



An Evaluation of the Safety of Pilots With Insulin-Treated Diabetes in Europe Flying Commercial and Noncommercial Aircraft

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OBJECTIVE

The risk of hypoglycemia in people with insulin-treated diabetes has debarred them from certain “safety-critical” occupations, including flying commercial aircraft. This report evaluates the effectiveness of a protocol enabling a large cohort of insulin-treated pilots to fly commercially.

RESEARCH DESIGN AND METHODS

This was an observational study of pilots with insulin-treated diabetes who were granted medical certification to fly commercial and noncommercial aircraft. Clinical details, pre- and in-flight (hourly and 30 min before landing) blood glucose values were correlated against the protocol-specified ranges: green (5–15 mmol/L), amber (low 4–4.9 mmol/L, high 15.1–20 mmol/L), and red (low <4 mmol/L, high >20 mmol/L).

RESULTS

A total of 49 pilots with type 1 (84%) or type 2 (16%) diabetes who had been issued class 1 or class 2 certificates were studied. Median diabetes duration was 10.9 years. Mean HbA_{1c} was 7.2% (55.0 mmol/mol) before certification and 7.2% (55.1 mmol/mol) after certification ($P = 0.97$). Blood glucose values ($n = 38,621$) were recorded during 22,078 flying hours. Overall, 97.69% of measurements were within the green range, 1.42% within the low amber range, and 0.75% within the high amber range. Only 0.12% of readings were within the low red range and 0.02% within the high red range. Out-of-range readings declined from 5.7% in 2013 to 1.2% in 2019. No episodes of pilot incapacitation occurred, and glycemic control did not deteriorate.

CONCLUSIONS

The protocol is practical to implement, and no events compromising safety were reported. This study represents what is, to our knowledge, the most extensive data set from people with insulin-treated diabetes working in a “safety-critical” occupation, which may be relevant when estimating risk in other safety-critical occupations.

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Because people with insulin-treated diabetes are at risk for developing hypoglycemia, they have been debarred from some “safety-critical” occupations, including flying commercial aircraft (1–3). Before the 1990s, it was widely accepted that insulin-treated diabetes signified an unacceptable aeromedical risk for pilots because hypoglycemia of any severity could cause cognitive impairment and potentially incapacitate them. Furthermore, the development of complications of diabetes might also interfere with flying performance (4,5). However, advances in insulin types, formulations, and delivery, and in glucose monitoring, during the past 20 years have greatly improved diabetes care, enabling the restrictions on flying to be reassessed.

Although several countries grant aeromedical certification for leisure purposes to individual pilots with insulin-treated diabetes on a case by case basis (1,4,6), others have campaigned to be licensed to fly commercial aircraft (1). Canada became the first country to permit carefully selected pilots with insulin-treated diabetes to fly commercial aircraft in 2002 (6). In 2010, the U.K. Civil Aviation Authority (CAA) convened an expert committee to review scientific knowledge and subsequently developed a protocol to ensure safe flying by insulin-treated pilots. At that time, glucose monitoring through blood samples obtained by finger stick was stipulated as a requirement for the protocol. Current European Union regulations do not permit the issuance of class 1 medical certificates (required to validate a commercial pilot’s license) or class 2 medical certificates (required to validate a private pilot’s license) to people with insulin-treated diabetes. However, a mechanism exists within the regulations whereby the identification of new medical technologies, medications, or procedures may justify the assessment of whether applicants are fit to fly. This required the development and evaluation of a medical assessment protocol through which a defined number of medical certificates may be issued to pilots, with appropriate limitations.

In 2012 the U.K. CAA created such a protocol and started to issue class 1 medical certificates to insulin-treated pilots (7). Ireland (2015) and Austria (2016) joined with the U.K. in progressing this initiative, and the protocol was approved by the European Aviation Safety Agency.

The protocol demands rigorous oversight, documentation, and systematic collection of data. The results from U.K. pilots who received a certificate from 2012 through March 2015 were published in 2017 (8). However, some commentators have expressed concerns about the practicality of performing in-flight glucose measurements and speculated that the avoidance of low glucose values because of the protocol would lead to suboptimal glycemic control and increase the risk of diabetes complications (3,9). This study collated data from 49 pilots from the U.K., Ireland, and Austria who have been using the protocol since its introduction in 2012. Pre- and in-flight blood glucose monitoring data, collected since 2012, have been evaluated.

