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# **U.S. Considers Authorizing Pilot Medical Certification for Insulin-taking Diabetics**

Diabetes mellitus, a disorder of the body's blood-sugar regulation system, is treatable. The U.S. Federal Aviation Administration (FAA) is reconsidering its regulation of denying medical certification to pilots who require insulin treatment.

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Pilots who take insulin for diabetes mellitus have been denied medical certification since 1959 by the U.S. Federal Aviation Administration (FAA), and its predecessors, for flight duty. U.S. Federal Aviation Regulations (FARs) Part 67 prohibits medical certification to pilots who have an "established medical history or clinical diagnosis of diabetes mellitus that requires insulin or any other hypoglycemic [blood sugar–lowering] drug for control."<sup>1</sup>

In 1986, the FAA ended its ban against diabetic pilots treated with oral drugs. In 1992, the FAA also put in place a procedure that enables air traffic controllers who are insulin-dependent diabetics to perform their duties. The procedure for insulin-dependent diabetic controllers was developed by a panel of endocrinologists and includes evaluation of the individual's medical history and the efficacy of his or her efforts to control the disease.

Air traffic controllers who manage well their diabetes through daily insulin intake are allowed by the FAA to perform traffic control duty. The FAA is currently considering a policy for pilots similar to that for air traffic controllers, authorizing flight crew medical certification on a case-by-case basis.

As a result of the progress made in the 1980s, diet-controlled diabetic pilots are relatively common today, including airline pilots who hold FAA first-class medical certificates. If the FAA allows insulin-taking diabetic pilots to be certified on a caseby case basis, experienced airline pilots who otherwise would have lost their medical certification may be able to continue their professional careers.

The human body uses glucose, a simple form of sugar, as an energy source for its metabolism — the chemical changes that power vital activities and processes. The term "diabetes mellitus" covers a range of glucose-metabolism difficulties. The conditions can be treated by interventions and controls involving diet, exercise, other lifestyle changes and oral pharmaceuticals. In some cases, insulin by injection is required for effective control of glucose metabolism.

Insulin is a hormone secreted from the pancreas (an endocrine system gland, part of the body's chemical control system) into the blood in response to blood sugar level. Insulin enables body cells to use and manage glucose, the body's "fuel." Insulin is necessary for the storage of glucose as glycogen, a form of starch, in the liver and muscles. Later, the glycogen can be converted to glucose for metabolic use. The breakdown of glucose into carbon dioxide and water allows release of stored energy.

In the disorder called diabetes mellitus, the body cannot control the amount of glucose in the blood. Either the body produces too little insulin, or the body resists its own insulin and cannot use it properly.

A person with Type I diabetes requires periodic injections of insulin because the normal internal supply process is malfunctioning.<sup>2</sup> In this type of diabetes, there may be a total lack of

internal insulin or there may be minimal, and inadequate, insulin production. Type I diabetes, also known as insulindependent diabetes mellitus (IDDM) or insulin-treated diabetes mellitus (ITDM), is rarer than "diet controlled" Type II diabetes, accounting for fewer than 10 percent of the total cases of all diabetes.

In Type II diabetes, there may be insufficient body insulin to manage the glucose metabolism under the usual daily activities and periodic food intake levels.<sup>2</sup> The body may be unable to use effectively the insulin it produces. This latter condition is also referred to as non-insulin-dependent diabetes mellitus (NIDDM) or adult-onset diabetes, because most of those it affects are over 40.

When metabolism fails, blood sugar levels become elevated, acidosis develops, and a diabetic person can go into a coma. Long-term afflictions associated with untreated diabetes include stroke, blindness, heart disease, kidney failure, and ulcers or gangrene of the feet.

## **Insulin Treatment Not Always Needed**

Type I requires lifelong treatment with insulin, taken by injection. There are various types of insulin, whose effect can last as long as 24 hours or as short as eight hours. The insulin is derived from beef, pork or laboratory synthesis. The type, dosage and timing of insulin injections is tailored to the individual's needs. Special attention must also be given to the diet (Table 1).

