly correct out-of-range blood glucose values. These are designed to consider individual variability and imperfections of the method. An example of such a scale is as follows: patients are asked to subtract two units from the usual pre-meal dose if capillary blood glucose is below $60 \text{ mg}\cdot\text{dL}^{-1}$ ($3.3 \text{ mmol}\cdot\text{L}^{-1}$) and subtract one unit if it is between 60 and $80 \text{ mg}\cdot\text{dL}^{-1}$ (3.3 and $4.4 \text{ mmol}\cdot\text{L}^{-1}$), depending on the established glycemic target. So if the target is between 80 and $120 \text{ mg}\cdot\text{dL}^{-1}$ (4.4 and $6.7 \text{ mmol}\cdot\text{L}^{-1}$), one unit is subtracted when blood glucose is $70 \text{ mg}\cdot\text{dL}^{-1}$ ($3.9 \text{ mmol}\cdot\text{L}^{-1}$), but if the target is 60 to $90 \text{ mg}\cdot\text{dL}^{-1}$ (3.3 to $5.0 \text{ mmol}\cdot\text{L}^{-1}$), as, for example, during pregnancy, negative supplementation is not required. When blood glucose is within goal range, potentially between 80 and $150 \text{ mg}\cdot\text{dL}^{-1}$ (4.4 and $8.3 \text{ mmol}\cdot\text{L}^{-1}$), there is no insulin supplementation. When blood glucose is above goal range, however, one, two, three or more units of insulin are added to the usual pre-meal bolus dose. Sometimes half unit increments are necessary and other times the scale must be doubled. Supplemental insulin scales are intended only for pre-meal boluses. Adjustments in basal insulin and even pre-meal bolus dose should be made every three to five days to stabilize blood glucose patterns. For instance, if one patient is requiring frequent insulin supplementation, for example, before breakfast, then the basal insulin covering the morning period must be adjusted accordingly. Ultimately, the supplementation needs help to design adjustments in the insulin dose.

When patients with diabetes get sick or are hospitalized for whatever reason, the "sick day rules" are put into effect. As a general principle, capillary blood glucose is monitored more frequently and, if levels are consistently above $300 \text{ mg}\cdot\text{dL}^{-1}$ ($16.7 \text{ mmol}\cdot\text{L}^{-1}$), urine ketones are also measured. Insulin supplementation or snacks or both are used to correct deviations. For patients who are sick and able to eat, we recommend blood glucose checks and insulin supplementation according to a scale similar to the one mentioned earlier before each meal, at bedtime and at 3:00 AM. The usual insulin regimen must not change and patients should continue with baseline insulin injections or continuous infusion and pre-meal boluses. For those sick patients who are unable to eat, capillary blood glucose measurements and insulin supplementation injections according to scale must be performed every four hours around the clock. The basal insulin dose is given at same dose daily and pre-meal boluses are discontinued.

If blood glucose concentration is not coming down, for example, below $200 \text{ mg}\cdot\text{dL}^{-1}$ ($11.1 \text{ mmol}\cdot\text{L}^{-1}$) in two days, the scale can be doubled and supplemental insulin added for all positive urine ketone tests. Depending on the gravity of the illness and if unsuccessful for three days, hospitalization for intravenous hydration and insulin infusion may be necessary and a visit to the Urgent Care Center is encouraged. If the patient can keep anything down, fluids with sugar, not dietary sugarless products, are recommended. These general rules for the supplementation of insulin are also applicable to patients who are in transition from an illness and hospitalization to outpatient management and vice-versa.

Patients are directly involved in planning the final strategies. There are essentially four insulin treatment regimens; each with advantages and disadvantages. Patients can choose between: 1) split mix insulin; 2) pre-mix insulin regimens with two injections of insulin daily or more complex regimens with either; 3) multiple daily insulin injections; or 4) continuous subcutaneous insulin infusion with the assistance of a pump.

Current Available Insulin Preparations

The insulin preparations currently available in the U.S. are summarized in Table 2. These are divided into rapid or short-acting, intermediate and long acting, and pre-mix formulas. The old formulation of regular insulin is being replaced by the short-acting analogs (Lispro, Aspart, and Glulisine) that have a better, quicker, and more physiologic "in-and-out" profile. As a result, the use of these analogs has been associated with a decrease in the incidence and less prolonged hypoglycemia. Of the intermediate acting insulins, neutral protamine Hagedorn (NPH) is the most popular preparation, though it is being gradually replaced by the peak-less long-acting insulin Glargine and the newly released insulin Detemir. The pre-mix insulin preparations are the NPH/Regular 70/30 or 50/50, or the NPH Aspart 70/30 and the Lispro/NPL 75/25.

The split mix program with two injections daily includes one insulin injection before breakfast and one before dinner. Intermediate acting NPH and rapid or short acting insulins are pre-mixed and administered at both times. This regimen is convenient and is able to cover both breakfast and dinner postprandial glucose excursions. It also provides adequate daytime basal insulin coverage and allows for fine-tuning of insulin dosage. On the other hand, this regimen is accompanied by mid-afternoon and early morning insulin peaks, which often require food intake to avoid hypoglycemia. Nighttime hypoglycemia is of particular concern because of the typical unawareness and high risk of irreversible damage to the nervous system. The dawn phenomenon, a natural morning rise in blood glucose seen upon awakening, remains uncovered by this insulin regimen. Finally, one additional potential problem with free mixing of insulins has to do with accuracy and reproducibility of the doses on a daily basis.

Table 2: Insulin Preparations

Type	Examples
Meal Insulin	
Rapid-acting	Regular
Short-acting	Lispro, Aspart, Glulisine
Basal Insulin	
Intermediate	NPH, Lente, Ultralente
Long-acting	Glargine, Detemir
Pre-Mixed Insulin	
NPH/Regular-based	70/30, 50/50
NPH/Aspart-based	70/30
Lispro/NPL-based	75/25

To improve the accuracy of insulin mixing several pre-mixed insulin preparations are commercially available. As an example, using the 70/30 or 75/25 intermediate/short-acting pre-mixed insulins twice daily, before breakfast and dinner, the same pattern as the split mix regimen can be accomplished. With this convenient simple regimen, the accuracy is improved, there is adequate postprandial coverage for at least two of the meals of the day, and the daytime basal insulin needs are met. On the other hand, the pre-mix regimens offer little or no flexibility in the dose adjustment and fixed meals are required to avoid hypoglycemia. Also, the risk of nighttime hypoglycemia is real and the delivery devices are costly. Some patients cannot afford the expense and not all insurance plans cover this type of insulin regimen. In view of these and other problems discussed earlier, both the split mix and the pre-mix regimens should be reserved for those diabetic patients who are not entirely independent and for whatever reason need assistance.

Multiple daily insulin injections (MDII) represent a more physiologic and superior option than the previous two regimens, especially with regard to glycemic control and the risk of hypoglycemia. MDII requires a minimum of three injections daily, a program which could include either the intermediate acting insulin NPH or long acting insulins Glargine or Detemir. A variety of combinations are possible, though the most popular is the NPH plus the short acting insulin mixed as a single injection in the morning before breakfast, the short-acting single injection before dinner, and the NPH injection at bedtime. The advantages of this triple daily injection program are that the patient still has good coverage for meals and meets daytime basal insulin requirements and there is a reduced risk of hypoglycemia during the night. It also covers the dawn phenomena in the early morning upon waking. The inconvenience rests upon the fact that it requires three injections daily and still does not address the mid-afternoon hypoglycemic risk, which requires a fixed meal or snack. The accuracy of free mixing is still an issue for some patients.

The option of the peak-less long-acting insulins Glargine and Detemir, which offer the advantage of maintaining a steady near 24-hour plasma level, has made the basal-bolus insulin regimen a favorite. This regimen requires an evening injection of Glargine, Detemir or Ultralente (has a broad peak), plus pre-meal boluses of short-acting insulins (regular, Lispro, Aspart, Glulisine). There is adequate coverage for basal insulin requirements for nearly 24 hours, especially with Glargine (Detemir = ~18 hrs), and multiple daily injections cover postprandial hyperglycemia in every meal. As a result, morning hyperglycemia improves and there is greater meal-time flexibility. This is a very important feature of this regimen since patients only inject pre-meal boluses when and if they eat. The absence of peak (Glargine and Detemir) provides adequate day and nighttime basal insulin coverage with minimal risk of hypoglycemia. The drawbacks of this regimen are: 1) the need for multiple daily injections and 2) that insulins cannot be mixed. Moreover, with reduced insulin clearance in renal failure, the risk of prolonged hypoglycemia is greater, and the use of long-acting insulin preparations should be avoided. A single injection of Glargine, Detemir or Ultralente at bedtime is convenient and often well accepted by patients as a transition schedule. It provides basal insulin coverage over 24 hours with a small risk of hypoglycemia especially when the peak-less Glargine and Detemir insulins are used. One additional advantage of the basal single insulin injection at bedtime is that it can be combined with daytime oral agents such as Glipizide or Glimepiride. These insulin secretagogue agents can provide coverage for the postprandial period, although some of the meal time flexibility is lost. Keep in mind, however, that some patients have little or no pancreatic reserve and will fail oral agents, unless there is substantial weight loss.

Insulin Delivery

There are several "insulin pumps" available in the market; each with its own features. They all use the same electro-mechanical principles of constant delivery of insulin into the subcutaneous tissue following a pre-programmed schedule to meet individual needs. One great advantage of the pump is that it can provide variable basal infusion rates and changes as little as 0.05 units of insulin at a time. In addition to the meal-time bolus flexibility, these features enable a variety of insulin regimens that can suit many lifestyles. Some pumps are water-resistant, though they do not function underwater. When safety is in question, a temporary change to a single basal insulin regimen before activities such as diving is recommended. Keep in mind that insulin pumps only deliver short-acting insulin and if there is malfunction, the immediate lack of insulin (within four hours) will become noticeable, and the risk of developing life-threatening acute hyperglycemia with DKA is high.

In order to initiate continuous subcutaneous insulin infusion one must first decide on the basal infusion rate. This can be done either by adding the total insulin dose over a 24 hour period that the patient was injecting before the pump or simply by using the ratio of 0.5 to 1.0 units of insulin per kilogram body weight. The estimate of the total daily requirements often comes down to a number

within this normal range. It is a good idea to reduce this total initial dose by 25% and move back up as needed. For example, someone on 15 units of NPH plus 5 units of Humalog in the morning, 10 units of Humalog before dinner and 10 units NPH at bedtime adds up to 40 units, and the total estimated pump delivery would be around 30 units per day. One half of the estimated total daily dose is given as basal and the other half is divided in pre-meal boluses. Therefore, 15 units divided by 24 hours comes to 0.625 units/hour; the remaining 15 units can be given as one unit for every 10 to 15 grams of carbohydrate for each meal, and could be distributed, for instance, as three to six units before breakfast, lunch and dinner. These are approximations used only as a safe starting plan and should be revised periodically.

There are several commercially available devices that can aid in the process of subcutaneous self-insulin administration for those individuals who dislike needles, cannot access the injection sites very easily, or need help with accurate insulin dosing. Insulin pens are portable, ready and easy to use and fit cartridges with up to 150 units of insulin. These pens can deliver 1 to 30 units of insulin in single unit increments with a high degree of accuracy. Automatic injectors are alternative devices to pens. They conceal the insulin syringes and needles and operate at the touch of a button. These injectors deliver insulin transcutaneously using an air-jet mechanism, therefore the needle stick is not perceived. The single dose container used with injectors is disposable and holds 5-30 units of single or mixed doses. Injectors are made of stainless steel. Other devices have memory functions which display time and amount of last insulin dose, and the injected unit amount is displayed after six seconds, when the full dose is delivered. These devices have a combined insulin delivery system with blood glucose monitoring, and they have an insulin dosing system that uses the One Touch Ultra Test Strips. The ones currently available can only be filled with the 3.0 mL NovoLog PenFill Cartridge and with NovoFine 30G, 8mm needles. The memory function records time and amount of last insulin dose together with the last 150 blood tests. Both the glucose monitoring and the insulin administration require active manipulation by the patient because they are not integrated or automated.

Hypoglycemia

Hypoglycemia is the most common and feared complication of insulin treatment in patients with diabetes. The most frequent causes of low blood sugar reactions are as follows: 1) excessive insulin dosage, particularly amongst individuals who have just been started on insulin therapy or those with some form of cognitive impairment; 2) insulin is ill-timed or of the wrong type, that is short-acting instead of long-acting or vice-versa; 3) unpredictable meal time, particularly with children; 4) planned or unplanned physical activity when the need for insulin tends to decrease, and if the usual dosage of insulin has already been administered, there is no way one can dissipate that; 5) alcohol consumption (contrary to what many may think, ethanol inhibits endogenous glucose production and depletes liver glycogen so that the normal defense mechanisms are lost); 6) weight loss, which is accompanied by improved insulin action and typically declining blood sugar levels; 7) drugs such as concomitant use of glipizide, glyburide or other insulin secretagogue (sulfonylurea) in combination with insulin, or during a steroid taper; 8) rare patients with Type 1 diabetes who have adrenalitis and/or adrenal insufficiency and a subsequent lack of cortisol; and 9) kidney failure with reduced insulin clearance from the circulation.

Under normal circumstances, blood glucose levels are closely regulated by a complex interaction between the action of insulin and the effects of the counter-insulin hormones. The main reason for this tight control of blood glucose levels is to avoid depriving the central nervous system of its exclusive source for fuel, the circulating glucose. When blood glucose decreases to levels near $80 \text{ mg}\cdot\text{dL}^{-1}$ ($4.4 \text{ mmol}\cdot\text{L}^{-1}$), insulin levels decrease immediately. Circulating insulin dissipates quickly (it has a half-life of six minutes) and the pancreatic secretion is shut down. As the glucose falls down to $70 \text{ mg}\cdot\text{dL}^{-1}$ ($3.9 \text{ mmol}\cdot\text{L}^{-1}$) glucagon is secreted to stimulate hepatic glucose production and hold the

blood levels steady. This hormonal balance takes place everyday, but we cannot tell because the presence of more or less of either insulin or glucagon will produce no symptoms. However, when blood glucose falls below $65 \text{ mg}\cdot\text{dL}^{-1}$ ($3.6 \text{ mmol}\cdot\text{L}^{-1}$) on the average, epinephrine is released and one feels hunger pangs, some anxiety and is tempted to ingest some food. If the blood sugar continues to decrease growth hormone and cortisol are also secreted in higher amounts in an effort to stimulate endogenous utilization of fatty acids and spare the circulating glucose for the brain. Unless the fall in glucose is interrupted, when it reaches values below $50 \text{ mg}\cdot\text{dL}^{-1}$ ($2.8 \text{ mmol}\cdot\text{L}^{-1}$), there is a dramatic increase in epinephrine release with the typical adrenergic surge including sweating, dry mouth, palpitations, nausea, headache, hunger and anxiety. This advances to impaired cognitive function with poor concentration, difficult speech, odd behavior, and blurred vision, lack of motor coordination, lightheadedness, seizures and coma. These neuro-glycopenic symptoms are a serious sign of very low blood glucose levels, which can lead to irreversible neural damage or death. Patients with Type 2 diabetes rarely if ever get to this point, but those with Type 1 diabetes and especially those with long-standing disease of more than 10 years may have compromised glucagon secretion, and the brain reduces the threshold for epinephrine secretion. As a result, the epinephrine-related warning symptoms are either attenuated or completely lost and an episode of hypoglycemia in these patients may be only recognized by cognitive dysfunction, or in extreme conditions by seizures and coma. This is the so-called "hypoglycemia unawareness" that requires immediate diagnosis and attention.

It is important to try to identify the cause(s) of hypoglycemic episodes. Prevention of repeat events is relatively easy when events are isolated with a clear-cut explanation and correction. Often, however, the cause is not immediately apparent and then, regardless of the cause, an adjustment in the insulin dosage is necessary. It is important to watch for the capillary blood glucose response to the change. The meal time, size and content may have to be revised and all medications should be reviewed to make sure that there is no interference with blood glucose values. It is also important to reconsider the timing of planned exercise with regards to the insulin injection and its peak and the meal time. As a rule, insulin treated patients should get into the habit of checking capillary blood glucose before engaging in exercise or in potentially dangerous activities such as operating machinery, driving a motorized vehicle or entering the operating room with someone else's life on the line. In addition, these patients should become familiar with the subcutaneous or intramuscular administration of glucagon. The 1.0 mg glucagon kit should be kept at home and at work in a safe place, and family and friends should be able to easily find and use it in case of emergencies.

When an episode of hypoglycemia takes place, the patient should be prepared to act promptly in order to avoid unnecessary delays. If the hypoglycemia occurs during the daytime and the patient is awake and conscious, it is recommended that they check their blood glucose before and 15 minutes after treatment. An equivalent to 15 grams of carbohydrate, either 1/2 cup of fruit juice or two to three crackers or sugar tablets should be consumed. Remember, fluids are always faster than solids and pure sugar is absorbed faster than when in mixed meals. If the hypoglycemic event takes place during the nighttime it is recommended that the dose is doubled since it may be more serious. This translates to consumption of 30 grams of carbohydrate or a full cup of orange or apple juice. Patients should always re-treat if the blood glucose is not increasing or if the symptoms persist 15 minutes after the initial carbohydrate feeding. Consider doubling the amount to 30 grams in the second attempt. Anytime an episode of hypoglycemia is associated with mental status changes the carbohydrate intake should be higher, 30 grams, and if the patient is not awake, glucagon should be injected; intramuscular, subcutaneous or even intra-venous. A visit to the emergency room or a call to the treating physician is advisable if the blood glucose is not increasing and symptoms persist after 30 minutes, and it is always prudent when mental status changes are involved. In the hospital, intravenous dextrose 50% (25-50 mL bolus) is administered and followed by a continuous dextrose infusion. If the hypoglycemic event is alcohol-related, the use of intravenous dextrose is preferred since glucagon is ineffective.

Hypoglycemia unawareness is a serious complication which tends to affect primarily patients with longstanding Type 1 diabetes mellitus who have recurrent hypoglycemia. As described earlier, the threshold for the release of epinephrine is lowered and the neuro-glycopenic symptoms manifest without any warning symptoms. This is a life-threatening condition that requires immediate attention. The diagnosis is suspected in individuals whose average HbA_{1c} is adequate or actually low, and there is substantial weight gain. To confirm the diagnosis the patient is asked to measure capillary blood glucose frequently during the day, seven or eight times, and set an alarm clock for 3:00 AM. If the blood glucose is below 50 mg·dL⁻¹ (2.8 mmol·L⁻¹) at this point and there are no symptoms, the diagnosis is confirmed and the entire therapeutic regimen for the patient must be revised. The glycemic goal range must be upgraded temporarily to 120 to 180 mg·dL⁻¹ (6.7 to 10.0 mmol·L⁻¹), and the insulin dosage decreased by 10-20%. It will be necessary to rewrite the supplemental insulin scale to enable the blood glucose to stay above 120 mg·dL⁻¹ (6.7 mmol·L⁻¹) and below 180 mg·dL⁻¹ (10.0 mmol·L⁻¹) for at least three months. The total caloric intake and the dietary recommendations must be reviewed to include mid-morning, mid-afternoon and bedtime snacks. It is advisable that these patients consider more physiological insulin replacement with peak-less basal insulin or insulin pump therapy, and even enroll in a transplantation program, if possible. While the adrenergic hypoglycemic symptoms are absent or mild, patients are instructed to avoid dangerous activities such as operating heavy machinery, driving or prolonged exercise, including diving expeditions. These are temporary measures since a substantial improvement is expected and noticeable after a few months of mild controlled hyperglycemia. This is possible because of the resetting of the autonomic nervous system as the brain sees higher circulating blood glucose levels. Meanwhile, it is prudent to review the use of glucagon emergency kit with family and friends.

Exercise and Diabetes

During exercise, as the skeletal muscle contraction is enhanced, so is the aerobic and anaerobic oxidation of fuel. There are several metabolic phases in the adaptation to the initiation and maintenance of the physical activity. The most important piece of information relevant to those interested in insulin is that the utilization of glucose by the exercising muscle becomes independent of insulin. As a result, the muscle oxidizes glucose extracted from the circulation at higher rates, and the blood glucose levels tend to fall. In normal non-diabetic individuals the pancreas shuts off the secretion of insulin and the liver and kidney increase the mobilization of glucose to meet the increasing body demands. In the diabetic patient, however, the insulin is injected in the subcutaneous tissue and the depot is rapidly absorbed during physical exertion. In the presence of insulin, therefore, because the release of glucose from the liver and kidney are blocked, blood glucose levels fall with prolonged and intense exercise.

There are essentially three major sources of fuel for oxidation during the metabolic phases of the exercise: circulating fatty acids, intramuscular glycogen, and circulating glucose. At rest, muscle oxygen consumption is predominantly utilized to generate energy from the oxidation of fatty acids and glucose extracted from the circulation, whereas the contribution of intracellular glycogen is negligible. During the initial phase of submaximal exercise, generally well within 15 minutes of the beginning of the exertion, the energy needs of the muscle contraction relies essentially on the oxidation of glucose derived from intramuscular glycogen. This continues until the blood flow to the muscle increases sufficiently to ensure the supply of fuel from the circulation. As the exercise progresses into 40 and up to 90 minutes, the contribution of fuels from the circulation, glucose and fatty acids, increases tremendously, while that of intracellular glycogen diminishes. At 180 minutes of exercise and beyond, during 26.2 mile (42 km) marathon runs, for example, the oxidation of fatty acids becomes the main source of energy to the skeletal muscle. One can appreciate that unless there is a continuous increase in the endogenous production of glucose or an exogenous intake of glucose, the rising needs will eventually cause blood glucose levels to drop to very low and dangerous levels.

This is a challenge that needs to be addressed by insulin-treated diabetic patients who exercise regularly. Careful planning is required to avoid exercise-induced hypoglycemia.

The following are basic rules for the safe practice of exercise in insulin-treated diabetic patients. It is preferable to exercise either before breakfast or before large meals, when there is little or no subcutaneous insulin depot. The capillary blood glucose must be checked before exercising. A single check is adequate for exercise lasting less than 30 minutes. Checks 30 minutes before and immediately preceding is appropriate for exercise lasting longer than 30 minutes. When engaging in severe, prolonged and dangerous activities, one should check blood glucose at least 30 minutes before and just before, and then frequently during the exercise. Appropriate corrective actions must be taken immediately. If the pre-exercise results indicate that the blood glucose is between 80 and 180 mg·dL⁻¹ (4.4 and 10.0 mmol·L⁻¹), the exercise can proceed as planned. However, if blood glucose is below 80 mg·dL⁻¹ (4.4 mmol·L⁻¹), the patient should eat a snack (solids are better than fluids in this case), and repeat the glucose testing within 30-60 min. If low blood glucose persists, then it is better to cancel the activity. When blood glucose is between 180 to 300 mg·dL⁻¹ (10.0 to 16.7 mmol·L⁻¹), the patient should receive a short-acting insulin bolus according to the supplemental scale, and then repeat glucose testing within two hours. It is necessary to wait at least for two hours to see the insulin take effect before deciding to commence the exercise. If the blood glucose is above 300 mg·dL⁻¹ (16.7 mmol·L⁻¹), the physical activity should be canceled to avoid the risk of going into uncontrolled hyperglycemia or diabetic ketoacidosis led by the surge in epinephrine that occurs during physical exertion in the absence of insulin. If the exercise time is known, it may be appropriate to reduce the insulin bolus by one to three units in the preceding meal. Finally, it is recommended that insulin-treated diabetic patients drink plenty of fluids with sugar during strenuous, prolonged exercise to avoid hyperglycemia and to keep the pace. Very important, beware of the delayed hypoglycemic effects of exercise and eat a substantial meal before you retire. Always keep snacks handy for any unplanned physical activity.

Future of Diabetes Management and Prevention

The foreseeable future, i.e., within three to five years, will bring some form of non-invasive glucose monitoring that is accurate and reproducible. These will be variations of the Glucowatch and transcutaneous sensors. There are also implantable sensors being developed that can be introduced percutaneously in the right atrium. These will make it possible to read blood glucose continuously on a watch receiving the telemetric data. The coupling of these glucose sensors with an artificial pancreas could integrate and regulate blood glucose and insulin delivery.

Another development soon to go public relates to the safe and efficacious use of inhaled and oral insulin preparations. The oral insulin is a very effective insulin formulation that could be mixed with agents to protect the active insulin molecule from digestion in the gastrointestinal tract. Recent work done at the Texas Diabetes Institute testing an oral insulin suspension called HIM-2, demonstrated a significant reduction in blood glucose production and enhancement in glucose utilization relative to equimolar subcutaneous insulin lispro injection (Wajcberg et al 2004).

Perhaps of greater interest are our current studies with the INGAP peptide. INGAP stands for islet neogenesis gene-associated protein and represents the functional peptide segment of a larger protein product of a gene capable of stimulating the differentiation of premature ductal pancreatic cells into islet cells. The histological appearance of a representative islet in the pancreas of mice made diabetic with streptozotocin injection can be altered substantially following systematic incubation with INGAP administration, whereas the administration of the vehicle alone is insufficient to recover the damaged islet. There are numerous peptides and other factors capable of stimulating the differentiation of embryonic and adult stem cells and transforming these into functional islet-cells.

Whole pancreas transplantation has not yet become very common therapy, for it requires donors (in short supply) and large doses of immuno-suppressants, which are associated with numerous adverse events. Islet-cell transplantation, on the other hand, is gaining popularity (Shapiro et al., 2005). Since Dr. Shapiro of Edmonton, Canada, in 1998, was able to introduce purified islet-cells into the liver of adult Type 1 diabetic patients transcutaneously and maintained them free of insulin injections for more than 10 years, several centers worldwide have reproduced their technique. Islet-cells are difficult to harvest (donor shortage), but once injected into the body there is minimal requirement for immuno-suppression and most regimens are steroid-free.

The more distant future will likely bring some form of artificial pancreas available for those patients in transition to either heterologous islet-cell transplant or stem cell differentiation therapy. We also expect to have forms of immuno-modulation that will arrest the autoimmune destruction of the pancreas in the early stages of Type 1 diabetes mellitus, and some type of genetic manipulation intended to correct the basic metabolic defects of Type 2 diabetes mellitus.

Acknowledgments

This work was partially funded by the American Diabetes Association, the University of Texas Health Science Center, The University Health System, and the Hyperbaric Medicine Society. Special thanks to Neal W. Pollock, Ph.D. for his review and editorial assistance with the final version of the manuscript.

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DIVING WITH DIABETES - THE BRITISH DATA

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Data have been collected from diabetic divers in the United Kingdom since 1991. Divers who are diabetic or diabetics who wish to dive must register with the database. They must also provide basic diving and medical information on an annual basis. All diabetic divers are asked to register, including both insulin-dependent and non-insulin-dependent types and includes those who are diet controlled only. The data obtained from 1991 to 2001 were summarised in *Undersea and Hyperbaric Medicine* (Edge et al., 2005). The aim of the database is to build up a picture of the ordinary diving habits of diabetic recreational divers. Divers are asked where they are diving and also the seasons in which they are diving. Most dive in both tropical and cold water. Several of the divers are diving in Stoney Cove in the middle of Leicestershire which is extremely cold at most times of year (water temperatures range from 4-10°C [39-50°F]). Divers are diving in tropical seas, in the Atlantic Ocean off the west coast of Scotland, and many other remote places as well.

Medical input occurs at the annual medical examination which is carried out by a diving medical referee. The records are then forwarded to a central collection point where a final decision is made as to whether the diver is, in fact, fit to dive. It is hoped that these data will both complement and augment the data available from monitored and controlled dive studies, such as those recently reported by Guy Dear and co-workers (Dear et al., 2004).

There have been three incidents of note. As previously reported, there have been two deaths, both victims being non-insulin-dependent diabetics. One of these cases was known to be cardiovascular in origin and not hypoglycemia-induced. The second, involving a fit, young female, was of unknown cause. There was also one recorded episode of a hypoglycemic attack underwater which was successfully treated using glucose paste in the manner prescribed. The diver afterwards remarked that she had "learned quite a lot" from the episode. There have been no further incidents of death or underwater hypoglycemia reported during the period 2001-2004.

In 2004, the database contained details of 447 divers (364 males [81 percent] and 83 females [19 percent]) which broadly reflects the male-to-female ratio in the British diving population. Some divers will only dive for one year, whilst some dive for two or three years. However, a few divers have been registered for the whole duration of data collection. Since the database started, there have been about 14,000 dives registered by diabetic divers. The results from the database are largely dependent upon self-reported data. Further checks are possible because there are diving incident databases which are maintained by the British Sub-Aqua Club and by some of the other diving organizations within the UK. Reports are also obtained from the Coast Guard of diving-related incidents.

Figure 1 shows a histogram of the ages of the diabetic divers on first joining the diabetic database since 1991 and reflects the very broad age range of these divers. Some have started diving in their teens, but there are many diabetic divers who are now in their forties and fifties. Some of the older diabetic divers are now in their seventies.

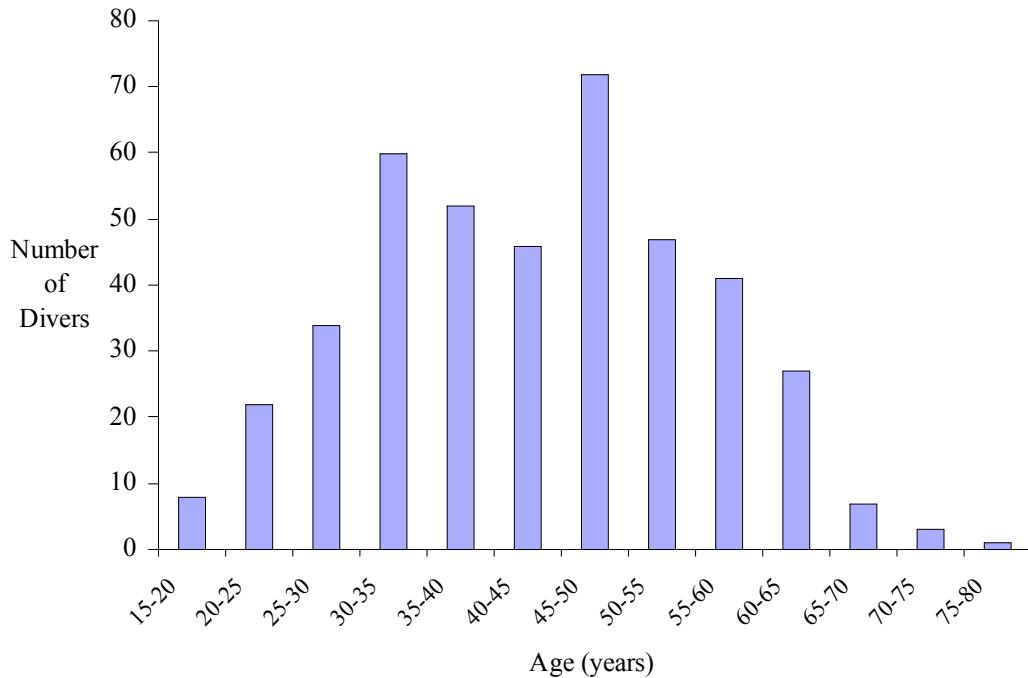


Figure 1: Age distribution of registered diabetic divers in the UK on joining the database

Figure 2 shows the average number of dives per diver categorized into depth range for the years 2002-2004. In the UK the number of dives that are being performed by the general diving population appears to have decreased and this is reflected by the decreased average number of dives recorded by the diabetic divers. Although it is recommended that diabetic divers do not dive to more than 30 meters of sea water (98 feet of sea water), some divers choose to ignore that. There are also a number of people who are undertaking regular decompression stops using Nitrox and there are a few divers who are using Trimix.

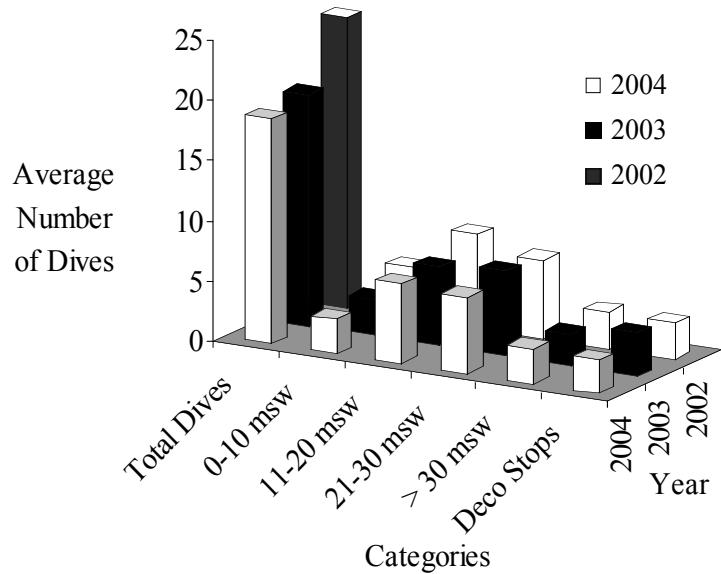


Figure 2: Average number of dives per diver by registered diabetic divers in the UK in 2002-2004, categorised by depth

Figure 3 shows the numbers of diabetic divers who are taking hypoglycemic medication (HNIDDM; the sulphonylureas are the medication of choice in many of the diabetics within the UK), those who are on metformin or controlled by diet alone (NIDDM) and those taking insulin (IDDM). The long-term blood glucose control that the three groups of diabetic divers are attaining can be seen in the graph of the percentage HbA_{1c} (Figure 4). Most diabetic divers appear to have a good long-term level of control, but there are individuals who are outliers. They have been permitted to dive because in the past their percentage HbA_{1c} values have generally been good and there has always been a good reason why they have gone out of control for a period of time. Repeat readings of the percent HbA_{1c} are requested of these individuals to ensure that they are improving their long-term control.

