Two Years On

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This is the last President's Page for 2021. And what a year it has been for all of us, and that none of us could have predicted all the events and changes over the last 12 months.

As of November 2021, it has been 2 years since the Federal Aviation Administration (FAA) announced a new protocol allowing pilots with Insulin-Treated Diabetes Mellitus (ITDM) to receive special issuance medical certificates for first- or second class to perform commercial pilot duties. This was a "blockbuster" announcement. The general opinion of the community of pilots with ITDM was that the FAA was steadfastly opposed to certificating ITDM pilots other than for general aviation (private pilot) regardless of the advances in current medical practice. The American Diabetes Association had actively lobbied the FAA to develop a protocol since the 1990s.

A bit of history here. In 1996 the Civil Aviation Medicine Branch of Transport Canada launched a protocol allowing ITDM pilots to receive medical certification for both commercial and general aviation. The United Kingdom announced a policy to allow pilots with ITDM to fly commercial aircraft in 2012. In both cases, the question posed to the FAA was "if the Canadians and the UK can do it, what is wrong with the U.S.?" In addition, the FAA had allowed pilots with ITDM to be granted special issuance medical certification for third-class (i.e., general aviation in the United States) since 1996 and allowed pilots with diabetes treated with non-insulin medications to be certificated under special issuance. The FAA did require ITDM general aviation pilots to take special precautions prior to and during flight. Yet the United States had not experienced any spate of aircraft mishaps or incidents involving either pilot group.

On the surface, the question above seemed very reasonable and logical. However, the FAA faced a difficult problem: other countries may, and do, require operational limits and requirements on the medical certificate, such as limiting a pilot flying for a major air carrier to "multicrew only," require the air carrier to provide training, or require the copilot to be trained or informed of the airman's medical condition. In the United States, the Federal Air Surgeon/Office of Aviation Medicine (AAM) may only set limitations related to the individual airman per law, regulation, and judicial precedents. In essence, AAM could not apply the same measures to mitigate risk that were used by other countries.

The big concerns for pilots with ITDM are the risks for sudden or subtle incapacitation related to unrecognized hypoglycemia or hyperglycemic conditions (e.g., diabetic ketoacidosis or non-ketotic hyperglycemia). Despite decades of research on hypoglycemia, the only universally accepted definition was onset of symptoms requiring intervention of another person. Most people experiencing hypoglycemia for the first time usually have physical symptoms. However, individuals who regularly have hypoglycemia may develop a phenomenon called "hypoglycemic unawareness" where the first sign is seizure or unconsciousness. Despite decades of research by experts in diabetes, there was no reliable way for prediction or early detection of hypoglycemia during flight. The closest available stratagem was to have a pilot do a finger-stick blood glucose test on a regular schedule, perhaps every 30 minutes. Even under optimal circumstances, such testing required the pilot to divert attention from piloting in order to perform the test, and the results could not say whether blood sugar was increasing or decreasing. In essence, a pilot with a blood sugar of 80 could not know if her/his blood sugar was rising towards a safe level or falling towards the hypoglycemic range.

Enter "continuous glucose monitoring" or CGM. By late 2021, devices providing continuous glucose monitoring were regularly advertised on television and other media. A mere 7 years ago these devices were essentially experimental. At the FAA, we became very excited by the new technology as a potential solution for our concerns about how to acceptably mitigate the aviation risks of ITDM. Specifically, CGM offered the promise of allowing the pilot to monitor his/her blood glucose via a smart phone application and display. The frequency of monitoring, high and low range settings, alerts/alarms, etc., could all be customized by the pilot, and the FAA could specify requirements. Another great benefit was that the pilot could submit detailed reports with monthly data, summaries, and other information to the FAA for review. CGM could be used in conjunction with insulin pumps for more effective and timely control of blood glucose and allow tighter control of blood glucose while minimizing risks from hypoglycemia. Another great benefit is that pilots can control their ITDM on the flight deck the same way they do on the ground: no special requirements.

Since launch, the FAA has had a substantial learning curve. However, case reviews are now more standard, consistent, and efficient. We are analyzing our first 2 years of experience with over 70+ cases to improve our program. Next up: the artificial pancreas?

As we move into end-of-year holidays, I'd like to thank the AsMA home office staff, Executive Committee, Council, and membership for all their efforts during the year. Happy New Year!

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