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Pilots and Diabetes Technology: Functional Health

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Diabetes technology is not only of help for patients to live a close to normal life from a medical point of view, it is also of important benefit when it comes to their professional lives. People with diabetes are active in (nearly) all jobs that exist. However, there are certain professions that are prohibited for them—but only in certain countries. Though the job and its setting may be identical, some countries prohibit people with diabetes from employment, while others do not. These international incoherencies are related to different types of diabetes as well as diabetes therapy, and appear to lack a clear medical rationale.

One poignant example is the professional piloting of aircraft. Flying an airplane is a highly demanding task. To enter this profession, an individual must meet all of a number of requirements regarding skills, knowledge and medical fitness. After more than 100 years of professional flying, it would seem that these requirements should by now be well validated and internationally harmonized.[1] Any changes brought by advances in aircraft technology or, as in the case of diabetes, medical therapy, should induce similar responses in national certification legislations. To our understanding, this is not the case. Different countries or regions (eg, the European Aviation Safety Agency) have different rules as to which planes a pilot is allowed to fly when she or he has diabetes, in some countries only cargo planes, in other all planes. The regulatory incoherencies extend to whether a given patient has already a pilot license before diagnosed (typically patients with type 2 diabetes) or if she or he has diabetes already when applying for a pilot license (typically patients with type 1 diabetes). It would also seem of relevance if the pilots are private or commercial pilots, if they intend to fly a double- or single-command airplane, and so on. In other words, there appears to be a lack of international harmonization for this job, even though it is international in its occupational setting, and there appears to be a lack of understanding of the necessary stratifications of the issue.

In the United States, the Federal Aviation Administration (FAA) does not allow medical certificates for people who use insulin to operate commercial aircraft, although they can apply for a third-class medical certificate, which allows them to perform private and recreational operations and fly as student pilots, flight instructors, or sport pilots.[2] The ADA is currently "developing recommendations to share with the US FAA that would enable the FAA to identify pilots who are at no greater risk for incapacitation than any other pilot," according to the association's position statement.[3] The ADA opposes a "blanket ban" and instead takes the position that individual assessment of people with diabetes is the appropriate approach to determining whether a person is qualified to perform certain activities. We fully agree with this position and will outline why we believe this is the right way to go.

What is the rationale for maintaining so diverse rules? Again we have to say, there are few studies/little data substantiating the current situation. It appears as if the rules are driven by the personal opinions of the physicians (in the best case, probably others are also involved) and their diabetes knowledge. Therefore, much of the following discussion also holds true for physicians that regulate car traffic or other working conditions. The regulations for patients with diabetes that have a driving license or want to get one, are quite diverse between countries and dependent on whether they drive only themselves or want to drive a cab or a bus.

This difference in how diabetes is regarded becomes obvious when it comes to the International Statistical Classification of Diseases and Related Health Problems (ICD) and the International Classification of Functioning, Disability and Health (ICF). Physicians in most countries are familiar with coding of diseases in ICD codes as this is relevant for their honorarium. This in turn has also an impact on the way she or he thinks. A patient with diabetes is thereby

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represented by the ICD codes that the physician has in mind for her or him; however, these diagnoses do not reflect the reality of daily life of the patient. In other words, the codes do not represent a close correlation about how well a given patient can participate in various activities and how his or her working abilities are. It is more than obvious that a given ICD has no meaning about how well a patient can fulfill a certain task. This is probably more obvious for the patients than for many physicians, who live in a different world/mind-set. In Europe/Germany, it is illegal to judge about the working abilities of patients based on ICD.

Switching to a different point of view can reveal interesting differences. ICF is a classification of the WHO which serves as a globally unified and standardized language for the description of functional health, handicap, social impairment, and the relevant environmental factors of a human being. With the ICF the bio/psycho/social aspects of sequelae can be described systematically while taking relevant other factors into consideration.[4] What does this mean for physicians and patients? This is relatively simple: as appraiser, the diagnosis is not of relevance, of importance is what the given patient can do what hinders her or him in her or his activities and participation in life. The ICF is not focused on which deficits a given patient has, it classifies "components of health": functional aspects of body, activities and participation plus environmental factors. As an example, the astronaut John Young wore glasses while piloting the first space shuttle flight.[5]

