

March 9, 2015

Michael P. Huerta
Administrator
Federal Aviation Administration
800 Independence Avenue, SW
Washington, DC 20591

RE: Expert Panel Recommendations for Pilots with Insulin-Treated Diabetes

Dear Administrator Huerta:

In a meeting on June 4, 2013, the Federal Aviation Administration, through its Federal Air Surgeon Dr. Fred Tilton, asked the American Diabetes Association to convene a panel of experts to form recommendations for a protocol to identify a subset of pilots who use insulin who pose no greater risk of incapacitation from hypoglycemia than any other pilot in the general population.

That Expert Panel convened on June 27, 2014, to develop the enclosed recommendations. The experts on the panel include five of the most renowned endocrinologists in the nation, including endocrinologists with a particular research and clinical expertise in hypoglycemia.

The Expert Panel concluded that there is a subset of pilots who manage diabetes with insulin who pose a nonzero, but insignificant risk of incapacitation from hypoglycemia in-flight. The panel reached this conclusion by reviewing the medical records of an anonymous pilot, the data from the United States and Canada which reveal no accidents or incidents by a pilot with insulin treated diabetes who had been cleared to fly while using insulin, as well as their own collective clinical expertise. We believe you will find the enclosed recommendations provide sound scientific basis for a change in FAA policy for airmen with insulin treated diabetes.

Thank you for the opportunity to share our expertise on diabetes and its management. If you have any questions or would like to discuss the recommendations further, please do not hesitate to contact Sarah Fech at 703.253.4823 or sfech@diabetes.org.

Sincerely,



Robert Ratner, MD, FACP, FACE
Chief Scientific & Medical Officer
American Diabetes Association



Daniel Lorber, MD, FACP, CDE (Panel Chair)
Director of Endocrinology
Associate Director of the Lang Center for Research
and Education
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Enclosure

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Diabetes Information

Call 1-800-DIABETES (1-800-342-2383)
Online: www.diabetes.org
The Association gratefully accepts gifts through your will.

The Mission of the American

Diabetes Association is to prevent and cure diabetes and to improve the lives of all people affected by diabetes.

INTRODUCTION

The Federal Aviation Administration (FAA) asked the American Diabetes Association (the Association) to convene a panel of experts to form recommendations for a protocol to identify a subset of pilots who use insulin who pose no greater risk of incapacitation from hypoglycemia than any other pilot in the general population.

The Panel convened on June 27, 2014, at the Association's National Office in Alexandria, Virginia. The panel membership included:

Endocrinologists:

- Dr. Daniel Lorber, Director of Endocrinology at New York Hospital Queens and Associate Director of the Lang Center for Research and Education (Chair)
- Dr. Martin Abrahamson, Senior Vice President for Medical Affairs of the Joslin Diabetes Center and Associate Professor of Medicine at Harvard Medical School
- Dr. Samuel Dagogo-Jack, Professor of Medicine and Chief of the Division of Endocrinology, Diabetes and Metabolism at the University of Tennessee Health Science Center and 2015 President, Medicine and Science of the American Diabetes Association
- Dr. Elizabeth Seaquist, Professor of Medicine at the University of Minnesota and 2014 President, Medicine and Science of the American Diabetes Association
- Dr. Desmond Schatz, Professor and Associate Chairman of Pediatrics, Medical Director of the Diabetes Center and Associate Director of the GCRC at the University of Florida and 2016 President, Medicine and Science of the American Diabetes Association

Aviation Medical Specialists:

- Dr. Keith Martin, Aviation Medicine Advisory Service
- Dr. Quay Snyder, Aviation Medicine Advisory Service

Former Professional Pilots with Insulin Treated Diabetes:

- William Blalock, American Airlines
- Eric Friedman, American Airlines

American Diabetes Association Representatives:

- Sarah Fech, Staff Attorney
- John Griffin, JD, former Association Chair of the Board
- Katie Hathaway, Managing Director of Legal Advocacy

Dr. James DeVoll, FAA, Office of Aerospace Medicine, Medical Appeals Branch attended the Expert Panel Meeting and offered insights and feedback during the meeting.

The Panel concluded that it is possible to identify a subset of pilots who manage diabetes with insulin who pose a nonzero, but insignificant risk of incapacitation from hypoglycemia.

