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REVIEW ARTICLE

WILEY

Pilots flying with insulin-treated diabetes

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Abstract

People with diabetes treated with insulin have often faced blanket bans from safety-critical occupations, largely because of fear of incapacitation due to hypoglycaemia. Recent advances in insulin therapies, modes of administration, monitoring, and noninvasive monitoring techniques have allowed stereotypical views to be challenged. The aviation sector has led the way, in allowing pilots to fly while on insulin. Recently, countries that have traditionally been opposed to this have changed their minds, largely due to the increasing evidence of safety. The purpose of this review was to gather all available information to update clinicans. The physiology and pathophysiology underpinning glucose regulation and the management of diabetes in the air allowing certain insulin-treated pilots to fly are discussed.

KEYWORDS
clinical physiology, insulin therapy

1 | INTRODUCTION

People with diabetes face daily discrimination and prejudice about the medical condition with which they live. This prompted the International Diabetes Federation to launch an International Charter of Rights and Responsibilities of People with Diabetes in 2011.[1] The vision of this charter was to optimize health and quality of life, enable as normal a life as possible, and reduce and eliminate barriers that deny realization of full potential as members of society as a whole. A right was stipulated that people with diabetes should be treated fairly in employment and career progression whilst acknowledging that there were certain occupations where identifiable risks may limit their employment. The overall aim was to reduce the barriers that deny realization of full potential as members of society but have to be balanced by public safety.[1] The risk of hypoglycaemia and incapacitation is the most widely quoted reason for a blanket ban policy preventing safety-critical occupations being performed by people with diabetes managed with insulin.[2] Advances including new insulin analogues, which reduce the risk of hypoglycaemia, insulin pumps, and non-invasive continuous glucose monitoring (CGM) devices and techniques have led to vastly improved glycaemic control in insulin-treated diabetes. There has been a reduced frequency of severe hypoglycaemic events and delayed diabetes-related comorbidities. It is thus possible to reappraise relative risk and extend the boundaries of what is possible, practical and safe.[2] Aviation has been at the forefront of these changes. The purpose of this review was to gather all available information to update clinicians. Methods included searches using PubMed, together with abstract research for aeromedical scientific meetings. The physiology and pathophysiology underpinning glucose regulation and the management of diabetes in the air, allowing certain insulin-treated pilots to fly, is discussed.

2 | CERTIFICATION OF PILOTS WITH DIABETES

There are international and regionally agreed standards for the issue of the medical certificates which validate a pilot's licence.[3] There are

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different classes of certificate corresponding to the types of licence privilege a pilot wants to exercise. In most countries, a Class 1 medical certificate is required for a commercial licence, and a Class 2 for a private pilot's licence (Class 3 in the United States). In Europe there is also a light aircraft pilot's licence (LAPL) and medical certificate, with similar licensing elsewhere for "sports" aircraft.[4] The medical standards are less demanding for Class 2 and again for LAPL, which reflects the more limited privileges and different levels of risks associated with these licences.

3 | HISTORY OF CHANGES IN CERTIFICATION FOR PEOPLE WITH DIABETES

In 1989, a British Royal Air Force pilot, Douglas Cairns, was diagnosed with type 1 diabetes. He was immediately discharged from flying duties. At the time, no country allowed private, commercial or military flying for pilots with insulin-treated diabetes. He then applied every year to the UK Civil Aviation Authority to enquire whether there was any change that might enable people with type 1 diabetes to fly. The United States in 1996 introduced a policy that allowed people with well-controlled type 1 diabetes to fly private aircraft, provided there was the demonstration of good blood glucose control and oversight. Following the United States's lead, approximately seven other countries are understood to have at least one private pilot flying with type 1 diabetes.[2] The US system for private flying allows pilots to fly any size of aircraft, single- or multi-engined, without any restrictions. A similar protocol existed in Israel.[2] In 2002, Canada became the first country to allow insulin-treated people to fly commercial airplanes and allow Class 1 and Class 2 certificates. This was done on a case-by-case basis under close supervision and employed a protocol of twice-hourly blood glucose monitoring.