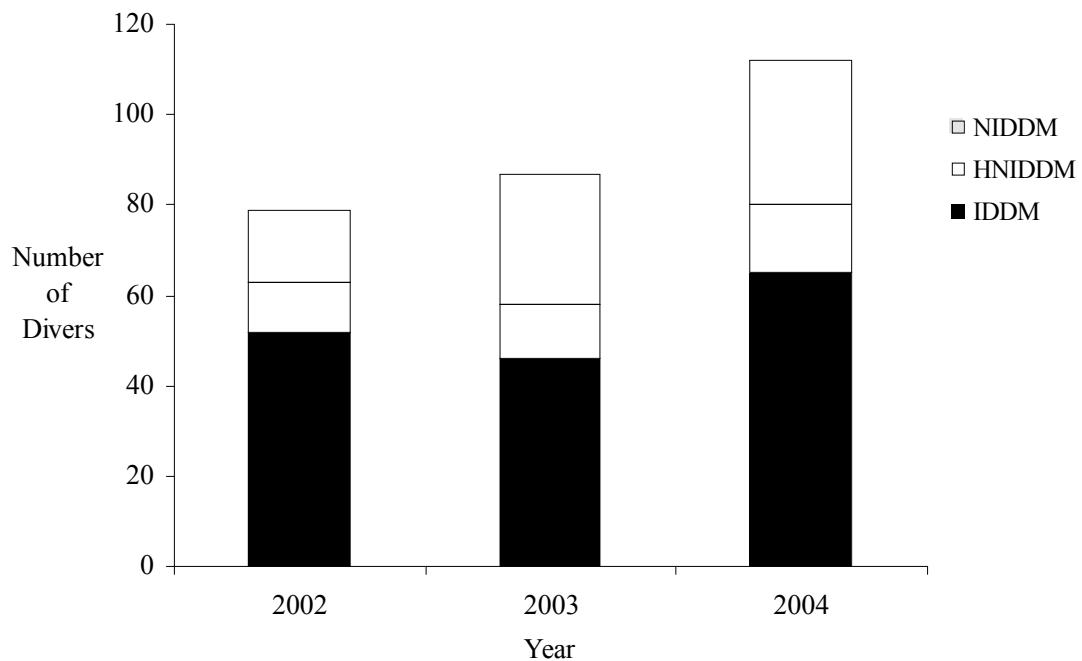


Figure 3: Registered diabetic divers in the UK in 2002-2004, categorised by disease status

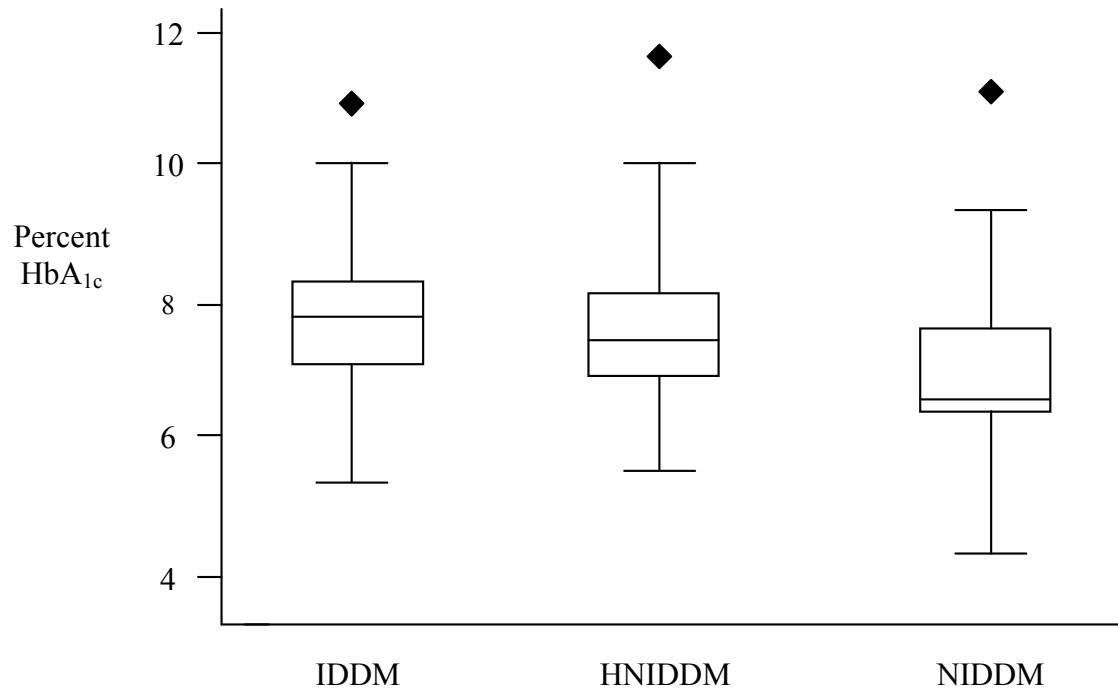


Figure 4: Box plot of mean and interquartile percent HbA_{1c} vs. diabetic type for registered diabetic divers in the UK, 2002-2004

Figures 5 and 6 present the pre- and post-dive glucose readings in two individual diabetic divers. Figure 5 presents a male diver with IDDM who has been diving with diabetes for many years. On several occasions he recorded a blood glucose of approximately $20 \text{ mmol}\cdot\text{L}^{-1}$ [$360 \text{ mg}\cdot\text{dL}^{-1}$]. Occasionally, the diver recorded that he consumed a glucose load before his dive. Many of these dives took place in the Red Sea, but some were in the cold water of Stoney Cove. A few of the dives are over an hour in duration, but the blood glucose did not appear to vary much over this time period.

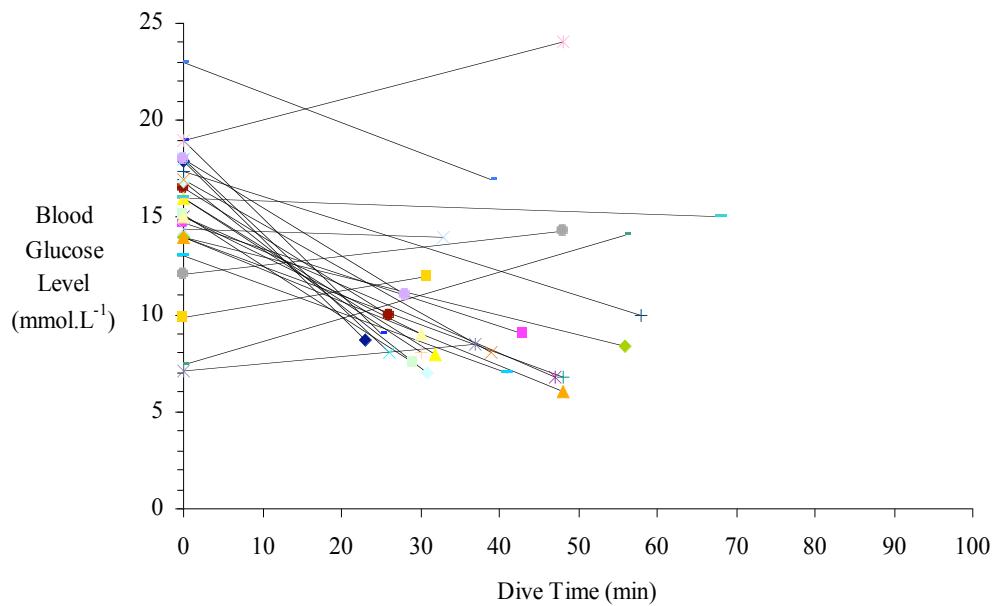


Figure 5: Pre- and post-dive blood glucose vs. dive time for one male diver over one season

Figure 6 shows the same pre- and post-dive information for a second male diver, again with insulin-independent diabetes. As before, the diving took place both in cold and tropical waters. One of the dives is of 100 minutes duration but, again, the blood glucose level appears to be quite constant, between about 10.0 and 8.0 mmol·L⁻¹ [180 and 144 mg·dL⁻¹].

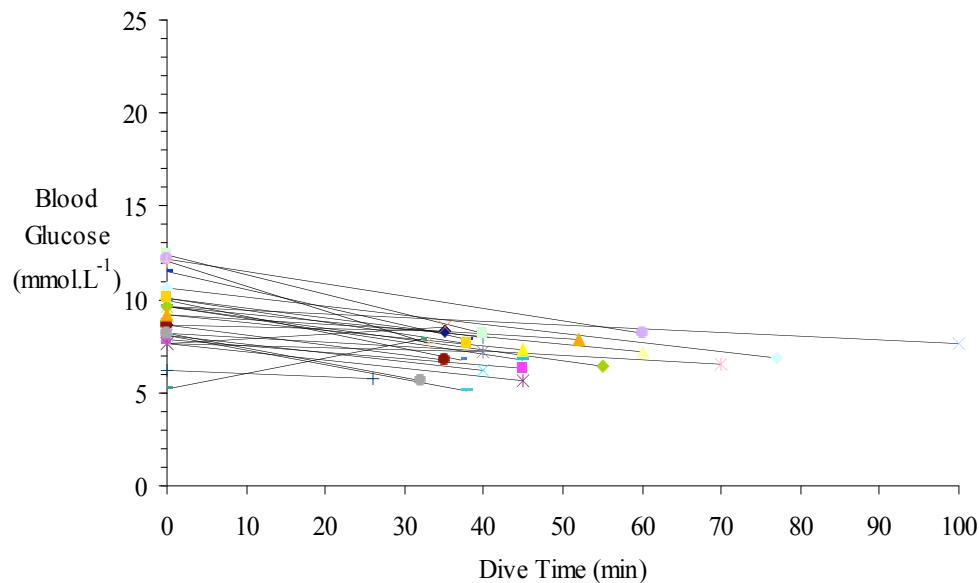


Figure 6: Pre- and post-dive blood glucose vs. dive time for one male diver over one season

This workshop is on diabetes and diving, but not specifically on insulin-dependent diabetes (Type 1 diabetes or Type 2 diabetes controlled with insulin). Most of the diving medical literature has only attempted to address the risk of hypoglycemia in insulin-dependent diabetic divers while diving. However, there are approximately 5-10 times the number of people with non-insulin-dependent diabetes as compared to insulin-dependent diabetes in the world and this number is increasing. Therefore, what if any, are the risks of diving with non-insulin-dependent diabetes as opposed to insulin-dependent diabetes? Hypoglycemia remains a concern, particularly in those taking oral hypoglycemic agents such as sulphonylureas (particularly the longer-acting compounds) or meglitinides. This is not a problem in those taking biguanides (such as metformin), thiazolidinediones or alpha-glucosidase inhibitors, and hypoglycemia is not a risk factor for those on dietary control alone.

There are long-term complications for non-insulin-dependent diabetes, just as there are for insulin-dependent diabetes. These include cardiac disease, stroke, nephropathy, neuropathy and retinopathy. There is also an association with the metabolic syndrome which includes central obesity (with possible implications for diving fitness), atherogenic dyslipidemia, hypertension, insulin resistance (or glucose intolerance), a prothrombotic state (of possible concern to those diabetic divers diving in hot climates), and also a proinflammatory state. The problem with this group of diabetic divers is that, within the UK, there is a lack of recognition on the part of the non-insulin-dependent diabetic divers of the seriousness of their condition. Some of the comments by such divers include: "I'm not injecting insulin so it can't be as serious a condition as diving with an insulin-dependent diabetes.>"; "I don't get hypos so why should I bother registering with the database?"; and "I'm controlled by diet so I never measure my blood glucose levels."

Furthermore, some of the diabetic divers in the United Kingdom may be treated sub-optimally, as there is now some evidence that treatment of the diabetic patient should be with aspirin, a statin, and either an angiotensin-converting enzyme (ACE) or angiotensin II (AII) inhibitor as well as anti-diabetic medication. Additionally, non-insulin-dependent diabetes has a higher incidence in the older individuals, which are well-represented in the diabetic database, as discussed above.

An interesting paper by Haffner et al. (1998) on the subject of mortality from coronary heart disease in subjects with Type 2 diabetes concluded that, "Diabetic patients without previous myocardial infarct have as high risk of myocardial infarct as non-diabetic patients who had a previous myocardial infarction. Wannamethee et al. (2004) concluded that "Men with diabetes only have a cardiovascular disease risk intermediate between men with angina and men with a prior myocardial infarction." This group included both insulin-dependent and non-insulin-dependent diabetic patients. McAlpine et al. (2005) discussed the complication rates amongst a population of diabetic patients in Scotland and confirmed that there was an "increased burden of microvascular disease in Type 2 diabetes" with a mortality of 14.6 per 1000 for Type 1 diabetes and 50.0 per 1000 for Type 2 diabetes. It would therefore seem reasonable to conclude, both from the two deaths recorded in diabetic divers in the UK who were both non-insulin-dependent, and from the data discussed above, that non-insulin-dependent diabetic divers may be at greater risk of medical complications whilst diving than their insulin-dependent counterparts.

Then there is the problem of diabetic diving instructors. Both Canada and the U.S. have roughly the equivalent of the United Kingdom's Disability Discrimination Act 1995 which states that discrimination occurs if, "*for a reason which relates to a disabled person's disability, the employer treats that disabled person less favourably than the employer treats or would treat others to whom the reason does not or would not apply; and the employer cannot show that this treatment is justified.*" Is it justifiable to bar diabetic divers from becoming diving instructors? If not, what medical guidelines should physicians follow in order to determine if such persons are fit to instruct novice divers in open water? There are at least three insulin-dependent diabetic instructors within the British Sub-Aqua Club who have been teaching (without remuneration) for a number of years, so far without problems. There are also professional diving instructors who are approved by the Health and Safety Executive in the United Kingdom. These people are earning part of their living as diving instructors. So far, each case has been considered on its merits by one physician specializing in this area, but such a state of affairs cannot continue indefinitely. This, and subsequent, workshops must consider this problem carefully.

How often should diabetic divers be recertified? Currently, it is possible for divers to be medically certified fit once and then never need further certification. This is unacceptable for diabetic divers, as the condition may be progressive, without the diver or his/her buddy becoming aware of the fact. This workshop must discuss the question of recertification and the timeframe for diabetic divers.

Finally, at what age should diabetic persons be allowed to start diving? Data from the DAN group have included diabetic persons 16-17 years of age (Pollock et al., *in press*). The UK database has one or two individuals of 17 and 18 who are diving who are insulin-dependent. This workshop should debate the lower limit for diabetic persons to start diving.

In conclusion, this and subsequent workshops should be debating the following topics:

- An international set of medical guidelines for diabetic persons wishing to dive. Such guidelines should include both a lower age limit for commencing diving and advice specific to older divers who have non-insulin-dependent (or Type 2) diabetes about their condition, emphasizing the potentially serious nature of the condition. The guidelines must also set out the time period for medical recertification of the diabetic diver.
- A set of medical guidelines for diabetic divers who wish to instruct recreational diving, together with the time period for medical recertification.

Acknowledgments

We thank the Trustees of the Diving Diseases Research Centre for support.

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LEGAL ADVOCACY AT THE AMERICAN DIABETES ASSOCIATION

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One of the goals of the American Diabetes Association is to improve the lives of all people affected by diabetes. The Association addresses this important goal in many ways, including research support, scientific meetings, community and professional education, and advocacy. The Association's advocacy efforts range from securing increased federal funding for diabetes research and prevention, to improving health care for people with diabetes, to ending discrimination against people with diabetes.

The American Diabetes Association works to end discrimination against people with diabetes through a four-step approach: educate, negotiate, litigate, and legislate – the goal being to resolve the problem at the earliest step possible. These efforts are guided by the Association's Legal Advocacy Subcommittee, a panel composed of health care professionals and attorneys with expertise in disability rights law. The Subcommittee provides resources for a wide variety of activities, including litigating diabetes discrimination cases throughout the country, providing support and consultation to other lawyers handling cases on behalf of individuals with diabetes, and collaborating with other organizations to develop appropriate standards to be used in evaluating individuals with diabetes.

Diabetes and the Law

Several important civil rights laws provide protection against discrimination in the workplace. The Americans with Disabilities Act (ADA), the Rehabilitation Act of 1973, and the Congressional Accountability Act are federal laws that protect workers with disabilities. In addition, almost all states have their own anti-discrimination laws. Although these laws are crucial tools for workers with diabetes, they also present a number of hurdles – the primary hurdle being that the individual must establish that he or she is a qualified person with a disability who was discriminated against because of diabetes. To do so, the person must have an actual disability, have a record of a disability, or be regarded as having a disability. Federal law defines a disability as a "mental or physical impairment that substantially limits one or more major life activities," such as walking, seeing, eating, or working. An added hurdle requires that the individual show this substantial limitation remains even after he or she has received treatment, such as insulin or oral medications. These standards can be met for people with diabetes but such a showing requires health care professionals with expertise in diabetes to explain the disease of diabetes, its management, and how it affects the individual who is alleging discrimination.

In order to gain protection by these laws, the individual must also establish that he or she is qualified for the job in question. A qualified worker is one who satisfies the skill, experience, education, and other job-related requirements of the position held or desired, and who – if given reasonable accommodation – can perform the essential functions of that position. An accommodation is any

change or adjustment to a job or work environment that enables a person with a disability to do the job. Common accommodations for a worker with diabetes are frequent breaks to check blood glucose levels, eat a snack, or use the restroom and the ability to keep diabetes supplies and food nearby.

Anti-discrimination laws forbid an employer from denying any benefit of employment to a qualified person with a disability, or from using qualification standards that screen out or tend to screen out individuals with disabilities. Yet, people with diabetes still encounter discrimination in a variety of forms – from employers who will not allow workers simple accommodations, to employers who determine that people with diabetes cannot perform a given job because the risk of hypoglycemia. These decisions are usually based upon minimal or outdated information and beliefs about diabetes, without benefit of consulting the treating physician or a diabetes expert.

Working Toward Individual Assessment: Safety-Sensitive Jobs and Diabetes

The Association recognizes that while not every person with diabetes is qualified to do every job, each person should be assessed individually with regard to how diabetes affects him or her. Staff and volunteers in the legal advocacy program at the Association work to ensure that employees with diabetes understand their legal rights, and that employers make decisions based upon how diabetes affects a particular individual – not based on stereotypes about the disease. One area where many individuals with diabetes encounter discrimination is with safety-sensitive jobs such as firefighting, law enforcement, or commercial truck driving. Many times, employers turn away a person with diabetes from these jobs because of a fear that the person will lose consciousness and constitute a safety threat to themselves or others around them. Too often, employers make decisions about the person's ability to do a job based on an assumption about diabetes rather than an individual assessment of the worker's capabilities and qualifications.

The Association has long worked to get rid of the so-called "blanket bans" that prohibit people with diabetes from working in a particular job simply because he or she has diabetes. The result of the Association's efforts has been some marked improvements in the way employers evaluate candidates with diabetes for safety-sensitive jobs. One example is the Association's recent work with the National Fire Protection Agency (NFPA) to develop guidelines for fire departments around the country. Until recently, NFPA recommended – and many cities adopted – a blanket ban that prevented all people treated with insulin from working as firefighters. As a result, many potential firefighters were not allowed to join fire companies, and some firefighters either lost their jobs or were put in dead end desk jobs. Many people with diabetes are successfully working as firefighters with no problems. The Association met with NFPA to explain both the medical reasons that such a blanket ban was unnecessary as well why such a ban was prohibited under anti-discrimination law. As a result, the NFPA standards committee and the Association began a collaboration that resulted in new physical qualification/medical guidelines to be submitted to the full NFPA for adoption early next year.

A similar collaboration with the Public Safety Committee of the American College of Occupational and Environmental Medicine (ACOEM) is in progress regarding standards for federal law enforcement positions, with final guidelines to be submitted in the near future. The Association became involved with this effort after hearing of the numbers of individuals with insulin-treated diabetes who were turned down for police officer jobs or any position that required the individual to carry a firearm – even if it was not truly a law enforcement position. In addition to working with ACOEM to develop better guidelines for evaluating people with diabetes, the Association has been involved with a number of court cases involving law enforcement positions. In one case in Texas, an individual who was turned down for a police officer job proved his Type 1 diabetes was no impediment to fulfilling his duties as a sheriff in a neighboring jurisdiction while his case wound its

way through the courts. This case, *Kapche v. City of San Antonio*, 304 F.3d 493 (5th Cir. 2002), cemented the legal position that blanket bans applicable to all people with diabetes are unlawful.

The Association has worked to replace blanket bans with individual assessment of people with diabetes in other areas, most notably in the area of commercial driving, where federal rules restrict who can operate a commercial vehicle in interstate commerce. Once exception to the rule against blanket bans is that such bans are lawful if required by another federal law or regulation. This was the case for interstate commercial driving. Until 2003, anyone who used insulin could not do such driving. That year, as a result of intensive lobbying, education, and new legislation, the Federal Motor Carrier Safety Administration (FMCSA) of the U.S. Department of Transportation began a limited exemption program to allow some insulin using individuals to drive commercial vehicles in interstate commerce. However, because an individual needs to have three years of experience driving a commercial vehicle while using insulin in order to even apply for an exemption – something that is difficult if not impossible to do in many states that do not allow people using insulin to operate commercial vehicles in intrastate commerce – the Association continues to work with legislators and FMCSA to make a reasonable individual assessment of truck drivers a reality.

These rules have everyday implications in the health of people with diabetes. One of my patients drives a city bus for a local New York company. In spite of diet, exercise, and three oral agents, he needs to take insulin in order to best manage his disease. He refuses to take insulin because he will lose his job. He is one of many who will benefit from Association-backed legislation pending in Congress that aims to make the federal exemption available to all insulin-treated drivers with diabetes who meet certain physical qualifications – qualifications that are strict to insure safety but are not hinged exclusively on whether or not the person uses insulin, but rather whether he or she is medically fit to operate a commercial motor vehicle. Many people who live in states that allow people who use insulin to drive commercially are doing so today without any diabetes-related problems.

The Many Forms of Diabetes Discrimination

Employment discrimination is not limited to firefighting, law enforcement, or commercial driving. The Association has fought to end discrimination in other safety-sensitive jobs such as baggage handling or truck mechanic, as well as jobs for which there is no inherent safety risk but the employer states safety concerns as the overarching reason for denying employment.

Another example of diabetes discrimination is the case of a national airline that fired baggage handlers who used insulin. The airline stated the reason for termination was because baggage handlers might have to drive small luggage trucks near planes and might damage a plane during a hypoglycemic attack. This resulted in a lawsuit brought by the Equal Employment Opportunity Commission (EEOC) and the ultimate settlement calling for a realistic individual assessment of people with diabetes.

In addition to combating discrimination in safety-sensitive jobs, the Association recognizes that discrimination also occurs outside of the workplace. Concert venues, airlines, and other public places can have restrictive policies that discriminate against people with diabetes. As a result of Association advocacy, in the 1990's the Federal Aviation Administration (FAA) began allowing individuals with insulin treated diabetes to hold Class 3 (non-commercial) pilot licenses. According to the FAA, their accident rate is lower than those without diabetes and there are no cases of hypoglycemia-induced accidents. Following September 11, 2001, the Association worked with the Transportation Security Administration (TSA) to develop travel guidelines that would allow people with diabetes to navigate the new security measures without sacrificing access to their diabetes supplies or jeopardizing their health. The result has been improved understanding of diabetes by security screeners, and an

increased awareness on the part of travelers with diabetes of what they must do to ensure there are no problems when they arrive at the airport. Similar success was attained when the Association worked with the U.S. Department of Justice to reach a settlement with a major concert promoter to ensure that people with diabetes are not separated from their supplies once they enter the concert venue.

Diabetes, Discrimination, and Scuba Diving

Why does the American Diabetes Association care about scuba diving? As noted at the beginning of this article, the Association's mission is to improve the lives of all people affected by diabetes. Ending discrimination is one way we carry out this mission. Just as each person with diabetes should be assessed individually for his or her ability to do a specific job, the same assessment should be utilized for each individual with diabetes who wishes to participate in activities such as scuba diving. Although there are clearly people with diabetes and other diseases (heart failure, uncontrolled asthma, seizures) who are at increased risk when participating in mountain climbing, sky diving, or scuba diving, there are many for whom the risk is minimal and acceptable. As I was told many years ago by scuba diving expert Dr. Tom Neuman, there is no way to make diving "safe." We can just minimize the risks. People with diabetes should have the same opportunity to experience the wonders of the underwater world as those without diabetes.

It is important to point out that this desire for open access must be tempered with medical judgment and common sense. Just like with firefighting, law enforcement, commercial driving, piloting airplanes, and working as a baggage handler or truck mechanic, not everyone with diabetes should be a scuba diver. The Association's goal is to develop reasonable guidelines for determining who is able to safely participate in these activities. The Association's work developing various standards – collaborating with other groups, involving legal and medical professionals – help inform what is needed to ensure that no person with diabetes is unnecessarily prevented from scuba diving because of diabetes.

It is important to note that diving is not just a recreational sport. There are a number of employment opportunities that require diving expertise and certification, ranging from divemaster to police rescue diver. Restricting divers from entry level training, by definition, restricts them from professions for which they may be otherwise qualified. In many cases, this restriction violates anti-discrimination laws. An example of how people with diabetes can face employment discrimination in scuba diving involves the case of Steve, a senior PADI (Professional Association of Diving Instructors) instructor with Type 1 diabetes since early childhood. Several years ago, Steve was directing a class when he noted that one of the students appeared confused and was perspiring freely. Because of his knowledge of diabetes, Steve was able to identify the student as having a hypoglycemic episode and institute appropriate treatment. The dive shop operator complimented Steve on his emergency response and asked how Steve knew so much about diabetes. Steve told his employer about his diabetes. He was fired the next day.

Another example of how scuba divers can have employment opportunities limited because of diabetes involves the medical standards employed by the National Oceanic and Atmospheric Administration (NOAA). The Association recently learned that NOAA standards disallow any individual who uses insulin or other hypoglycemic agents from participating on a dive team, thereby restricting the individual's ability to work in certain jobs or move up within the organization. According to the NOAA form, "Medical History and Physical Examination – NOAA Diving Exclusions and Qualifications, Absolute and Relative Contraindications for Occupational Diving":

Recreational versus occupational fitness to dive evaluations are done for a patient within the context of two distinct settings. The first, for the sport diver, is based solely on the medical safety considerations for the patient; where the patient assumes all liability for their own choices to dive or not.

The second, for the occupational diver, is based upon the interests of both the organization and the diver. In the occupational setting, other considerations include: economic, medical-legal, and liability issues (as liability rests solely with the organization).

While NOAA can take into account the safety of the diver and others, this policy unlawfully ignores the requirement for individual assessment of each potential diver with diabetes.

Recommendations

As it is likely that professional divers will be held to a higher standard than recreational divers, any guidelines developed by Undersea and Hyperbaric Medical Society (UHMS) and Divers Alert Network (DAN) must take into consideration the impact on employment, not just recreation.

The Association's position statement on Hypoglycemia and Employment/Licensure provides some guidance (ADA, 2005). The document states that:

People with diabetes should be individually considered for employment based on the requirements of the specific job. Factors to be weighed in this decision include the individual's medical condition, treatment regimen...and medical history, particularly in regard to the occurrence of incapacitating hypoglycemic episodes.

The implications of this statement are that individual assessment is an essential component of any employment (and by extension, recreation) medical evaluation.

Guidelines developed in collaboration with NFPA and ACOEM have several common themes:

- No recent hypoglycemia (1-2 years)
- No hypoglycemia unawareness
- Good physical condition (as appropriate for the job/task in question)
- Caution if certain diabetic sequelae present
- Input from diabetes expert physician

In keeping with the above concepts, in determining who is fit to dive, it is important to consider that:

- All divers need to be fit mentally and physically
- Divers with diabetes must have an excellent understanding of self-management, particularly regarding the effects of exercise
- Hypoglycemia unawareness or severe hypoglycemia (requiring the assistance of others) in the past year are contraindications to scuba diving

The diver with Type 2 diabetes or long-standing Type 1 diabetes is at greater risk for overt or clinical macrovascular disease, including myocardial infarction, coronary artery bypass grafts, congestive heart failure, cerebrovascular accident or significant valvular disease. When present, these complications are contraindications to scuba diving.

Conclusion

For most people, diabetes and its treatment should not be a barrier to recreational or professional scuba diving. The key is appropriate individual assessment. Many people with diabetes today are working as firefighters, police officers, truck drivers, baggage handlers, pilots, and in countless other jobs because their employer recognized that their diabetes posed no barrier to safe work and that they were qualified for the job in question. Scuba divers – both those who dive recreationally and those for whom there are employment implications – should be evaluated and assessed individually to determine whether and how their diabetes affects their diving safety. The experience of many divers and the research presented at the June 2005 UHMS/DAN meeting indicate that the risk of hypoglycemia can be minimized with appropriate planning. "Plan your dive and dive your plan" includes "know your blood sugar and how it responds to diving and plan your glucose management and follow your diabetes plan."

Acknowledgments

Thanks to Shereen Arent and Katie Hathaway of the American Diabetes Association for information and editing.

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Diabetes Care 2005; 28: S61.

DIVERS ALERT NETWORK (DAN) DIABETES AND DIVING: HISTORY AND DATA

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Divers Alert Network (DAN) was established in 1980 to assist divers in the case of emergencies. DAN developed a medical information line in 1982 to manage non-emergency inquiries. The call volume increased exponentially over the next 10 years. A substantial number of non-emergency calls concerned diabetes. In addition, there were 29 emergency calls involving a diabetes question from 1994-1999. DAN met the need for information on this topic through the series of initiatives described here.

1993 DAN Survey

The first DAN study of diving and diabetes was a survey distributed through the Alert Diver magazine in 1993 (Divers Alert Network, 1993) to gather anonymous data from active divers with diabetes. DAN had 115,300 members at that time; an unknown number of which may have had diabetes or knew divers with diabetes.

A total of 164 divers with diabetes responded to the survey. A review of the first 116 respondents identified 72 percent with insulin-requiring diabetes mellitus (IRDM). The divers reported completing an average of 100 dives. Twenty-nine percent reported secondary complications associated with the disease (kidney, heart and/or eye). The occurrence of hypoglycemia while diving was reported by 14 percent of respondents with IRDM and six percent of respondents with non-insulin-requiring diabetes mellitus (NIRDM). Much higher frequencies of hypoglycemia were reported during other exercise (46 percent and 16 percent, respectively). A variety of techniques to maintain normal or elevated blood glucose levels while diving were described, including sugar ingestion, altering medication dosages, and regulating times of dives and meals (Dear, 1994).

1994 American Diabetes Association Subcommittee

The American Diabetes Association (ADA) established a subcommittee in 1994 to discuss the implications of diving with diabetes. A DAN representative, Joel Dovenbarger, was included in this deliberation. The group concluded that there were a significant number of persons with diabetes actively diving and insufficient data to justify a blanket prohibition. The need for further research was strongly recognized. The subcommittee produced a list of conditions that should preclude diving by individuals with diabetes until further data was made available. The list included: a history of severe hypoglycemia (unconsciousness, seizures or requiring assistance) in the past 12 months; advanced secondary complications; hypoglycemic unawareness; and inadequate control or understanding of diabetes and the effects of exercise on it. The principal risk was concluded to be hypoglycemia. The importance of honest appraisal by each individual of the risks to him or herself, buddies and dive leaders was stressed.

1996 Undersea and Hyperbaric Medical Society (UHMS) Fitness to Dive Workshop

The 1996 annual scientific meeting of the UHMS included a one-day, pre-course workshop – ‘Some Diabetics are Fit to Dive, But Who?’ – to discuss the pros and cons of diving with diabetes. A wide range of views, from liberal to conservative, were displayed at this meeting. The participants present at the workshop did reach consensus on six major points (Dear, 1997):

- 1) Divers with diabetes are at risk of sudden loss of consciousness. As divers, this carries the ultimate risk of drowning and implies additional risks for their healthy buddies.
- 2) Individuals with diabetes, however well the diabetes is controlled, should not be passed as fit to dive without restrictions.
- 3) Individuals with diabetes who meet certain criteria can dive provided they dive in accordance with detailed procedures, such as those of the U.K. Sports Diving Medical Committee.
- 4) Divers with diabetes should be examined periodically for complications of their disorder that could disqualify them on the grounds of additional risks.
- 5) Hypoglycemia in deep dives could be wrongly perceived by a diver with diabetes as nitrogen narcosis.
- 6) Many questions remain unanswered; additional data collection from the field is essential.

DAN volunteered to collect data on persons with diabetes who were already scuba diving.

1996 DAN/Camp DAVI Collaboration

A representative from the DAN research department, Donna Uguccioni, attended a diving camp for adolescents with diabetes (Camp DAVI) held in the U.S. Virgin Islands. The camp director, Steve Prosterman, and medical director, Dr. George Burghen, were generous in sharing the protocols developed and lessons learned through their experience.

1997-2000 DAN Diabetes and Diving Study

An observational study was designed to study currently certified, adult divers with IRDM. Monitoring took place during several group trips to sub-tropical and tropical locations. Participants with diabetes paid regular fees for trips that had scientific/medical monitors present. The control group was established with apparently healthy non-diabetic participants (customers and staff) on the same trips. Trips were arranged to both day boat resorts and liveaboard dive boats. The physical stressors associated with these diving venues were typically modest.