In developing the following fitness for duty criteria and protocol, the panel has drawn on the established Canadian, British, and US 3rd class protocols for individually assessing pilots who use insulin.

Airmen with Insulin Treated Diabetes Mellitus

The Panel recommends that this policy be established to permit the special issuance medical certification of certain insulin-treated applicants for first-, second-, and third-class medical certification. Consideration should be given only to those individuals who have a proven record of management and who have been clinically stable on their current treatment regimen for a period of 6 months or more.

Individuals certificated under this policy will be required to provide substantial documentation regarding their history of treatment, any accidents related to their disease, and current medical status. If certificated, they will be required to adhere to stringent monitoring. The following is a summary of the evaluation protocol and an outline of the conditions that the panel recommends the FAA apply:

Initial Certification

1. The applicant must have had no recurrent (two or more) episodes of hypoglycemia resulting in loss of consciousness, seizure, impaired cognitive function or requiring intervention by another party, or occurring without warning (hypoglycemia unawareness) in the past 5 years and none in the preceding 1 year, excluding any period of pregnancy.
2. The applicant will be required to provide copies of all medical records as well as any accident and incident records pertinent to their history of diabetes.
3. A report of a complete medical examination preferably by a physician who specializes in the treatment of diabetes will be required. The report must include, at a minimum:
 - i. Two measurements of glycosylated hemoglobin (hemoglobin A1C concentration and the laboratory reference range), the first at least 90 days prior to the current measurement.¹
 - ii. Self-monitored blood glucose readings from the previous 30 days.

1. 80% of the self-monitored blood glucose values must be between 70mg/dl and 250mg/dl.ⁱⁱ
 2. Airmen using CGM technology must adhere to the ADA Clinical Practice Guidelines for self-monitoring blood glucose with a finger stick test to provide the data for the 30 days of data required at the initial certification phase.
- iii. Specific reference to the applicant's insulin dosages and diet.
 - iv. Specific reference to the presence or absence of cerebrovascular, cardiovascular, or peripheral vascular disease or neuropathy.
 - v. Specific reference to the presence or absence of decreased hypoglycemia awareness.
 - vi. Confirmation of the absence of clinically significant eye disease via dilated eye exam performed by an ophthalmologist.
 - vii. Verification that the applicant has been educated in diabetes and its control and understands the actions that should be taken if complications, especially hypoglycemia, should arise. The examining physician must also verify that the applicant has the ability and willingness to properly monitor and manage his or her diabetes, as guided by the ADA clinical practice guidelines.ⁱⁱⁱ
 - viii. If the applicant is age 40 or older, a report, with ECG tracings, of a maximal graded exercise stress test.
 - ix. The applicant shall submit a statement from his or her treating physician, aviation medical examiner, or other knowledgeable person attesting to the applicant's dexterity and ability to determine blood glucose levels using a recording glucometer.
 - x. Pilots who use insulin pump delivery systems should submit details of their 'back-up' non-pump regimen in the event of pump failure.

Follow-on monitoring:

1. For documentation of diabetes management, the applicant will be required to carry and use a whole blood glucose measuring device with memory and must report to the FAA immediately any severe hypoglycemic incidents,^{iv} any involvement in any accidents that result in serious injury (whether or not related to hypoglycemia); and any evidence of loss

of control of diabetes, change in treatment regimen,^v or significant diabetic complications. With any of these occurrences, the individual must cease flying until cleared by the FAA.

2. At 3-month intervals, the pilot must be evaluated by the treating physician. This evaluation must include a general physical examination, review of the interval medical history, and the results of a test for glycosylated hemoglobin concentration. The physician must review the record of the pilot's daily blood glucose measurements and comment on the results. The results of these quarterly evaluations must be accumulated and submitted annually unless there has been a change. (See No. 1 above – If there has been a change the individual must report the change(s) to the FAA and wait for an eligibility letter before resuming flight duties).
3. On an annual basis, the reports from the examining physician must include confirmation by an ophthalmologist of the absence of clinically significant eye disease.
4. At the first examination after age 40 and at 5 year intervals, the report, with ECG tracings, of a maximal graded exercise stress test must be included in consideration of continued medical certification.