Taking this opportunity, Douglas Cairns obtained a license from the Federal Aviation Authority (FAA) in the United States and embarked on a series of awareness flying projects including the Diabetes World Flight, which involved an around-the-world trip and also breaking a 15-day record to land in every state in the United States. In 2011, he flew to the North Pole with the Diabetes Polar Flight, which set a solo speed record from Alaska to the North Pole. In 2007, several former and aspiring pilots who had diabetes formed a group titled "Pilots with Diabetes" with the aim of persuading aviation authorities around the world to allow pilots to fly commercial aircraft.[2]

In 2010, the UK Civil Aviation Authority organized an expert committee to review the scientific knowledge and basis of the blanket ban and to see whether international policies concerning flying needed to be amended. It was concluded that a protocol for safe flying could be developed and this was published on the UK Civil Aviation Authority website.[5] At that time, the committee felt that noninvasive glucose monitoring devices did not provide sufficient accuracy and a protocol based on finger-prick blood glucose monitoring was developed. In 2012, the United Kingdom began issuing Class 1 medical certificates for commercial flying using the protocol (see below). Around this time, European Commission regulation came into force for the issue of Class 1, 2 or LAPL medical certificates in the European Union. The regulation allowed the application for a derogation for a joint research programme conducted by two or more member states to permit the issue of aeromedical certificates.[4] In 2014, the European Aviation Safety Agency (EASA) approved a joint research project by the United Kingdom and Ireland to certify insulin-treated pilots. There was significant resistance and concern from several member states and, in 2015, the EASA, an agency of the commission, clarified interpretation of the regulation such that initial applicants were no longer able to obtain a Class 1 medical certificate through the protocol. Only those applicants who already held a commercial licence were able to obtain a Class 1 certificate. In 2016, Austria joined the protocol which extended the aircraft that could be flown to any registered in the United Kingdom, Ireland and Austria. In 2019, the FAA announced that they would certificate pilots with insulin-treated diabetes, including those flying commercially, and published a process on their website. This included the use of CGM systems and remote glucose monitoring (see below).[6] In light of this announcement, other countries are likely to review their existing policies in the forthcoming months and years.

4 | EFFECTS OF AVIATION AND ALTITUDE ON THE PHYSIOLOGY AND PATHOPHYSIOLOGY OF DIABETES

Fasting glucose levels in healthy people exposed acutely or chronically to very high altitudes have been demonstrated in studies to increase, decrease or remain unchanged.[7–10] It was felt that the difference in results might be explained by the duration of altitude exposure to which people were exposed. Most papers suggest that there is an initial increase in glucose levels with altitude and that with prolonged exposure there may be a decrease as people acclimatize. The effect of exercise may also influence the levels, with some reports suggesting increased blood glucose levels in response to exercise at altitude but not in individuals under resting conditions. Altitude combined with sympathetic activity during exercise and increased catecholamine levels is thought to be responsible for these phenomena. Several studies have consistently shown an increase in plasma and urinary catecholamines in response to acute altitude exposure.[11,12] Others have suggested that the reported elevation of cortisol during short-term exposure to high altitude could also contribute to the hyperglycaemia. In contrast, decreased blood glucose levels have been observed after acute exposure to hypobaric hypoxia in people without diabetes whilst in a prolonged fasting state[7].

The conventional understanding, therefore, is that hyperglycaemia may develop after exposure to high altitudes, probably secondary to increased stress-related hormones (cortisol and catecholamines), but hypobaric hypoxia may have an additional effect of lowering blood glucose levels that becomes more dominant with prolonged exposure to high altitude.[7] In practical terms, commercial aircraft, although flying at 9 144 metres, are pressurized to simulate internal atmosphere somewhere between 6000 and 8000 feet, and

