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A UK Civil Aviation Authority protocol to allow pilots with insulin-treated diabetes to fly commercial aircraft

People with diabetes sometimes consider that they are subjected to unfair discrimination in the occupational or work environment. Relevant occupations include safety critical activities such as operating machinery and vocational driving.[1,2] Some occupations, such as the military and civilian uniformed services, preclude the use of medications that lower blood glucose, particularly insulin. Safety regulators, occupational health physicians, and national organisations frequently have to balance the competing priorities of individual freedom against public safety. The International Diabetes Federation launched the first international charter of rights and responsibilities for people with diabetes in 2011,[3] which included a right for social justice balanced with public safety.

Modern treatment for diabetes, with advances in insulin therapy and glucose monitoring, combined with rigorous clinical assessment and review, has allowed stereotypical attitudes towards people with diabetes to be challenged and individual assessment with respect to safety criteria is advocated. Several national authorities (Australia, Canada, the UK, and the USA) have, over the past 2 decades, allowed private pilots with insulin-treated diabetes to fly for leisure.[4] In 2002, Canada became the first country to allow pilots treated with insulin to fly commercial planes, and licences have been granted to a small number of people with insulin-treated diabetes on a case-by-case basis under close supervision.

In 2010, the UK Civil Aviation Authority (CAA) convened an expert committee to review current scientific knowledge and international policies concerning flying. The committee concluded that a protocol for safe flying could be developed and produced, and a first iteration was subsequently refined and published;[5] a summary of the final protocol is given in the appendix. Like other regulatory authorities (eg, the UK Driver and Vehicle Licensing Agency) it was decided that non-invasive monitoring (continuous glucose monitoring [CGM]) did not provide sufficient accuracy; therefore, finger-prick blood glucose monitoring was stipulated as a requirement in the protocol. A number of pilots use CGM systems as an additional aid, but their use is not a requirement of the current protocol. In 2012, the UK CAA began issuing Class 1 medical certificates for commercial flying to pilots with insulin-treated diabetes, and having published the protocol,[5] we started systematic collection of data. In this Comment, we review data from the first 26 pilots who were given certification and monitored using this protocol between May, 2012, and March, 2015.

See Online for appendix

The protocol's rigorous oversight and reporting system was created to support the safety case for allowing certification of pilots with insulin-treated diabetes, and to provide evidence for future medical rulemaking. We defined acceptable in-flight blood glucose concentrations and ranges to prompt appropriate specified actions, designated as green (acceptable, >5–15 mmol/L), amber (caution, 4–5 mmol/L and >15–20 mmol/L) and red (immediate action, <4 mmol/L and >20 mmol/L; appendix; figure). Low values required immediate ingestion of 10–15 g of readily absorbable glucose and a recheck of blood glucose concentration after 30 minutes. High values required review of insulin dosing or modification of carbohydrate intake, or both. We undertook 6-monthly clinical review of all Class 1 certified pilots at the UK CAA to ensure stability of their condition and compliance with the protocol. The protocol stipulated that pilots who failed to comply with the surveillance requirements or who demonstrated unacceptable stability of their diabetes would be assessed as unfit to fly; however, none of the pilots assessed met these criteria. All participants gave written consent for the use of their anonymised data for publication.

Up to March 16, 2015, 26 pilots with insulin-treated diabetes had been issued with Class 1 medical certificates. All were men, with a median age of 41 years (IQR 34–47). Most pilots (22 [85%]) had type 1 diabetes, with a median duration of 7·5 years (IQR 4·0–11·8; appendix). The mean duration of follow-up after certification was 19·5 months (SD 7·8). The mean pre-certificate HbA_{1c} was 7·0% (53·1 mmol/mol; 95% CI 49·7–56·5); the mean final follow-up HbA_{1c} was 7·2% (54·8 mmol/mol; 50·9–58·8). A paired t test comparison between average pre-licence and post-licence HbA_{1c} showed no significant change in glycaemic control (p=0·25). 16 (62%) of 26 pilots had exercised their Class 1 licence privileges (the others either had not found jobs as pilots or had applied for certification for non-flying work, such as as simulator instruction). The pilots recorded 8897 pre-flight and in-flight blood glucose values over 4900 h of flight time (appendix). Including pre-flight readings, pilots of short-haul and medium-haul flights (<6 h duration) recorded 7515 (96%) of 7829 blood glucose values as acceptable (green), and pilots of long-haul flights (>6 h duration) recorded 1036 (97%) of 1068 readings as acceptable.