Monitoring and Actions Required During Flight Operations:

1. To ensure safe flight, the insulin using pilot with diabetes must carry during flight a recording glucometer; adequate supplies to obtain blood samples; and an amount of rapidly absorbable glucose, in 10 gm portions, appropriate to the planned duration of the flight. Airmen using insulin pump delivery systems must carry appropriate insulin supplies to maintain diabetes management in the event of pump failure.
 1. The following actions shall be taken in connection with flight operations:
 - a. One half hour prior to flight, the airman must check his or her blood glucose value. If it is less than 100 mg/dl the individual must ingest an appropriate (not less than 10 gm) carbohydrate snack and measure the glucose concentration one half hour later. If the concentration is within 100 -- 300 mg/dl, flight operations may be undertaken. If less than 100, the process must be repeated; if over 300, the airman may not fly until the concentration is below 300 mg/dl.
 - b. Pilots who use insulin pump delivery systems should perform a visual check of the tubing for bubbles prior to and following ascent to altitude.
 - c. One hour into the flight, at each successive hour of flight, and within one half hour prior to landing, the airman must perform a blood glucose check. If the concentration is less than 100 mg/dl, a 20 gm carbohydrate snack shall be ingested. If the concentration is 100 -- 300 mg/dl, no action is required. If the concentration is greater than 300 mg/dl, the airman must pass control to another pilot or crewmember and may not resume flight control until the

glucose concentration returns to the 100 -- 300 mg/dl range. If flying solo, the airman must land as soon as practicable.

- d. In respect to determining blood glucose concentrations during flight, the airman must use judgment in deciding whether measuring concentrations or operational demands of the environment (e.g., adverse weather, etc.) should take priority. In cases where it is decided that operational demands take priority, the airman must ingest a 10-15 gm carbohydrate snack and measure his or her blood glucose level as soon as possible after the operational demands abate, not to exceed one hour later. If measurement is not practical at that time, the airman must ingest a 20 gm carbohydrate snack and pass control to another airman or crewmember, or land as soon as practicable if flying on a solo operation, so that a determination of the blood glucose concentration may be made.

DISCUSSION

The treatment of insulin treated diabetes has improved dramatically over the past thirty-five years with the advent of accurate determinations of blood glucose levels using meters with sophisticated memory chips and built in analytical programs. These developments also include continuous glucose monitors, continuous subcutaneous insulin infusion pumps, and improvements in short and long acting insulin analogues. These improvements permit real-time measurement of blood glucose levels, and have made it far easier for people with insulin treated diabetes to maintain near-normal blood glucose levels. This, in turn, drastically reduces the risk of both short and long term complications of diabetes with significant reduction in the rate of both hyper- and hypoglycemic glucose levels. Careful monitoring and management of insulin treated diabetes is now routine and the processes involved have become streamlined such that school children often self-manage their glucose levels with minimal or no adult intervention.

The enormous progress in management of the disease justifies a change in FAA policy, which dates from 1949. That policy is that pilots with insulin treated diabetes may not receive first or second class medical certificates, thus barring them from commercial operations. While the 1949 ban was justified by the science that then existed, it is no longer justified by evidence-based medicine.

Given these developments in the treatment of diabetes, the Association has been committed to advancing the FAA's policy to bring it into harmony with the current state of modern medicine. In a meeting on June 4, 2013, the FAA, through its Federal Air Surgeon, Dr. Fred Tilton, observed that the Association possesses the requisite expertise in diabetes medicine to address this topic. Accordingly, the FAA requested that the Association convene a panel of experts to provide recommendations to the agency regarding identifying pilots with insulin treated diabetes who pose an acceptably low level of risk. Following this meeting, in a letter dated July 15, 2013,

FAA Administrator Huerta revised the charge to the Association. He requested that the Association identify a subset of airmen whose hypoglycemia risk is no greater than the general public.