Table 1 Ideal Diabetic Diet*	
Fat	
30% or less of total calories:	
10% or less saturated fat	
10% polysaturated fat	
10% monosaturated fat	
Carbohydrates	
50%–60% total calories	
Protein	
12%–20% total calories	
* Applies to Type I and Type II diabetes. Source: Kelley <sup>3</sup>	

Type II (NIDDM) can be managed by a combination of dietary care, obesity reduction (weight control is an important part of glucose-level control), reasonable exercise and other lifestyle adjustments such as not smoking and minimizing alcohol consumption. Such practices can make the use of injected insulin unnecessary.

The American Diabetes Association adds that a diabetic diet requires one more quality: consistency. It advises the diabetic to:

- Eat about the same number of calories each day;
- Plan meals and snacks for the same times each day; and,
- Never skip meals.

Oral antidiabetic agents, which stimulate the pancreas to increase production of insulin and thereby lower the blood-sugar concentration, are prescribed for some Type II patients.

# Hypoglycemia Mirrors Diabetes

The converse of diabetes is hypoglycemia, a condition of low blood sugar, which in extreme cases can also cause loss of consciousness. Hypoglycemia can occur in its own right or as a result of "overtreating" diabetes. Excessive insulin can cause hypoglycemia, which is readily countered by eating a piece of candy or a cookie. Premonitory symptoms include a feeling of restlessness and may include sweating. Some people may feel hunger, dizziness and lightheadness.

Hyperglycemic reactions — caused by an unduly high bloodsugar level — develop more slowly than do hypoglycemic reactions. Hyperglycemic reactions are not immediately lifethreatening. The symptoms of hyperglycemia include an increasing thirst, a flow of urine increasing in amount and frequency and ultimately, a lack of alertness. These symptoms are rapidly offset by insulin injection.

Persons who take insulin can learn these symptoms and, through planning, immediately counter the effects. A major key to the proper control of both Type I and Type II diabetes is an understanding by the individual with the condition of how glucose metabolism operates.

By using an automated blood-sugar digital readout assessment device, which takes a blood sample from the finger, an instantaneous indication of blood sugar can be obtained and the appropriate quantity of insulin taken immediately. This device can be provided with a computerized memory for later readout of adequacy of blood sugar control.

## Blood-glucose Level Can Be Self-monitored

Throughout the day blood-glucose levels must be monitored by the individual and kept within an acceptable range (for example, 90 milligrams–120 milligrams per deciliter fasting). Table 2 (page 3) shows acceptable measurements of blood glucose in a diabetes control program.

"Another important test," says the American Diabetes Association, "done by a doctor every three to six months, is a 'glycohemoglobin test.' This measures the average blood-sugar level over the past 30 to 60 days."

Table 2 Levels of Blood Glucose in a Diabetes Control Program		
Time Period	Acceptable	
Fasting*	70 mg/dl–130 mg/dl	
Premeal	70 mg/dl–130 mg/dl	
Postmeal	Less than 200 mg/dl	
Early-morning (2 a.m.–3 a.m.) period	Greater than 70 mg/dl	
* For pilots, ideal fasting levels could be between 90 mg/dl and		
120 mg/dl, a midrange of control. Source: Kelley <sup>3</sup>	mg = milligrams dl = deciliter	

Many insulin-taking diabetics almost never experience hypoglycemia because they manage their daily lifestyle activities intelligently and with discipline. An occasional viral infection might increase the body's needs for insulin, and the person who increases the dose may overshoot the target and experience a hypoglycemic reaction. Nevertheless, individuals suffering from a viral attack or other illness should not fly anyway, so the presence of a transitory illness leading to temporary hypoglycemia should not jeopardize flight safety.

In past decades a limited range of insulin preparations existed, often containing unwanted substances and with "batch-to-batch" variations in insulin strength. Also, less was known about glucose metabolism and various metabolic abnormalities. At the time, the term "brittle diabetic" referring to management of a difficult case was common. A brittle diabetic was a person whose day-to-day glucose control fluctuated widely despite efforts of the treating physician to manage effectively the glucose levels.

Today, with the better knowledge and the newer insulins, brittle diabetics are relatively rare unless the patient is uncooperative or, as modern diabetic specialists say, the treating doctor is "brittle" — unable to apply modern knowledge and pharmaceuticals to managing the more complex diabetic patient.

In societies where modern medicine prevails, insulindependent diabetics pursue all sorts of activities, including professional athletics. A major proportion of these patients do not experience serious hypoglycemia or other diabetic management problems.