therefore it is unlikely that these changes will have a significant effect on glucose metabolism during flight. A much greater influence will be alterations of diet, lack of exercise, and timing of carbohydrate and food intake in relation to insulin administration. During an emergency decompression, there may well be a minor effect due to sudden pressure differences and hypobaric hypoxia but other factors, such as unintended insulin delivery from insulin pumps via tubing due to pressure differences and dissolved gasses, may play a greater role. An innovative study from Australia[13] demonstrated that insulin pumps delivered more insulin than set during decompression associated with flight. It was noted that when commercial aircraft ascend to 12 192 metres, the cabin pressure decreases by 200 mmHg from 760 mmHg at sea level (international standard atmosphere) to 560 mmHg, equivalent to a height of 2438 metres. The Australian group used a model of examining rates of insulin delivery from pumps placed in a hypobaric chamber where pressures were altered to mimic ascent over 20 minutes and descent over 20 minutes.[13] The pumps on average delivered 0.7 units excess during ascent and a deficit of 0.5 units during descent. During a simulated catastrophic decompression from 760 to 260 mm over 1 minute, all pumps delivered insulin of >8 units due to plunger movement.[13] The follow-on study looked at real flights in a Boeing 767-338 and similar findings were exhibited. In all studies, the insulin excess or deficit was consistent with the prediction of bubble volume changes due to pressure changes in the syringe and tubing using Henry's Law.[13] With this in mind, the UK and European Protocol for flying with diabetes stipulates that, during an emergency decompression, all pilots should ingest carbohydrate to counteract the potential excess delivery from insulin pumps. There is no literature on the effect of pressure changes on subcutaneous insulin depots. Thus, overall glucose metabolism may alter subtly with acute changes in pressure; the effects are small and are likely to be outweighed by changes in eating patterns and lack of exercise during flights. Additional problems due to acute decompression are important for people on insulin pumps and corrective action should be taken and clear instructions given as part of any flying protocol.

5 | DIFFERENT PROTOCOLS USED BY COUNTRIES TO ALLOW PEOPLE TREATED WITH INSULIN TO FLY

All protocols have a similar structure, with a detailed clinical assessment looking for hypoglycaemic awareness thresholds, complication surveillance, and diligence and aptitude in self-managing diabetes. During flight, blood glucose is measured by a variety of means at varying time intervals (Table 1). All require monitoring 30 minutes prior to landing. There are differing acceptable glucose ranges. All require carbohydrate ingestion if the low threshold is breached (Table 1).

5.1 | United Kingdom/Ireland/Austria

Pilots with insulin-treated diabetes who apply to join the protocol[5] are assessed with essential clinical information including a letter of support from their diabetes specialist, biochemical and lipid profiles, diabetes complication surveillance, and a complete ophthalmological assessment. A detailed history of hypoglycaemia is taken, including glycaemic thresholds, Gold score for awareness, and detailed assessments of glucose monitoring records.[14] Frequency and rate of out-of-range results are recorded and a flight test is performed with an instructor/examiner to assess the ability to follow the inflight blood testing protocol. Pilots test their blood sugar before flight duty (at least 1 hour before reporting for duty, or at least 2 hours before flying; this allows satisfactory glycaemic control to be confirmed or notification of unfitness). Blood glucose determination occurs 30 minutes before take-off, each hour within flight, and 30 minutes before the anticipated landing time.

A traffic-light system is used, with "green" signifying acceptable (5.0-15.0 mmol/L), "amber" indicating caution (low 4.0-4.9 mmol/L; high 15.1-20.0 mmol/L) and "red" requiring immediate action (low <4.0 mmol/L; high >20.0 mmol/L). Low 'amber' values require the ingestion of 10 to 15 g readily absorbed carbohydrate and re-measurement after 30 minutes. Low 'red' values require the pilot to