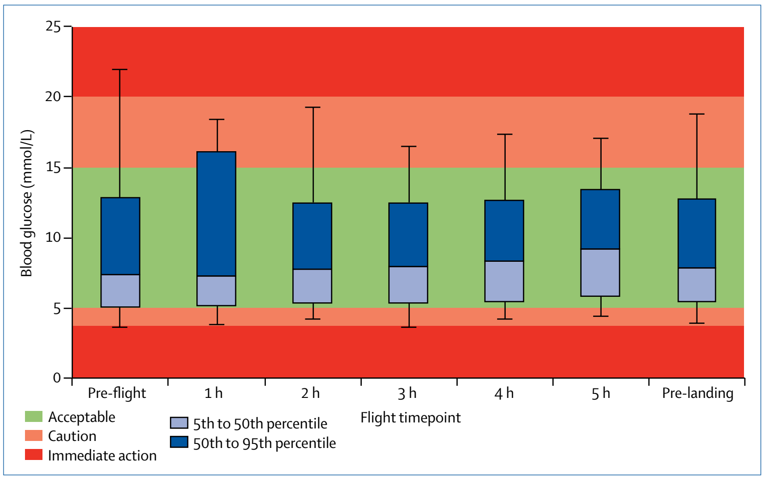

Figure: **Pre-flight and in-flight blood glucose values measured during short-haul and medium-haul flights**
7829 measured glucose values are shown and bars denote maximum and minimum of range.

No difference in the performance of the protocol was observed between short-haul and long-haul flights. Overall, 186 (4%) of 4741 blood glucose readings during flights were out of range; of these, 181 indicated caution (amber) and five immediate action (red; appendix). Of the amber readings, 126 were in the low range and 55 were in the high range. All five red readings were in the hypoglycaemic range (<4 mmol/L), with 3·6 mmol/L the lowest value recorded. These red readings occurred at various stages of flight, were recorded in three individuals during five of 2273 flights, and all pilots had type 1 diabetes. Appropriate action was taken with all out of range readings and no safety events were reported. No pilot incapacitation was associated with a low or high blood glucose concentration in these insulin-treated pilots.

Historically, people with insulin-treated diabetes have been subject to blanket bans from pursuing occupational and leisure activities that include flying, train driving, maritime work, deep sea diving, and working in the armed and emergency services.[2,3] With modern treatment and monitoring capabilities, whether this remains appropriate is questionable. Scarcity of information and data about glycaemic control, particularly in the aviation domain, has prevented detailed assessment of capability for safe flying while receiving treatment with insulin. Our review of implementation of the UK CAA protocol has shown that it has functioned satisfactorily, with no reported safety issues. Some commentators predicted that pilots would allow their blood glucose to run at high levels to avoid hypoglycaemia, jeopardising their glycaemic control and increasing the risk of diabetic complications;[6] however, this premise is not supported by our findings as these certified pilots have maintained good glycaemic control.

The range of blood glucose levels based on a traffic light model was designed to allow caution zones (amber) for preventive action to be taken before any potential loss of performance could occur because of hypoglycaemia or hyperglycaemia.[7] Over 4900 flight hours, very few values outside the green range were recorded; only 19 red readings were recorded, and most of these (14 [74%]) were before flying. In these instances appropriate action was taken, blood glucose was retested, and no safety concerns arose. No adverse feedback from co-pilots without diabetes has been received with respect to the standard operating procedure or in-flight test protocol and verification. The programme has been supported by the largest pilots' trade union in the UK. Although the protocol has placed additional oversight requirements on individual pilots and the UK CAA, these have not caused substantive problems and have provided a high degree of scrutiny.

The current protocol[5] has been shown to be feasible, practical and, to date, safe. This programme represents a major advance in allowing motivated and cooperative individuals with insulin-treated diabetes to perform complex safety-critical occupational duties. This protocol might also be suitable for application in other occupational settings, such as vocational and emergency-service driving.[5] European aircrew regulations were changed in 2016; the protocol was revised and Ireland joined the UK in applying the protocol and collecting data. These findings provide evidence to encourage other countries who presently do not allow pilots using insulin to fly to support application of a protocol to maintain employment of pilots with insulin-treated diabetes.[6]

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