The Association then convened a panel of endocrinologists, aerospace medical experts, and other stakeholders, which met on June 27, 2014. The panel's seven medical experts agreed that any patient who uses insulin can hypothetically experience incapacitation from hypoglycemia, since insulin lowers blood glucose values. This possibility is not identical to those individuals who do not administer insulin. If a patient administers too much insulin, has hypoglycemia unawareness, and does not perform blood glucose checks, that patient can become hypoglycemic over time. However, the members of the Panel concluded that the risk should not merely be assessed *hypothetically*, but should instead be based on an individualized assessment of each airman's unique medical data. As long as the risk of a particular pilot who uses insulin experiencing sudden incapacitation is the same as, or lower than the risk of pilots who do not have insulin treated diabetes, such pilots should not be excluded simply by reason of their use of insulin. The FAA accepts some risk of pilot incapacitation in many forms. Pilots with a vast number of medical conditions pose some risk of incapacitation in a variety of ways.^{vi} The FAA evaluates that risk, though, on *an individual* basis, not a hypothetical basis. Rather than prohibiting all pilots with high blood pressure from being eligible for a first or second class medical certificate, it evaluates the pertinent risk factors such as family history, extent of any damage to the heart, response to medication, diet, and so on. It then makes an individualized decision for each pilot with a potentially incapacitating medical condition, and certifies those pilots whom the FAA determines pose an acceptably low level of risk. Notably, the FAA assesses the risk posed by each pilot with insulin treated diabetes individually for the issuance of third class medical certificates.

The panel then undertook to identify a subset of airmen who pose a nonzero, but insignificant risk of incapacitation from hypoglycemia. After extensive and robust discussion, it developed the assessment criteria and in-flight protocols outlined above.

In developing the assessment criteria, the medical experts relied on their collective 150 years of clinical expertise in treating patients with insulin treated diabetes. Treating patients involves analyzing trends and correlations between certain lab values and a patient's propensity for hypoglycemia. Clinical expertise, rather than global risk analysis, is particularly important in making an individual assessment. This expertise greatly informed the panel's ability to develop the assessment criteria. The panel also considered the data from Canada's experience certifying pilots with insulin treated diabetes to fly since 1992 as well as the data from the United States allowing pilots to fly with third class medical certification, including solo operations, since 1996. The twenty years of data from these two countries indicate that there has never been a diabetes-related accident or incident involving a pilot with insulin treated diabetes who has been granted certification to fly while using insulin. Based on the available evidence, the panel concluded there is no incremental risk of permitting certain airmen with insulin treated diabetes to fly.

Next, the panel evaluated the medical records of one anonymous pilot with insulin treated diabetes. The panel agreed that examining the records of an actual pilot would be informative to meeting its goals. The panel set forth in its recommendations that 80% of a pilot's blood glucose readings would need to be between 70 mg/dl and 250 mg/dl. They agreed that this would indicate to them, as expert clinicians, that a pilot had the ability to prevent hypoglycemia from occurring at all before or during flight. In the 11 months of blood glucose readings the anonymous pilot submitted, not a single reading was below 70 mg/dl. Only 0.8%, or 4/500 of the pilot's previous blood glucose readings were at or above the range the panel established with readings of 250, 252, 253 and 257. The pilot's treating endocrinologist indicated that the pilot had no hypoglycemia unawareness and diligently managed his diabetes on a day to day basis. The pilot also had no evidence of diabetes complications. Based on these medical records, and in particular because this pilot had no evidence of hypoglycemia whatsoever, the panel agreed that this pilot posed a nonzero, but extremely remote risk of incapacitation from hypoglycemia.

After considering all the evidence and clinical experience outlined above, the expert panel concluded that there are pilots with insulin treated diabetes whose risk of incapacitation in flight is equivalent to, or lower than pilots who do not have insulin treated diabetes. Their risk, like the risk presented by pilots who do not have insulin treated diabetes, is nonzero, but extremely improbable. It is the recommendation of the Expert Panel that FAA policy should be updated to reflect current diabetes medicine and permit such pilots medical certification at the first, second, and third class level.

ⁱ There is no Hemoglobin A1c value that should be absolutely disqualifying, as no particular Hemoglobin A1c suggests a lower or higher risk for an incapacitating, hypoglycemic event. However, if an airman's Hemoglobin A1c is 8.5% or greater *and increasing*, this may signal a problem with the airman's diabetes management and warrants further assessment by the treating physician.