The key term is "functional health." This means, the importance of the ICD diagnosis is not as important for the rating as the real existing impacts of physical, mental or psychological modifications of the normal conditions. If it becomes possible to compensate disadvantages/limitations imposed by a disease on a given patient to such an extent, that in her or his daily routine she or he fulfills the requirements of "normal" functionality, this clearly has also an impact on her or his professional setting. This in turn means, that an evaluation of the realistic risk a patient represents when fulfilling a job/work should not focus on a given diagnosis, but on the acceptable risk a given patient represents. By taking the "functional health" into consideration when it comes to the "acceptable risk" is not only appropriate, it also avoids discrimination. This approach is the one to go for, because people with functional health are not handicapped despite a given diagnosis and risk might be avoided that are induced when a given activity is forbidden.

Recently presented data from an adequately designed and performed study have shown that the risks associated with flying can be reduced to such a level, that patients with diabetes appear to be safe pilots when their functional health can be ensured by clear guidelines; however, the time is not ripe for single command from our point of view. The study data indicate that patients with insulin-treated diabetes can be safe aircraft pilots. In 2012, the United Kingdom became the second country in the world—after Canada—to issue class 1 medical certificates for commercial pilot licenses (CPLs) to people with diabetes who are treated with insulin (or sulfonylureas/glinides) and who are deemed low risk for hypoglycemic events and follow a set protocol for glucose monitoring and adjustments.[6] The prerequisites are participation in a high quality diabetes training and with no diabetes related late complications. Approximately 70 people have been granted such CPLs thus far. Data for 26 of those individuals were presented at the EASD 2016.[7] Over an average follow-up of nearly 2 years, more than 95% of glucose readings were in the designated "safe" range of 90-270 mg/dL, and no episodes of pilot medical incapacitation due to low or high blood sugar were reported. One limit of this study was that it was conducted only in men who already had CPLs when they developed diabetes. So, no data are available for young men or women with long-standing diabetes.

A key element of the study was a comprehensive protocol developed by a panel of medical and aviation experts governing the medical certification of insulin-treated pilots and based on available literature regarding hypoglycemia risks and experience from various transport modalities. To qualify, pilots had to have normal renal function, no significant retinopathy or neuropathy, good hypoglycemia awareness and understanding.

The program, directly overseen by the UK Civil Aviation Authority (CAA) medical department, includes the following elements:

- Three specified glucose ranges, indicating levels considered safe ("green") for flying of 90-270 mg/dL; levels of caution ("amber") with designated corrective actions, 72-90 mg/dL for hypoglycemia, and 270-360 mg/dL for hyperglycemia; and urgent ("red") levels requiring priority action <72 or >360 mg/dL ranges.
- Pilots must perform their blood glucose measurements (BGMs) at least 2 hours before flying and at least 1 hour prior for commercial pilots reporting for flight duty and again less than 30 minutes before the flight. If the levels fall into the "red" zone, the pilot can't fly.
- During flight, those on insulin should test BGM at least once every hour. For those taking sulfonylureas or glinides, they should test BGM at least every 2 hours while flying.
- BGM testing is done again within 30 minutes prior to landing, with repeat if approach or landing is unexpectedly delayed.
- Glucose levels must be tested at any stage if any diabetic symptoms are experienced.
- If any in-flight glucose level falls into the "red" range, the pilot must hand over the controls to the copilot.
- Pilots can cut back the BGM testing on formal rest breaks but must restart prior to resuming control of the plane.
- Clinical surveillance by the CAA every 6 months (or 12 for private pilots).

- Pilots are permitted to use insulin pumps and CGM as adjuncts, but they are required to carry backup injected insulin supplies and must still perform BGM per protocol. (One reason for this is that CGM use isn't validated at high altitude)
- The 26 insulin-treated pilots issued class 1 medical certificates were all male, with an average age of 41 years. Most (85%) had type 1 diabetes, with an average diabetes duration of 8.1 years.
- The average follow-up duration post–license issue was 19.5 months. HbA1c levels didn't change pre– to post–license issue (from roughly 7.0% to 7.2%, $P = .25$).
- A total of 8,897 BGM values were recorded during 4,900 flight hours, with a median of 332 per pilot.
- For flights <6 hours, 96% of 7829 BGMs were in the "green" range. For flights >6 hours, 97% of 1068 readings also felt within "green" parameters. Just 19 (0.2%) readings were in the "red" ranges, and there were no reports of pilots experiencing medical incapacitation due to hypo- or hyperglycemia. The pilots found the protocol practical and feasible in the cockpit and compatible with safe performance of their other flying duties.
- Currently the program is available only for people who were already licensed pilots before developing insulin-treated diabetes, but the team is collecting safety data for people with pre-existing diabetes who are training to become certified pilots in order to satisfy requirements of the European Aviation Safety Agency. Several other European states have expressed interest in the program.