The rules guiding participation of the diabetic group were consistent with Camp DAVI protocols. IRDM group divers provided detailed medical history before the trip. IRDM group subjects were to have: no secondary complications of diabetes; no hospitalization within past 12 months for severe hypoglycemia or ketoacidosis; documentation of $\text{HbA}_{1c} \leq 9$ percent within two weeks preceding the trip; documentation of a good understanding of plasma glucose/exercise relationship, and medical approval. Control group subjects were apparently healthy divers (not medically evaluated) diving on the same trips.

Plasma glucose was measured in all subjects via finger stick at planned times of 60, 30 and 10 min pre-dive & immediately post-dive in IRDM group subjects and 10 min pre-dive and immediately post-dive in control group subjects. The actual times varied, for the typical reasons associated with any dive and since dives were delayed for correction through carbohydrate ingestion if plasma glucose levels fell below $80 \text{ mg}\cdot\text{dL}^{-1}$ ($4.4 \text{ mmol}\cdot\text{L}^{-1}$). Plasma glucose monitoring employed Bayer

Elite Glucometers (Tarrytown, NY). The glucometers were self-calibrating and required approximately 3 L of blood per test and 35 s to analyze a sample.

The body composition of participants was estimated with seven site skinfolds on trips conducted after the first trip in February, 1997.

Diving activity was monitored with downloadable data loggers that recorded time/depth profiles. The divers on all but one trip also rated each dive for mean physical effort and thermal comfort. A log of carbohydrate ingestion and any adverse events – whether associated with diving or outside of diving – was maintained by each participant.

Several interim reports were published as the data accumulated. These included several abstracts delivered at scientific meetings (Uguzzioni et al., 1998a, 1998b, 2000) and five articles in diving organization periodicals (Dear 1994; Uguzzioni and Dovenbarger, 1996; Dear and Uguzzioni, 1997; Clendenen and Uguzzioni, 2000; Pollock et al., 2005).

A final report of the study was published in the refereed journal *Undersea and Hyperbaric Medicine* (Dear et al., 2004). A total of 83 divers participated; 40 with IRDM and 43 serving as controls. A total of 1059 dives were monitored; 555 by divers with IRDM and 504 by divers serving as controls. Results are described as mean \pm standard deviation with ranges where appropriate.

IRDM group divers had been diving for a mean of almost nine years and had diabetes for a mean of over 15 years. They had body mass index values of 25.3 ± 3.9 ($18.4\text{-}39.8$) $\text{kg}\cdot\text{m}^{-2}$ (mean \pm standard deviation followed by range) and pre-participation HbA_{1c} measures of 7.5 ± 1.2 ($5.8\text{-}11.9$) percent. Their dives were generally modest with maximum depth of 64 ± 20 fsw (20 ± 6 msw) and underwater time of 41 ± 10 min. No symptoms or complications related to hypoglycemia were reported or observed in conjunction with diving during the study. Post-dive plasma glucose fell below $70 \text{ mg}\cdot\text{dL}^{-1}$ ($3.9 \text{ mmol}\cdot\text{L}^{-1}$) in seven percent of the IRDM group dives and only one percent of the control group dives. Moderate levels of hyperglycemia (plasma glucose $>300 \text{ mg}\cdot\text{dL}^{-1}$ [$16.7 \text{ mmol}\cdot\text{L}^{-1}$]) were recorded for 23 divers with IRDM on 84 occasions.

The results by gender are summarized in Figure 1. Plasma glucose levels were lower and stable for control divers as expected. There were no significant differences in plasma glucose between male and female divers with IRDM or between single and repetitive dives (data not shown).

The study concluded that while large plasma glucose swings from pre-dive to post-dive were noted, the data indicate that plasma glucose levels, in adults with at least moderately-controlled IRDM, could be managed to avoid hypoglycemia during uncomplicated recreational dives under benign to modest environmental conditions and diving exposures.

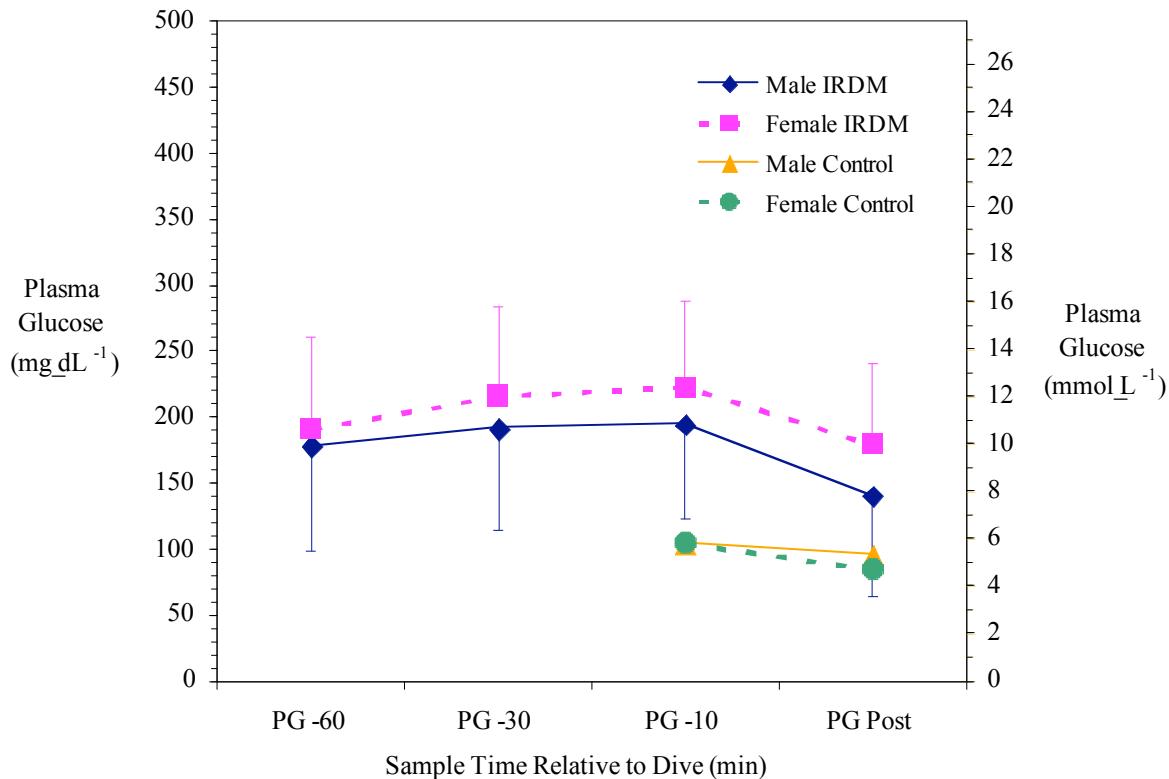


Figure 1: Plasma glucose response to diving: no significant differences by gender or for single vs. repetitive dives by adult divers of either group.

2004 DAN Teenage, Novice Divers with Diabetes Study

An opportunistic observational study was conducted to study novice, teenage divers with IRDM. Data were collected during a special tropical scuba camp program (Dream Big) organized by the Barton Center for Diabetes Education. The program was held in the U.S. Virgin Islands with Steve Prosterman serving as the camp director. The inclusion criteria were the same as for the 1997-2000 adult study with the additional requirement of parental approval.

The monitoring protocol was similar to the 1997-2000 adult diver study. Participants had an additional obligation to check for urine ketones first thing in the morning and one hour prior to each planned dive (urine ketone reagent strips, Becton Dickinson, Franklin Lakes, NJ). The plasma glucose monitoring schedule was the same, with planned times of 60, 30 and 10 min pre-dive and immediately post-dive. A different glucometer was employed (Bayer Ascensia® Contour™, Tarrytown, NY). The glucometers were automatically-calibrating and required approximately 0.6 L of blood per test and 15 s to analyze a sample. Plasma glucose was required to be greater than 120 mg·dL⁻¹ (6.7 mmol·L⁻¹) and rising on successive tests prior to the dive. Plasma glucose levels below this level on the pre-dive measurement, or falling levels, were to be treated with oral glucose gel administered by the diver him/herself. Dives would then be delayed until samples tested at 10-15 minute intervals confirmed that the desired effect was achieved. Formal maximal limits were not established.

Dive profiles were recorded with downloadable data loggers. Divers provided subjective reports after each dive, including information on decompression stop status, thermal comfort, perceived work rate during the dive and post-dive, and whether any problems occurred or symptoms developed.

The results of this study were presented at the 2005 UHMS annual scientific meeting and accepted for publication (Pollock et al., *in press*). A brief summary of the findings is provided here. Results are described as mean \pm standard deviation with ranges where appropriate.

Seven, 16-17 year old divers with IRDM participated in the study; four females and three males. Participants had body mass index values of 22.5 ± 2.9 ($19.9-27.4$) $\text{kg} \cdot \text{m}^{-2}$ and pre-participation HbA_{1c} measures of 7.3 ± 1.1 (5.3-8.5) percent. There was no control group. A total of 42 dives were monitored. Dives were generally modest with maximum depth of 56 ± 20 fsw (17 ± 6 msw) and total underwater times of 44 ± 14 min were modest. Pre-dive plasma glucose tended to be high, exceeding $300 \text{ mg} \cdot \text{dL}^{-1}$ ($16.7 \text{ mmol} \cdot \text{L}^{-1}$) in 22 percent of dives. Males had significantly higher pre-dive levels and greater pre-post-dive changes than females (Figure 2). Post-dive plasma glucose fell below $80 \text{ mg} \cdot \text{dL}^{-1}$ ($4.4 \text{ mmol} \cdot \text{L}^{-1}$) in two male cases (61 and $70 \text{ mg} \cdot \text{dL}^{-1}$ [3.4 and $3.9 \text{ mmol} \cdot \text{L}^{-1}$]). No symptoms or complications related to hypoglycemia were reported.

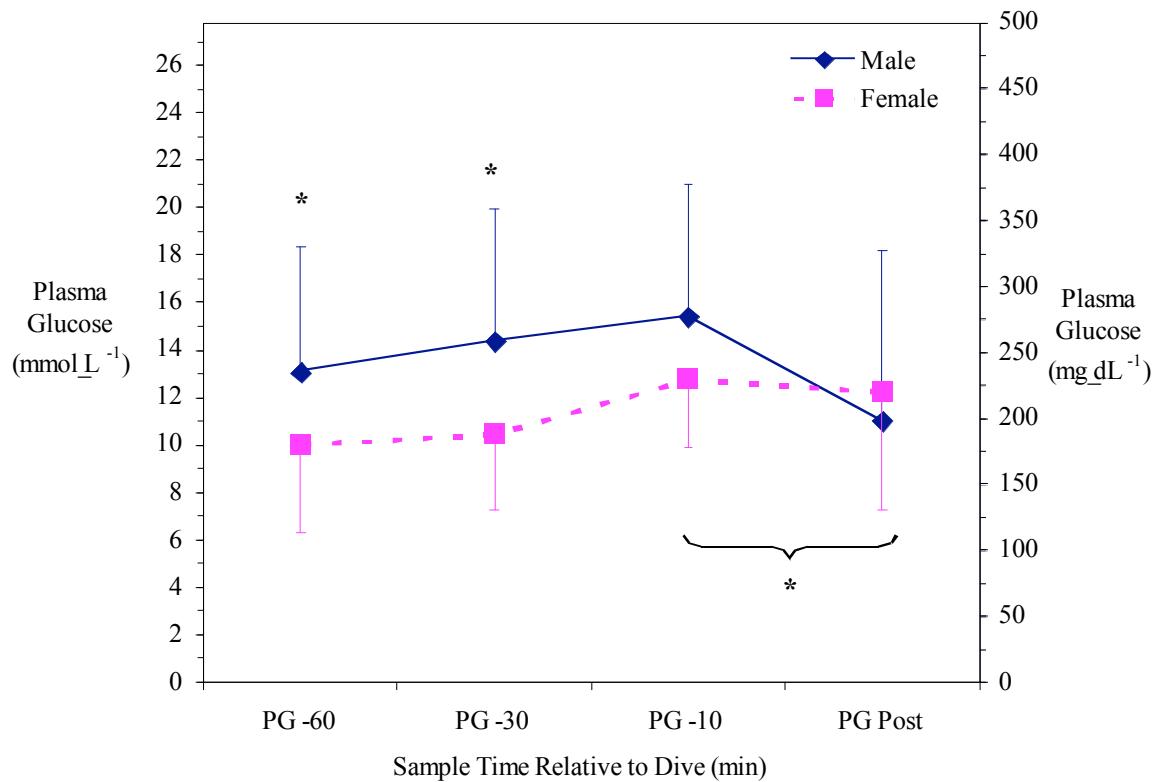


Figure 2: Plasma glucose values of teenager divers with IRDM; significantly greater 60 and 30 min pre-dive values for males; significantly greater pre- to post-dive drop for males (* analysis of variance gender contrast; $p < 0.05$)

The ability to rapidly learn to adjust plasma glucose levels in conjunction with diving was evident in the individual who presented the greatest post-dive value ($559 \text{ mg}\cdot\text{dL}^{-1}$ [$31.1 \text{ mmol}\cdot\text{L}^{-1}$]). All pre- and post-dive values were more modest for this individual in each subsequent day (Figure 3).

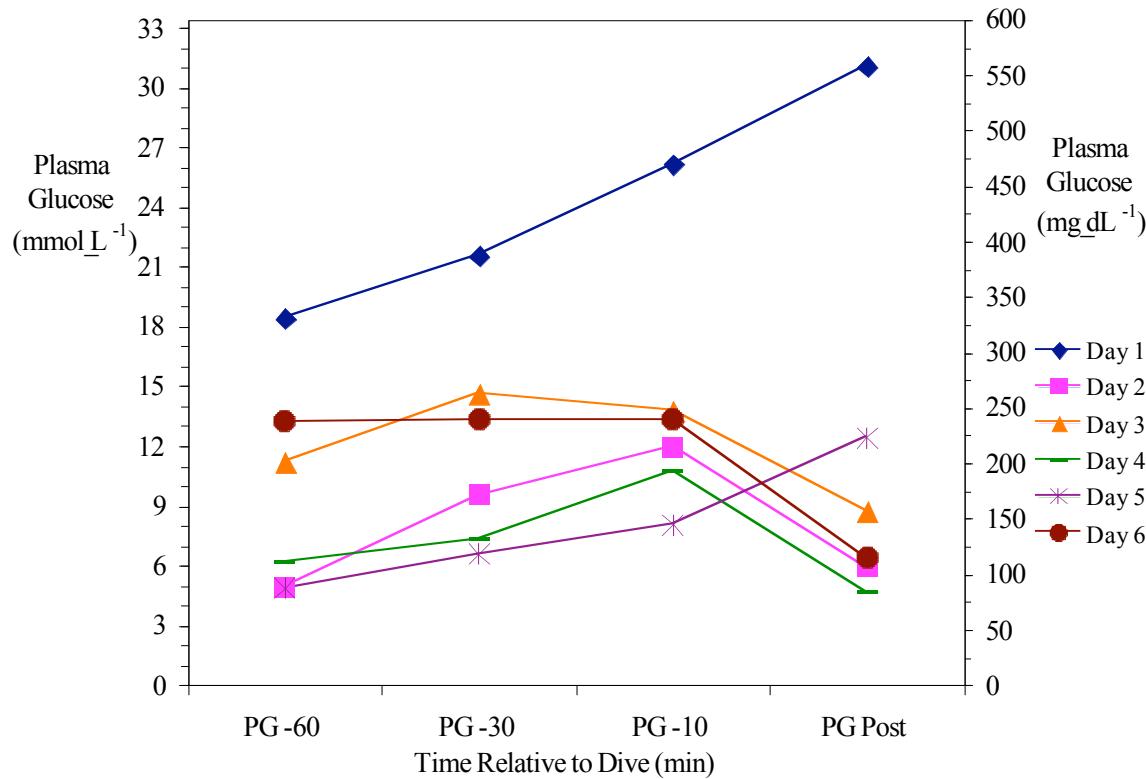


Figure 3: Plasma glucose values at four standard sample points show rapid learning by teenage male subject with most extreme first dive values

The study concluded that the data, although few in number, demonstrated that some adolescents with IRDM, operating within a well-structured and monitored program, can effectively manage their plasma glucose in relation to diving under relatively benign conditions. Education must stress management to avoid either hypoglycemia or excessive hyperglycemia.

Future Initiatives

The data collected through DAN and DAN-affiliated efforts are encouraging as to the ability of modestly controlled, generally healthy and responsible individuals with IRDM to dive with reasonable levels of risk. There remains, however, additional work to be accomplished. Further studies should:

- 1) substantiate the existing data;
- 2) evaluate the impact of acute voluntary elevation of plasma glucose on chronic health and, potentially, dehydration and decompression safety;
- 3) evaluate the plasma glucose response to a wider range of environmental conditions and demands of diving;
- 4) evaluate the efficacy of different strategies of insulin therapy (including short- vs. long-acting agents, insulin pumps, and new and evolving management techniques);

- 5) determine if appropriate reductions in insulin are greater for diving than for other sporting activities of similar exercise intensities; and
- 6) determine whether the distractions associated with diving create a particular influence on self-awareness of hypoglycemia.

Initiatives to collect data must include educational components. Individuals with diabetes are diving; openly or while hiding their status. Educational efforts must include divers (those with diabetes and those who may dive with individuals with diabetes), persons with diabetes interested in diving, and diving professionals. The development of reasonable standards and implementation of awareness and education programs will improve our understanding and hopefully increase the level of safety for all involved.

Acknowledgments

DAN members and volunteers who support our research initiatives.

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A DIVING WITH DIABETES PROGRAM: THE YMCA EXPERIENCE

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History

Are diabetics fit for participation in scuba diving? This question was one of the most controversial issues faced by the entire diving community during the early 1990s. Diabetes mellitus was considered an absolute contraindication for participation in scuba diving by the Undersea and Hyperbaric Medical Society (UHMS), National Oceanic and Atmospheric Administration (NOAA), Divers Alert Network (DAN), and all of the major training agencies. Yet, it was a well-known fact that many "closet" diabetics were diving successfully, with no apparent ill effects or evidence of increased diving accidents. Furthermore, there was no body of scientific data to support a blanket ban. The Americans with Disabilities Act (ADA), which came into force in this period, mandated that the diving community reevaluate its position on various fitness-to-dive issues, including diabetes. The need for separating fact from fiction was apparent. Subsequently, a committee was formed consisting of members of the UHMS and the Council on Exercise of the American Diabetes Association. The committee convened in June, 1994 and reached the following conclusions (Scott and Marks, 2004):

- 1) At present there are insufficient data to justify a blanket prescription against diving for individuals with diabetes mellitus. Clearly, additional research is necessary in this area.
- 2) There are a significant number of individuals treated with insulin or oral hypoglycemic agents for their diabetes mellitus who are now diving.
- 3) There is evidence that individuals treated with insulin or oral hypoglycemic agents are at increased risk in diving, principally from hypoglycemia.
- 4) Individuals with diabetes mellitus treated with insulin or oral hypoglycemic agents who choose to dive should consider that others, including companions, instructors and families share this risk.
- 5) Until further data become available, it seems prudent to exclude the following from diving:
 - a) Individuals with a history of any episodes of severe hypoglycemia (i.e., loss of consciousness, seizures, or requiring the assistance of others) within the preceding 12 months.
 - b) Individuals with advanced secondary complications, such as proliferative retinopathy, neuropathy, or coronary artery disease.
 - c) Individuals with hypoglycemia unawareness (lacking stress symptoms associated with mild hypoglycemia).
 - d) Those individuals who do not have adequately controlled diabetes (as determined by their physician) or who do not have a good understanding of the relationship between diabetes and exercise.
- 6) There remains a group of individuals with well controlled diabetes mellitus, treated with insulin or oral hypoglycemic agents, with good understanding of their disease, who, with suitable training and by following a specially designed management protocol, may be considered for recreational diving.

In essence, the Diabetes and Diving committee's panel of experts dispelled the myth that physically fit, well-controlled diabetics could not participate in scuba safely. It established the first criteria for a

diabetic's fitness to dive. The lack of scientific data concerning diabetes and diving was recognized. The danger of developing hypoglycemia underwater was clearly defined as a major risk for the diabetic diver. Importantly, the committee's findings opened the door for various entities to further explore the issue of diving and diabetes.

The committee's findings were supported by surveys conducted by DAN in 1991 and 1995 (Uguzzoni and Pollock, 2005). Also, both Type 1 and Type 2 diabetics have been diving in Europe since 1991 under the supervision of the British Sub-Aqua Club (BSAC), the Sub-Aqua Association (SAA) and the Scottish Sub-Aqua Club (SSUB) (Edge et al., 2005). These divers are scrutinized carefully and must meet strict criteria for fitness to dive. A study of these divers revealed that they had logged over 1000 dives without any adverse events secondary to hypoglycemia. Four divers did report mild symptoms that they attributed to early hypoglycemia. Reportedly, all four of these divers' symptoms cleared by ingesting an oral glucose paste while underwater. All four continued their activity. None were confirmed to have glucose levels in the hypoglycemic range. A questionnaire developed by Dr. Fred Whitehouse, Division Head Emeritus, Division of Endocrinology and Metabolism, at Henry Ford Hospital, was responded to by 18 divers with insulin-dependent diabetes mellitus (IDDM). All of the divers denied having had any hypoglycemic episodes while diving. Based on these findings, he also concluded that fit diabetics could safely dive if they followed an appropriate diabetic management plan (Kruger et al., 1995).

Dr. Chris Edge of the United Kingdom Sports Diving Medical Committee and co-workers reported on a study of eight IDDM scuba divers in 1997. Each diver performed one simulated hyperbaric chamber dive to 100 feet and one simulated surface dive of equal exertion and duration. All of the divers were certified and experienced. After a fasting blood sugar was drawn, each subject was allowed their usual pre-dive breakfast and insulin dose. One hour later a pre-dive blood glucose was measured. Then each diver performed vigorously for 16 minutes on an exercise bike. The total dive time for each subject was 23 minutes (18 minutes bottom time and five minutes ascend time). Blood glucose levels were monitored at regular intervals for a five-hour period beginning with the onset of the dive. During that period the divers were prohibited from taking any fluids, food, or insulin administration. Despite this, no significant hypoglycemic events were experienced by any of the subjects (Edge et al., 1997).

The UK data revealed several significant findings. Firstly, no statistically significant differences were noted in corresponding blood glucose levels drawn at ambient pressure from those drawn at four atmospheres of pressure. Therefore, his data suggest that at least within the normal depth range for recreational scuba, increased pressure on the diver does not alter the blood glucose level. Secondly, none of the subjects developed symptomatic hypoglycemia despite vigorous exercise and an unusual post-dive period of deprivation.

Dr. George A. Burghen, Chief of Endocrinology and Metabolism at the University of Tennessee, introduced diabetic management guidelines for scuba diving in 1995 (unpublished; personal communication). These guidelines were consistent with the recommendations of the 1994 Diabetes and Diving Committee. They offered a diabetes management plan, general safety guidelines, measures for recognition and prevention of hypoglycemia, and appropriate emergency care for hypoglycemia. Dr. Burghen's plan advocated frequent self-monitoring of blood glucose (SMBG) and ketone testing before and after diving. He recommended specific pre-dive blood glucose levels in order to prevent hypoglycemic events.

Dr. Burghen worked with Stephen Prosterman, the Diving and Field Supervisor of the University of the Virgin Islands in St. Thomas, and others to develop a scuba camp for persons with diabetes that became known as Camp DAVI (Diabetic Association of the Virgin Islands) (Winsett et al., 1992;

Winsett et al., 1996). The success of the camp was echoed by Drs. Michael Lerch and Ulrike Thurm of Germany. These investigators studied seven IDDM divers who essentially followed Dr. Burghen's guidelines. None of the divers experienced any adverse events or hypoglycemic episodes (Lerch et al., 1996).

The divers at Camp DAVI followed a diabetic management plan, which was a modification of Dr. Burghen's original plan. Prosterman developed a flow sheet to assist the diabetic diver in managing his or her diabetes before, during and after diving activities (Prosterman, 2001). Camp DAVI remains an excellent venue for diabetic divers to increase their skills and learn to dive safely. Diabetic divers attending his camp have not suffered any significant hypoglycemic episodes.

Dr. Duke Scott, Medical Director of the YMCA SCUBA Program, introduced the YMCA scuba protocol for divers with diabetes in early 1995 (Scott, 2000). The protocol was designed for the training of qualified diabetics to scuba dive. It also adhered to the recommendations of the 1994 Diabetes and Diving Committee. The plan included guidelines for pool activities and open water dives. It recommended that the diabetic student perform simulated open water dives while in the safety of the pool environment. These simulated dives included pre- and post-dive SMBG, pre- and post-dive meals, pre- and post-dive adjustment of insulin dosages, participation of an informed buddy, and appropriate responses to a hypoglycemic event. During the 10 years of its existence, no adverse events have been reported from its use. YMCA SCUBA is the only training agency with a specific program for diabetic divers.

DAN began an observational research project in 1997 to study the blood glucose response of IDDM and control divers. Their main objective was to determine if and how often hypoglycemic episodes occur when following accepted guidelines. The guidelines developed by Dr. Burghen and Steve Prosterman formed the basis of their dive management plan. A total of 40 divers with "at least moderately controlled" IDDM were studied while participating in "tropical dive vacations." The divers regulated their own diet, insulin doses, and dive activity. Their blood glucose levels were required to be greater than $80 \text{ mg}\cdot\text{dL}^{-1}$ ($4.4 \text{ mmol}\cdot\text{L}^{-1}$) immediately pre-dive. A total of 555 dives were performed over a two to seven day period (divers performed a mean from 1.0 to 4.2 dives per day). No complications secondary to hypoglycemia were reported during or after any of the dives. Two post-dive blood glucose levels were in the hypoglycemic range (41 and $61 \text{ mg}\cdot\text{dL}^{-1}$ [2.3 and $3.4 \text{ mmol}\cdot\text{L}^{-1}$]) but the divers were asymptomatic and able to take corrective measures. The authors concluded that "Our observations support the contention that, when adhering to an easy to follow regimen, plasma glucose levels in well-motivated individuals with at least moderately controlled insulin-requiring diabetes mellitus can be managed to avoid hypoglycemia during uncomplicated dives conducted under controlled recreational diving conditions with minimal environmental stresses and low decompression risk dive profiles" (Dear et al., 2004).

Physiology

Hypoglycemia is considered the major risk for any physically fit diabetic who chooses to participate in scuba. The brain's function is very sensitive to low concentrations of plasma glucose, leading to poor judgment, lack of concentration, and, eventually, unconsciousness. Such a scenario during a scuba dive would endanger not only the diabetic diver, but also his fellow divers. The potential for developing hypoglycemia is greater in diabetic divers with Type 1 diabetes than in those with Type 2. During exercise, the muscles increase their use of oxygen, glucose, liver glycogen, muscle triglycerides and free fatty acids. In non-diabetics, the increased glucose utilization triggers a variety of homeostatic responses in order to maintain the blood glucose concentrations within normal ranges. Insulin declines and concentrations of counter-regulatory hormones (glucagon, growth hormones, catecholamines and cortisol) rise, increasing hepatic gluconeogenesis. The harmonious action of these

hormones allows for a considerable increase in muscle oxygen consumption while maintaining the body in metabolic homeostasis. These normal metabolic responses are disrupted in Type 1 diabetes. There is no endogenous source of insulin for self-regulation and the counter-regulatory mechanisms are impaired. Therefore, prudent regulation of the diabetic diver's exogenous insulin and carbohydrate intake are of the utmost importance in order to assure that reasonable metabolic homeostasis is maintained, while avoiding the severe consequences of hypoglycemia.

In Type 2 diabetes, the metabolic response to exercise may be impaired, but generally not to the degree seen in Type 1 diabetes. Usually plasma insulin does not decline and glucose production is slowed, but the resulting drop in blood sugar rarely approaches the point of hypoglycemia. Exceptions to this rule include Type 2 diabetics taking sulfonylines and/or requiring exogenous insulin. The diabetic's physician may address this problem by adjusting the diabetic's caloric intake, insulin and/or hypoglycemic medication. It is recommended that diabetics who participate in scuba not be treated with sulfonylines due to their unpredictability with regard to hypoglycemia.

Strategies for avoiding hypoglycemia during scuba include meal scheduling, decreasing the insulin dose, appropriate site and type of insulin administration, increasing caloric intake, and prudent pre- and post-dive self-monitoring of blood glucose. Meticulous attention to the development of and adherence to a diabetic dive management plan is essential. This plan should include such issues as symptoms of hypoglycemia, emergency treatment of hypoglycemia, and the participation of an informed dive buddy. The informed dive buddy should be non-diabetic, have an understanding of diabetes, and be willing and able to respond to a hypoglycemic event.

Delayed hypoglycemia is another potential danger for the diabetic diver. During exercise, the skeletal muscle cells develop increased sensitivity to insulin, allowing for increased glucose intake. Also, there is an increased demand for glycogen, leaving the glycogen stores of the skeletal muscles and liver depleted. Therefore, following exercise, the diabetic's blood glucose concentration may be decreased and glycogen synthesis is increased. The glycogen stores of the liver are replenished more slowly than those of skeletal muscle. The resulting impairment in hepatic glycogenesis leaves the diabetic diver vulnerable to the development of post-dive hypoglycemia. It may occur at night, 6 to 15 hours after the day's dives are completed. It most often occurs, but is not limited to, those in excellent metabolic control. The potential for this complication is present when the diabetic diver performs multiple dives over several consecutive days, such as during a dive vacation, due to the prolonged periods of increased exertion. Preventive measures include increased food intake, pre- and post-dive consumption of complex carbohydrates, increased fluids, abstention from alcohol, reduction of non-dive-related exercise, careful monitoring of post-dive blood glucose levels, and prudent reduction of insulin doses when indicated. Also, night dives should be avoided, unless the diabetic diver has developed a specific management plan and trained for night dives.

Another potential risk for diabetic divers is complications arising from hyperglycemia. This is more likely to occur when the diabetic is in poor metabolic balance. Unfortunately, some diabetics who participate in recreational scuba fit into this category. Also, many diabetic divers apparently initiate their diving activity in a self-imposed extreme hyperglycemic state. They reason that the elevated pre-dive blood glucose will prevent hypoglycemia during the dive. Although this is a reasonable assumption, they must exercise caution not to leave themselves in a severe state of insulinemia. An observational study conducted by DAN involving 16 recreational diabetic divers revealed that just prior to diving, their blood sugars were $234 \pm 62 \text{ mg} \cdot \text{dL}^{-1}$ ($13.0 \pm 3.4 \text{ mmol} \cdot \text{L}^{-1}$) (mean \pm standard deviation) before first dives and $215 \pm 65 \text{ mg} \cdot \text{dL}^{-1}$ ($12.0 \pm 3.6 \text{ mmol} \cdot \text{L}^{-1}$) before repetitive dives (Uguzzoni et al., 1998). The divers were not monitored for urine or blood ketones. I feel that a pre-dive blood glucose concentration of over $240 \text{ mg} \cdot \text{dL}^{-1}$ ($13.3 \text{ mmol} \cdot \text{L}^{-1}$) may be potentially dangerous. If a diabetic diver initiates a dive with significant hyperglycemia and/or preexisting mild ketosis, the

subsequent vigorous exercise may precipitate ketoacidosis. If insulinemia exists, the exercising muscle cell cannot utilize glucose effectively despite the state of increased insulin sensitivity. Also, glucagon-induced production of glucose by the liver is unopposed and fatty acids are mobilized to supply the increased demand for fuel. This results in increasing hyperglycemia, ketosis, and acidosis. In my opinion, SMBG and blood or urine ketone testing should be performed before and after every dive. Prevention should be aimed at keeping the diabetic diver under good metabolic control. Every Type 1 diabetic diver must learn to regulate insulin doses and ingest appropriate snacks in order to duplicate the system that functions automatically in non-diabetic divers. The YMCA scuba program's simulated open-water dives (in the pool) assist the diabetic diver in obtaining that goal. I have found that every diabetic diver is required to make adjustments to meet his or her own unique needs.

Fitness to Dive

In my opinion, diabetics who participate in scuba diving must be held to a high standard. In order to qualify for diving, they should be physically fit, exercise on a regular basis, and have a thorough understanding of diabetic management during exercise. They should chart their daily glucose patterns and know the effects of strenuous exercise on their blood glucose levels. They should have no findings of significant systemic diabetes; for example, retinopathy, peripheral neuropathy, nephropathy, microvascular disease, macrovascular disease, or diabetic foot. They must be in good metabolic balance, demonstrated by blood glucose levels in the acceptable range and glycosylated hemoglobin (HbA_{1c}) levels consistently at eight percent or lower (6.5-7.5 percent is desirable). They should have no recent history of episodes of hypoglycemia while at rest or during exercise; no history of hypoglycemic unawareness, such as nocturnal or asymptomatic hypoglycemia; and no recent history of diabetic ketoacidosis. They must understand the importance of and be willing to perform SMBG and ketone testing. The potential diver must demonstrate that he or she is mentally sound and mature enough to dive safely with diabetes. Of course, the diabetic's personal physician should have the final say in determining fitness to dive.