ⁱⁱ It should be noted that continuous glucose monitoring (CGM) technology is becoming increasingly prevalent, especially amongst patients aiming for tight control of their diabetes. CGM devices often record transient postprandial spikes in glucose levels that return to an acceptable range well before the next pre-meal fingerstick capillary glucose determination would be carried out. Such transient glycemc elevations are likely to be present in most people with diabetes but are of no clinical significance. In order to avoid over-interpretation of these brief hyperglycemic excursions, we recommend that decisions regarding eligibility of an ITDM airman be made using capillary blood glucose determinations (fingerstick).

ⁱⁱⁱ Patients on multiple-dose insulin (MDI) or insulin pump therapy should perform blood glucose monitoring prior to meals and snacks, occasionally postprandially, at bedtime, prior to exercise, when they suspect low blood glucose, after treating low blood glucose until they are normoglycemic, and prior to critical tasks such as driving.

^{iv} Defined as "an event requiring assistance of another person to actively administer carbohydrate, glucagon, or other resuscitative actions." *Defining and Reporting Hypoglycemia in Diabetes, Diabetes Care* Vol. 28 No. 5 at 1247 (May 2005).

^v To be defined as a 25% change in total daily dose of insulin, a change in the type of insulin, a change from an insulin pump to injections or from injections to the insulin pump, or adding any drug for diabetes treatment.

^{vi} Studies show that the leading cause of sudden incapacitation is from myocardial infarction. See *Aviation, Space, and Environmental Medicine* x Vol. 83, No. 1, January 2012.

PHYSICIAN EVALUATION FORM FOR AIRMEN WITH INSULIN TREATED DIABETES

I. INTRODUCTION

The educated and motivated airman with well-managed insulin-treated diabetes mellitus can be capable of safe and effective job performance. An individualized assessment of the airman's or applicant's diabetes should be performed including an assessment of the following:

- history of blood glucose control;
- current stability of blood glucose;
- risk for significant hypoglycemia or hyperglycemia;
- presence of diabetic complications; and
- knowledge of diabetes and its management.

Risk of hypoglycemia remains the major concern in regard to those with diabetes being or becoming airmen. This risk occurs primarily in those taking insulin, particularly those with type 1 diabetes, although it may also occur in those with type 2 diabetes who take insulin and/or sulfonylureas and other secretagogues.

Operating aircraft entails a unique set of conditions that need to be considered in regard to those with diabetes and the risks of either hypo or hyperglycemia. These may include:

- responsibility for others in the aircraft;
- sustained attention for prolonged periods of time;
- dynamic awareness of the pilot's own aircraft position and vector relative other aircraft and airspace in the National Airspace System;
- rapid decision making regarding mechanical or weather-based complications;
- rapid analysis of complex visual stimuli;
- rapid, concise, accurate communications with crew members, passengers and air traffic controllers;
- dexterity to perform manual tasks in a turbulent and/or visually compromised environment and;
- control of one's emotions under stress.

II. ASSESSMENT

1. Airman has been under the care of an endocrinologist or other physician knowledgeable about diabetes management. Outpatient and in-patient medical record(s) of the last three years or since date of diagnosis (whichever is shorter) should be reviewed by the treating physician and provided to the FAA.

My credentials as a physician knowledgeable about diabetes management are as follows (or attach CV):

This person has: type 1 diabetes type 2 diabetes

Date of diagnosis: ____ / ____ / ____

Attached records for prior 3 years or since onset of diabetes whichever is shorter for:

out-patient treatment in-patient treatment

2. Patient has been on a basal/bolus regimen or an insulin pump using analogue insulins for the six (6) months prior to evaluation. The airman has been clinically stable on their current insulin regimen for those 6 months prior to evaluation.

Current insulin regimen: _____

Insulin pump brand and model: _____

Pump settings:

Start Time					
Basal Rate					

Start Time					
Basal Rate					

Usual bolus doses:

Breakfast _____

Lunch _____

Supper _____

Other _____

Correction factor _____

Multiple dose insulin (specify regimen):

Basal: _____

Bolus: _____

Starting date on current regimen: ____/____/____

4. Has documentation of ongoing self-monitoring of blood glucose. This must be done with a glucose meter that stores every reading, records date and time of reading and from which data can be downloaded. Monitoring records must be available covering the previous 30 days.