So, in the United Kingdom pilots with an insulin-dependent diabetes can get a license in case that the really existing risks are compensated adequately by modern technical options, in this case by continuous glucose monitoring (CGM). It is clear that patients that want to fly must be very well trained in diabetes therapy in general, but also on the usage of CGM and insulin pumps (plus combinations of these 2 devices). One should also take into consideration that many problems of human-machine interaction have been solved in recent years.

One might be concerned that factors during flight might impair proper functioning of CGM systems, that is, the hypobaric conditions. The air pressure in a plane is like that on the top of mountains and to our knowledge not all CGM systems are validated/approved for high altitudes. However, recent publications showed the good performance of CGM systems of up to 5500 meters.[8] This study was performed with an outdated CGM system, which is not in use anymore; however, to our understanding the basic technology remained the same with the recent generations. In contrast, it might be that CGM systems are more reliable under such conditions than many BG meters, a reduced oxygen partial pressure is an issue for a number of these![9-13] So, recalibration of CGM systems can be misleading due to the reduced oxygen content in the planes; this should not be done with inadequate meters in such conditions.

Other authors have suggested that pilots should have high blood glucose levels during flights to reduce the risk of hypoglycemic events.[3] However, from our point of view it is vastly misleading to recommend plasma glucose levels of 270 mg/dl (>15 mmol/l). We believe that such cut-off levels are far too high based on studies with skydivers in which the cognitive function in patients with type 1 during hypobaric conditions were assessed.[14] Patients with diabetes are not worse than healthy subjects while having normoglycemia. Also, a single data point, set strangely high, in the belief that it is a safety margin, may make the pilots completely miss the trend. An aviation analogy is the altitude. If an airplane, as a single value, is at 2000 feet above ground level, it is 2 very different situations if it is slowly ascending, or if it is in fact descending through 2000 feet at a vertical airspeed of 150 knots.

Don't get us wrong, not each and every patient that has diabetes and want to fly should be allowed to do so—extending that thought motivates a further look, and stratification, into who actually should, from a medical point of view, be allowed to work as a pilot. However, in view of the rapid progress made in the last years with CGM technology and now having the first (hybrid) closed-loop system approved in the US by the FDA, is it not time to rethink what patients with diabetes are allowed to do when it comes to jobs? The times of blocking patients doing all jobs should be something of the past! We see and understand the need to differentiate between different diabetes types and therapies. However, as stated the concerns that insulin-treated patients cannot perform complex occupational duties safely are outdated. Aviation is accustomed to pushing forefronts of technology, if diabetes technology is used intensively in this context, this should in turn support patients with diabetes to come to a level of functional health that allows them to perform other demanding professions as well.

Aviation safety, overall and internationally, should ideally as an end result of such a process be improved. Flying is not a human right, but if there is no good reason to prohibit pilots with diabetes who have great glucose control, then they should be allowed to fly—at first with double command and a co-pilot who has not diabetes. Clearly, a register should be established to follow such a cohort, internationally. If all pilots with diabetes submit their data to a registry, this will back up this move by more data quickly.

The question is, will all airlines and regulatory agencies worldwide go ahead and update the regulations for pilots in all countries? We ask for harmonization of the respective rules on a global basis. One has to acknowledge that for example in Germany this is not the case until now. Probably it is time that the IATA becomes active!

Abbreviations

BGM, blood glucose measurement; CAA, UK Civil Aviation Authority; CGM, continuous glucose monitoring; CPL, commercial pilot license; FAA, Federal Aviation Administration; ICD, International Statistical Classification of Diseases and Related Health Problems; ICF, International Classification of Functioning, Disability and Health.

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