Diabetic Dive Management Planning

There is no specific body of evidence to declare any specific pre-dive blood glucose range as ideal. This is further complicated by the fact that every diabetic is unique with regard to metabolic state, insulin and/or hypoglycemic medication regimen, diet, exercise experience and general health. All of these factors must be taken into consideration when developing each individual's diabetic dive management plan. Additionally, due to the rapid progress in diabetic therapy, such as the improvement in the insulin pump and new forms of insulin, the various treatment regimens are in a constant state of flux. The underlying goal of the various management plans is the prevention of hypoglycemia during the diving activity, especially while the diver is underwater.

The prototype for most diabetic dive management plans is the unpublished one authored by Burghen in 1995. All of the plans recommend a self-imposed pre-dive state of hyperglycemia. They did not recommend specific adjustments in pre-dive insulin administration or diet in order to obtain this goal. Dr. Burghen recommended a "balanced meal" one to two hours before a dive. The diver was then to perform three SMBG determinations and three tests for ketones - 60 minutes pre-dive, 30 minutes pre-dive, and immediately pre-dive. He emphasized that the blood glucose level should be rising or stable with each successive test. The recommended blood glucose range for each time frame was: 1) 60 minutes prior to diving, $80\text{-}250 \text{ mg}\cdot\text{dL}^{-1}$ ($4.4\text{-}13.9 \text{ mmol}\cdot\text{L}^{-1}$); 2) 30 minutes prior to diving, greater than previous blood glucose and between $120\text{-}250 \text{ mg}\cdot\text{dL}^{-1}$ ($6.7\text{-}13.9 \text{ mmol}\cdot\text{L}^{-1}$); and 3) immediately before diving, greater than previous blood glucose checks and between $150\text{-}250 \text{ mg}\cdot\text{dL}^{-1}$ ($8.3\text{-}13.9 \text{ mmol}\cdot\text{L}^{-1}$). If the blood glucose level was above $250 \text{ mg}\cdot\text{dL}^{-1}$ ($13.9 \text{ mmol}\cdot\text{L}^{-1}$) and/or ketones were present in the urine (or blood) the diving activity was to be cancelled. The diabetic was to seek advice

and adjust the diabetic management plan to achieve better metabolic control. If the blood glucose level fell $20 \text{ mg}\cdot\text{dL}^{-1}$ ($1.1 \text{ mmol}\cdot\text{L}^{-1}$) or more during the hour before the dive, Dr. Burghen recommended that an appropriate snack be taken and serial SMBG and ketone testing performed until the blood glucose level stabilized within the acceptable range. At that point, the diver was able to proceed with the planned diving activity. These acceptable pre-dive glucose levels were empirical, but based on acceptable levels established for other strenuous sporting activities.

The YMCA SCUBA diabetic diver protocol has similar guidelines for acceptable pre-dive blood glucose levels (Scott, 2000). The one hour, 30 minute, and immediately pre-dive SMBG and ketone tests are required. However, it allows for a pre-dive blood glucose range of $120\text{-}230 \text{ mg}\cdot\text{dL}^{-1}$ ($6.7\text{-}12.8 \text{ mmol}\cdot\text{L}^{-1}$). I believe that, at this time, only physically fit, well-controlled diabetics who exercise on a regular basis should qualify for participation in scuba. Such individuals should already have an understanding of how to adjust their diabetic management plan during exercise. The protocol offers specific instructions concerning the adjustment of pre-dive insulin doses, meals, snacks and fluids. A pre-dive complex carbohydrate snack (20 to 30 grams) is mandatory. Diving is restricted to bottom times of 30 minutes or less and maximum depths of 60 to 100 feet (18 to 30 m), based on experience. Most importantly, the YSCUBA plan provides for simulated open water dives to be performed in the safety of the pool while being monitored. During these dives, the diabetic has the opportunity to work out any flaws in the diabetic dive plan. If he or she discovers that pre-dive glucose concentration is not high enough to ensure the prevention of hypoglycemia, appropriate corrective measures may be taken. I have found that most diabetic divers can perform recreational dives safely with a pre-dive blood glucose concentration of $120\text{-}180 \text{ mg}\cdot\text{dL}^{-1}$ ($6.7\text{-}10.0 \text{ mmol}\cdot\text{L}^{-1}$) if they follow the protocol and their diabetes is well-controlled. Therefore, the potential danger of extreme hyperglycemia, complicated by dehydration from diuresis, may be avoided and the diabetic diver may be maintained in a reasonable state of metabolic control. However, the pre-dive blood glucose level should be increased (150 to $200 \text{ mg}\cdot\text{dL}^{-1}$ [8.3 to $11.1 \text{ mmol}\cdot\text{L}^{-1}$] or more) and the bottom time decreased (maximum of 20 minutes) when diving under adverse conditions, such as strong current, cold water or excessive workload. It is recommended that all diabetic divers participate in simulated dives periodically, especially after changes in their diabetic regimen. The validity of these simulated dive activities is based on the Edge et al. (1997) study, which demonstrated that increasing atmospheric pressure does not alter an individual's blood glucose levels. Therefore, pool dives can be constructed to simulate a typical two-dive open water experience, including varying degrees of workload, and appropriate diabetic management during surface interval time.

Since most diving activities involve multiple dives during a day, this issue needs to be addressed with regard to diabetes. We recommend that diabetics limit their diving activity to no more than two dives daily. SMBG and ketone testing should be performed immediately upon completion of the first dive. Based on these results, the following post-dive plan should be followed:

- 1) If the random blood sugar (RBS) value is $230 \text{ mg}\cdot\text{dL}^{-1}$ ($12.8 \text{ mmol}\cdot\text{L}^{-1}$) or above and/or blood ketones are present, terminate the diving activity. Respond to this situation as directed by your personal physician. Monitor RBS and blood ketones closely.
- 2) If RBS is below $80 \text{ mg}\cdot\text{dL}^{-1}$ ($4.4 \text{ mmol}\cdot\text{L}^{-1}$), treat as hypoglycemia (see section on responses to hypoglycemia).
- 3) If RBS is $80 \text{ mg}\cdot\text{dL}^{-1}$ ($4.4 \text{ mmol}\cdot\text{L}^{-1}$) or above, a complex carbohydrate snack is appropriate. Perform serial SMBG to insure the blood glucose level is not dropping.
- 4) Drink 16 ounces of fluid or more.

Recommendations for the management of the surface interval time, time between the first and second dive, are as follows:

- 1) The surface interval time should be at least one hour in duration.
- 2) Rest for the first 30 minutes.

- 3) Perform no strenuous activity.
- 4) Perform periodic SMBG, and immediately if any symptoms of hypoglycemia develop.
- 5) Appropriate meals and snacks should be taken.
- 6) Administration or omission of scheduled insulin dosages should be determined by the diabetic's exercise experience, personal physician's advice, and SMBG values. Generally, we recommend the omission of doses or, if administration is necessary, that the second dive be cancelled.
- 7) Insulin pump therapy (using insulin Lispro): if not hypoglycemic after SMBG, reattach pump and decrease the basal insulin infusion to 50% of the usual rate during the surface interval (or as directed by personal physician). Perform SMBG periodically and respond appropriately to values obtained.
- 8) Pre-dive SMBG and blood ketone testing should be performed, and snacks and fluids consumed, before the second dive in a manner identical to the first dive.

Hypoglycemia

The signs and symptoms of hypoglycemia include:

- 1) Early warning signs - unusual hunger, headache, alteration of mood, nervousness, and/or fatigue.
- 2) Mild reaction - tremors, pounding and/or rapid heart rate, sweating, clamminess of skin, and/or extreme fatigue.
- 3) Moderate reaction - Severe head and/or neck pain, extreme alterations of mood, irritability, and/or extreme fatigue.
- 4) Severe reaction - decreased awareness or unresponsiveness, unconsciousness, and/or convulsions.

Responses to Symptoms of Hypoglycemia

The diabetic diver must be alert for any signs of developing hypoglycemia while underwater. I agree with other authors who recommend that the diabetic diver and his informed buddy should carry a carbohydrate source during a dive. Steve Prosterman recommended Insta-Glucose if available, with honey in a plastic bottle as a good substitute (Prosterman, 2001). Diabetic divers of the BSAC carry a glucose paste with them. Dr. Edge reported that if signs of hypoglycemia develop, the diver ingests the paste underwater by inserting the nozzle of the tube into their mouth with the regulator mouthpiece in place. Before a diabetic diver chooses to use this method, it should be practiced to perfection in the pool. I feel, however, that if any suspected signs of hypoglycemia develop the diabetic diver and his informed buddy should immediately terminate the dive and make a safe ascent to the surface. If symptoms are severe, immediately ingest the glucose paste or honey. If not, return to the boat (or shore, etc.) and perform SMBG first, in order to ascertain if the symptoms are truly due to hypoglycemia. If the diver's blood glucose is in the hypoglycemic range, corrective measures should be taken and the diabetic's management plan reevaluated. If the blood glucose level is normal, other reasons for the symptoms should be considered, including barotrauma, decompression sickness, and other dive-related injuries.

I recommend the following responses for a diabetic diver with hypoglycemia:

- 1) If only early warning signs of hypoglycemia and the SMBG is $80 \text{ mg}\cdot\text{dL}^{-1}$ ($4.4 \text{ mmol}\cdot\text{L}^{-1}$) or above, look for other causes of diabetic diver's symptoms, including anxiety, sea sickness, dehydration, heat exhaustion, and/or early signs of decompression sickness.
 - a) Eat an appropriate complex carbohydrate protein snack.
 - b) Repeat SMBG in about 30 minutes.

- c) If symptoms clear and SMBG is $80 \text{ mg}\cdot\text{dL}^{-1}$ ($4.4 \text{ mmol}\cdot\text{L}^{-1}$) or above, and no other contraindications are determined, then the diabetic diver may continue with his or her scuba diving activity in accordance with the protocol.
- 2) If only early warning signs of hypoglycemia but the SMBG is below $80 \text{ mg}\cdot\text{dL}^{-1}$ ($4.4 \text{ mmol}\cdot\text{L}^{-1}$), the diabetic diver should:
- a) Take 10 to 15 grams of sugar, such as four to six ounces of fruit juice, six lifesavers, or four teaspoonfuls of sugar.
 - b) Repeat SMBG at 30 minute intervals or as indicated.
 - c) Continue this process until blood sugar value is $80 \text{ mg}\cdot\text{dL}^{-1}$ ($4.4 \text{ mmol}\cdot\text{L}^{-1}$) or above and symptoms have cleared.
 - d) Watch carefully for relapses.
 - e) Eat a complex carbohydrate-protein snack. Cease all scuba diving activity and seek medical advice.
 - f) Hydration is a priority.
- 3) If mild signs of hypoglycemia develop and SMBG is below $80 \text{ mg}\cdot\text{dL}^{-1}$ ($4.4 \text{ mmol}\cdot\text{L}^{-1}$), the diabetic diver should:
- a) Initiate same treatment as for early warning signs (Section 2 above).
 - b) Four glucose tablets may be substituted for sugar snack (easier to carry).
- 4) If moderate hypoglycemia develops and SMBG is below $60 \text{ mg}\cdot\text{dL}^{-1}$ ($3.3 \text{ mmol}\cdot\text{L}^{-1}$), the diabetic diver should:
- a) Immediately take 4 to 6 glucose tablets or large sugar snack, or spoonfuls of sugar.
 - b) Repeat SMBG at 30 minute intervals or as indicated.
 - c) Continue treatment with glucose tablets and interval monitoring until symptoms clear and SMBG value is $80 \text{ mg}\cdot\text{dL}^{-1}$ ($4.4 \text{ mmol}\cdot\text{L}^{-1}$) or above.
 - d) Watch carefully for signs of relapse. Recovery is usually longer.
 - e) Cease all scuba diving activity and seek medical advice.
 - f) If the diabetic diver becomes confused, disoriented, or combative, he or she may require assistance from his or her "informed" dive partner
 - g) If the diabetic diver is unable to take sugar snack or glucose tablets, then 1.0 mg glucagon should be given subcutaneously or intramuscularly in the shoulder or anterior thigh. A positive response should be noted in 10 to 15 minutes. Proceed with sugar snack, etc.
 - h) Observe SMBG carefully for rebound hyperglycemia (high blood sugar).
 - i) Do not give the diabetic diver food or fluids by mouth until he or she is alert enough to swallow, in order to avoid possible aspiration into the lung and/or choking.
- 5) If severe hypoglycemia develops (the SMBG value will generally be below $60 \text{ mg}\cdot\text{dL}^{-1}$ [$3.3 \text{ mmol}\cdot\text{L}^{-1}$]), the diabetic diver's informed dive partner should:
- a) Immediately administer 1.0 mg glucagon subcutaneously or intramuscularly to the diabetic diver, as described above.
 - b) If available, and a trained medical person is present, then intravenous glucose and fluid should be given.
 - c) Seek emergency medical service and advice.
 - d) Cease all scuba diving activity.
- 6) The diabetic diver and his or her informed buddy should practice responding to a hypoglycemic episode in the pool during a simulated dive. While underwater the diabetic should give an established hand signal (such as the letter L made with the thumb and index finger) to indicate the possibility of hypoglycemia. They should make a safe ascent to the surface, establish positive buoyancy, and move out of the pool. The informed buddy should then check the diabetic's blood glucose.

Dive Kit for the Diabetic Diver

Watertight container to hold the kit, clearly marked
The Protocol
Personal medical history
Personal physician name and phone number
SMBG monitor and glucose Oxidose sticks, with instructions
Glucose paste, tablets, honey or substitute
Glucagon for subcutaneous or intramuscular injection
Instructions and supplies for administering glucagon
Diabetic identification tag or bracelet (identification should be worn during and following diving activity)

Dive Log for the Diabetic Diver

All dives should be logged, including details relevant to the diabetes such as information on insulin administration, SMBG, blood ketone tests, comments related to diabetes management, environmental conditions, and any adverse reactions. Such records will be valuable for both retrospective analysis and future planning.

Conclusions

There is sufficient evidence at this time to recommend that physically fit, well-controlled, properly trained diabetics may safely participate in scuba. It is essential that the diabetic has a thorough understanding of his or her disease and the management of exercising with diabetes. Development of hypoglycemia while underwater is an inherent risk that the diabetic, his companions, and family must recognize and accept. The degree of this risk may be minimized by adherence to a meticulously developed diabetic dive management plan, participation of an informed dive buddy, and a common sense approach to the activity. No definitive optimal pre-dive blood glucose range has been determined at this time. However, present data suggest that the empirical values recommended by existing management plans appear to be adequate. Further research and data collecting is necessary in order to establish absolute guidelines. Simulated dives in the pool are required to allow the diabetic and his informed buddy to work out flaws in the diabetic's dive management plan. Practicing appropriate responses to a hypoglycemic event should also be performed during the simulated pool dives.

In my opinion, the success of any standard for diabetic divers depends on the establishment of a detailed protocol that is comprehensive and easily understandable by both the diabetic dive student and his or her scuba instructor. The challenges include the wide diversity in the maturity, educational level, and ability of diabetics as well as scuba instructors. Another problem is the lack of conformity in how the different training agencies approach the diabetic dive student. The development of a single standard for training diabetics adopted would be an important step forward.

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SCUBA DIVING WITH DIABETES MELLITUS: FRENCH DATA, PROCEDURES AND REGULATIONS

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I. Introduction

Leisure diving in France is regulated by the Fédération Française d'Etudes et de Sports Sous-Marins (FFESSM, French federation for underwater diving). A total ban on diving for diabetic patients existed until the end of 2004, mostly due to the risk of hypoglycemic events underwater and consequent drowning. It is well known that despite this ban, many diabetic patients were still diving in France, most of them hiding their diabetic condition, and thus possibly not receiving the proper education, medical advice and support that would allow them to dive with greater safety.

Historically, the list of medical contraindications to diving was designed when diving was considered an extreme activity, primarily reserved for the military and industry. With the omnipresent risk of hypoglycemia, insulin-requiring diabetes mellitus (IRDM) was an example of a chronic disease disqualifying individuals from extreme activity. Nowadays, diving has become a leisure activity for the masses, and is usually practiced in easy, shallow and low decompression stress conditions. Moreover, the changes in diabetes knowledge and care options have made it much easier for diabetic patients to integrate into normal life and practice activities that were once forbidden. Despite these changes, the fear of letting a diabetic patient practice leisure diving is still deeply rooted in the medical subconscious. Allowing IRDM patients to dive was, certainly in France, a subject of controversy and hostility.

The need for an evidence based approach of this problem conducted us to organize a working group, search for available data and study the possibility for diabetic subjects to be allowed to dive within the FFESSM.

A review of available literature shows that it is reasonably safe for some diabetics to dive in easy diving conditions (Taylor and Mitchell, 2001; Edge et al., 2002, 2005; Dear et al., 2004; Tabah, 2005).

If the risk of hypoglycemic episodes can be reduced with a reduction of insulin treatment and blood glucose-based diving procedures, the remaining risks for the diabetic divers will be secondary to the degenerative complications of diabetes. In available diving incident reports, it is clear that high blood pressure and heart disease are frequent health conditions contributing to diving accidents and fatalities (Vann et al., 2000). Special attention should be given in screening for macro- and micro-angiopathy in diabetic candidates for diving.

Non-insulin-requiring diabetes mellitus (NIRDM) diabetics were excluded from our studies, as reduction of oral treatment would be easy to do for them, but the high frequency of degenerative complications and co-morbidity make diving with NIRDM a totally different issue of study.

We conducted a field study in October 2003 to determine whether specific blood glucose (BG) based guidelines could be employed to allow selected diabetics to dive with acceptable safety (Lormeau et al., 2005). The results of our first study led the FFESSM to allow selected diabetic patients to dive in France by following a strict set of rules and diving procedures.

A second study was conducted in January 2005, in a warmer sea, to compare blood glucose variations when diving in tropical conditions and to obtain more data from continuous glucose monitoring underwater.

Actual diving procedures and restrictions for IRDM divers protect against the development of hypoglycemia while diving. This will be confirmed by a long term follow-up of the diabetic diving population in France, based on an annual self-reported questionnaire and collection of blood glucose and diving profiles.

II. First Field Study, October 2003, French Riviera

This study took place when the FFESSM had the diabetic disease listed as a permanent contraindication to diving. Evidence from other countries indicated that diabetics were diving successfully. The belief that many IRDM subjects were diving in France while hiding their diabetic condition, led us to organize this study to determine if it could be possible for selected diabetic subjects to dive safely. The settings, methodology and results of this study are described in detail in a recent paper (Lormeau et al., 2005); a short summary is provided here.

Our main objectives were to analyze the behavior and BG tendency of IRDM subjects when diving and to develop blood glucose-based diving procedures and guidelines for the IRDM divers to allow them to dive in security within the structures of the FFESSM. Fifteen IRDM patients were enrolled in a four day diving trip to Golfe Juan, in the French Riviera. They averaged 40 years of age, all with well-controlled diabetes and no degenerative complication related to the disease. Most of them were beginners in scuba-diving and had to complete a beginning course in a swimming pool prior to the study. Medical monitoring was provided by four diabetologists and a hyperbaric physician.

All dives were limited to a maximum depth of 20 m (66 fsw) and a 30 minute duration. We used BG-based diving procedures similar to those found in our actual guidelines, with three BG tests before and after diving and a pre-dive BG target of $1.5 \text{ g} \cdot \text{L}^{-1}$ ($8.3 \text{ mmol} \cdot \text{L}^{-1}$). Insulin doses were adjusted every evening during meetings between the diabetic divers and physicians.

Divers contended with bad weather and rough seas, underwater visibility ranging from 1-10 m (3-33 ft), and water temperature of 16°C (60°F). One hundred dives were conducted with no instances of hypoglycemia or faintness related to diving. We did observe one case of middle ear barotrauma and several cases of sea sickness onboard related to the rough sea conditions.

The mean daily caloric intake was 3225 kcal (13.5 MJ), excluding onboard meals (averaging 25 g of carbohydrates per dive). Insulin doses for the subjects were reduced an average of 19.3% by the end of the trip. The bolus was reduced more (26%) than the base (12.3%). The mean BG just before immersion was $2.04 \text{ g}\cdot\text{L}^{-1}$ [range 0.89-3.65] ($11.3 \text{ mmol}\cdot\text{L}^{-1}$ [range 4.9-20.3]). The mean BG just after reboarding the boat was $1.64 \text{ g}\cdot\text{L}^{-1}$ [range 0.52-2.75] ($9.1 \text{ mmol}\cdot\text{L}^{-1}$ [range 2.9-15.3]). The average pre-to-post-dive decrease (delta BG) was $0.4 \text{ g}\cdot\text{L}^{-1}$ (2.2 mmol·L⁻¹). The kinetics of the BG levels proved to be important. Specific levels could not be the only target; it was also important that BG was stable or increasing. Diabetic divers should avoid starting a dive with a decreasing blood glucose level.

The air consumption of each diabetic diver was compared to the non-diabetic members of his diving group (instructors and medical staff). The average air consumption was 110% in the IRDM group. This moderate excess in consumption is usual for beginners and is most likely related to inexperience in diving rather than the diabetic condition.

Our immersion procedures proved to be safe. None of our patients had symptoms related to hypoglycemia underwater or onboard.

We consider that the "ideal" BG before immersion should be $2.0\text{-}2.5 \text{ g}\cdot\text{L}^{-1}$ ($11.1\text{-}13.9 \text{ mmol}\cdot\text{L}^{-1}$). We used a lower BG target for this study: $1.5 \text{ g}\cdot\text{L}^{-1}$ ($8.3 \text{ mmol}\cdot\text{L}^{-1}$). This caused a need for a massive carbohydrate intake before diving to reach the BG target, up to 155 g of carbohydrates for a single dive. This was not pleasant on a moving boat and caused sea sickness in several of our subjects. We therefore recommend lowering the long acting insulin dose by 30% on the night before the dive and both the long acting and regular insulin by 30% on the diving days.

The results summarized above (Lormeau et al., 2005) were first presented at the 2004 European Underwater and Baromedical Society (EUBS) annual meeting in Corsica, allowing us to initiate discussions with the medical committee of the FFESSM. Once the possibility was raised that IRDM subjects could dive without an unacceptably increased risk, the next step was to establish rules and propositions to adapt our diving procedures to allow IRDM patients to dive in security, with no medical monitoring, and without disturbing the normal course of diving on a dive boat.

Our propositions for restricted qualification requirements were agreed upon on 17th October 2004 by the medical, technical and directory committees of the FFESSM. IRDM divers were then allowed to dive within the FFESSM dive clubs with the restrictions and procedures discussed below. Compared with other guidelines for IRDM divers, the French policies might seem more restrictive. They have to be recognized as the first stage in allowing subjects with chronic diseases to dive in a country where scuba diving was historically reserved for the perfectly fit.

III. Current Regulations and Procedures for Diabetic Divers

The French ministry of sports delegated its powers to the FFESSM regarding all the leisure subaquatic activities. Therefore, the FFESSM policies are equivalent to law. The following diving

procedures and guidelines are officially recommended by the FFESSM and mandatory for IRDM subjects to dive within its structure (Grandjean, 2005).

A. Diabetologic Fitness to Dive

French regulations classify diving as an extreme sport, and specify that a yearly medical certificate of fitness to dive must be acquired by all the divers. The diabetic diver needs to undergo fitness and diving medical examinations on a yearly basis. The diver's diabetologic condition must first be checked by his or her usual diabetologist to ensure that all the education regarding sports practice, insulin dose adjustment and blood glucose changes are satisfactory before passing the usual medical fitness to dive examination. The diabetologist has to check seven diabetologic contraindications to diving before giving him the Diabetologic certificate of non-contraindication for diving (Figure 1).

CERTIFICATE OF DIABETOLOGIC FITNESS TO DIVE <i>It is mandatory to have this certificate completed by an Endocrinologist-Diabetologist before the final certificate of fitness to dive is provided by a diving specialist affiliated to the FFESSM</i> I, Doctor, with certification as an Endocrinologist – Diabetologist, am aware of the seven diabetologic conditions for fitness to dive clearance recommended by the Fédération Française d'Etudes et de Sports Sous-Marins. I hereby certify that Mr/Ms....., born on....., for whom I have ensured the follow-up for at least one year, meets these seven conditions and, up to now, does not have a diving diabetologic contraindication relevant to the restricted set of rules and procedures for diving with diabetes provided by the FFESSM. Conditions required for approval 1. Insulin requiring diabetic 18 years or older; 2. Consistent diabetologic follow-up (≥ 3 times a year), by the same diabetologist. 3. HbA _{1c} " 8.5% "; 4. Regular self-monitoring of blood glucose ≥ 4 times per day; 5. No history of severe hypoglycemia or ketoacidosis during the past year; 6. Good perception of hypoglycemia ($>0.5 \text{ g} \cdot \text{L}^{-1}$; $2.8 \text{ mmol} \cdot \text{L}^{-1}$); 7. No macroangiopathy, microangiopathy or degenerative complications of diabetes. This certificate is valid for one year from the date of issuance. Signature _____ Date _____ Stamp _____ (day/month/year)

Figure 1: Certificate of diabetologic fitness to dive (modified from two-sided form)

Divers with the Diabetologic certificate in hand can consult a diving specialist who will perform the fitness to dive examination and check for any other contraindications to diving. The main reason for this dichotomy is to allow the specifics of sports with IRDM and diving medicine to be treated by specialists of each discipline.

B. Insulin Dose Reduction

We recommend to reduce insulin doses:

Day before diving: Bolus – 30%

Diving days: Base – 30% and Bolus – 30%

Insulin dose reduction should be adapted with the diabetologist on a case-by-case basis, depending on the subject's treatment and usual reaction when practicing sports.

C. Blood Glucose-Based Immersion Procedure

Diabetic divers will have to follow procedures requiring a minimum of three capillary BG tests before the dive. BG has to be tested approximately 60 min before diving (when preparing to board), 30 min before diving (when preparing the diving equipment) and 15 to 5 min before diving (just before entering the water). Details are provided in Table 1.

Table 1: Blood glucose testing targets and rules

Blood glucose target before diving: $2.0 \text{ g}\cdot\text{L}^{-1}$ ($11.1 \text{ mmol}\cdot\text{L}^{-1}$)	
T-60 min:	BG $<1.6 \text{ g}\cdot\text{L}^{-1}$ ($8.9 \text{ mmol}\cdot\text{L}^{-1}$): eat 30 g of glucose BG $1.6\text{-}2.0 \text{ g}\cdot\text{L}^{-1}$ ($8.9\text{-}11.1 \text{ mmol}\cdot\text{L}^{-1}$): eat 15 g of glucose BG $>2.0 \text{ g}\cdot\text{L}^{-1}$ ($11.1 \text{ mmol}\cdot\text{L}^{-1}$): re-check at T-30 min BG $>3.0 \text{ g}\cdot\text{L}^{-1}$ ($16.7 \text{ mmol}\cdot\text{L}^{-1}$): check for ketonemia or ketonuria If positive: STOP - <u>cancel the dive</u>
T-30 min:	BG $<1.6 \text{ g}\cdot\text{L}^{-1}$ ($8.9 \text{ mmol}\cdot\text{L}^{-1}$): eat 30 g of glucose BG $1.6\text{-}2.0 \text{ g}\cdot\text{L}^{-1}$ ($8.9\text{-}11.1 \text{ mmol}\cdot\text{L}^{-1}$): eat 15 g of glucose BG $>2.0 \text{ g}\cdot\text{L}^{-1}$ ($11.1 \text{ mmol}\cdot\text{L}^{-1}$): re-check at T-15 min
T-15 min:	BG $<1.6 \text{ g}\cdot\text{L}^{-1}$ ($8.9 \text{ mmol}\cdot\text{L}^{-1}$): STOP - <u>cancel the dive</u> BG $1.6\text{-}2.0 \text{ g}\cdot\text{L}^{-1}$ ($8.9\text{-}11.1 \text{ mmol}\cdot\text{L}^{-1}$): eat 15 g of glucose, OK to dive BG $>2.0 \text{ g}\cdot\text{L}^{-1}$ ($11.1 \text{ mmol}\cdot\text{L}^{-1}$): OK to dive
BG has to be checked once after the end of the dive	

The timing of tests is recognized as approximate since it is unreasonable to expect a strictly timed procedure when diving in leisure conditions. However, it is necessary to have three BG tests in the hour preceding the dive, with the last one immediately before diving. BG should be stable or increasing and $>1.6 \text{ g}\cdot\text{L}^{-1}$ ($8.9 \text{ mmol}\cdot\text{L}^{-1}$) in all cases for diving to be allowed.

It is usually recommended for IRDM patients to check for ketones (urine or capillary) when BG exceeds $3.0 \text{ g}\cdot\text{L}^{-1}$ ($16.7 \text{ mmol}\cdot\text{L}^{-1}$). In our guidelines, ketones are only checked once, at T-60 min. Ketonemia is an acute complication of insulin deficiency that will need some time or the presence of another condition (e.g., infection) to develop. Checking for ketones one hour before the dive is a sufficient measure to detect ketosis or ketoacidosis, which should be diagnosed before boarding the boat to allow for easier treatment. If ketones are not found at T-60, an acute hyperglycemic episode lasting for a few hours is not likely to cause a pathologic state in the diver.

D. Diving Restrictions for Diabetic Divers

The following restrictions will appear on the certificate of fitness to dive:

- No decompression diving;
- No diving below 20 msw (66 fsw);
- No dive duration to exceed 30 min;
- No diving in bad climatic conditions (current, rough sea, water temperature below 14°C [57°F]), or any condition that would prevent easily following the diving procedures or coming back to the diving boat easily in the case of a hypoglycemic episode (no diving from inflatable boats, no night diving);
- Only one diabetic diver per diving group;
- All dives have to be accompanied by a divemaster or diving instructor.

The main points of these rules are to ensure that, in the case of an underwater hypoglycemic event, the diver will be able to reach the surface rapidly without undue risk of decompression sickness. We know that restricting diving from inflatable boats will prevent diabetics from diving in many places, but we wanted to make sure that the following blood glucose based diving procedure would be easy to follow.

Diving restrictions (except the 30 min maximum duration) correspond to the restrictions of level 1 Confédération Mondiale des Activités Subaquatiques (CMAS or World Underwater Federation) certification, equivalent to an "Open Water" certification level in the PADI system.

E. In Case of Hypoglycemia

In the event of a hypoglycemic episode while diving, the IRDM diver must immediately inform the divemaster or instructor, who will assist the diver during the ascent. The dive is canceled and the entire diving group has to surface, ascent being done at controlled speed (as recommended by computers or tables), with no safety stop. Glucose paste is to be eaten upon arrival at the surface.

The requirement for immediate surfacing is the main reason for not allowing IRDM patients to do decompression dives. The few minutes needed to reach the surface during direct descent from no more than 20 msw (66 fsw) is short enough to preclude the complexity and risks of eating underwater.

F. Other Guidelines for the Diabetic Diver

Diabetic divers should always have with them (on board):

- Their usual blood glucose monitoring system, test strips, lancets, and a mean of measuring ketonuria or ketonemia;
- Their usual treatment, including fast acting insulin;
- At least 60 g of carbohydrates;
- Carbohydrates conveniently packed to carry in their buoyancy compensator during the dive (e.g., Glucodose® sachets, condensed sweet milk, or any kind of well packed snack bars).

Diabetic divers should always inform their divemaster/diving instructor and their diving buddy of their diabetes and the basic guidelines to follow in case of a hypoglycemic episode. It is recommended to also have the divemaster/dive instructor carry 15-20 g of carbohydrates in the form of a snack bar during the dive.

IV. Second Field Study: La Réunion Island, January 2005

This study was designed in February-March 2004, at which time diabetics were not allowed to dive. The FFESSM accepted our proposals and changed the regulations to allow diabetics to dive in October 2004. The study dives were subsequently conducted in January 2005, when a greater degree of flexibility was possible. The medical monitoring of the diabetic divers was strongly reduced from the first study, giving divers more autonomy, and allowing us to observe diabetic divers under more realistic conditions. We were also able to obtain data from continuous glucose monitoring.

A. Methods

Eleven Type 1 IRDM diabetic subjects were enrolled for a dive trip to La Réunion Island, a French territory in the Indian Ocean.

All the dives were conducted following the diving procedures provided by the FFESSM, except that dive time was allowed to exceed the 30 min limit (to a maximum of 45 min) in order to assess the effect of a longer dive on glycemic decrease.

The trip lasted for a total of seven days: three diving days, followed by two resting/leisure days, then two more diving days. A total of 11 dives could be made by each diver, two per dive day plus one night dive.

Capillary blood glucose and β -ketone (β -hydroxybutyrate) levels were quantified with Medisense Precision Xtra[®] (Abbott, North IL, USA). β -ketone was tested when BG exceeded $3.0 \text{ g}\cdot\text{L}^{-1}$ ($16.7 \text{ mmol}\cdot\text{L}^{-1}$), by using ketone strips instead of the usual blood glucose sensor strips.

B. Results

La Réunion enjoys tropical weather, moist with occasional storms. During the study period, air temperatures ranged from $30\text{-}35^\circ\text{C}$ ($86\text{-}95^\circ\text{F}$) during the day and water temperature remained stable at 27°C (80°F) with no thermoclines within the sport diving range. The current ranged from light to heavy at different sites.

Only preliminary results are available, as reported at the March 2005 Alfediam meeting in Lyon (Lormeau et al., 2005). A comparison of the results of the two field studies appears in Table 2.

C. Discussion

All dives were completed with no significant problems or incidents either underwater or at the surface. We observed one case of hypoglycemia and one case of ketonemia related to diving in the 111 person-dives, an event-incidence of 1.8%.