TABLE 1 Comparrison of flying protocols

Protocol	Full clinical assessment	Mode of glucose monitoring	Frequency of in-flight testing	Monitoring before landing	Range of acceptability whilst flying	HbA1c assessments	Complication surveillance	Published data
Israel	Yes	Blood	2-hourly	30 minutes	>5.5 mmol/L	3-monthly	Yearly	No
Canada	Yes	Blood	Every 30 minutes	30 minutes	6-15 mmol/L	6-monthly	Yearly	No
United Kingdom/ Ireland/ Austria	Yes	Blood	Hourly	30 minutes	5-15 mmol/L	6-monthly	Yearly	Yes
New Zealand	Yes	Blood	Hourly	30 minutes	>5.5 mmol/L	Not stipulated	Yearly	No
United States	Yes	CGM	CGM		4.4-10 mmol/L	3-monthly	Yearly	No

Abbreviations: CGM, continuous glucose monitoring; HbA1c, glycated haemoglobin.

hand over duties to the other pilot or, if flying solo, consider landing as soon as is practical, as well as ingesting 10 to 15 g readily absorbed carbohydrate. High readings >15.0 mmol/L necessitate a review of insulin dosing, modification of planned carbohydrate intake, or both. A high "red" reading also requires duties to be immediately transferred to the other pilot and, if flying solo, the pilot must consider landing as soon as is practical.

5.2 | Canada

All subjects apply with the support of their specialist endocrinologist. A clinical assessment precertification is performed, including complication surveillance and full ophthalmology assessment. Applicants have to exhibit good control and self-management with normal hypoglycaemic thresholds. A meter with a memory chip must be used and, prior to flight, a blood glucose of 6 to 15 mmol/L must be documented. Glucose must be measured every 30 minutes during flight. If blood sugar less than 6 mmol/L is recorded, 10 g of carbohydrate must be ingested.

5.3 | Israel/New Zealand

Military pilots treated with insulin have been reported to be allowed to fly with a protocol requiring 2-hourly (Israel) and hourly (New Zealand) blood glucose determinations. The Israeli protocol requires action if blood sugar falls below 5.5 mmol/L. Pilots are assessed for clinical signs of complications and hypoglycaemic thresholds. Full medicals including glycated haemoglobin (HbA1c) review take place annually. The protocols have not been formally published.

5.4 | United States

Initial applicants in the United States need to demonstrate at least 6 months of stability and adequate control using CGM data on a device that meets FAA requirements. A longer period is required for those recently diagnosed. Finger-prick data for the previous 90 days is also required. They must also submit blood tests, including HbA1c, full blood count, and biochemical and lipid profiles. Eye and cardiac evaluation are required, including stress electrocardiograms for those over 40 years old. The applicant must undertake a medical examination with an examiner and all the information is submitted to the FAA for consideration.

Following successful certificate issue, there is frequent follow-up with the submission of 3 monthly endocrinology and blood test reports that are collected and submitted to the FAA every 6 months, along with notification of flying activity, CGM data, and a record of any in-flight actions required to maintain blood glucose levels within an acceptable range. Regular eye and cardiology reviews are also required. Pilots may use insulin pumps as long as they have the ability to suspend insulin for predictive low glucose or predicted pressure changes. Both pumps and CGM devices must be US Food and Drug Administration-approved and compatible with each other.

5.5 | Comparison of aviation with other modes of transport

There are over 18 million people with diabetes in the United States and a large proportion drive motor vehicles. Driving is not a right but greatly facilitates work, family and social interactions and access to facilities/services. The volume of road transport driving has led to advances in transport regulation concerning the medical fitness of a person with diabetes to drive and the means of assessing and regulating such driving.

The European Commission directives on driving, particularly one in 2006, led to the current evolution of European statutory regulations for driving by people with diabetes in all European States, including the United Kingdom. This evolution has led to better-defined criteria for Group 1 vehicle licences and broadening of access to driving for Group 2 licence holders.[15]

The focus on hypoglycaemia as the principal safety factor in driving has led to a logical divide between the processes used for drivers treated with insulin, insulin secretagogues or other medicines known to produce hypoglycaemia as compared to drivers treated solely with medicines that do not produce hypoglycaemia and are unlikely to impair driving performance.[15–17]