During the previous 30 days, the airman must have followed the ADA Clinical Practice Guidelines for self-monitoring blood glucose prior to meals and snacks, occasionally postprandially, at bedtime, prior to exercise, when the airman suspects low blood glucose, after treating low blood glucose until the airman is normoglycemic, and prior to critical tasks such as driving.

The airman:

is adhering to the ADA Clinical Practice Guidelines' recommended schedule for testing.

is **not** adhering to the ADA Clinical Practice Guidelines' recommended schedule for testing.

The airman is sufficiently dexterous to successfully check blood glucose with a glucometer.

Yes

No

80% of self-monitored blood glucose values must be between 70 mg/dl and 250 mg/dl.

The airman:

has complied with the above described blood glucose values.

has not complied with the above described blood glucose values.

Self-monitoring glucometer logs:

- are attached for review
- are not attached for review (please explain): _____

5. The airman must exhibit no signs of decreased hypoglycemia awareness. Please evaluate:

6. Has been educated in diabetes and its management, including healthy dietary choices, and has been thoroughly informed of and understands the procedures that must be followed to monitor and manage his/her diabetes and what procedures should be followed if complications arise.

The individual has completed the following diabetes education (include year of completion):

7. If an insulin pump user, documents:

- proper understanding and education in the use of the insulin pump
- start date for the use of the pump
- history of insulin site infections
- history of pump cessation and pump malfunction
- backup plan for pump malfunction including use of injectable insulin
- frequency of infusion set changes

The individual has completed the following education in the use of a continuous insulin infusion pump (indicate year of completion): _____

The individual routinely carries appropriate supplies to compensate for pump malfunction, including syringes and insulin vials or insulin pens.

- Yes – please submit details of backup system

- No – please explain: _____

8. Has this individual used a continuous glucose monitor?

- Yes
Manufacturer and model of CGM: _____
Dates used: _____

Why used: _____

Frequency of use: _____

No

- 9. Has had hemoglobin A1C measured at least twice over the last 12 months prior to evaluation if diagnosis has been present over a year, the first at least 90 days prior to the current measurement.

Date	HbA1C
_____	_____
_____	_____

- 10. Impairing events – Has not had any within the past one (1) year and no more than two (2) episodes in the past five (5) years, or since diagnosis of diabetes (whichever is shorter) episodes of severe hypoglycemia (loss of consciousness, seizures or coma, requiring the assistance of others or needing urgent treatment [glucagon injection or IV glucose], or occurring without warning)

Has this individual had an episode of hypoglycemia as described above?

Yes No

If the individual has had such episode(s), please describe episodes and provide dates and medical records (if applicable) of episodes:

- 11. Has had a complete eye exam by a qualified ophthalmologist or optometrist, including a dilated retinal exam, documenting or the degree of retinopathy and/or macular edema if present (using the International Classification of Diabetic Retinopathy and Diabetic Macular Edema).

Copy of ophthalmology or optometry report is attached:

Yes No – please explain: _____

Copy of automated visual perimetry field test (Humphrey or equivalent) is attached:

Yes No – please explain: _____

- 12. Has normal vibratory testing with 128 Hz tuning fork, has normal testing with 10 gram Semmes-Weinstein monofilament and normal orthostatic blood pressure and pulse testing.

Vibration sensation: _____

Monofilament: _____

BP supine: _____

Pulse supine: _____

BP standing: _____

Pulse standing: _____

- 13. If age 40 or older, has normal cardiac physical exam and normal cardiac stress testing to at least 12 METS. Cardiac stress testing should be administered every 5 years for any airman using insulin age 40 or greater. Copy of stress test, with ECG tracings, report performed within the last 12 months is attached:

Yes No – please explain: _____

14. Has normal renal function based on albumin/creatinine ratio $\leq 30:1$, and measured or calculated creatinine clearance > 60 mL/min.

Serum Creatinine: _____

Estimated GFR (eGFR) _____

Urine microalbumin/creatinine ratio: _____

15. Has no cerebrovascular, cardiovascular, or peripheral vascular disease or neuropathy.

III. Treating Physician Statement

Please provide additional information, not included above, that may be helpful to the FAA:

Signature of Physician

Date

Printed or Typed Name of Physician

Telephone Number