From the preliminary analysis, water temperature does not seem to change BG variations in IRDM subjects diving with our procedures.

Table 2: Comparing the results of two studies on the field with diving diabetics

	Golfe Juan November 2003 Water T - 14°C (57 F)	St Gilles de la Réunion January 2005 Water T - 27°C (81 F)
Subjects	15: 12M/3F	11: 8M/3F
Age (years) [range]	40.0 [28-55]	41.5 [22-54]
Diabetes Duration (years) [range]	9 [1-30]	8.9 [0.5-22]
HbA _{1c} (%)	7.2	6.6
Total Number of Dives	87	111
Mean Dive Duration (min)	30	39
Mean Delta BG (pre-to-post-dive) (g·L ⁻¹)	0.40 (1.64-2.04)	0.67 (2.07-2.74)
Mean Delta BG (pre-to-post-dive) (mmol·L ⁻¹)	2.2 (9.1-11.3)	3.7 (11.5-15.2)
Insulin Dose Decrease Day 1(%)	5.3	19.9
Mean Insulin Dose Decrease (%)	19.3	23.2
Mean Sugar Intake Pre-Dive (g) [range]	25 [0-155]	16 [0-90]
Dives with No Pre-Dive Sugar Feeding (n)	44	68
Hypoglycemia Related to Diving (n)	0	1: after a 46 min dive
Cases of Ketonemia Related to Diving (n)	0	1: after a night dive on 3 rd dive of the day

One of the divers (female) suffered from a mild hypoglycemia when returning on board after a 21 m (69 fsw), 46 min uneventful dive, second dive of the day, second diving day. Symptoms were weakness (she was still able to board the boat and remove her diving equipment without the need for outside help) and pallor. Her blood glucose measures and carbohydrate intake are summarized in Table 3.

Table 3: Blood glucose values and carbohydrate intake for subject experiencing an immediately post-dive hypoglycemic episode

T-60	T-30	T-5	46 min 21 m (69 fsw) exploration dive	Post-dive
2.76 g·L ⁻¹ (15.3 mmol·L ⁻¹)	1.85 g·L ⁻¹ (10.3 mmol·L ⁻¹)	2.0 g·L ⁻¹ (11.1 mmol·L ⁻¹)		0.37 g·L ⁻¹ (2.1 mmol·L ⁻¹)
	Carbohydrates 20 g			Carbohydrates 30 g

Her insulin doses for that day were reduced 14% below her usual treatment: Lantus® 10 IU (usual dose 14 IU), insulin analogs: breakfast 4 IU (100% of usual dose) and lunch 10 IU (usual dose 12 IU). The fast decrease of BG levels between T-60 and T-30 (-0.9 g·L⁻¹ [-5.0 mmol·L⁻¹]) shows an excess of fast acting insulin, which could not be compensated by only 20 g of carbohydrates. Even if BG increased slightly at T-5, her BG was following a fast decreasing pattern, thus the 0.37 g·L⁻¹ (2.1 mmol·L⁻¹) BG when boarding post-dive.

The same diver suffered from ketonemia on the night dive: 3rd dive of the day, 4th diving day. It was a night dive that took place at 9:00 PM, after a five hour surface interval, before dinner and Lantus injection. After surfacing, BG was high, and ketonemia measured at 1.4 mM. Ketonemia and blood

glucose levels returned to normal after insulin treatment with the usual dose of analog insulin, 10 IU, and the daily Lantus® injection.

This episode of ketonemia is due to the conjunction of several factors. The basal insulin, Lantus®, normally injected at 8:00 PM, was administered late in this patient (24 hours between administration provides stable levels with this ultra long insulin). The night dive was planned for 7:30 PM so she planned to take the basal dose afterwards. The dive, however, was delayed until 9:00 PM. The glucose intake to keep BG levels high before diving was not balanced by bolus insulin treatment, so she was suffering from insulin deficiency which explains this ketonemia episode.

From these two episodes in the same diver, we learn that BG tendency in the hour before diving is of major importance to predict a drop in BG levels during that dive. The ketonemia episode recalls that a diabetic diver remains an insulin-treated subject above all, and that following strict BG procedures should not make us forget the basics of insulin management.

IV. Continuous Glucose Monitoring

We monitored interstitial glucose levels continuously in four (one in the 2003 study, three in 2005) of our divers using a continuous glucose monitoring system (CGMS) (Medtronics Minimed, Northridge, USA) placed in a homemade waterproof and pressure-proof casing. The subcutaneous sensor (glucose sensor, ref MMT-7002) was placed on the abdominal wall and fixed with an OpSite® semipermeable adhesive dressing (Smith and Nephew, United Kingdom). The CGMS uses a glucose-oxidase reaction to measure interstitial glucose (IG) every five seconds. The readings are averaged on a five minute basis to provide numerical summary results and an IG tendency curve. The CGMS is currently used in diabetic patients to obtain a continuous follow up on glucose levels for treatment adaptation. The system is not perfect (Tansey et al., 2005); the interstitial measures may differ from blood glucose sampling. Obtained values should reflect tendencies and should not replace BG measurements. The utility of the technique is being able to observe IG variations during otherwise unmonitored dives.

We were able to monitor three of our subjects with CGMS in the 2005 study. One of the subjects was the patient monitored during our first study, providing us with comparative data between warm and temperate waters. A total of 19 dives were successfully monitored with CGMS for these patients. Dive profile data from diving computers (Aladin®, Uwatec, Nova Antipolis, France) were available for these 19 dives. Subjects were also monitored during the two resting days, used to visit the island, with long hikes ($4\text{-}8 \text{ h}\cdot\text{day}^{-1}$) to the top of the volcanoes. An example of the CGMS data appears in Figure 2.

As expected for IRDM patients, interstitial glucose showed wide variations during the day and night. It is well known that in the hours following exercise there is a decrease of BG levels, corresponding to the rebuilding of glycogen reserves. IRDM divers should continue close monitoring of their BG in the hours following a dive. We did not observe a major glycemic decrease related to diving. In the dives where IG decreased, it followed a gentle slope. These findings are consistent with the assumption that if starting with a minimum stable or rising BG of $1.6 \text{ g}\cdot\text{L}^{-1}$ ($8.9 \text{ mmol}\cdot\text{L}^{-1}$), the risk of a hypoglycemic episode in the course of a 30 min dive is small.

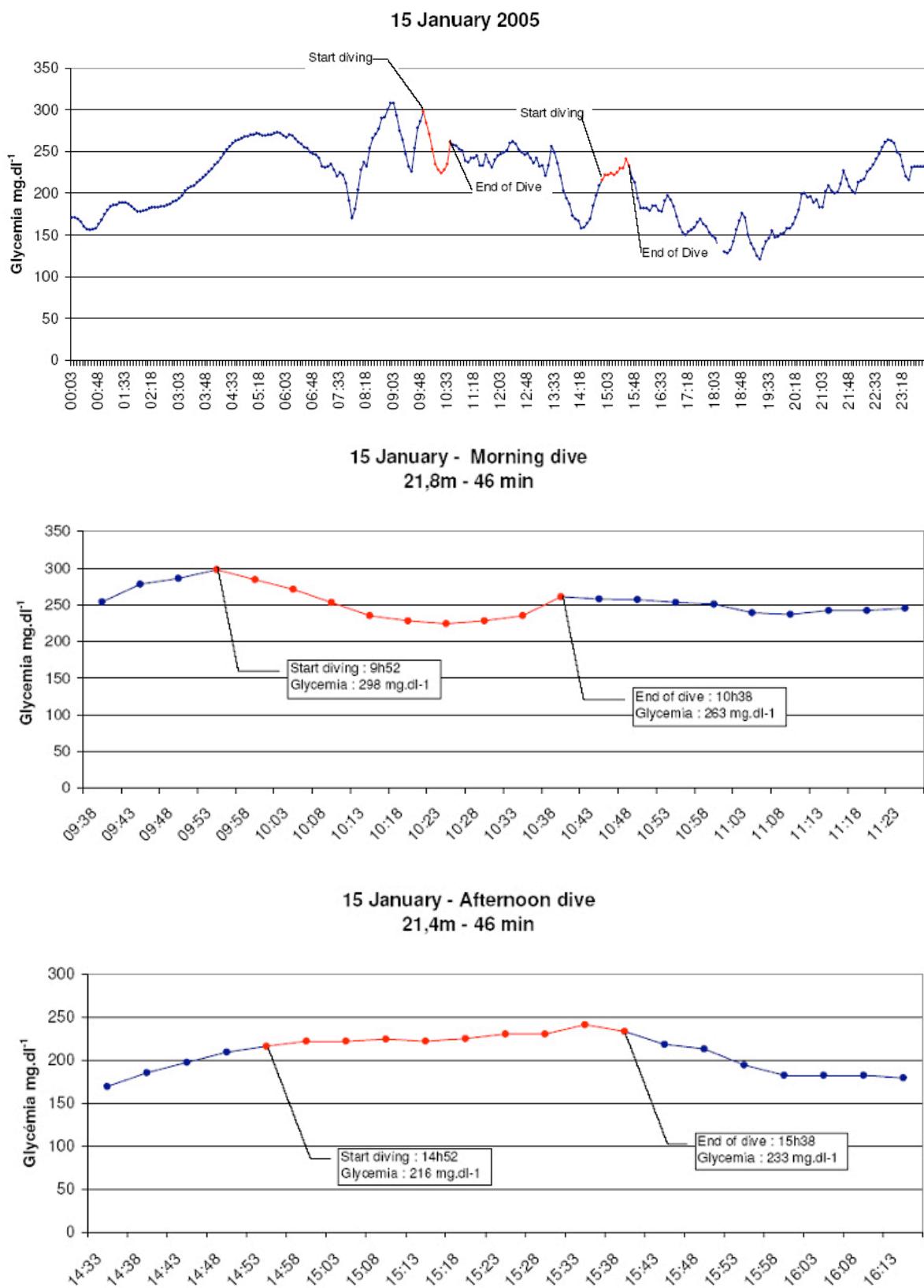


Figure 2: CGMS data for a single day of diving.

The effectiveness of using the CGMS with IRDM divers requires further evaluation. More dives and more subjects should be monitored. The CGMS devices were only tested once with a healthy volunteer in a dry hyperbaric environment to ensure proper operation in hyperbaric conditions. Since the CGMS is placed in a pressure-proof case, it remains at normal atmospheric pressure. Only the subcutaneous sensor was subjected to the ambient pressure during the dive. Although it seemed to work correctly for that single dive, and none of our recordings in diving conditions shows inconsistent measurements, a controlled testing of the CGMS in a dry hyperbaric chamber needs to be performed.

V. Perspectives

A. Diving Hand Signal for a Hypoglycemia Event

We proposed the FFESSM for a new diving signal for hypoglycemia: a wide gesture of the arm, with the hand out flat and moving back and forth towards the mouth and the regulator. It is still being discussed by the FFESSM technical committee if it is a good idea to introduce a new hand signal, and if it would be a risk of confusion with another distress signal. At the time of our studies, we did not know about the two fingers "L" signal used in other countries for hypoglycemia, which in fact is more practical and could be proposed as a new diving sign.

In the case of a hypoglycemic episode while diving, the diabetic diver should immediately inform the divemaster/dive instructor and/or buddy (using the new hypoglycemia hand signal, or using the usual "something is wrong" signal). The dive should be ended immediately, with the entire diving group surfacing at controlled speed, without performing a safety stop.

Once at the surface, the diabetic diver will eat some sugar, and, with assistance, get back to the diving boat immediately. Some divers chose to eat or drink carbohydrates while underwater to prevent or treat a hypoglycemia episode. This is also something common in non-diabetic divers, and systems made to drink easily underwater exist. We do not want to recommend that our divers eat while diving. In the case of a hypoglycemic episode while diving, the diver will be in a stressful situation, and if he or she is not well trained to eat underwater, there is a high risk of inhalation, likely worsening the situation.

B. Log Book for Diabetic Divers

We have designed a specific log book for diabetic divers. Along with the usual dive parameters and profiles, they will be able to log all the important information regarding glucose levels, insulin doses and diabetes related information (Figure 3).

The log book is not yet available, and still has to be accepted by the FFESSM. The final version will contain all the information needed by a diabetic diver to dive within our guidelines: a summary of FFESSM policies for diabetic divers, the blood glucose-based diving procedures, and various recommendations. By using this log book for all dives the diabetic diver will have a record of the information needed to adjust his or her treatment and diet in conjunction with his diabetologist and diving doctor. Furthermore, he or she will have logged the information valuable for programs to monitor diabetic divers.

C. Long Term Follow Up

We are in the process of building a database of divers with diabetes that will allow us to achieve a long term follow up of the diving diabetic population. There will be an administrative form to complete in order to enter the study, with administrative data about the diabetic diver. Once this form is returned, the subject will obtain an individual coded number that can be used for anonymous submission of data. Two other forms will be available on our internet web site (<http://www.diabeteplongee.com>), secured with a SSL connection, but also downloadable for collection by regular mail. Connection to the secured website database (MySQL, Uppsala, Sweden) will be allowed with the individual coded number and a user-selected password.

Dive #		Date			Time	
Dive Site	Interval	Time		Depth	Temperature	
Comments				Stamp		
						
	Morning	T-60 min	T-30 min	T-5 min	Post-Dive	Others
Blood Glucose						
Sugar intake						
Insulin Ketonemia						
Comments						

Figure 3: A page from the proposed diabetic diver log book

The administrative form will be completed once a year. One part will ask for information about the diver: level of instruction, number of dives, depth, problems encountered while diving, use of our procedures, etc. Additional questions will address the diabetic disease, treatment, metabolic control, eventual degenerative complications and co-morbidities. Another part will consist of a simplified copy of our log book, where the diabetic diver will be asked to enter for each one of his or her dives: depth and dive time, water temperature, blood glucose before and after the dive. There will be a checkbox for signaling a hypoglycemic episode or an incident during the dive, and lastly a free text box allowing the subject to enter unformatted comments.

This data will provide us the basic epidemiologic information asked by the FFESSM for discussing actual policies in a term of three years in order to improve our guidelines.

Acknowledgments

The field studies were supported by research grants from Abbott Medisense, Roche Diagnostics, BD, Lipha, Medtronics, Merck, Novartis, Novo Nordisk, Takeda, MSD, AXA, Aladin and FFESSM ile de France. We are indebted to Neal W. Pollock, Ph.D. for helpful reviews of the manuscript.

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UNITED STATES FEDERAL AVIATION ADMINISTRATION DIABETES POLICY AND EXPERIENCE

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The U.S. Federal Aviation Administration (FAA) convened a panel of endocrinologists and members of the aerospace community to develop a program to evaluate the impact of insulin-requiring diabetes mellitus (IRDM) on air traffic controller safety. The positive results of this initiative led to a review of the certification practices for pilots. The FAA changed the regulations in September of 1996 to allow special issuance of third-class medical certificates (non-commercial) for candidates with IRDM (FAA Policy Statement, 1996). Special issuance is not allowed for IRDM with first- or second-class (commercial) medical certificates.

Prerequisites for Special Issuance Medical Certificates for Insulin-Requiring Pilot Candidates

Third-class medical certificates are good for 36 months for individuals less than 40 years of age, and for 24 months for individuals more than 40 years of age (14 Code Federal Regulation Part 61.23). The FAA examination is not a preventive health exam. The concern is the time interval for which the medical certificate is in effect.

Additional requirements are in place for candidates with IRDM. The current policy requires the candidate to be stable in their diabetes for at least six months. Candidates must not have had any recurrent episodes of hypoglycemia in the past five years, and none in the preceding one year. An episode, for these purposes, includes cases resulting in loss of consciousness, seizures, impaired cognitive function or other complications requiring intervention by a third-party or occurring without warning. A letter of support is also required from the individual's treating physician. This may be any physician, not necessarily an endocrinologist.

The physician letter must include several standard elements. Two measures of glycosylated hemoglobin (HbA_{1c}) are required; the first one at least 90 days prior to the current one. A description of the insulin treatment plan and diet must be provided. The treating physician must also make specific comments regarding the presence or absence of cerebral vascular, cardiovascular, peripheral vascular or any neurologic pathology. Pilots may be allowed to fly with some degree of secondary complications, but we must know the specifics.

The physician letter must also provide a statement confirming that the candidate has had education regarding his or her diabetes. It is important to know that the individual can monitor and manage his or her condition successfully. Candidates must use a recording glucometer for the monitoring.

A separate report is required from an ophthalmologist or optometrist describing visual health.

Certification requirements vary with age. Candidates 40 years or older must have a maximal graded stress test.

A letter from a flight instructor confirming that the candidate can effectively control an airplane while sampling his or her blood glucose is not required, but a desirable option.

Recertification requires an applicant to see his or her treating physician every quarter. Applicants are supposed to bring their recording glucometers to have their glucose patterns and monitoring checked.

Special Issuance Limitations

The medical certificate is restricted to non-commercial licenses and flying within the USA. Canada, conversely, allows commercial licensing only. One of the pilots of a multi-pilot commercial flight can have IRDM.

A medical follow-up is required every 12 months. This puts a 12 month limit on the medical certification of individuals with IRDM. HbA_{1c} measures may be accepted as high as 9.9 percent but, if so, additional screening may be required. Candidates may have to come in every six months. High HbA_{1c} values are rare, though. Most diabetic pilots are pretty well controlled; close to ideal patients who really take care of themselves.

Pilots with IRDM require annual eye examinations and a repeat stress test every five years. If the stress test (Bruce protocol) is positive, a stress echo or a nuclear stress test is required.

Pilots with IRDM are required to conduct scheduled blood glucose monitoring in conjunction with flight operations. The first required measure is taken 30 min prior to flight. If it is less than 100 mg·dL⁻¹ (5.6 mmol·L⁻¹) they are to ingest 10 g of glucose and measure their blood glucose again 30 min later. Flight can commence when the blood glucose is between 100 and 300 mg·dL⁻¹ (5.6 and 16.7 mmol·L⁻¹).

In-flight measures are required at 60 min intervals and within 30 min of landing. If the blood glucose at any point is less than 100 mg·dL⁻¹ (5.6 mmol·L⁻¹), the pilot is to ingest 20 g of carbohydrate. If it exceeds 300 mg·dL⁻¹ (16.7 mmol·L⁻¹), the pilot is to land at the nearest suitable airfield and take the appropriate steps to move the value back into the approved range before continuing the flight. Specific action to correct high blood glucose values is not specified.

If the operational demands of flying make it unsafe to maintain the monitoring schedule, the pilot is to ingest 10 g of carbohydrate, continue flying, and take the measure at the next scheduled point. The pilot is to land at the nearest suitable airfield if the second scheduled assessment cannot be completed.

Pilots with IRDM who have any accidents or incidents are supposed to notify the FAA. They must provide an up to date HbA_{1c} measure and a record of their blood glucose monitoring prior to the incident. This would include either an automobile or aircraft incident or accident. The special issuance medical is immediately withdrawn if the satisfactory documentation is not provided.

Certification Records for U.S. Pilots with IRDM

The FAA processes the medical records of 450,000 examinations per year. There are 603,000 U.S. pilots. The overall denial rate is 0.01 percent. The number of pilots in the entire system that have some sort of pathology, one or multiple, is 191,479 (32 percent of the total). There are currently 425 third-class medicals issued to individuals with a diagnosis of IRDM. A total of 173 medical applications were denied to applicants with IRDM between January 01, 2001 and December 31, 2004.

An internal study was conducted to evaluate the performance of all pilots who had special issuance waivers in the year 1996. Pilots who had waivers were 60 percent less likely to be involved in an accident than pilots without waivers. While preliminary, these data support continuation of the waiver program.

Incidents Involving Pilots with IRDM

The FAA maintains the Civil Aerospace Medical Institute (CAMI) in Oklahoma City. This serves as an accident and incident research and training facility. Additionally, the National Transportation Safety Board (NTSB) investigates all aviation accidents. The following four cases involved those with pilots with IRDM occurring between 1998 and 2000. Diabetes was not determined to be a contributing factor in any of the incidents. The investigation of a fifth incident that occurred recently is not yet complete and will not be discussed here.

Case #1: October 25, 1998. Involved a Piper Seneca (PA-34-200) twin-engine aircraft. The pilot was 52 years of age with a current third-class medical and 522 logged flight hours. The aircraft contacted the runway and bounced approximately 15 feet in the air and landed "violently."

The nose gear strut was driven up through the fuselage. The NTSB concluded that the probable cause was an improper flare under pilot control. The presence of a crosswind was identified as a contributing factor.

Case #2: November 29, 1999. Involved a Piper Cherokee (PA-28-161) single-engine aircraft. The pilot was 72 years of age with a current third-class medical and 122 logged flight hours. The airplane was on final approach. The sink rate increased and the pilot added power but the sink rate was not adequately arrested. The aircraft hit a sign at the approach end of the runway, rotated to the right, landed right of the runway and collided with a chain-link fence.

The pilot had no injuries. His blood glucose level measured just prior to the flight was $125 \text{ mg}\cdot\text{dL}^{-1}$ ($7.0 \text{ mmol}\cdot\text{L}^{-1}$) and his HbA_{1c} was 7.1 percent.

The NTSB concluded that the probable cause was the pilot's failure to adequately adjust engine power to compensate for wind on final approach. No action was taken regarding the pilot's medical clearance.

Case #3: August 07, 1999. Involved a Cessna 177 single-engine aircraft. The aircraft was destroyed on impact with terrain following a loss of control during a go-around under clear conditions (visual meteorologic conditions – VMC). Both pilot and the passenger were fatally injured.

This case involved an inadvertent stall brought on by pilot performing an abrupt maneuver at low altitude. A stall develops when the nose of the aircraft is too high to maintain sufficient speed for air flowing around the wing to maintain lift.

Case #4: March 11, 2000. Involved a Cessna 150 single-engine aircraft. The student pilot was 47 years of age with a current third-class medical and 44 logged flight hours. He ran out of fuel after becoming lost/disoriented during a cross-country (greater than 75 nautical mile) solo training flight. The aircraft was damaged during a forced landing following the loss of power. Blood glucose measures were obtained throughout the flight and were acceptable. The airman's HbA_{1c} levels were 6.6 and 5.5 percent in January and May, 2000, respectively. His fasting blood sugar level on the morning of the accident was 132 mg·dL⁻¹ (7.3 mmol·L⁻¹). His blood glucose level 50 minutes into the flight was 185 mg·dL⁻¹ (10.3 mmol·L⁻¹).

There was no usable fuel found in the tanks after the crash. The probable cause of the accident was determined to be fuel exhaustion. A contributing factor was a lack of suitable terrain for the forced landing.

Oral Diabetes and Aviation

The FAA also allows persons with diabetes on oral hypoglycemics to fly. The current rules do not allow medical clearance for persons with diabetes who use thiazolidinediones and insulin, but they do allow for use of sulfonylureas.

There are persons with diabetes flying who are on as many as four oral hypoglycemic agents. Current standards do not allow combinations of oral agents and beta-blockers or combinations of insulin and beta-blockers. While the latter combination is a popular treatment regimen, it is not recommended for the aviation environment. Beta-blockers and metformin are allowed. The FAA accepts the use of four oral hypoglycemic agents and beta-blockers. They are Glucophage® (metformin), Actos® (pioglitazone), Avandia® (rosiglitazone) and Acarbose (precose). These medications do not result in hypoglycemia.

The number of persons with diabetes controlled with oral agents that hold current medical clearance to fly is substantial (Table 1). We also have a small number of persons with diabetes on oral agents and insulin who have had infarcts. There are currently 35 airmen issued third-class medical certificates who have reported coronary artery disease along with their diabetes on insulin therapy.

Table 1: Number of persons with diabetes controlled with oral hypoglycemic drugs holding current medical clearance

Medical Class	Number Currently Approved
First	493
Second	988
Third	3,819

Conclusion

The Federal Aviation Administration has been granting third-class medical certification for private pilots with diabetes mellitus treated with insulin through its waiver process since 1996. Only five incidents/accidents have been reported since the inception of this policy, with diabetes not being a factor in at least the four incidents for which investigations are complete. The initial workup and follow up process for these airmen appears to be sound. There are no plans in the near future to expand medical certification to second- or first-class airmen.

References

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DIABETES IN RECREATIONAL DIVING: WHERE TO FROM HERE?

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Diving by diabetics has been one of the most controversial issues in “fitness to dive” debates for several decades. This is hardly surprising since there are several valid concerns about diving by diabetics which are well documented elsewhere (Taylor and Mitchell, 2001; Dear et al., 2004). Coupled with sporadic reports of fatalities or complications linked to diabetic diving (Thomas and McKenzie, 1981; Betts, 1983) these concerns seemed reason enough for diving physicians to take a conservative stance on the matter during the 1980s and 1990s. Indeed, diabetes requiring medication has been (and still widely is) considered a contraindication to diving.

Over the last decade there has been a gradual softening of attitudes to diving by diabetics. This has its roots in several simultaneous developments. First, the philosophy of assessment of fitness for diving is gradually shifting from a strictly prescriptive approach to one of individual risk assessment and, where appropriate, informed risk acceptance by the diving candidate (Gorman, 1994; Bennett, 2004). Second, there have been several studies demonstrating the feasibility of safe blood glucose management by diabetics who dive (Lerch et al. 1996; Dear et al., 2004). Third, it has become abundantly clear that diabetics are participating in recreational diving whether the diving medical organisations endorse this or not (Dear et al., 1994). Moreover, notwithstanding the potential for bias in the relevant surveys, they appear to be diving with an incidence of problems similar to that recorded among populations of non-diabetic divers (Dear et al., 1994; Edge et al. 2005). Much of the relevant experience has been presented in the earlier papers at this workshop, and particular attention is drawn to the large series recently published by Edge et al. (2005).

In the face of increasingly strident opposition, diving physicians now frequently find themselves defending a conservative edict on diabetes and diving that Dr. John Williamson succinctly described as “dogma-rich but data-free” (Williamson, 1996). Indeed, it could be argued that the “pro-diving” viewpoint is now more strongly supported by data, though we should be very cautious in applying the conclusions from these controlled and volunteer studies to the general diabetic community. Volunteer surveys are notoriously subject to bias, while highly controlled conditions are likely to underestimate risk when applied to the general population. Nevertheless, there is an emergent stream of evidence that supports participation of properly selected diabetics in diving. Under these circumstances it behooves the diving medicine community to review its stance or risk becoming irrelevant.

This Workshop has been convened for that purpose. The diabetic diving experience of various regional groups has been discussed by earlier presenters, as has the involvement of diabetics in analogous risk activities such as flying. The meeting now moves on to consider a synthesis of the various reported means of incorporating diabetics into diving as a “blueprint” for the future.

This paper is generated as a “straw man” to give some structure to the subsequent discussion of this contentious issue. It is not intended as a definitive proposal, and is written in the full knowledge that dissection by a group of learned workshop participants will result in much being changed.

Some comments on the assumptions and scope of the proposal are appropriate at this point.

First, it must be understood that this paper is based on an assumption of agreement that it is appropriate for some diabetics to dive, provided issues of selection, surveillance and diving method are addressed. We acknowledge that some diving physicians may still believe diving by medicated diabetics is inappropriate under any circumstances. This paper does not argue the pros and cons of this stance, but it remains an option for workshop participants.

Second, the "protocols" for diving by diabetics are intended for recreational diving (as subsequently defined), not for occupational diving. We will discuss occupational diving elsewhere in the paper, with particular reference to diving instructors and dive guides.

Defining the Important Issues

Two recurring themes arise in papers that discuss participation by diabetics in mainstream recreational diving.

1. Selection and surveillance

Selection of appropriate diabetics for diving is important because many of the acute and chronic complications of diabetes are of potentially profound significance in diving. This has been discussed elsewhere (Taylor and Mitchell, 2001) and detailed review is beyond the scope of this paper. However, a brief synopsis of the major concerns is given in Table 1.

It seems appropriate that diabetics prone to acute complications (such as hypoglycaemia) or suffering chronic complications that might impact significantly on diving safety should be excluded from participation. A policy on selection of diabetics for diving is therefore required.

Not surprisingly, with few exceptions (Dear et al., 1994), the data that can be interpreted as supportive of diving by diabetics were generated from groups subject to some form of medical selection (Lerch et al., 1996; Dear et al., 2004; Edge et al., 2005). In recognition of the progressive nature of many complications of diabetes, it is also clear that there should be longitudinal health surveillance and periodic reassessment of suitability over the period of a diabetic's participation in diving.

2. Diving method.

There is general agreement that not all diving activities are suitable for a diabetic, even if he or she appears suitable for diving. Thus, a series of appropriate limitations needs to be specified.

It is also generally agreed that diabetics should adopt a strategic approach to management of their blood glucose during a diving day. The means by which appropriate methods of glucose management can be communicated or taught to potential diabetic divers must also be considered.

Table 1: Acute and chronic complications or associations recognized in diabetes, and potential interactions with diving

Complication	Potential Interaction with Diving
Hypoglycaemia	<ul style="list-style-type: none"> - May be precipitated by stress, cold and exercise during diving. Hyperoxia reduces blood glucose by an unknown mechanism in hyperbaric oxygen patients (Trytko and Bennett, 2003), but this effect was not demonstrated at the PO₂s encountered in simulated dives (Edge et al., 1997) - Potentially catastrophic consequences due to impaired mentation and consciousness underwater - We speculate that impending symptoms may be less likely to be noticed during diving - Potential for confusion with symptoms of decompression illness (Betts, 1983) or other possible problems such as hypothermia or sea sickness
Hyperglycaemia	<ul style="list-style-type: none"> - May augment dehydration stress; a possible risk factor for decompression illness - May worsen outcome in neurological decompression illness (Moon, 2003)
Coronary artery disease	<ul style="list-style-type: none"> - Impairment of exercise tolerance - Possibility of myocardial ischaemic event
Resetting of hypothalamic glucose control	<ul style="list-style-type: none"> - Release of adrenaline after neuro-glycopenia when patient may become incapacitated before noticing hypoglycemic symptoms: a phenomenon known as "hypoglycaemia unawareness" (Braatvedt, 2000)
Autonomic neuropathy	<ul style="list-style-type: none"> - Blunting of adrenaline release expected when blood glucose falls, thereby worsening potential for hypoglycaemia (Braatvedt, 2000)
Peripheral neuropathy	<ul style="list-style-type: none"> - Possible confusion with signs of decompression illness (Betts, 1983)
Peripheral vascular disease	<ul style="list-style-type: none"> - Impairment of exercise tolerance
Renal impairment	<ul style="list-style-type: none"> - Multiple possibilities depending on severity

Selection and surveillance

Literature

Various groups have suggested similar approaches to the problem of selection. The key elements of several selection protocols for diabetics in diving are summarized in Table 2. Others are probably in use and additional policies may be described at this meeting. Those in Table 2 were selected because of their availability to the authors.

Table 2 contains a "mixed bag" of documents. The Camp DAVI (Diabetes Association of the Virgin Islands) protocol (Winsett et al., 1992) is cited because this group was one of the first to offer training to diabetic divers in a systematic fashion. The protocol, which is attributed to Dr. George Burghen and Mr. Stephen Prosterman, was designed for use at this single site. The YMCA 1995 protocol is cited because, along with the BSAC protocol (Edge et al., 2005), the YMCA is one of the few recreational training organizations with a permissive policy to diving by diabetics. Indeed, these two protocols are the only ones reviewed that are designed specifically to be applied within the general diving population for divers who might be trained at a variety of facilities. The papers by Lerch et al. (1996) and Dear et al. (2004) describe studies in which diabetic divers were monitored before and after diving, mainly to assess any tendency to hypoglycaemia. Lerch et al. (1996) examined the efficacy of a specially tailored diabetic diver course that emphasized prevention of hypoglycaemia. Dear et al. (2004) studied established diabetic divers who were monitored for blood glucose levels before and after "normal" dives. Both studies specified certain selection criteria for diabetics considered appropriate for diving, and these are relevant to the present discussion.

Table 2: Selection protocols for diabetics who wish to dive. See text for brief description of studies

<u>Authors</u> <u>Parameter</u>	Winsett et al., 1992	YMCA, 1995	Lerch et al., 1996	Dear et al., 2004*	Edge et al., 2005* BSAC
Age	"Young adults"	Not specified	18 – 65 years	"Adults"	Not specified
Diabetes	"Insulin-dependent"	Diet, IDDM, NIDDM	"Insulin-dependent"	"Insulin-requiring"	"IDDM and NIDDM"
Duration**	Not discussed	Not discussed	≥9 months insulin use	Not discussed	Not discussed
Hypoglycaemia	No hospitalization last 12 months; able to recognize in self and others and respond appropriately	"Stable" and "good control"	No severe LOC over previous year. No hypoglycaemia unawareness	No hospitalizations last 12 months	No hypoglycaemic attack last year. No hospitalizations last 12 months
Hyperglycaemia	No hospitalizations last 12 months	"Stable" and "good control"	HbA _{1c} 5.5 – 9%	HbA _{1c} ≤9%. No hospitalizations last 12 months	No hospitalizations last 12 months
Other diabetic complication exclusions	"Retinopathy, CVD and/or nerve damage"	"Severe or progressive vascular disease, retino-, nephro- or neuropathy"	Retinopathy, polyneuropathy, nephropathy.	Retinopathy, neuropathy, CVD	Microalbuminuria, vasculopathy, retinopathy >minor; neuropathy; any hospitalization last 12 months
Other illness exclusions	Any that would "add safety risk"	Not discussed	Any preventing diving, pregnancy, history of DCS, drug abuse	Pregnancy	Any preventing diving (usual diving medical)
Fitness / Exercise	"Regular exercise;" able to swim 200 yd non-stop	"Good physical condition"	Normal "PWC ₁₅₀ "	Healthy divers, nil else specified	Diabetologist to confirm physical fitness
Examination / Documentation	"Physician" examination using "specifically developed" form	"Personal physician approval;" standard YMCA scuba form; "heart stress test" "should" be done	Study physician. "Diving medical exam" includes exercise ECG, CXR, CBC, PFT, ophthalmoscopy	All divers previously certified and active (observational study of established diabetic divers)	Standard diving medical plus approval and report on control from personal diabetologist
Special skills	"Safe, accurate" BG monitoring	Not discussed	Diabetes education; self-managed insulin	Understanding of glucose and exercise	Not discussed
Central screening***	Not applicable (single location protocol)	Not discussed	Not applicable (single location protocol).	Not applicable (single location protocol).	BSAC Medical Committee, annual
Surveillance	Lifelong certification "may not be appropriate"	Not discussed	One year certification; annual medical exam	Time-limited certification discussed	Annual questionnaire and diabetologist report

BG = blood glucose; CBC = complete blood count; CVD = cardiovascular disease; CXR = chest X-ray; ECG = electrocardiogram; LOC = loss of consciousness; PFT = pulmonary function test; PWC₁₅₀ = physical working capacity in watt·kg⁻¹ body weight at a heart rate of 150 beats·min⁻¹.