Drivers treated with insulin, insulin secretagogues, or other medicines known to produce hypoglycaemia are required to demonstrate a safe or acceptable level of hypoglycaemia awareness, with a move away from unrealistic or ill-defined criteria such as full awareness of hypoglycaemia. The concept of severe hypoglycaemia has been defined as requiring the assistance of others, and parameters have been defined to allow Group 1 driving in closely regulated situations once this has occurred.[15–17] Drivers treated with insulin, insulin secretagogues, or other medicines known to produce hypoglycaemia are required to demonstrate adequate glucose testing at times relevant to driving. The dataset required of Group 2 drivers is considerably more detailed.[15–17]

Drivers treated solely with medicines that do not produce hypoglycaemia and are therefore unlikely to impair driving performance have experienced more open regulation and, in some circumstances, may not need to inform regulatory bodies for Group 1 or Group 2 licensing.[16]

Diabetes complications causing visual impairment or peripheral sensory loss have evolved to be dealt with separately under the assessment processes for driving.[16,17] The evolution has been swift, has demonstrated safety, and has been accepted by both drivers with diabetes and by other road users/society.

6 | PUBLISHED DATA OF PEOPLE TREATED WITH INSULIN WHO ARE ALLOWED TO FLY

Although several countries allow pilots to fly for leisure, no data have been published to evaluate the safety and the performance of any of their protocols. A study from Israel described the use of a different

protocol of self-monitoring by five military aviators, who measured blood glucose half an hour before take-off and every 2 hours on long flights, but any out-of-range levels were not reported, nor was whether any remedial action was required.[18] Similarly, results from insulin-treated pilots certified to fly commercially in Canada have been reported as personal abstracts at aero-medical meetings but, to our knowledge, no formal evaluation of blood glucose levels or rate of out-of-range values have been published.[19]

The first peer-reviewed paper reporting data from insulin-treated commercial pilots came from the United Kingdom.[20] This reported 9000 flying hours from 16 Class 1 pilots. There were no reported safety issues and the protocol was found to be feasible and practical. The medical records for all Class 1 pilots with insulin-treated diabetes certificated by the UK Civil Aviation Authority were reviewed. Demographic information, diabetes history and management data were collated. All available HbA1c values pre- and postcertification were obtained, together with all in-flight blood glucose monitoring values.

Class 1 medical certificates had been issued to 26 pilots with insulin-treated diabetes between 2012 and 2015. All were male, with a median age of 41 years, 22 (84.6%) had type 1 diabetes, with a median (range) duration of diabetes of 7.75 (1-19) years.

Before and after certification HbA1c was unchanged (53.1 mmol/mol [95% CI 49.7-56.5] vs 54.8 mmol/mol [95% CI 50.9-58.8]), with a mean follow-up of 19.5 months. This result unequivocally showed that pilots did not run with higher blood glucose levels and overall diabetes control did not deteriorate with the attainment of a Class 1 medical certificate. The blood glucose measurement protocol was demonstrated to be both practical and feasible. Pilots had cumulative recordings of 8897 pre- and in-flight blood glucose values for 4900 hours of flying. Only 186 readings were out of range: 181 were in the "caution" amber range (4.0-5.0 mmol/L or 15.0-20.0 mmol/L), with five in the "immediate action" red range (<4.0 or >20.0 mmol/L). Appropriate action and retesting were undertaken and no adverse safety events were reported.

A much more extensive follow-on study, reporting over 22 000 flying hours with 49 pilots from the United Kingdom, Ireland and Austria (partners in the EASA ARA.MED.330 protocol) has recently been reported, and represents the largest amount of systematically collected data from insulin-treated people undergoing a safety-critical occupation.[21]

A total of 49 pilots issued Class 1 or Class 2 medical certificates for type 1 (84%) or type 2 (16%) diabetes were studied. The median diabetes duration was 10.9 years. The mean precertification HbA1c was 55.0 mmol/mol (7.2%) and the postcertification mean was 55.1 mmol/mol (7.2%; $P = 0.97$). A total of 38 621 blood glucose values were recorded during 22 078 flying hours. Overall, 97.69% of measurements were within the "green" range, 1.42% of values were within the low "amber" range, 0.75% were within the high 'amber' range, 0.12% were within the low "red" range and 0.02% were within the high 'red' range. An interesting observation was that out-of-range readings decreased from 5.7% in 2013 to 1.2% in 2019. This may be attributable to the widespread introduction of noninvasive CGM systems which most pilots use in parallel to the finger-prick glucose monitoring protocol. No safety concerns have emerged using this established protocol, which has allowed pilots with insulin-treated diabetes to safely undertake complex safety-critical occupational duties.