Controllers who have passed the evaluation are monitored by periodic blood-sugar testing while on duty. Their blood sugar may be maintained at a somewhat higher than usual level to reduce the likelihood of incapacitating hypoglycemia. The protocol also requires close supervision and prohibits solo flight control duty.

On Dec. 29, 1994, the FAA solicited comments via a notice of proposed rule making (NPRM) in the *Federal Register* on

the possibility that medical certification could be given on an individualized basis to "certain insulin-using diabetic individuals."<sup>4</sup>

In describing the background of the policy change under consideration, the NPRM remarked that under FARs Part 67.19, Special Issue of Medical Certificates, the U.S. Air Surgeon can issue medical certificates on a discretionary basis to pilots who do not qualify for first-, second- or third-class medical certificates.

The NPRM said that current policy is based on "concerns about the long-term medical risks associated with diabetes, including cardiovascular, neurological, opthalmological and renal pathologies. Of even greater concern, especially in the aviation environment, is the immediate risk posed by hypoglycemia or low blood sugar. Every diabetic is at some risk for hypoglycemia, which can produce impaired cognitive function, seizures, unconsciousness and death. Moreover, functional incapacitation associated with hypoglycemia may occur insidiously and may not be recognized by the diabetic or by other observers. Diabetics using insulin are at greater risk for hypoglycemia than those treated by diet or oral hypoglycemic agents."

The NPRM said that the new policy under consideration for insulin-treated pilots had been formulated by the same group of endocrinologists responsible for the revised regulations concerning air traffic controllers.

Insulin-treated diabetic pilots could be evaluated for individualized medical certification under the proposed policy if they:

- "Have had no recurrent (two or more), severe hypoglycemic reactions requiring intervention by another party during the past three years"; and,
- "Have no current history of hypoglycemia resulting in impaired cognitive function without warning symptoms (hypoglycemia unawareness)."

## New Policy Would Require Strict Monitoring

Once granted special issuance of a medical certificate, pilots would be subject to continual monitoring. Among other things, they would be required to:

• "Submit to a medical evaluation by a specialist every three months. Such evaluation must include readings of glycated hemoglobin ... concentrations. This evaluation shall also contain the specialist's evaluation as to whether the individual has the ability and willingness to monitor and manage properly his or her diabetes and whether diabetes will adversely affect his or her ability to safely control an aircraft;

- "Carry and use a digital whole blood–glucose monitor device with a computerized memory. Records of all bloodglucose measurements must be provided to the specialist for review during each three-month evaluation"; and,
- "Provide, on an annual basis, confirmation by a specialist that the individual can demonstrate accuracy of measurements of blood-glucose concentration."

The proposed policy would also require insulin-taking diabetic pilots to "maintain appropriate medical supplies at all times while acting as a pilot-in-command or in any other capacity as a flight crew member. Such supplies shall include, at a minimum, a whole blood–glucose monitor with memory, test strips, blood sampling lancets, a source of rapidly absorbable glucose, insulin and syringes or a portable insulin pump as appropriate."

But the NPRM added that the policy change advocated by the panel of endocrinologists was only one among several possibilities under FAA consideration. Comment was also requested concerning a policy of not granting special issuance of airman medical certificates to any ITDM pilots, regardless of a monitoring procedure; or restricting certification of ITDM pilots by class (e.g., only third-class medical certificates), by airman certificate class (e.g., only private pilots) or by operational limitations (e.g., no multiengine aircraft or single-pilot aircraft).

The three-month comment period ended March 29, 1995. As of early November, the FAA had made no decision. The American Diabetes Association says that "allowing selected well-qualified individuals with ITDM to obtain medical certification will have a negligible impact on public safety," and is strongly urging the FAA to adopt the proposed medical certification guidelines.◆

## References

- 1. U.S. Federal Aviation Administration (FAA). *Airman Medical Standards*. Paragraph (f)(1) of Federal Aviation Regulations Part 67.13, 67.15 and 67.17 (for first-, secondand third-class medical certification respectively). 1995.
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- 4. FAA. "Policy Concerning the Special Issuance of Medical Certificates to Diabetic Airman Applicants. Request for Comments, 14 CFR Part 67, Docket No. 26493." *Federal Register*, Dec. 29, 1994: 67246-67248.

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