* These authors have published multiple commentaries on this subject over a long period.

These studies are interpreted as representing their current stance on the issue.

** Duration refers to the duration of diabetic medication use.

*** Central screening refers to a screening process in which all diabetic diver medical evaluations are sent to a central authority for checking and approval.

The policies outlined in Table 2 contain several strong common threads. First, there is invariably a statement about the quality of diabetic control, with exclusion of those with a history of poor control in general and recent hypoglycaemia in particular. A second invariable thread is a proscription against diving in the presence of secondary complications of diabetes. Third, there is a requirement for medical assessment that is more comprehensive than that required of non-diabetics. Fourth, there is general agreement that periodic surveillance of fitness to dive is necessary in diabetics, given the propensity of the disease and its complications to progress.

Proposal

In view of the lack of data describing the relative merits of one strategy over another, defining a protocol for selection of diabetics for diving will ultimately reduce to a process of "consensus opinion of experts." These authors admit that with one or two exceptions, the process of drafting this proposal has been an exercise in perusing other people's ideas and picking those that seem sensible. Many of the "limits" and "thresholds" are arbitrarily selected and will be debated by the workshop participants.

Protocol 1. Selection of diabetics for scuba diving

Candidates diagnosed with diabetes, provided the following criteria are met, may undertake recreational scuba diving within the bounds subsequently defined:

1. Age 18 years or over.

Comment: It would be inappropriate for children who may struggle with the complexity of diabetes management (and who may not be independent in this regard) to attempt another complex and potentially dangerous activity simultaneously. A threshold even older than 18 may be appropriate.

2. At least six months have passed since the initiation of treatment with oral hypoglycemic agents (OHAs) or one year since the initiation of treatment with insulin. An established diver using OHAs who is started on insulin should wait at least six months before resuming diving.

Comment: Since there is much emphasis on stability of glucose control and absence of a hypoglycaemic tendency over time, then an appropriate "observation period" must be imposed after introduction or major change of medication. In addition, successful application of the blood glucose management protocol described later depends heavily on the diabetic's skill in self- management (particularly where insulin is being used). Acquisition of such skill, in turn, depends heavily on experience of medication management.

3. There must have been no hypoglycaemic episodes requiring intervention from a third party for at least one year, and no history of "hypoglycaemia unawareness".

Comment: A proscription against a history of hypoglycaemic episodes is necessary but difficult to precisely define. We note that Edge et al. (2005) stipulate no "hypoglycaemic attack" over the preceding year; however, it is unclear exactly what constitutes an "attack". The present wording is an attempt to bring objectivity to the criterion, and to focus on the type of event that would be most troublesome in diving. "Hypoglycaemia unawareness" (Braatvedt, 2000) refers to hypoglycaemic events in which the diabetic becomes incapacitated with no warning, or so little warning that they have insufficient time to respond appropriately.

4. *HbA_{1c} ≤9% when measured no more than one month prior to initial assessment and at each annual review.*

Comment: This is a potentially controversial (and admittedly arbitrary) criterion. However, we believe that it is useful since failure to meet this standard must mean either that the candidate is incapable of good control, or insufficiently motivated to achieve it. In either case, they are almost certainly inappropriate candidates for diving.

5. *There must have been no admissions or emergency visits to hospital for any complications of diabetes for at least one year.*

6. *There must be no known retinopathy (worse than "background" level), nephropathy (including microalbuminuria), neuropathy (autonomic or peripheral), coronary artery disease or peripheral vascular disease.*

Comment: an exclusion based on “any” degree of retinopathy is probably too stringent given that “background” retinopathy can occur very early in diabetes, and seemingly well in advance of other more significant complications.

7. *No more than two months prior to the first diving medical assessment (see 8 below) and each annual evaluation, a review is conducted by the candidate's personal diabetologist who must confirm that: criteria 3–6 are fulfilled; the candidate demonstrates accurate use of a personal blood glucose monitoring device; and that the candidate has a good understanding of the relationship between diet, exercise, stress, temperature and blood glucose levels.*

Comment: This may be seen by diabetics as an imposition, yet those who are sufficiently focused to want to dive should be under the care of a diabetologist, or at least be prepared to be reviewed by one. It is inappropriate to leave these elements of the process to the diving doctor who may not have the expertise or skills in this area. The diabetologist review must take place before assessment by a diving doctor (see 8 below), and this process is best directed by use of a standard form such as that proposed by Edge et al. (2005).

8. *No more than two months prior to commencing diving for the first time and at each annual review, a diving medical examination is completed by a doctor who has completed a post-graduate diving medical examiners course. The diabetologist review report must be available. This examination will include appropriate assessment of exercise tolerance, and for candidates over 40 years of age will always include an exercise ECG.*

Comment: This second medical consultation is necessary in order to consider specific diving-related matters, which most diabetologists are not qualified to do. In addition, a compulsory review of the candidate by a diving doctor who is equipped with the diabetologist’s report appears to be the only practical option for avoiding a system of central review or arbitration such as that described by Edge et al. (2005). Central review has worked well in the UK environment and ideally it should be universally instituted, if for no other reason than the facilitation of data collection on diabetic diver activity. However, the goal of this workshop is to consider a pragmatic system that can be generalized, and a requirement for central review would raise problems in many countries. Even in a country like the USA, it is not immediately obvious who would administer a centralized registry for diabetic diving approvals.

Evaluation of exercise tolerance is important, but is left to the discretion of the examining doctor because it is difficult to construct rules. A 25 year-old diabetic athlete who runs marathons would need no assessment beyond the taking of this history. However, a very low threshold for objective assessment and the use of exercise/stress ECGs is strongly advised.

9. As part of the assessment by the diving medical examiner, the candidate acknowledges (in writing) receipt of and intention to use the diabetic diving protocol (see later); the need to seek further guidance if there is any material that is incompletely understood; and the need to cease diving and seek review if there are any adverse events in relation to diving suspected of being related to diabetes.

Comment: We identify this consultation as the point at which the diabetic receives the diabetic diving protocol and other supporting information. When two of the authors last reviewed this issue (Taylor and Mitchell, 2001) we held the view that in addition to resolving issues of selection, the diving medical community would demand specific diabetic diver training courses. However, we recognize there are two potential problems with imposing the inconvenience of sourcing scarce and expensive extra training. First, properly selected diabetics are already participating in diving without diabetic-specific training courses and there is recent evidence (unavailable at our previous review) suggesting there is no problem with this practice (Edge et al. 2005). Second, while we can indulge our inclination to conservatism by imposing rigorous demands on prospective diabetic divers, this may result in little more than perpetuation of the current situation: viz, diabetics bypass the system and just "get on with it" on their own. The recent reports (Dear et al., 2004, Edge et al., 2005) of effective diving by properly selected diabetics who in most cases did not undertake a specific diabetic diver course do engender some confidence in the system outlined here.

A draft pro-forma, which could be used to record acknowledgments similar to those specified above, is included at Appendix 1.

10. Steps 2 – 9 of this protocol must be fulfilled on an annual basis. It is strongly advised that where possible the same diabetologist and diving medical officer are used for these annual reviews.

In countries other than the UK where the BSAC Medical Committee already undertakes this role, appropriate organizations (such as the Divers Alert Network [DAN]) could survey the activity and diving related complications of diabetic divers by questionnaire at these reviews. This sort of audit would be very important if the rules on diabetics and diving are "liberalized" in line with these recommendations.

Diving method

There are two issues that require consideration. First, thought must be given to the scope of diving undertaken by diabetics; and second, guidelines for blood glucose management on the day of diving must be provided for selected diabetics participating in appropriate diving activities.

Scope of diving by diabetics.

One potential outcome from this workshop might be the endorsement of diving by properly selected diabetics. However, this does not mean that all forms of diving will be considered appropriate. Most data that can be interpreted as supportive of diving by diabetics is derived from recreational diving as opposed to occupational diving. In addition, the vast majority of data comes from no decompression dives to less than 30 m (100 ft) depth, and a substantial proportion of the data come from warm water diving. There are good reasons for believing that occupational diving, deep diving, decompression diving, solo diving, prolonged dives and diving in colder water infer greater risk for diabetics.

Protocol 2. Scope of diving by diabetics

Diabetics selected according to Protocol 1 of this document and who satisfactorily complete a recognized diver training course are considered suitable for recreational diving. The following stipulations and strong recommendations regarding diving activity and methods apply:

1. Diabetic divers are suitable for recreational diving. This does not include occupational activities such as diving instruction and dive guiding ("dive-mastering").

Comment: In the opinion of these authors, occupational diving by diabetics should not be endorsed by this workshop. By definition, occupational diving usually involves focus on a task or purpose that demands attention and concentration. This will inevitably detract from self-monitoring by diabetics and may increase the risk of emerging problems remaining unrecognized until too late. A strong work ethic and motivation to complete a task is a characteristic of many occupational divers, and even if a problem is recognized, a diabetic diver might try to "work through it" in order to get the task completed. This extra personal risk is to some extent transferred on to other divers present, and this is especially so in occupational situations.

Unfortunately (and controversially we suspect), these issues are particularly relevant to diving instruction and dive guiding. An incapacitated instructor or dive master with a class or group of novice divers in open water is clearly a potential disaster. There will always be conspicuous examples that appear to "give the lie" to this concern (such as Mr. Stephen Prosterman of Camp DAVI). Indeed, any proscription against diving instruction by diabetics would require an "each-case-on-its-own-merits escape clause" to allow continued participation of exceptional individuals already established in the industry. However, for the purposes of drafting policy for prospective application, it must be remembered that we are operating in a contemporary diver training industry populated mainly by young fast-track instructors with limited diving experience.

Even in the absence of these safety considerations, diving should not be considered a strategic career option for a diabetic since, at any stage, they might develop complications which would then disbar them from their primary source of income (Seckl, 1995).

2. It is strongly recommended that diabetics do not undertake dives deeper than 30 metres of seawater (100 fsw), dives longer than one hour, dives that mandate compulsory decompression stops, or dives in overhead environments.

Comment: Deep diving, diving in overhead environments, or diving a time - depth profile that mandates decompression stops ("decompression diving") all hamper rapid access to surface support. The potential for hypoglycaemic events in diabetic divers constitutes one important reason why rapid access to the surface may be important to this group. Not surprisingly, strong advice against diving deeper than 30 m (100 ft) and avoidance of decompression diving are recurring themes in the literature (Lerch et al., 1996; Scott and Marks, 2004; Edge et al., 2005). The choice of 30 m (100 ft) seems reasonable since it is difficult to spend significant time deeper than this without incurring a decompression stop obligation, and the effects of nitrogen narcosis would make it increasingly difficult to recognize hypoglycaemia at such depths. Moreover, it is notable that the vast majority of the data describing diving activity by diabetics is derived from dives shallower than 30 msw (100 ft) (Dear et al., 2004; Edge et al., 2005) and shorter than one hour (Dear et al., 2004). There is insufficient data from more provocative exposures to form an impression of the associated risk.

3. It is strongly recommended that diabetics do not undertake more than two dives per day and that an absolute minimum surface interval of two hours be employed.

Comment: This is an intuitive recommendation based on recognition that diving can be a physically demanding activity and that fatigue is common following "a normal diving day," even for non-diabetic divers. Others concur with this stance (Scott and Marks, 2004; Scott, 2005). A minimum of two hours surface interval is seen as necessary to give time for adequate relaxation and eating before invoking the one hour pre-dive blood glucose testing regimen recommended below.

4. Diabetic divers must dive with a buddy who is informed of their condition and aware of the appropriate response in the event of a hypoglycaemic episode.

Comment: The potential for hypoglycaemic events and the consequent need for assistance in diabetic divers seems reason enough to recommend they avoid diving alone. There are references in the literature to the value of having a buddy who is not diabetic himself or herself, and who is informed of the diabetic diver's condition. (Winsett et al., 1992; Lerch et al., 1996; Edge et al., 2005) Safety should be further enhanced if the non-diabetic buddy understands the appropriate response to an apparent hypoglycaemic event (Winsett et al., 1992; Dear et al., 2004; Edge et al., 2005).

5. It is strongly recommended that diabetic divers avoid combinations of circumstances that might be provocative for hypoglycaemic episodes such as prolonged, cold dives involving hard work.

Blood glucose management on the day of diving

Literature

Various groups have suggested similar approaches to the problem of blood glucose management on the day of diving. The key elements of several management protocols are summarized in Table 3. Again, we acknowledge that others are probably in use, but may not be readily available in the literature. Additional protocols will be described at this workshop.

Most of the papers described in Table 3 were mentioned earlier. The newcomer, by Kruger et al. (1995) took the form of a letter to the editor published in Diabetes Care and was reportedly researched and written in response to the authors being asked to sign diving medical release forms for diabetics.

Mention must be made again of the YMCA and BSAC protocols since they are issued by credible diving organizations, are broadly permissive, and are designed to facilitate safe diving by selected diabetics training in the "mainstream" context. It is of interest that despite encouraging similar practices, these documents approach the task from two different extremes. The YMCA protocol is highly prescriptive and inclusive of practical detail, whereas the BSAC document generally leaves it to the well-informed diabetic to tailor the detail of his or her management strategies to their own needs. This is not a critical observation; nor do the present authors wish to infer any preference for either strategy. Nevertheless, it is inevitable that some consideration will need to be given to this Workshop's approach to the problem.

Table 3: Comparison of protocols of blood glucose management in diving

Authors Parameter	Winsett et al., 1992	YMCA, 1995	Kruger et al., 1995	Lerch et al., 1996	Dear et al., 2004	BSAC
Diabetes	"Insulin-dependent"	Diet, IDDM, NIDDM	"IDDM"	"Insulin-dependent"	"Insulin-requiring"	"IDDM and NIDDM"
Pre-dive OHA mods	Not specified	Omit OHAs in pm prior and am	Not specified	Not specified	Not specified	Not specified
Pre-dive insulin mods	No specific, but reference to basing "intervention." for future dives on previous experience	PM prior ▶ long-acting insulin 20%. In AM, if BG 75-160 mg·dL ⁻¹ (4.2-8.9 mmol·L ⁻¹) ▶ short-acting insulin by 50% and long-acting by 20%.** Between dives: omit insulin if possible. Pumps at 50% usual dose.	Not specified	33% decrease in am short acting insulin dose on day 1. Other mods based on results. Trend to lower pm insulin doses over six days of diving	Not specified	Not specified
Pre-dive BG testing	1-3 h, 30 min and immed. prior	60, 30 min and immediately prior	Measure "before dive"	60, 30 min and immediately prior	60, 30 and 10 min prior	Test, but no times specified
Pre-dive BG threshold* (mg·dL ⁻¹ [mmol·L ⁻¹])	Not specified	≥120 (6.7) but <230 (12.8) start of dive. 20-30 g carb snack prior dive. If hypo <80 (6.7) with symptoms or BG >230 (12.8) prior diving = cancel	>150 (8.3) before dive. "Dive should follow a meal". Eat 5 g glucose per 25 (1.4) under 150 (8.3)	≥160 (8.9) at start of dive. No fixed maximum but target 220. Eat 12 g glucose if <160 (8.9) or any fall across 3 tests even if >160 (8.9)	≥80 (4.4) and stable or rising at 10 min prior	"Slightly high blood sugar" raised if necessary by consuming glucose
Rescue strategy in water	Informed and trained buddy; glucose paste	Informed buddy; glucose paste	Informed buddy; liquid glucose	Informed and trained buddy; glucose; glucagon	Informed buddies and other support staff	Informed buddies; glucose tablets or paste
Post-dive BG testing	Immediate, and others "may be necessary"	Immediate	Measure "after dive"	Immediate plus at least six others, incl. 12-15 h post	Immediate	Immediate
Rescue strategy surface	Glucose	Graduated glucose protocol; glucagon.	Glucose	Glucose; glucagon	Readily available sources of glucose	Informed supervisors; glucose; glucagon
Integration of previous experience	Document relevant diabetic data	Based on dive log with relevant diabetes data	Not discussed	Based on dive log: "reference data for similar dives." Use emphasized.	Document relevant diabetic data	Dive log
Other		Increase fluid intake, no alcohol; medic alert bracelet	No alcohol 24 h prior diving	Drink 1.5-2.0 L water prior to first dive		

BG = blood glucose; OHA = oral hypoglycaemic agents; IDDM = insulin-dependent diabetes mellitus; NIDDM = non-insulin-dependent diabetes mellitus.

* All blood glucose levels are in mg·dL⁻¹.

** Protocol assumes that control usually tight. If "loose," then insulin reductions are half those recommended here.

As was the case with approaches to selection, the protocols summarized in Table 3 contain several strong common threads. First, three of the six papers make direct reference to modification of the usual diabetes medication regimen in the hours before diving. Second, there is unanimous agreement that blood glucose levels must be checked prior to diving. Suggestions vary, but four of the six protocols suggest three measurements over one hour with attention being given not only to the absolute values, but also the trends. Third, all protocols emphasize the desirability of an informed buddy, and consider it mandatory to carry some form of rescue glucose that can be administered underwater. Fourth, there is unanimous agreement that blood glucose levels must be checked immediately after diving and that rescue glucose must be available for rapid administration at the surface. Three of the six protocols recommend having parenteral glucagon available. Finally, there is agreement that all diabetic diving activity should be logged, along with an account of the medication and dietary strategies utilized, and blood glucose outcomes. This record should be utilized to guide future management.

Proposal

Diabetic divers who are selected according to Protocol 1 of this document, and who participate in appropriate diving activity as specified in Protocol 2, must use this protocol to manage their health on the day of diving.

1. *On every day on which diving is contemplated, the diabetic must assess him or herself in a general sense. If he or she is uncomfortable, unduly anxious, unwell in any way (including sea sickness), or blood glucose control is not in its normal stable pattern – DIVING MUST NOT BE UNDERTAKEN*

Comment: Blood sugar control is notoriously susceptible to disturbance by changes in routine, stress, anxiety, concurrent illness and other influences.

2. *The pivotal goal for the diabetic approaching any dive is to establish a blood glucose level of at least 150 mg·dL⁻¹ (8.3 mmol·L⁻¹), and to ensure that this level is either stable or rising before entering the water. Compliance is determined by three measurements of blood glucose, taken 60 minutes, 30 minutes and immediately prior to gearing up. Diving should be postponed if blood glucose is <150 mg·dL⁻¹ (8.3 mmol·L⁻¹), or there is a fall between any two measurements.*

a. *Where relevant, strategic and individually tailored reductions in doses of OHA medication or insulin on the evening prior or on the day of diving may assist in complying with these parameters. Initial testing of individual protocols should be conducted under very controlled circumstances.*

b. *Where relevant, a regimen of incremental glucose intake to correct inappropriate pre-dive levels or trends may assist in complying with these parameters.*

Comment: We have elected to be less prescriptive of diabetic management than the YMCA protocol. We consider that the risk of prescriptive detail is that it may not suit individual diabetics, and it may become redundant as new trends in diabetes management emerge and become popularized. We feel that greater emphasis should be placed on setting targets and letting well informed diabetics hit them by whatever means are best suited.

3. Attempts to comply with the requirements of 2 (above) should not result in a blood glucose level greater than $220 \text{ mg}\cdot\text{dL}^{-1}$ ($12.2 \text{ mmol}\cdot\text{L}^{-1}$), and diving should be cancelled for the day if levels are higher than $250 \text{ mg}\cdot\text{dL}^{-1}$ ($13.9 \text{ mmol}\cdot\text{L}^{-1}$) at any stage.

Comment: Prescription of a strict upper limit is always going to be somewhat arbitrary, but $250 \text{ mg}\cdot\text{dL}^{-1}$ ($13.9 \text{ mmol}\cdot\text{L}^{-1}$) clearly approaches the renal threshold for glucose, and there is some evidence that diabetics involved in diving do dehydrate more readily than non-diabetics (Lerch et al., 1996).

4. Diabetics must carry oral glucose in a readily accessible and ingestible form at the surface and during all dives. It is strongly recommended that the diabetic also have parenteral glucagon available at the surface. If premonitory symptoms of hypoglycemia are noticed underwater, the diver must surface, establish positive buoyancy, ingest glucose and leave the water. An informed buddy should be in a position to assist with or initiate this process.

5. Blood glucose levels must be checked at the end of every dive. Appropriate response to the measured level can be determined by the individual cognizant of their plans for the rest of the day. It should be noted that the requirements for blood glucose status outlined at point 2 remain the same for any subsequent dive.

a. In view of the recognized potential for late decrements in blood glucose levels following diving it is strongly recommended that the level is checked 12-15 hours after diving.

6. Diabetics are strongly recommended to drink between 1000 and 1500 mL of extra water over a period of several hours prior to their first dive of the day.

7. Diabetics must log all dives, associated diabetic interventions, and results of all blood glucose level tests conducted in association with diving. This log can be used to refine future interventions in relation to diving.

This protocol would be combined into an information package to be given to the diabetic by the examining doctor on completion of their diving medical examination. Other ancillary information, and tips and tricks that are not sufficiently critical to be specified in the protocol could be incorporated in this package. For example, a pro-forma for a diabetic dive log could be included, as could advice about simulated "dive trips" to swimming pools as "dress rehearsals" in glucose management (as have been recommended by the YMCA). This is a possible "repository" for more minor pieces of advice that may be raised by the workshop participants.

Conclusion

We reiterate that this document is prepared in accordance with the original terms of reference set down by the workshop organizers: as a "straw man" to form the basis for a structured debate. We have attempted to draw on the experience of others to produce a protocol that is both pragmatic and inclusive of strategies to address most major concerns arising from diving by diabetics. We do not purport to have produced the "perfect protocol," and expect much debate and many modifications.

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Mitchell et al. Appendix 1

Draft pro-forma statement for use when counseling diabetics about diving.

STATEMENT REGARDING DIABETES AND DIVING

I, _____ hereby acknowledge my understanding and acceptance of the following issues:

1. Altered consciousness, heart attack, or exhaustion during diving may lead to drowning and other life-threatening complications.
2. A history of diabetes implies a greater risk of these events.
3. Diving itself may make these events more likely in a diabetic by precipitating hypoglycaemia, or imposing high physical demands in certain situations.
4. That because of the issues described at 1 – 3, diabetics are frequently considered unfit to dive.

I also understand:

5. That the extra risk in diving for a diabetic who meets certain criteria for selection as a diver and who practices appropriate diabetic diving technique is likely to be relatively small.
Unfortunately, this risk cannot be exactly quantified.
6. That any decision for a diabetic to dive must be based on the perceived benefit weighed against the potential risk.

Having decided to proceed with diver training, I acknowledge:

7. That Dr. _____'s assessment of my risk in diving has been based in part on my own reports of blood glucose control, and my general state of health. I acknowledge my responsibility for the accuracy of those reports.
8. That if the pattern of my diabetes changes significantly, or if I suffer any adverse diabetes-related event in which I require assistance or medical consultation at any time, then the risk of diving may be increased and I should cease diving and discuss the issue with Dr. _____ again.
9. That I should not dive during any period likely to be associated with worsening of my glycaemic control, such as during a cold or other illness.
10. That if I find diving precipitates any problems in relation to my diabetes, I should cease diving forthwith and seek review with Dr. _____.
11. That I understand the necessity to more closely monitor and adjust my glucose levels on diving days, in accordance with the diabetic diving guidelines.
12. That I have read, understood, and had an opportunity to ask questions about the diabetic diving guidelines.
13. That I understand the necessity to inform my dive buddy and dive group about my diabetes.
14. That I must undergo annual review with Dr. _____ or another diving doctor as long as I continue to dive.

Finally, I understand that being informed of the above issues, having had my questions answered, and having been counseled about my risk in diving I accept that I am responsible for my decision to dive. I hold no one else responsible for any adverse consequences of this decision.

Signature: _____ Date: _____

CONSENSUS DISCUSSION

Editor's Note: The following text was excerpted from a transcript of the meeting provided by a court reporter. Editorial changes were made to correct grammar and remove extraneous comments. References to earlier points were moved to consolidate the relevant text. Every effort was made throughout to retain the spirit and intent of the original discussion. The "straw man" text used to guide the discussion was inserted at the start of each relevant section of discussion. The draft text agreed upon in the workshop session follows each section. The guidelines appearing in the front of this publication reflect the final form generated after review and discussion of draft materials circulated electronically to participants.

DR. DEAR: The remainder of the workshop will be spent going through the talking points provided by Simon Mitchell to determine if we can produce a consensus standard. We will discuss any areas of contention.

DR. MUELLER: I would like to make a general comment before we go. I am representing the German Society of Hyperbaric Medicine here. We have had very detailed recommendations for recreational divers in effect for many years, and I am only talking about recreational divers here, not occupational divers because they are absolutely banned with diabetes. For the recreational divers we have a rather relaxed approach.

I would like to compliment Simon Mitchell for his elaborate points here because we are so relaxed compared to what you are drafting. I think we could go well along these lines at the end because this would not restrict our diabetic divers further. We could give our divers something in their hands they could use as additional guidelines.

We refer to Type 1 and Type 2. They can dive if they have no vascular pathologies, if they are capable of controlling their blood glucose themselves and manage it successfully and if they had no critical hypoglycemia episodes in recent years, but we do not specify for how many years, and if no secondary organ manifestations are present. And then we recommend that they carry a glucose source when they dive and maintain a well hydrated status on the days they are diving.

The dive instruction of diabetics has to be done under the care of specially trained instructors. And it is mandatory that diabetic divers inform their dive partners. We have had this recommendation in place since 1998. We do not have any records of how many of our divers are diabetics so we do not know the denominator. I personally see about 100 diver's medicals every year, and none of them has ever admitted to be diabetic. So, probably a large number of them are lying to me, most likely. But we have no recorded incidents related to diabetes.

DR. MILLAR: My comment regards the scope of our discussions. Everyone has talked about recreational diving but it is an easy jump to occupational diving within the recreational business. I think that we should include the word "recreational" in the title or in the introductory statement so that it is quite clear from the start what that this workshop has not addressed - specifically the myriad types of occupational diving beyond recreational.

DR. DEAR: It does say recreational in the opening text.

DR. MITCHELL: The bullet points are talking points that I put in for my presentation. They were not intended to be part of the written protocol.

DR. DEAR: Leave it there because it reminds us what we should be thinking about.

DR. YOUNGBLOOD: I know we are still divided by our common language, but I just want to point out the courts in the U.S. have interpreted "protocol" as being something that you would say is mandatory, as we would say "guidelines" leave a position. We have both terms in this document.

DR. WOODS: Are these going to be guidelines or rules? I guess that gets back to what is our role going to be as physicians. You can give me guidelines, but I can tell you there are 16 year-olds that are more mature than 18 year-old patients. I would like as a physician to tailor my care to the individual and not necessarily to a set of rules. Rules tie our hands and the kids may dive anyway.

DR. DEAR: We are not making rules. We are making guidelines. We hope that it will make sense for people to follow them, but there is no obligation.

DR. MITCHELL: Practicing within a guideline designed by a group like this provides you with some safety.

DR. WOODS: Absolutely.

1. Selection and surveillance of diabetics in scuba diving

STRAW MAN TEXT

Recreational scuba diving within the bounds subsequently defined may be undertaken by candidates using medication (oral hypoglycemic agents or insulin) to treat diabetes provided the following criteria are met....

1.1. Age 18 years and over

- may be inappropriate for children who struggle with diabetes management*
- an older threshold may be appropriate*

MR. PROSTERMAN: Just to comment on the lower age limit, I agree that I have had many divers 15-16 year-olds who were much more mature than 30 year-old divers, let alone 18 year-old divers. I think anytime they are going to be under 18 they are going to need parental permission anyway. So, personally, I would like to see that lowered.

I have had divers, especially those with parents involved, who have been able to handle it. You might want to say for kids under 18 it would be two years of insulin treatment or something like that so they have more time to get used to it. But I personally think that 16 would be a better lower limit as long as there is parental involvement.

DR. MITCHELL: What do you mean by parental involvement?

MR. PROSTERMAN: I prefer to see parents dive with them. I would prefer to see one parent involved. So, put in something like that as a suggestion if they are younger than 18. I do not think we would get a lot of feedback that would be negative towards that from the participants either because I think most parents that want to get their kids into diving that are younger than 18 are going to want to do it with them anyway.

DR. VANN: Just to remind the group, and I do not know that this was brought out, but our initial intention was to have a good, solid representation from the recreational diving industry here. I think whatever guidelines come out need eventually to have that involvement. I would not see that without that proper representation or consultation that we are going to have a complete set of guidelines that we can feel comfortable going forward with. So, what we do here may be just an interim step.

DR. DEAR: Although we do obviously need complicity with training agencies, we are a body of physicians with serious thoughts on the matter. I think we need to direct those thoughts. We clearly are responsive and will listen to any sensible arguments, but I do not think necessarily that it has to be a complete document today.

DR. VANN: I would agree with you, but my point is that there may be things that you are not thinking about that they will bring up. That is what needs to be taken into consideration.

DR. SCOTT: At the YMCA, we like the 16 years too. We insist on either parental involvement or the presence of another adult who the family recommends to assume that role. The parent or acting guardian can be a YMCA-trained diver. They become the informed buddy who stays with the student during the course. These are, after all, kids coming to learn to dive.

DR. MACRIS: I think a couple points were brought up, it is not only the age we can debate, 16 or 18 years, but you brought up an excellent point regarding the onset of disease. It may be appropriate to require a two year hold for a new onset and perhaps one year for an established case.

MR. PROSTERMAN: That would come under a different guideline.

DR. MACRIS: But, unfortunately, the only way you are going to get through this U.S. legal system with guidelines and mandates is maybe just 18 makes a lot of people breathe easier unless there are special programs and those special programs UHMS would need to define. I think we have to give a cutoff today.

DR. DEAR: Just to say that much like the RSTC [Recreational Scuba Training Council] document that was sorted out a number of years ago, that went back and forth on various components. If we could refocus our attention back on the age, are we going to stick on 18?

MR. FLAHAN: [Representing NAUI]. There are already some recreational age guidelines that are already out there. You might want to talk to the recreational side of this before you start putting age in. The other concern that I have from my perspective is how instructors are going to fit into this and how this is going to affect training classes. Guidelines, many times, if there is a legal action taken, these are brought into court. My big concern is with all these protocols is who is going to ensure that a student enrolled in a training class follows all these protocols before they are involved in a diving activity. How are we going to ensure that they have had their annual physical? How do they present that? These are the nuances that to me I have a great concern because I think the instructor, at least at my level in the training class, needs to have the final word as to whether somebody is going to participate in a training dive or participate in an activity.

DR. MITCHELL: I think that this is a statement of what we as a group are happy with. It is not our job to put in place a system by which there is assurance that everyone sticks to it. If the recreational training organizations are uncomfortable with that, then they just will not train diabetic divers. What we see out there is that they are training them and they are doing it with less guidelines, less protocol, less information than we are providing with these protocols that we have designed. I hear what you are saying, but I think we have just got to come up with something we are happy with and assume that

it will be implemented, but that is not really our problem. We are going to discuss the issue of periodic surveillance and how we might ensure that that happens. But I think at this stage this is an expression of what we – and the industry – want us to do this. They have been wanting us to do this for years. Let them run with it. They are already operating without our guidance.

DR. WOODS: I am a physician. I am also a NAUI instructor. I am glad that a NAUI representative came. I just want to mention that the legal age for driving in the United States with diabetes is 16. So use that as a guideline.

DR. GAREY: I wanted to make a couple comments on this. Number one, this is a recreational activity, and it is not an employment activity. Number two, when we are talking about the age in some of these guidelines, one of the things, I deal more with the medical side than the diving side. One of the things that is hard with young diabetics is to encourage them to comply with the things you are teaching. Diabetes produces a state of hopelessness for a lot of young people. Diving is a great opportunity to give them something to shoot for, a reward; a goal. I think trying to proscribe diving at a young age does a disservice. Putting in guidelines with strict control and understanding is great and within those guidelines then we are encouraging these young diabetics to be active, knowledgeable and well controlled.

SPEAKER: I would also like to point out the FAA in gliders, they can solo at 14 and there is no medical requirements.