7 | IMPLICATIONS FOR EMPLOYMENT SECTORS OTHER THAN AVIATION

The high-value, closely controlled, and regulated environment of aviation has facilitated data collection in controlled situations, which now becomes applicable to wider uses including driving, occupational health, and relative risk assessment.[21] The large volumes of detailed data produced by pilots provide a protocol and basis for the safe functioning of individuals treated with hypoglycaemic agents. These protocols and data now allow the empowerment of individuals with diabetes and the return of a valuable sector of society to some productive activities.

8 | NEW TECHNOLOGIES AND THE FUTURE

Advances in insulin analogue design leading to more predictable and physiological insulin pharmacokinetic and pharmacodynamics profiles has helped considerably in enabling flying protocols to work. Insulin delivery systems are also advancing and recent advances in digital technology may also help to tailor insulin to physiological need. Although there have been major advances in closed-loop systems and the algorithms that govern them, the different insulin delivery at altitude discussed earlier, although minor, will have to be evaluated formally before such systems can be certified in the future.

Noninvasive glucose monitoring techniques are being widely introduced and have led to an increase in the time in range and also reduce the number of episodes of, severity of and time spent in hypo- and hyperglycaemia.[22,23] This technology has been suggested as applicable for use in the cockpit of aircraft.[22,23] Many of the pilots flying as a result of the EASA ARA.MED.330 protocol use CGM devices in addition to the protocol-stipulated testing of finger-prick blood samples during duty periods. It is of considerable interest that the number of out-of-range glucose levels while flying has declined considerably since the widespread introduction and availability of noninvasive CGM systems. Further research on the use of real-time CGM during flying is needed and a formal evaluation of CGM is being undertaken in parallel with the EASA ARA.MED.330 protocol and should report in 2021 (NCT04225455).

This new technology and recent consensus guidance concerning desirable glucose ranges, including new definitions of hypoglycaemia, could lead to modifications of the current protocols which are based on glucose monitoring using finger prick and meters.[24] Once the safety of this technology has been proven, it could play a fundamental role in persuading aviation and driving regulatory authorities worldwide to adopt more flexible licensing policies for pilots and drivers with insulin-treated diabetes mellitus. The US FAA has recently

announced that the United States, like Canada, the United Kingdom, Ireland and Austria, will allow pilots with insulin-treated diabetes to fly commercial aircraft. Allowing CGM in the US protocol represents a major step forward in this debate.[6]

9 | CONCLUSION

Until relatively recently it was considered an unacceptable risk to allow insulin-treated pilots to fly aircraft. With the advent of new monitoring systems, modern insulin analogues and insulin delivery systems it has been shown that the risks are now acceptable. In parallel with the improvement in clinical care has been a reevaluation of societies' discrimination laws that also has enabled progress. Many countries are now on the cusp of following Canada, the United Kingdom, Ireland, Austria and, more recently, the United States in certificating insulin-treated pilots.

CONFLICT OF INTEREST

D.L.R.-J. is contracted as an independent advisor to the UK Civil Aviation Authority, and has received research funding and advisory board honoraria from Astra Zeneca, Dexcom, Lilly, Novartis, Novo Nordisk and Sanofi. E.J.H. is contracted to the UK Civil Aviation Authority and has no conflict of interest. G.A.R. is contracted as an independent advisor to the Irish Aviation Authority and has received research funding and advisory board honoraria from Novo Nordisk, Menarini, Mundipharma and Sanofi.

PEER REVIEW

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DATA AVAILABILITY STATEMENT

Data derived from public domain resources

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