DR. POLLOCK: If you have someone who is under 18 years of age, parental permission should be required before they participate in a training course. Stating "16 years of age with parental approval," particularly with special training that can involve the parents, makes a lot of sense.

DR. MITCHELL: I think that what we should do to represent the feelings of this meeting accurately is say as a footnote that this is what we did with the workshop, like where there were issues like that, we put a comment that there was a strong sense that parental involvement would be desirable with diving candidates less than 18 years of age.

MR. PROSTERMAN: Why not put that as a guideline?

SPEAKER: It is a given.

MR. PROSTERMAN: Permission from a parent and taking part in the program to learn about the rest of the diving protocols are two different things. I think more people would rather see, that voted for 18, would rather see that the parent or responsible adult is going to learn about the diabetes program with the 16 year-old. So, I think it should be part of the statement of the guidelines.

SPEAKER: I think it is nice to have parents, but if you have a motivated kid who is smart and he just has a sluggard of a parent, it is going to cause a problem. I voted for the 16 because it is special training. I think you can find kids who should have the opportunity even without direct parental involvement.

DR. MITCHELL: Okay. Special training.

DR. DEAR: Let us vote on this package.

DR. MITCHELL: The whole package. Age 18 years or over and this may be lowered to 16 years of age when special training is available. Yes?

DR. DEAR: Any argument with this? No. Accepted.

FINAL TEXT

Recreational scuba diving may be undertaken by candidates using medication (oral hypoglycemic agents [OHAs] or insulin) to treat diabetes provided the following criteria are met.

1.1. Age 18 years and over (limit may be lowered to 16 years if special training* is available)

****special training will include dive training programs designed specifically to meet the education needs of individuals with diabetes and, desirably, to include participation by parents and/or responsible family members or guardians.***

STRAW MAN TEXT

1.2. At least six months have passed since the initiation of treatment with OHAs or one year since the initiation of treatment with insulin. An established diver using OHAs who is started on insulin should wait at least six months before resuming diving.

- need record of stability over time***
- need experience at glucose management on part of diabetic***

DR. LORBER: This is roughly four times the duration that the ADA and the National Fire Protection Agency and the American College of Occupational Environmental Medicine for firemen and for police officers. I will acknowledge that divers with diabetes could be dangerous to others, but not anywhere near as much danger as a fireman or a police officer. I think this is excessive.

DR. MITCHELL: Is it too long?

DR. LORBER: I think it is much too long. I think the American Diabetes Association has recommended one month and three months for the same two.

MR. PROSTERMAN: I respect Dan Lorber a great deal, but I am going to have to disagree. This may not be the exact time that would be optimal, but I think one month and three months are too short. Again, this is where we might want to get into the age dependency of this type of thing where if it is a young diabetic who has only had diabetes six months, we might want to have him have more time as they are trying to figure it out. If there was a way we could ensure that they had this initial education, it would be a much easier job with all of this. But we need to, I believe, show we could go to at least two HbA_{1c}s that are well within acceptable limits, which would be more of a six-month period on insulin. But I think at one and three months, the disease is still new to the person getting used to it. Because they might be inactive during that time also when they are first getting used to new programs and lifestyle changes. Some people need a total lifestyle change when they get diabetes. Whether they accept that or not is one of the bigger problems with diabetes in general. But when you are doing a lifestyle change, I think you need some time to get used to that if you are going to be successful.

DR. LORBER: I think this is a place where you need to separate Type 1 and Type 2. But Steve is right, the new Type 1 needs a longer period of time than the established Type 2 who has been on diet and then begins on medication or has been on oral agents for five years and then needs insulin. We may need to clarify more here.

DR. TORP: I have trouble with it. I think it might be too long especially for those who are diet controlled and then just start taking the pill. So, it is all arbitrary, but I would suggest three and six.

DR. SILBERMAN: Point of clarification from the FAA. It is 60 days for an oral. We require 60 days when they are first put on the oral and if there is a change. And you saw six months for an insulin diabetic, six months.

DR. MITCHELL: Why do we not go three and six?

DR. HART: Make sure you include the change in oral hypoglycemics potentially.

DR. DEAR: You mean switching from oral to insulin, different drug?

DR. HART: Between different orals.

DR. TABAH: I think that three months is more than enough for oral medication. But when you are starting with insulin, you might need one year to start, as you say, to start knowing how your body reacts to the insulin and start doing other sports maybe to understand how insulin and sports work together. Before having the chance to dive, you might need to do some jogging or some other things to understand it. This would take some time. Because when you are discovered with diabetes, you begin with a few days or weeks in the hospital while starting with the medication. Everything takes a lot of time. I think we might need more time than six months.

DR. LORBER: I think one of the ways that we can separate this out is the Type 1s and Type 2s. So, for example, if we say an established diver using OHAs, then actually, this does not tell us at all about the new diver.

DR. LORBER: Then I think I agree with Steve. I think the Type 1s probably need a year of disease for us to have a sense of stability. I think Type 2s start on insulin under any circumstances, I can live with six months, although I would be happy to vote for eight months.

MR. PROSTERMAN: I was just thinking we should put alteration of treatment for both and not just for the OHAs. A lot of times with insulin, treatments are going to change. When somebody is a new diabetic, they might go to two shots a day and then to four or five shots a day. Anytime that is been done, you need a time period to get used to that. So that might cover, we might want to say, three months and six months after stability of the control or something like that.

DR. LORBER: The problem with that is how do you define alteration. Is that just a change in the basal rate? This is one of the issues we have addressed in some detail was exactly this question. What we did is define it as the addition of a new insulin or new oral agent.

DR. LORBER: I thought it was suggested to go back to one year on just the insulin.

DR. TABAH: You are saying alteration of treatment with insulin. If we recommend to lower insulin doses before diving, this might be understood as an alteration of treatment, and maybe this word is not appropriate.

SPEAKER: Alteration meaning nothing other than dosage adjustments.

DR. LORBER: I think there is room for adjustments in this.

DR. DEAR: We will include a footnote distinguishing adjustments from alterations.

SPEAKER: I prefer to go back to a year for insulin starters.

DR. DEAR: I wanted to see what we have got. Now we have got three months for current. If we put in a year, how many nos do we have? Change the six months to a year.

DR. MITCHELL: If we change it to a year for new.

SPEAKER: I just want to point out we all agree it is 12 months of hypoglycemia.

DR. MITCHELL: That is why it was a year.

SPEAKER: Right. I do not see how you can, how you can be – we are not internally consistent.

DR. DEAR: We need to be internally consistent. That is a very good point. Everybody seemed to agree on the one year for complications and everything else. That leads to one year for a new diabetic.

MR. PROSTERMAN: Then we might want to change the period of the alteration for the insulin in that case.

DR. MITCHELL: To be honest with you, I am not sure that alteration of insulin needs to be there.

SPEAKER: Go back to that one-year period.

DR. POLLOCK: Leave the footnote and we will develop the wording for that later.

DR. DEAR: Naysayers at this point? Done.

FINAL TEXT

1.2. For a new diver at least three months have passed since the initiation or alteration of treatment* with OHAs or one year since the initiation of treatment with insulin. An established diver using OHAs who is started on insulin should wait at least six months before resuming diving.

**"alteration of treatment" is defined as a change in medication(s) or dosage(s) that could result in significant deviations from current status (changes likely to include only moderate change from current status would be described as "adjustment of treatment").*

STRAW MAN TEXT

1.3. There must have been no episodes of hypoglycemia requiring intervention from a third party for at least one year, and no clear history of hypoglycemia unawareness
- proscription against history of hypoglycemia is necessary but hard to express in objective terms.
- what is hypoglycemia?
- seems sensible in this context to base the definition around an event that the diabetic needs help to manage.

MR. PROSTERMAN: We need something covering that persistent hyperglycemia.

SPEAKER: We need to address stability. Hyperglycemia would be as unstable as hypoglycemia.

MR. PROSTERMAN: Glycemic control encompasses hyperglycemia and ketoacidosis.

DR. MITCHELL: Why do we not just add ketoacidosis?

SPEAKER: Because Type 2s do not get it.

MR. PROSTERMAN: "Persistent hyperglycemia?"

DR. HART: Requiring intervention covers it.

DR. DEAR: Any issues with these modifications? No? Accepted.

FINAL TEXT

1.3. There should have been no episodes of hypoglycemia or hyperglycemia requiring intervention from a third party for at least one year, and no history of hypoglycemia unawareness.

STRAW MAN TEXT

1.4. $HbA_{1c} \leq 9\%$ when measured no more than 1 month prior to initial assessment and at each annual review.

- failure indicates either inability to control or to motivate sufficiently.*
- either would deem the candidate inappropriate.*

DR. TAYLOR: Question? Does anybody here know what the average HbA_{1c} is in diabetic management?

DR. LORBER: 8.6 percent in this country.

DR. TAYLOR: Is that for Type 1 or Type 2?

DR. LORBER: That is mostly Type 2s.

DR. MITCHELL: This is a debate about the HbA_{1c} percentage, I think.

SPEAKER: I have learned a lot today, and I think 9 percent is a bit high. I would suggest, I think we saw a 7.5 percent. I just heard a couple of comments from the authors of the papers.

DR. GAREY: I think it is more important what the trend is. To me I would rather see two levels that show stability or improvement than one level with a specific number. I have a diabetic who is 13 percent and comes in six months later and he is now 9.8 percent. I would rather let him dive than a diabetic who is 7.5 percent and comes in at 8.5 percent six months later.

DR. LORBER: The only correlation between HbA_{1c} and hypoglycemia is low HbA_{1c} s. So right now all we are doing by saying that the HbA_{1c} s should be higher, cannot be higher, is saying we are concerned that these people are going to have long-term complications, which we know is a correlation. That has nothing to do with their acute safety to dive. Because I have plenty of people with HbA_{1c} s in the six percent range who are in lousy control because they are bouncing back and forth between glucoses of 40 and 400 $\text{mg}\cdot\text{dL}^{-1}$ [2.2 and 22.2 $\text{mmol}\cdot\text{L}^{-1}$]. I do not think we should have an HbA_{1c} criterion.

DR. EDGE: I would advocate a higher HbA_{1c} for the reasons that Dan Lorber has specified. Secondly, I think we have got the most number of diabetics, and I can tell you I am not automatically disqualifying people who have HbA_{1c}s more than 9 percent. We have got quite a number of them. I realize that these guidelines are being drawn up under the auspices of DAN and the Undersea Hyperbaric Medical Society. When you are considering these guidelines, remember that America is not the only place in the world where diabetics are diving. Just think about that when you are asking for various tests or the frequency of tests. I come from the United Kingdom, where health care resourcing is a challenge. If you do not believe me, look at the number of cardiologists and endocrinologists that are available. I would expect backup from Phil Bryson.

DR. BRYSON: Yes.

DR. EDGE: We still have a large number of people diving with diabetes. You have to remember, everyone here, these guidelines have got to be applicable worldwide.

MR. PROSTERMAN: Again, I have to respectfully disagree. I do think that some semblance of diabetes treatment, understanding and control needs to be there. The breakthroughs with treatment and education in the past 10 years are phenomenal. Kids today versus when I was a kid in the sixties versus the seventies or eighties or nineties even are getting so much better of an education, I think we can easily have people under 9 percent without instances of serious hypoglycemia that they cannot recognize and treat themselves. So I do think it is important to have people in my class who understand how to treat diabetes. If I see a 12 percent value coming in, I have concerns. If I see a 9 percent or thereabouts there is a degree of comfort.

DR. BRYSON: As Chris Edge has said, this is an effort to produce a set of guidelines useful worldwide. It might be worth putting in there "ideally." Because I think that what we should do with divers is encourage them and educate them because they want to go diving. We can gradually bring them down.

DR. LORBER: One of the ways we have addressed this in the other criteria is to say if it is above a certain number, then the individual, we recommend the individual consult his or her physician to address improving control.

DR. MITCHELL: Can I make a suggestion that we do what George Macris is suggesting to me in my ear here. Just say it is recommended that HbA_{1c} is less than 9 percent. We will put opinion saying if it is not – I can buy that. Let us face it, Chris Edge is right. What we are worried about here is complications.

SPEAKER: If you go to the website for the American Heart Association or American Diabetes Association, you will see that they have a recommended goal. But if you start off at 14 percent, that goal cannot be the same for those people as the ones who start at 9 percent. So I like these last three suggestions.

DR. MITCHELL: If levels are higher, review is recommended. If we get someone whose levels are higher, it would be a good idea to refer them to someone.

DR. DEAR: Let us vote on this modified form. Accepted.

FINAL TEXT

1.4. $HbA_{1c} \leq 9\%$ when measured no more than one month prior to initial assessment and at each annual review. If $HbA_{1c} > 9\%$ the diver should contact his/her diabetes specialist for further evaluation and modification of therapy.

STRAW MAN TEXT

1.5. There must have been no admissions or emergency visits to hospital for any complications of diabetes for at least one year

DR. WILKINSON: My interpretation is that any complication of diabetes is broad. When you were mentioning it before you were talking about concern related to hyper and hypoglycemia. I was wondering if the wording should relate to those concern conditions. I guess what I am suggesting is maybe something like visits to hospital for any complication related to diabetic blood sugar and glucose control. That gets picked up on the organ systems.

DR. MITCHELL: What complications of diabetes?

DR. WILKINSON: I guess it might be something as simple as an infected subcutaneous injection site. What you are concerned about is control of the sugar.

DR. MITCHELL: That is the main thing.

DR. WILKINSON: So maybe the guidelines should be directed more towards that.

DR. DEAR: There is one point though. Would you then exclude the acute admission for blindness from diabetic retinopathy?

SPEAKER: That is picked up in other guidelines. I want to rule out simple things.

DR. WOODS: What about the diabetic who loses control secondary to another illness, say the flu or pneumonia, and walks in out of control?

DR. MITCHELL: Again, when we designed this protocol, it was based on all the other ones that are out there. We assumed that the people who designed those protocols, most of the people sitting in this room would be saying the same kind of things. Now, no one actually says, this excludes people who get sick because of other illnesses. I think the intention is that they are there. If they have a hypoglycemic crisis because of cold or the flu, then that qualifies. You can have a very long and highly detailed list of things.

DR. WOODS: I understand that, but that is why we are here. Again, as a physician, it is easy to take the easy route and just be prescriptive. But I want to treat that person as an individual. In fact, I am obligated to. And if the person has a hypoglycemic crisis secondary to an infection and presents, then I feel like there should be an option there for me to use my own discretion.

DR. MACRIS: I do not know how valuable this is going to be. I do EMS online control. There are many diabetics the EMTs turn around after giving them insulin. This guideline may also cause the diabetic to say, I better not go to a hospital, do not get me to a hospital because I am not going to be able to dive. Then you have to trust capturing all this information. So, I do not even know if it is necessary. Something about symptomatic hypoglycemia with a third party, that prescriptive thing was good, but the ER is not.

DR. SCOTT: I do not think you need 1.5. It is opened up Pandora's door, as far as I am concerned.

DR. MITCHELL: I am happy to ditch it. We actually said that we would ditch anything.

DR. DEAR: Who feels vehemently that we must keep 1.5? No one? Eliminated.

FINAL TEXT
1.5. Point deleted.

STRAW MAN TEXT

1.6. There must be no known: retinopathy worse than "background" level; autonomic or peripheral neuropathy; nephropathy (including microalbuminuria); coronary artery disease or peripheral vascular disease.

- background retinopathy is common

DR. MITCHELL: Any issues with point 1.6

DR. MACRIS: I think it is too complicated right now.

DR. DEAR: Chris Edge has a problem with 1.6.

DR. EDGE: It is now well known that diabetics can have microalbuminuria. If they then start taking ACE inhibitors, they can get rid of microalbuminuria. It is very difficult to specify microalbuminuria of being a disqualifying factor. That is a problem of recent therapy. I quite accept that in some of our older protocols we still need to have that. I think you need to say frank proteinuria. Because that will not be gotten rid of by ACE inhibitors or antagonists.

SPEAKER: Something more general would be appropriate to screen out relevant complications or organ disease.

DR. DEAR: Do you want to say "any secondary complications of diabetes?"

MR. PROSTERMAN: "Serious secondary complications."

DR. SILBERMAN: I love this discussion. There is an Aeromed list. I got off of it because I guess I got into trouble. Look, remember, you are going to have guys – because I look at these cases all the time. You are going to have folks coming in that say they have got mild filament, mild peripheral neuropathy, you are going to knock those persons out. Are you trying to be preventive medicine specialists? You just do not want anybody to have a sudden event while they are diving, right, that is the purpose of this? So if they have some of this stuff and it is mild, you are going, you are canning them here. Remember, I have got diabetics who also have CAD [coronary artery disease] and are flying. Just so you know, everybody with a first or second class medical who has any coronary artery event in our group has to be evaluated by a group of cardiologists. So, if the cardiologist lets them go on an oral hypoglycemic, they are flying. I know that we have third class airmen that also have CAD, all kinds of CAD that also are on insulin. You see there have only been four accidents, now five. So the question is, why are you doing this? Are you trying to be preventive medicine specialists or are you just trying to keep a person from getting hypoglycemic and having an event? Who cares if along down the line they ultimately get something which, granted, in preventive medicine is not good for the person's longevity of the life, but you do not care about that. I hate to be crass, but I am telling you, why even have this.

DR. EDGE: With great respect to Dr. Silberman, one thing you do not get in an aircraft is decompression unless you are going up to extremely high altitudes. One of the reasons we put in peripheral neuropathy is because if these guys get an episode of decompression illness, then how is the physician in the chamber going to treat them and know when that neuropathy is a result. That becomes much more difficult.

DR. REED: Let me answer Dr. Silberman in that although we can argue over the exact level of exertion necessary for recreational diving, it is far in excess of what is required for control of an aircraft, especially those operated under third-class [non-commercial] medicals. The increased requirement for physical activity raises the possibility of cardiac incidents during and immediately after the dive. The presence of diabetes would indicate some higher level of probable micro- and macro-vascular diseases. Given the higher requirement for physical activity, our risk tolerance should be lower. There was something about confounding illnesses. With the guidelines as written, DCS should not be an issue. But the BSAC data indicates that pretty much once a lot of these people get in the water they are going to more or less do what they want. This is our one and only time that we can set the bar somewhere. If we set it low with the assumption that every diver will adhere to our recommendations in terms of decompression stress, I think we are probably being narrowly optimistic.

DR. LORBER: There are two issues on this slide that I think should remain. One is significant peripheral retinopathy, which I suggest is at risk with diving because of the pressure changes - but that is a guess because there is no data on it. I think that we need to do some preventive medicine here. We need to prevent people from dying in the middle of hypoglycemic attacks. The only other thing on that slide that is relevant to acute episodes is autonomic neuropathy.

DR. TAYLOR: One more comment. There are population-based statistics showing the distribution and incidence of a lot of the issues you are discussing. You can determine what percentage of the population you would be excluding, and what percentage of the population with these complications then has attendant associated complications. You can set your limits at 25. Most of them are a bell-shaped curve, cut it at 25 percent off each end, 10 percent off each end. We need some normative data here as well to kind of help with these decisions. A lot of the things that you are talking about are linked. There are some linkages between them and between the short and long-term complications. It would be nice to have that data available while formulating these kinds of guidelines. In addition to clinical, there is an epidemiologic base too.

DR. MACRIS: Again, this is messy, but I think a good diving physical is going to pick up these nuances. I mean, peripheral neuropathies change. Can we change it to read, "all efforts will be made to evaluate complications of diabetes, such as..." something to that effect?

DR. MITCHELL: How about if we change it to "should?"

SPEAKER: Say "significant."

DR. MITCHELL: Say "significant autonomic or peripheral neuropathy."

DR. DEAR: Any further discussion. Vote on the modified text. Accepted.

FINAL TEXT

1.6. There should be no: retinopathy worse than "background" level; significant autonomic or peripheral neuropathy; nephropathy causing proteinuria; coronary artery disease or significant peripheral vascular disease.

STRAW MAN TEXT

1.7. No more than two months prior to the first diving medical assessment and each annual evaluation, a review is conducted by the candidate's diabetologist who must confirm that: criteria 1.3 -1.6 are fulfilled; the candidate demonstrates accurate use of a personal blood glucose monitoring device; and that the candidate has a good understanding of the relationship between diet, exercise, stress, temperature, and blood glucose levels.

- diabetics motivated to dive should have a diabetologist
- DMOs lack the training for this assessment
- pro-forma to guide the process (e.g., Edge et al., 2005)

DR. DEAR: Point 1.7; the diving medical examination. Any discussion?

DR. LORBER: I think that it is going to have to be the treating physician.

DR. SILBERMAN: Quick thing to tell you that I did not mention in my presentation. The FAA, not the medical folks, just came up with a rule that started last September that has created a whole new subset of aircraft that is less than 1,320 pounds gross weight, so that you just fly with a driver's license. Which means that as long as your medical was never denied, suspended or revoked by the FAA. So I would be fine if I either developed a seizure disorder since the last time I had my FAA medical or if I had never had an FAA medical and my doctor thought I was safe. And, physicians out there are telling Joe pilot all the time without knowledge of altitude medicine, "Joe, you are good to go." We get beat up about this all the time.

DR. LORBER: It should be physician experienced in diabetes care.

DR. MITCHELL: What about a PCP [primary care physician] with an interest in diabetes?

DR. LORBER: The kind of description we used in the other documents is that the individual must be under the care of a physician knowledgeable in current treatment of diabetes. And then we said that the treating physician should be knowledgeable and experienced in modern treatment of diabetes.

DR. DEAR: Any conflict with a PCP knowledgeable in treating diabetes? We do not have enough diabetologists in the world. No. Any other discussion? Vote. Accepted.

FINAL TEXT

1.7. No more than two months prior to the first diving medical assessment and at each annual evaluation, a review is conducted by the candidate's primary care physician (knowledgeable in treating diabetes) who must confirm that: criteria 1.3 - 1.6 are fulfilled; the candidate demonstrates accurate use of a personal blood glucose monitoring device; and that the candidate has a good understanding of the relationship between diet, exercise, stress, temperature, and blood glucose levels.

STRAW MAN TEXT

1.8. No more than two months prior to commencing diving for the first time and at each annual review, a diving medical examination is completed by a doctor who has completed a post-graduate diving medical examiner's course. The diabetologist review report must be available. This examination will include appropriate assessment of exercise tolerance, and for candidates over 40 years of age this will always include an exercise ECG

- most diabetologists are not qualified to do this.

- DMO is only practical option for avoiding central review.

- rules for exercise tolerance difficult to formulate and are intentionally left discretionary (a solid history may be OK).

- exercise ECG is a good option.

SPEAKER: Point of information. Are there enough DMOs [diving medical officers] in different parts of the country to satisfy that requirement?

DR. DEAR: I think the answer is no. There are two possible contentions. The DMO and the ECG over 40. The DMO question first.

SPEAKER: How do you define a DMO?

DR. WOODS: DAN has developed a DMO course. Am I going to take that because there is a need to have some consistency internationally. Am I correct in understanding that as a military DMO you are to be excluded unless you have taken that particular DMO course?

DR. MITCHELL: No. Any course will suffice. You can be trained in the military. We can put that as a footnote if you like.

DR. LORBER: I think we have to have "if available" because given what you said before how few there are.

DR. DEAR: I have a problem with postgraduate diving medical examiners course because I do not believe we have enough in the country. We can present it as "ideally" or "suggested," but I do not think it can be a hard statement.

DR. STONE: There is no requirement in the United States at this point for any diver to be examined for recreational purposes by a diving medical officer. By doing this you are adding a complication only for the diabetics. Unless you make that a criterion for all training, I think – you can say preferably or preferably by a physician knowledgeable in diving medicine, but I do not think you should put it in there as an absolute.

DR. DEAR: We are going to change the word to "preferably" or "suggested" or some other phrase like that.

MR. PROSTERMAN: Supporting an earlier comment, somebody "familiar with hyperbaric medicine" rather than "if possible." We could put "if possible" or "somebody familiar with."

DR. SCOTT: I just think you ought to do away with it. We have competent physicians in this country. They are doing this examination and they are going to look at these guidelines. I do not know why you would say preferably by a doctor that has completed a postgraduate course. How far back? If you had it 30 years ago, is that okay?

DR. WILKINSON: We as competent medical practitioners familiar with diving should not lower our standards to allow any medical practitioner to perform in an area where we have an experience where we know that they repeatedly are inadequate in their performance and their skill. These are our guidelines. We should be proud of them. I would suggest we should expect the diving medical examination to be performed by a doctor that has some experience in diving medicine.

DR. BRYSON: Just to pick up on the issue of competent primary care physicians. I review the diving medicals for the Coral Cay Conservation Society and I recently had a volunteer from the United States who was an epileptic diabetic passed as fit by his primary care physician to go to a very remote tropical destination. I would completely disagree that all doctors know what they are doing in diving medicine.

DR. MACRIS: Also, add "in consultation with." How many of us here have seen someone evaluated and inappropriately cleared by a clinician not familiar with diving medicine.

DR. MITCHELL: "Preferably by or in consultation with."

DR. EDGE: I would agree with what Phil Bryson said. In the UK, we have managed to get it such that most diabetic divers are examined now. We would prefer them to see somebody who has some knowledge of diving medicine. There is no point in doing a diving medical otherwise.

DR. DEAR: Vote on the top section of point 1.8; with the DMO changed to a physician who has completed postgraduate diving medical examiners course. Carried.

DR. DEAR: Now to the bottom section; do we want an ECG for divers over 40 years of age?

DR. MACRIS: How about a modification? Something like workup should include, if possible, some type of sophisticated cardiac examination, whether it be resting or exercise ECG as determined by the evaluating physician, and then the age cutoff.

DR. DEAR: I think personally that we need to have it fairly short and obvious. This is all for discussion by the individual physician and the patient. There is nothing to say you have to do exactly what we say. But we need to have a number that somebody can use as a reference.

DR. DEAR: Looking at the data regarding, it is silent ischemia that prompts the cutoff at 40 years of age.

DR. TABAH: I totally agree with the age. Just one point. We maybe should say is performed at least once and maybe at least once every five or something years.

DR. MITCHELL: So it would become an annual thing.

DR. DEAR: Do we have surveillance?

DR. LORBER: The guidelines are changing for the American Heart Association and American Medical Association. We could simply recommend evaluation for silent ischemia. Not too specific, because there are several ways to do the evaluation.

DR. DEAR: Over 40 years of age?

DR. LORBER: Combines with common AHA guidelines.

DR. DEAR: Is that internationally acceptable?

DR. MUELLER: Our cardiologists tell us that the cutoff age is 40 and we have got to do that as an exercise ECG, nothing else.

DR. DEAR: The evaluation of silent ischemia at Duke may well include a stress/exercise ECG. So that is fine.

DR. MITCHELL: Do you want to make it mandatory or strongly recommended?

DR. DEAR: Let us leave it at strongly recommended. Vote on bottom section of 1.8. Any nos? Good. Accepted.

FINAL TEXT

1.8. No more than two months prior to commencing diving for the first time and at each annual review, a diving medical examination is completed, preferably by (or in consultation with) a doctor who has completed an accredited post-graduate diving medical examiner's course*. The review report completed by the primary care physician must be available. It is strongly recommended that formal evaluation for silent ischaemia be undertaken for candidates over 40 years of age.

**Any accredited course (one certified as fulfilling certain standards by a national and/or regional professional association) in diving medicine is acceptable*

STRAW MAN TEXT

1.9. At the assessment by the DMO, the candidate acknowledges in writing receipt of and intention to use the diabetic diving protocol; the need to seek further guidance if there is any material that is incompletely understood; and the need to cease diving and seek review if there are any adverse events in relation to diving suspected of being related to diabetes

- key issue is “course vs. information sheet”
- diabetics are diving without specific courses
- imposing a course may perpetuate the current situation
- such documentation will improve comfort levels for DMOs

DR. DEAR: Any issues with point 1.9? No. Vote. Accepted.

FINAL TEXT

1.9. At the diving medical examination, the candidate acknowledges in writing the receipt of and intention to use the diabetic diving protocol; the need to seek further guidance if there is any material that is incompletely understood; and the need to cease diving and seek review if there are any adverse events in relation to diving suspected to be related to diabetes.

STRAW MAN TEXT

1.10. Steps 2 – 9 must be completed annually using the same diabetologist and DMO where possible.

- periodic surveillance is non-negotiable
- introduces opportunity for data collection

DR. DEAR: Point 1.10. We will change the word from diabetologist to treating physicians. Any other issues?

DR. BRYSON: One of the things we have had problems with is instituting an annual exercise test for over forties. I, for one, know at least three divers who cannot get this completed. The only way to get things done in our country is privately, otherwise, it can take up to 19 months if there is no clinical indication. If you do it privately, it is £400 plus [~700 USD]. I am very interested in the FAA's guidelines that it should be done every five years rather than every year. I am concerned that divers will go off to dive irrespective of whatever guidelines.

DR. TABAH: There is no point in having an exercise ECG every year.

DR. DEAR: We will add a footnote about the ischemia test.

DR. BRYSON: The FAA decided that once every five years is a good recommendation. I know that when we looked at it initially, Chris Edge and I, we thought every year was an appropriate thing to have done because of the guidelines at the time. I am just interested in the difference.

DR. DEAR: It clearly has to work for people. And if we mandate that it must be annual, and it does not work, then it is going to fall at the first hurdle.

DR. HART: To address the international colleagues' concerns, how about "in compliance with locally accepted or nationally accepted guidelines?" For cardiac evaluations, that is the point we were discussing. We do not set the guidelines for evaluating cardiac ischemia silent or otherwise. That is done by folks that are much more knowledgeable in that field than we are. We are just asking that we do it in compliance with their locality, and it is different for different nations' accepted guidelines.

DR. SILBERMAN: I am actually kind of surprised that the FAA went for every five years. Because in cardiac issues, we tend to be a little bit more conservative, but we are sure not anywhere near as conservative as the internationals. Because, just so you know, internationally and even in order to even get your medical in most countries, especially in Europe, you get a stress test every year after age 40, every year. Even to get your medical, we do not have a rule like that. I mean, we did that in the Army and you would be surprised how many false positives you got just for a plain Bruce protocol. We ended up catheterizing them. So be careful.

DR. EDGE: I hate to argue with you, Dr. Silberman, but I am a pilot. I have never had an exercise ECG, as you call them. And, unfortunately, I am well over 40 years of age.

SPEAKER: Did we say anything about exercise capacity?

DR. DEAR: No.

DR. DEAR: Any discussion? No. Vote. Accepted.

FINAL TEXT

1.10. Steps 1.2 – 1.9 must be completed annually using the same treating physician where possible.

After the initial evaluation, periodic surveillance for silent ischemia can be in accordance with accepted guidelines for evaluation of diabetics.

2. Scope of Diving by Diabetics

STRAW MAN TEXT

Diabetics selected according to protocol 1 of this document who satisfactorily complete a recognized diver training course are considered suitable for recreational diving. The following stipulations and strong recommendations regarding diving activity and methods apply...

2.1. Diabetic divers are suitable for recreational diving. This does not include occupational activities such as diving instruction and dive guiding (“dive-mastering”).

- too many distractions
- acknowledge existing instructors
- real world is populated by young inexperienced fast-track instructors
- job insecurity

DR. MITCHELL: The issue is whether we wish to mention occupational diving at all. I think we are going to get into trouble on this point. The easiest way to resolve it is to remove any reference to “occupational.”

MR. PROSTERMAN: I would take it out.

DR. MITCHELL: We are referring only to recreational diving.

DR. DEAR: Exactly. Take it out.

DR. TORP: Yes. There are people out there who think that recreational divers include dive instructors and divemasters. I do not think that is right.

DR. MITCHELL: No, I do not either, but it is whether we want to address that point.

DR. TORP: If we are making recommendation about diabetes and diving, I think we need to address diving instructors and divemasters. I have personal experience with diabetic dive instructors who were not adequately controlled. I think we should say something about that.

DR. MUELLER: We know that most agencies do not see their dive instructors as professionals in the sense of occupational diving. We do not have to address it here; we leave that to the occupational agencies. We look at recreational divers.

MR. FLAHAN: The diving agencies are going to have the responsibility for applying this in the field. I think they need to be an important part of this. Whether they are all here or not, I do not know. I know the other guys are not here. I know I am the only one here from NAUI. But this is going to have to be talked about because we are the group who is going to have to go out and enforce this along the way. You gloss over where it says that this applies to people who have satisfactorily completed a recognized diver training course. We are ultimately going to be responsible for all of these protocols. Has the diver done this, has the diver done that, do they have to submit an annual proof that they have been recertified before we can go off to the next course. Do I have to make sure that they have all the proper training. Do they have to have all the right testing equipment with them. Do I have to make sure that all their glucose levels are within allowable limits. These are all the things that you are prescribing that somehow we are going to become responsible for. Why? Because there are the liability issues. If we have an accident and someone gets hurt, everything will come out in court. Did the diving instructor reasonably deal with these issues. On the other hand, if I refuse to train somebody, it is also going to come into court because these are going to be used by the ADA

[Americans with Disabilities Act], and I have already had a couple of ADA instances. These are things I want to consider. Another one I want to look at in the big perspective, you started off by saying, the diving student goes into the store, checks off diabetes, finds out they have to have this physical exam so they go to the next store and do not check it off. If I am a diving student and I check this off and the guy says, these are all the protocols you have to follow to get certified, I am going to go to next dive store and say, guess what I have to do, I am not going to check it off. Have we really solved the problem? I think we need to come back with all the agencies in some other setting because we would not do well in this setting to discuss our issues and bring those forward. I think that is really, really important.

DR. DEAR: Interesting points.

MR. PROSTERMAN: Just to respond, I think the reason we are all here is because there are individuals diving with diabetes every day. They can easily hide it. We want to give them the best tools possible to make diving as safe as possible for them and those with them. I think we have to carry on with this. I also want to comment that maybe we could address these types of professions in a separate venue or at least a separate paragraph so we can get on with this.

DR. DEAR: I think we will take that out as it seems to be too contentious. I agree that there is considerable issue with training agencies, but I do not think we can deal with it here. It is an important issue that should be addressed at the appropriate level. We respect the fact that the agencies have some issues, of course.

DR. MACRIS: This is in response to NAUI. This is a situation where many physicians are uncomfortable bending to the industry. We have an emerging diabetic population globally, and it is aging. This is why we are doing what we are doing. But how we are going to manage this; we talked about this as one of the few instances where there may need to be a recertification requirement. Part of good diabetic management is going to see your doctor at least three times a year, maybe four. This is where online training or recurrent training or something could be provided. Our priority is not the needs of industry. We gave in with flying and diving. They redid the numbers and they found out that maybe we were a little bit too conservative. But, remember, it is hard to do an autopsy finding of hypoglycemia. Our goal is foremost to do no harm. I say we move forward. We can come up with some type of a recertification or recurrent training, whether it be quick online, something a dive shop has, or a newsletter they sign. We can always come back and revisit this. But we cannot just give into the industry in this matter. Safety first.

DR. TABAH: I would like to make a comment because we had this discussion in France; that is why our regulations are so restrictive. I think one thing we should write is that the divemaster or the diving instructor or the dive shop is not responsible for damages if they are following the guidelines. Maybe if we write this down, the liability problems go away. Just say they should have a medical certificate of fitness to dive and should follow the guidelines.

DR. CURLEY: I would like to say that from my perspective, we are here to deal with medicine, give the best guidance that you have medically to help divers who have diabetes to dive safely. Issues of liability, certification, and all the rest of that is important, but they are not the primary focus of why we are here today. I recommend that that is what we focus on and keep our eye on the ball. But the most important thing is the best medical advice that we can give from our area of expertise. Then we will take it to the lawyers. Then we will take it to the certification agencies. But at least we will have our focus and our job is done.

MR. FLAHAN: You support the issue that we all get together on this. I want to counter one thing that was just said because the comment was made, well, when they show up to the class, or when they apply, it is their responsibility to have their physical, the physician has signed it off and they are ready to go. That is really not true. Because in a class situation I will look at their physicals, and as an instructor I am still responsible for the safety of all of those people in that training program. Not only the individual that has the physical who had a physical can be way out of whack on all of these other considerations which you have given days after the physical is issued. How that affects an incident that may occur in a class that makes it difficult for me to deal with other students at the same time. Everybody's safety is a consideration in that training program.

DR. MITCHELL: The only solution to your problem is to go back to NAUI and have the organization decide whether to accept diabetics or not. If you do not want to teach them, make a policy not to teach them. We can only provide them with guidelines for their fitness.

DR. DEAR: Any further discussion. Vote on the modified form. Accepted.

FINAL TEXT

Diabetics selected according to Section 1 of this document who satisfactorily complete a recognized diver training course are considered suitable for recreational diving. The following stipulations and strong recommendations regarding diving activity and methods apply. Individual divers must bear responsibility for their health and safety and for adherence to established guidelines developed to improve their protection.

2.1. Point deleted.

STRAW MAN TEXT

2.2. It is strongly recommended that diabetics do not undertake dives deeper than 30 meters of seawater (100 fsw), dives longer than one hour, dives that mandate compulsory decompression stops, or dives in overhead environments.

- rapid access to surface*
- nitrogen narcosis*
- longer dives probably increase risk of hypoglycemia*

DR. DEAR: Point 2.2. Depth and time.

DR. MITCHELL: And decompression stops and cave diving.

DR. YOUNGBLOOD: This is approaching an area that concerns me, which I think we do not have the answers to. I think it needs to be very strict because one thing we have not addressed today is the phenomenon we see in hyperbaric medicine where in higher oxygen partial pressures you can become hypoglycemic very rapidly. Closed-circuit oxygen rebreathers in relatively shallow water and other advanced technical things can really be a problem.

DR. DEAR: I understand looking at the literature that there is still some debate about hyperbaric hypoglycemia. I know Caroline Fife has published widely on it. Chris Edge and company produced some data* that indicates that it does not happen breathing air at 30 meters [98 feet] on a cycle ergometer.

[*Edge CJ, Grieve AP, Gibbons N, O'Sullivan F, Bryson P. Control of blood glucose in a group of diabetic scuba divers. Undersea Hyperb Med 1997; 24(3):201-7.]

DR. MITCHELL: It happens in hyperbaric patients.

DR. DEAR: Do you feel that these numbers are appropriate?

SPEAKER: I certainly agree they are appropriate. There should maybe be a caveat put in that this is a limit.

DR. MITCHELL: We are just giving them some bounds within which we think it is reasonable to dive.

DR. TABAH: I think that one hour is too much. I think after one hour of diving you are exhausted, and that it is way too much. I think 45 minutes would be appropriate. Warm or cold.

MR. PROSTERMAN: I would rather keep it at one hour. There are going to be diabetics who exercise more than one hour.

DR. EDGE: Why not take out the length of time. We do not have anything about that in our procedures. The diabetic divers know themselves how long to dive for. Just take it out, make it simpler.

DR. MITCHELL: How about we just take "strongly" out and leave the "one hour" in. It is just a recommendation.

DR. STONE: Why not leave out the depth and the time and just leave it.

DR. DEAR: Let us vote on it as is. How many nos on as is? None. Accepted.

FINAL TEXT

2.2. *It is recommended that divers with diabetes do not undertake dives deeper than 30 meters of seawater (100 fsw), dives longer than one hour, dives that involve compulsory decompression stops, or dives in overhead environments.*

STRAW MAN TEXT

2.3. *It is strongly recommended that diabetics do not undertake more than two dives per day and that an absolute minimum surface interval of two hours be employed.*

- largely intuitive

- two hours seems necessary to relax, eat, and invoke one hour pre-dive glucose testing regimen

DR. DEAR: Point 2.3. Two dives per day and two hour surface interval. Debate?

DR. LORBER: I have any problem with the two hour surface interval, why just two?

MR. PROSTERMAN: I have trouble with two hours, too.

DR. P.B. BENNETT: I hate to exploit the word industry again, but all the charter boats will have a one-hour surface interval or less. And if you require two hours, that is going to create conflict. The industry will come back and say that you are going to cost us millions and millions of dollars. They will not accept it.

MR. PROSTERMAN: I believe that the DAN data* showed that they have been successfully doing up to four dives a day.

[*Dear GdeL, Pollock NW, Uguccioni DM, Dovenbarger J, Feinglos MN, Moon RE. Plasma glucose response to recreational diving in divers with insulin-requiring diabetes. *Undersea Hyperb Med* 2004; 31(3): 291-301. - Forty divers with IRDM completing 555 dives performed a mean (\pm standard deviation with range) of 2.7 ± 0.8 (1.0-4.2) dives per day.]

DR. DEAR: That is right. We are about to get to the recommended timing of pre-dive glucose checks, which are at 60, 30 and 10 minutes pre-dive or something similar. If we start with a 60 minute check, then the shortest surface interval will be 61 minutes.

DR. MACRIS: Do we need this at all? This is one of those messy things.

DR. MITCHELL: It can go. It is simply one of the straw man points for consideration.

SPEAKER: There is no evidence to show that they need – move to strike.

DR. DEAR: Does anyone feel the need to keep the requirement for a two hour surface interval? Nobody wants to keep it. Strike.

FINAL TEXT

2.3. Point deleted.

STRAW MAN TEXT

2.4. Diabetic divers must dive with a buddy who is informed of their condition and aware of the appropriate response in the event of a hypoglycemic episode.

- self explanatory
- stipulate non-diabetic buddy?

DR. MITCHELL: Does this need to be a non-diabetic buddy?

DR. MACRIS: I do not know how many of you have been lost from the boat with a buddy, in gathering dark, when you are drifting away. Supposing both divers are diabetics - they are going to be in trouble.

DR. DEAR: If we add a sentence that says, "It is recommended that two diabetic divers do not dive together?"

MR. PROSTERMAN: They may dive within a group. You may have two buddies who know each other well, go traveling together and want to familiarize somebody else in the group.

DR. LORBER: Recommend that the buddy does not have diabetes.

DR. CURLEY: The buddy should be aware or must be aware of the appropriate response. I would think they must be aware.

SPEAKER: How about recommending that the buddy should be in good health.

DR. DEAR: Any further discussion? Vote on modified text. Accepted.

FINAL TEXT

2.4. Divers with diabetes should dive with a buddy who is informed of their condition and is aware of the appropriate response in the event of a hypoglycemic episode. It is recommended the buddy does not have diabetes.

STRAW MAN TEXT

2.5. It is strongly recommended that diabetic divers avoid combinations of circumstances that might be provocative for hypoglycemic episodes such as prolonged, cold dives involving hard work.

SPEAKER: Take "strongly" out.

DR. DEAR: Anybody object to point 5 with "strongly" removed. No. Accepted

DR. DEAR: Now, onto the glucose management section.

FINAL TEXT

2.5. It is recommended that divers with diabetes avoid combinations of circumstances that might be provocative for hypoglycemic episodes such as prolonged, cold dives involving hard work.

3. Glucose Management on the Day of Diving

STRAW MAN TEXT

Diabetic divers who are selected according to protocol one of this document, and who participate in appropriate diving activity as specified in protocol two, must use this protocol to manage their health on the day of diving...

DR. LORBER: I think there are a number of different good protocols out there.

DR. DEAR: Should use "a protocol."

DR. POLLOCK: We will use an alternative word, probably "section," for the different components of the final version of the guidelines to avoid confusion through overuse of "protocol."

FINAL TEXT

Divers with diabetes who are selected according to Section 1 of this document, and who participate in appropriate diving activity as specified in Section 2, should use a protocol to manage their health on the day of diving. The following is provided as an example.

STRAW MAN TEXT

3.1. On every day on which diving is contemplated, the diabetic must assess him or herself in a general sense. If he or she is uncomfortable, unduly anxious, unwell in any way (including sea sickness), or blood glucose control is not in its normal stable pattern – DIVING MUST NOT BE UNDERTAKEN

DR. MITCHELL: This is a very general statement regarding the diver's acute health status. It recognizes the fact that there are lots of things that could affect their safety on a particular day.

DR. DEAR: No problems? Vote. Good. Accepted.

FINAL TEXT

3.1. For every day on which diving is contemplated; the diabetic should assess him or herself in a general sense. If he or she is uncomfortable, unduly anxious, unwell in any way (including seasickness), or blood glucose control is not in its normal stable pattern – DIVING SHOULD NOT BE UNDERTAKEN.

STRAW MAN TEXT

***3.2. The pivotal goal for the diabetic approaching any dive is to establish a blood glucose level of at least 150 mg·dL⁻¹ (8.3 mmol·dL⁻¹), and to ensure that this level is either stable or rising before entering the water. Compliance is determined by three measurements of blood glucose, taken 60 minutes, 30 minutes and immediately prior to gearing up. Diving should be postponed if blood glucose is <150 mg·dL⁻¹ (8.3 mmol·dL⁻¹), or there is a fall between any two measurements.
- one pre-dive check and lower threshold for non-insulin requiring diabetics***

DR. MITCHELL: Everyone has talked about three measurements: 60, 30 and 10 minutes or immediately pre-dive.

DR. DEAR: Does anybody have any issues?

DR. BRYSON: Certainly in our work we have not insisted upon or indeed encouraged three pre-dive measures. They have not done 60, 30 and immediately prior, and they have been fantastic mostly. I accept the sense of repeat measures, but I think you need to be careful not to overdo it.

MR. PROSTERMAN: These are guidelines. The 150 mg·dL⁻¹ [8.3 mmol·L⁻¹] limit, for example, may be modified by an individual with diabetes accustomed to doing triathlons. They might adjust it so they are 120 mg·dL⁻¹ [6.7 mmol·L⁻¹] when they finish. Modifications are fine. We need a starting point and I think this is a pretty acceptable one.

DR. EDGE: I do not think you need to have a fixed blood glucose level. We have 14,000 dives in our series. We do not have measurements of them all. You saw this morning that there are people who have started far above 150 mg·dL⁻¹ [8.3 mmol·L⁻¹]. Sometimes their blood glucose goes down during the dive and sometimes it goes up. The point is that while I quite accept that these are guidelines, you have got to remember that these people know better than we do how to control their diabetes. I would not include the number limits. The diabetic person has to be comfortable with what they are doing. This is not Camp DAVI. This is not diving in a controlled program. This is what real people are doing in the whole world.

MR. PROSTERMAN: Would you accept "slightly elevated from normal" for beginning blood sugar?

DR. EDGE: You then come down to what is normal for that person. We are not talking about a population. We are talking about individuals here.

MR. PROSTERMAN: I think there is an established normal for glucose control.

DR. EDGE: I have quite a lot of data on practicing divers that I did not show you this morning. They are diving quite happily, quite healthily over a whole season. They do not have these restrictions and regulations put upon them. If you want to impose further restrictions, then put them in. But the vast majority of people are not going to accept them and will dive happily on their own.

DR. MITCHELL: Chris Edge, can I just ask you to comment on something. To be fair, your population is a group that have sort of found their way into diving and a lot of them are well established divers. These recommendations are going to be applied to a lot of people. People are suddenly going to wake up to the fact that diabetics can dive. This will be applied to a group of people who are not as experienced.

DR. EDGE: Where in the presentation this morning did I say those people are experienced? We have new divers coming in all the time who have never dived before.

DR. MITCHELL: If you divide the number of dives by the number of divers, there are some pretty experienced people in there.

DR. BRYSON: From 2001 to 2004 there were 200 new divers. These were not experienced. However, you are also quite correct that we have some very experienced diabetic divers who are doing thousands of dives.

MR. PROSTERMAN: Without recommending numerical limits for blood glucose, I think the whole day is a waste. We are looking for blood sugar guidelines to make it safe for these people to go in the water and when they get out of the water. I know we have to have some sort of slight elevation for a guideline especially for beginning divers. We have seen the data that DAN has collected. I think it is important that we know that there will be some drops. The magnitude will depend on insulin therapy and feeding strategies. I was personally surprised at the amount in some cases. I think it is very important if we do nothing else today that this step stays in and stays similar to what it is.

DR. MITCHELL: Are you happy with the $150 \text{ mg}\cdot\text{dL}^{-1}$ [$8.3 \text{ mmol}\cdot\text{L}^{-1}$] value?

MR. PROSTERMAN: I am happy with it. If somebody is not happy with putting an exact number, we could say slightly elevated.

DR. MACRIS: I think we need a number. Our goal right now is to prevent in-water hypoglycemia. Regarding the pre-dive monitoring schedule, perhaps inserting "ideally" will provide some flexibility.

DR. MUELLER: I thought we were developing medical guidelines, not industrial or operational guidelines. We are looking at individuals. In one of the previous statements, we said that we require them to have well controlled diabetes, no hypoglycemic episodes and whatsoever, it is already in there. By demonstrating that, we all have agreed that these individuals are capable of controlling their diabetes well. We do not have to give them numerical limits.

MR. PROSTERMAN: We need to find if there is a fall in the blood sugar at any time. I think that trends are more important than simple levels.

DR. TABAH: The reason why we might want to keep this here is to provide some guidance for the diabetic who will begin diving on vacation without a lot of advance planning.

DR. DEAR: Take out "compliance." We suggest three measurements.

DR. TABAH: One comment on the target blood glucose values. I agree with at least 150 mg·dL⁻¹ [8.3 mmol·L⁻¹], but I would like to see a higher target, possibly 200 mg·dL⁻¹ [11.1 mmol·L⁻¹]. I have seen for a single dive or 40 minutes sugar levels drop more than 150 mg·dL⁻¹ [8.3 mmol·L⁻¹].

DR. DEAR: I take your point. Our divers could enter the water at only 80 mg·dL⁻¹ [4.4 mmol·L⁻¹] as part of the protocol. Most were, of course, much higher. We did see some huge falls but, despite that, we saw no episodes of significant hypoglycemia associated with the dives.

DR. DEAR: Let us look at the numbers, the 150 mg·dL⁻¹ [8.3 mmol·L⁻¹].

DR. MITCHELL: Let us vote on this statement, the whole thing. Any dissent? No. Accepted.

DR. MITCHELL: Now, how do we deal with diabetics not using insulin?

DR. LORBER: I am volunteering to do this one offline with you another time because it is different based on medication.

DR. MITCHELL: We will insert a statement specifying the need for additional guidelines for OHAs. This should say that if people find their levels dropping they should take a bit of glucose. Sometimes they will adjust their insulin the night before. It is just to give you an idea of the available strategies.

SPEAKER: Probably a good idea.

DR. MITCHELL: What about your experienced divers who have actually taught some diabetics to dive?

DR. LORBER: I am going to come at this from the other side because now I am a diabetes expert advising the patient what to do. It is soft but it does remind people to stop and think about it. I think that it is valuable.

DR. M.H. BENNETT: I second that motion. I think it is useful.

DR. DEAR: Does anybody object to it? No. Accepted.

FINAL TEXT

3.2. The suggested goal for the diabetic approaching any dive is to establish a blood glucose level of at least 150 mg·dL⁻¹ (8.3 mmol·L⁻¹), and to ensure that this level is either stable or rising before entering the water. The workshop recommends that this be determined by three measurements of blood glucose, ideally taken 60 minutes, 30 minutes and immediately prior to diving. Diving should be postponed if blood glucose is <150 mg·dL⁻¹ (8.3 mmol·L⁻¹), or there is a fall between any two measurements.

- a. Where relevant, strategic and individually tailored reductions in doses of OHA medication or insulin on the evening prior or on the day of diving may assist in meeting these goals. Initial testing of individual protocols should be conducted under very controlled circumstances.*
- b. Where relevant, a regimen of incremental glucose intake to correct inappropriate pre-dive levels or trends may assist in meeting these goals.*

STRAW MAN TEXT

3.3. Attempts to comply with the requirements of 2 (above) should not result in a blood glucose level greater than $220 \text{ mg}\cdot\text{dL}^{-1}$ ($12.2 \text{ mmol}\cdot\text{L}^{-1}$), and diving should be cancelled for the day if levels are higher than $250 \text{ mg}\cdot\text{dL}^{-1}$ ($13.9 \text{ mmol}\cdot\text{L}^{-1}$) at any stage.

- concern is dehydration rather than ketoacidosis
- higher threshold

DR. MITCHELL: We will change “requirements” to “suggestions.”

MR. PROSTERMAN: I would like to move it to $300 \text{ mg}\cdot\text{dL}^{-1}$ [$16.7 \text{ mmol}\cdot\text{L}^{-1}$] to agree with the FAA limit. Even at that, I know people who might bring it up past that before some athletic events.

DR. DEAR: Chris Edge showed some divers going into the water at $20 \text{ mmol}\cdot\text{L}^{-1}$ [$360 \text{ mg}\cdot\text{dL}^{-1}$].

MR. PROSTERMAN: I think we should remove the reference to $220 \text{ mg}\cdot\text{dL}^{-1}$ [$12.2 \text{ mmol}\cdot\text{L}^{-1}$].

DR. MITCHELL: I agree.

DR. LORBER: I think we need to separate something out here. Does this represent hyperglycemia after treating hypoglycemia or a response to concern about heading towards hypoglycemia. If the former, this is an acute, temporary rise. For example, this may be somebody who has had a glass of juice on the boat because their sugar is dropping. Blood glucose is going to go up and right back down because the only reason their sugar was dropping in the first place was that they had largely elevated levels of insulin already. So if the glucose in that situation is $300 \text{ mg}\cdot\text{dL}^{-1}$ [$16.7 \text{ mmol}\cdot\text{L}^{-1}$], all they have to do is wait until it comes back down again, which should happen pretty quickly. I think this is very different from the person who is running $300 \text{ mg}\cdot\text{dL}^{-1}$ [$16.7 \text{ mmol}\cdot\text{L}^{-1}$] because they did not take enough insulin that morning. Or $320 \text{ mg}\cdot\text{dL}^{-1}$ [$17.8 \text{ mmol}\cdot\text{L}^{-1}$], whichever number you are talking about, it is the same principle.

DR. DEAR: Some of our data shows that for quite a number of dives the sugar just kept rising pre-dive. Remember the young fellow who was starting at $300 \text{ mg}\cdot\text{dL}^{-1}$ [$16.7 \text{ mmol}\cdot\text{L}^{-1}$] and went to $556 \text{ mg}\cdot\text{dL}^{-1}$ [$30.9 \text{ mmol}\cdot\text{L}^{-1}$]. Clearly that was poor diabetic control and not related to trying to fix a hypoglycemic event. I would be happy recommending $300 \text{ mg}\cdot\text{dL}^{-1}$ [$16.7 \text{ mmol}\cdot\text{L}^{-1}$].

DR. DEAR: Does anyone object to recommending $300 \text{ mg}\cdot\text{dL}^{-1}$ [$16.7 \text{ mmol}\cdot\text{L}^{-1}$] to be consistent with the FAA? Additional discussion? Vote. Accepted.

FINAL TEXT

3.3. It is recommended that diving should be postponed or cancelled if blood glucose levels are higher than $300 \text{ mg}\cdot\text{dL}^{-1}$ ($16.7 \text{ mmol}\cdot\text{L}^{-1}$).

STRAW MAN TEXT

3.4. Diabetics must carry oral glucose in a readily accessible and ingestible form at the surface and during all dives. It is strongly recommended that the diabetic also have parenteral glucagon available at the surface.

If premonitory symptoms of hypoglycemia are noticed underwater, the diver must surface, establish positive buoyancy, ingest glucose and leave the water. An informed buddy should be in a position to assist with or initiate this process.

DR. DEAR: We might say that “somebody has” parenteral glucagon. “Somebody is available.” “Parenteral glucagon is available.”

DR. TABAH: We have this problem in France. I asked for a recommendation to have parenteral glucagon. The comment was, who is going to inject the parenteral glucagon into an unconscious person other than a physician.

DR. LORBER: The answer is anybody who is a good Samaritan. For example, in the schools, it can be a trained teacher, depending on the law in New York State, at least. Depends on each individual state. So the buddy is a logical person for this and that should be part of teaching a buddy how to respond to hypoglycemia.

DR. SCOTT: I concur that our informed buddy has to learn to give that injection. They must dive with their informed buddy.

DR. DEAR: Anything further? Any dissent? No. Vote. Accepted.

FINAL TEXT

3.4. Divers with diabetes should carry oral glucose in a readily accessible and ingestible form at the surface and during all dives. It is strongly recommended parenteral glucagon is available at the surface. The dive buddy or other person at the surface should be knowledgeable in the use of glucagon. If symptoms or indications of hypoglycemia are noticed underwater, the diver should surface, establish positive buoyancy, ingest glucose and leave the water. An informed buddy should be in a position to assist throughout this process.

STRAW MAN TEXT

3.5. Blood glucose levels must be checked at the end of every dive. Appropriate response to the measured level can be determined by the individual cognizant of their plans for the rest of the day. It should be noted that the requirements for blood glucose status outlined at point 2 remain the same for any subsequent dive.

*a. In view of the recognized potential for late decrements in blood glucose levels following diving it is strongly recommended that the level is checked 12-15 hours after diving.
- set other measurement times (e.g., 4 hours and 12 hours)?*

DR. DEAR: Change “must” to “should.”

DR. MITCHELL: All the other protocols recommend post-dive checks. Everyone should measure their glucose when they come out of the water.

DR. LORBER: The last line, check frequently for 12 to 15 hours after diving?

MR. PROSTERMAN: Or “repeatedly.”

DR. DEAR: “Sometimes?”

SPEAKER: No. Because it should be certainly more frequently than you normally would, but it is different. The problem is that post-exercise hypoglycemia may be delayed 24 to 36 hours. I would just say frequently for 12 to 15 hours after diving, and that is individually determined.

Any further issues? No. Vote. Accepted.

FINAL TEXT

3.5. Blood glucose levels should be checked at the end of every dive. Appropriate response to the measured level can be determined by the individual mindful of his or her plans for the rest of the day. It should be noted that the requirements for blood glucose status outlined in 3.2 remain the same for any subsequent dive. In view of the recognized potential for late decrements in blood glucose levels following diving it is strongly recommended that the level is checked frequently for 12-15 hours after diving.

STRAW MAN TEXT

3.6. Diabetics are strongly recommended to drink between 1000 and 1500 mL of extra water over a period of several hours prior to their first dive of the day.

DR. DEAR: Is there any evidence that this should be recommended.

DR. MITCHELL: This was in there because several of the groups mentioned it and the Lerch group actually measured it*. They measured a hematocrit increase, a significant hematocrit increase, and they were quite impressed by that. What does everyone think?

*[*Lerch M, Lutrop C, Thurz U. Diabetes and diving: can the risk of hypoglycemia be banned? SPUMS J 1996; 26(2): 62-66. The authors reported that the significant increase in hematocrit observed in divers with diabetes was eliminated by ingestion of 1.5-2.0 L of fluid not more than one hour prior to the first dive of the day.]*

DR. MITCHELL: George Macris is suggesting that we simply recommend paying particular attention to hydration. Would everyone be happy with that?

DR. DEAR: Any argument? No. Vote. Accepted.

FINAL TEXT

3.6. Divers with diabetes are strongly recommended to pay particular attention to adequate hydration on days of diving.

STRAW MAN TEXT

3.7. Diabetics must log all dives, associated diabetic interventions, and results of all blood glucose level tests conducted in association with diving. This log can be used to refine future interventions in relation to diving.

DR. DEAR: Final point. Does anybody object to us collecting data as scientists?

DR. MITCHELL: We will change it from “must” to “should.”

DR. DEAR: Anybody object to this? No.

DR. LORBER: I think that somewhere in the document should appear a statement that this is a work in progress that may evolve as we collect data. So diabetic divers should be encouraged to supply their data to research groups.

MR. PROSTERMAN: What about a recommendation for a more formal recommendation for the instructor teaching to learn more about diabetes and its treatment?

DR. DEAR: No.

MR. PROSTERMAN: Skip it? Okay.

DR. DEAR: Any further discussion. Vote. Accepted. A job well done.

FINAL TEXT

3.7. Divers with diabetes should log all dives, associated diabetic interventions, and results of all blood glucose level tests conducted in association with diving. This log can be used to refine future planning in relation to diving.

DR. MACRIS: I think this is all great. The industry must be aware that including diabetic divers will create some complicated training issues. There may be one person required to pay special attention to them. Certification and recertification issues must also be considered.

MR. FLAHAN: Let me say one thing first. I am not opposed to anything you are going to do.

DR. MACRIS: We may change the guidelines as the science evolves. To provide the certification once only is not the way to go. Recertification may be appropriate, with participants signing off on the latest recommendations.

MR. FLAHAN: Let me address two issues. From my perspective, I have no problem with what you are trying to do. I think these guidelines are great. I am looking at it from how do we cast things in stone. We have operational responsibility in the field with these issues. The second one is the conditional certification, expiring certification, whatever you want to call it, that is been batted around in the industry for a long time. That would be something that all of the agencies would have to get together on and implement at the same time for it to be effective. Whether this would be a unique one to try to implement that with, I do not know until we look at it. But if you are talking about certifications that may expire annually, that might be an area for us to look at. If I had to look at the entire package of guidelines, I would say that the glucose management section really addresses the issues that diabetics need to know about to dive safely, which apparently they have been doing for a long time without a real problem. The other useful part is advice to physicians as to what they need to look for when screening divers. The diver is also reminded to go back annually to their physician. It does not necessarily say we need a sign off on our end for them to do that.

DR. BRYSON: What is the definition of recertification? In the UK, we require diabetics to have annual medicals. It does not mean they have to go back and redo their dive certification. They turn up at the dive centre, show their valid medical certificate and they can then carry on diving as appropriate. I think we have done relatively well working very closely with the recreational diver and we have thus built up our experience with them. We are now moving on to the HSE [Health and Safety Executive] training diver. All instructors and dive guides now have to be medically certified

under the HSE every year. The fact that we have put this part of the debate on hold here does not mean we have stopped our initiatives. I think that is important because it is time to conclude the amateur part of the debate and then move on to decide what is next later.

SPEAKER: Diving instructors, I think, need to have their liability insurance renewed each year. So they could be regulated that way. They do not get their insurance if they do not meet the requirements.

DR. DEAR: If you have read the RSTC document, now with a W in front of it [for World Recreational Scuba Training Council], has clearly a small section that is for the diver and a large section that is for the physician. I think that we address both with a little wordsmithing.

I think we have got some good guidelines. Clearly we are not at the end of the road by any means. We will write it up and circulate it for review. Thank you, ladies and gentlemen.

(Meeting adjourned)

APPENDIX A

List of Acronyms Used

AII	Angiotensin II
ACE	Angiotensin-converting enzyme
ACOEM	American College of Occupational and Environmental Medicine
ADA	American Diabetes Association <u>or</u> Americans with Disabilities Act
AHA	American Heart Association
BG	Blood glucose
BSAC	British Sub-Aqua Club
CAD	Coronary artery disease
CAMI	Civil Aerospace Medical Institute
CBC	Complete blood count
CGMS	Continuous glucose monitoring system
CMAS	Confédération Mondiale Des Activités Subaquatiques (World Underwater Federation)
CME	Continuing medical education
CVD	Cardiovascular disease
CXR	Chest X-ray
DAN	Divers Alert Network
DCCT	Diabetes control and complications trial
DESA	Diabetes Exercise and Sports Association
DAVI (Camp)	Diabetes Association of the Virgin Islands
DCS	Decompression sickness
DIGAMI	Diabetes mellitus insulin-glucose infusion in acute myocardial infarction
DKA	Diabetic ketoacidosis
DMO	Diving medical officer
ECG	Electrocardiogram
EEOC	Equal Employment Opportunity Commission
EMS	Emergency medical services
EUBS	European Underwater and Baromedical Society
FAA	Federal Aviation Administration (U.S.)
FDA	Federal Drug Administration (U.S.)
FFESSM	Fédération Française d'Études et de Sports Sous-Marins (French Federation for Underwater Diving)
FMCSA	Federal Motor Carrier Safety Administration
fsw	feet of seawater
GP	General practitioner
HbA _{1c}	Glycosylated hemoglobin
HNIDDM	Hypoglycemic-medication-treated non-insulin-dependent diabetes mellitus
HSE	Health and Safety Executive
IDAA	International Diabetes Athletic Association
IDDM	Insulin-dependent diabetes mellitus
IRDM	Insulin-requiring diabetes mellitus
IG	Interstitial glucose
INGAP	Islet neogenesis-associated protein
LOC	Loss of consciousness
MDII	Multiple daily insulin injections
MI	Myocardial infarction

msw	meters of seawater
NAUI	National Association of Underwater Instructors
NFPA	National Fire Protection Agency
NOAA	National Oceanic and Atmospheric Administration
NIDDM	Non-insulin-dependent diabetes mellitus
NIRDM	Non-insulin-requiring diabetes mellitus
NPH (insulin)	Neutral protamine Hagedorn
NTSB	National Transportation Safety Board
OHA	Oral hypoglycemic agents
PADI	Professional Association of Diving Instructors
PCP	Primary care physician
PFT	Pulmonary function test
PWC ₁₅₀	Physical working capacity at a heart rate of 150 beats·min ⁻¹
RBS	Random blood sugar
RSTC	Recreational Scuba Training Council
SAA	Sub-Aqua Association
SMBG	Self-monitoring of blood glucose
SSI	Scuba Schools International
SSUB	Scottish Sub-Aqua Club
T1DM	Type 1 diabetes mellitus
T2DM	Type 2 diabetes mellitus
TSA	Transportation Security Administration
UHMS	Undersea and Hyperbaric Medical Society
UKPDS	United Kingdom prospective diabetes study
VMC	Visual meteorologic conditions (allowing adherence to visual flight rules)
WRSTC	World Recreational Scuba Training Council
YMCA	Young Men's Christian Association

APPENDIX B

Workshop Participants

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APPENDIX C **Workshop Agenda**

2005 UHMS/DAN Diabetes and Recreational Diving: Guidelines for the Future

Sunday, June 19, 2005

Las Vegas, NV

Time	Duration	Presentation	Presenter
8:00 – 8:15	:15	Welcome/Overview	Dear
8:15 – 8:35	:20	Insights of a Diving Instructor Teaching and Managing Diabetes	Prosterman
8:35 – 9:50	1:15	Insulin Therapy in Diabetes Mellitus - State of the Art	Cersosimo
9:50-10:10	:20	BREAK	
10:10-10:35	:25	Diving with Diabetes: British Data	Edge
10:35-11:00	:25	American Diabetes Association	Lorber
11:00-11:20	:20	Divers Alert Network Diabetes and Diving: History and Data	Ugugioni
11:20-11:55	:25	YMCA Diving with Diabetes Experience	Scott
11:55-12:20	:25	Diving with Diabetes in France	Tabah
12:20-1:45	1:25	LUNCH	
1:45-2:15	:30	FAA Diabetes Policy and Experience	Silberman
2:15-2:45	:30	Diabetes and Diving: A Protocol for the Future	Mitchell
2:45-3:00	:15	BREAK	
3:00-6:00	3:00	DISCUSSION	