RESEARCH DESIGN AND METHODS

Pilots who have received a certificate are required to measure capillary blood glucose using an ISO 9000–accredited meter. Measurements must be made within 2 h before reporting for duty, within the 30 min before takeoff, every hour while flying, and within the 30 min before landing. The pilots must attend a clinical review every 6 months to monitor their diabetes management and their compliance with the protocol.

A “traffic light” system was devised to govern acceptable pre- and in-flight glucose ranges (8), with green signifying “acceptable” (5.0–15.0 mmol/L [90–270 mg/dL]), amber indicating “caution” (low 4.0–4.9 mmol/L [72–88 mg/dL]; high 15.1–20.0 mmol/L [272–360 mg/dL]), and red requiring immediate action (low <4.0 mmol/L [<72 mg/dL]; high >20.0 mmol/L [>360 mg/dL]). Low amber values require the pilot to ingest 10–15 g readily absorbed carbohydrate and remeasure glucose after 30 min. Low red values require the pilot to hand over duties to the copilot or, if flying solo, consider landing as soon as is practical, as well as to ingest 10–15 g readily absorbed carbohydrate and retest capillary blood glucose after 15 min. High readings >15.0 mmol/L (>270 mg/dL) necessitate a review of insulin dosing, modification of planned carbohydrate intake, or both. A high red reading also requires the pilot to immediately transfer duties to the copilot and, if flying solo, the pilot must consider landing as soon as is practical.

Glycemic control was assessed on the basis of glycated hemoglobin (HbA_{1c})

before certification, most recent HbA_{1c}, and flight-related blood glucose values. All blood glucose results were recorded by the individual pilots and entered into their logbooks. The validity of the glucose results of the pilots flying commercial aircraft had to be verified by their copilot. The results were subsequently transferred into an Excel spreadsheet for further analysis, with the pilots’ consent. Analysis of qualitative data and statistical analysis were performed by using Microsoft Excel 2010 and SPSS statistics software version 25 (IBM). Data are expressed, where appropriate, as the mean and SD or median and interquartile range (IQR).

RESULTS

Between May 2012 and December 2019, 49 pilots with insulin-treated diabetes (84% with type 1 diabetes, 16% with type 2 diabetes) participated in the study. Of these pilots, 30 (61%) had been issued a class 1 medical certificate and 19 (39%) a class 2 medical certificate. Their demographic details are shown in Table 1. Most (96%) were men, with a median age of 44 years (IQR 34–56 years) and median diabetes duration of 10.9 years (IQR 7.3–14.9 years). The mean duration of follow-up after issuance of their certificate was 4.3 years (SD 2.3 years). The mean HbA_{1c} before certification was 7.2% ([SD 0.89%] 55.0 mmol/mol [SD 9.74 mmol/mol]), and the final follow-up mean HbA_{1c} was 7.2% ([SD 0.88%] 55.1 mmol/mol [SD 9.57 mmol/mol]). A comparison (paired *t* test) between the mean HbA_{1c} values before and those after certification showed that no significant change had occurred in glycemic control (*P* = 0.96).

Since the protocol was introduced to our pilots, no neuropathy (determined by 10-g monofilament perception at each 6-month medical review) or evidence of nephropathy (measured on the basis of an estimated glomerular filtration rate >60 mL/min/1.73 m² and the absence of clinical evidence of microalbuminuria) has been reported. All pilots had normal visual acuity. Seventeen pilots had evidence of diabetic retinopathy at baseline or at the time of one or more annual retinal screening reviews during the study period. In 5 pilots the background retinopathy had resolved by their next annual retinal review, whereas in 12 pilots the retinopathy persisted but did not progress. One pilot, before

Table 1—Pilot demographics (n = 49)

Age, median years (IQR)	44 (34–56)
Sex	
Male	47 (96)
Female	2 (4)
Pilot certificate class	
1	30 (61)
2	19 (39)
Type of diabetes	
1	41 (84)
2	8 (16)
Duration of diabetes, median years, (IQR)	10.9 (7.3–14.9)
HbA _{1c}	
Before certification	
Percentage (mean %)	7.2 (SD 0.89%)
Mean (SD), mmol/mol	55.0 (9.74)
Most recent (4.3 years after certification)	
Percentage (mean %)	7.2 (SD 0.88%)
Mean (SD), mmol/mol	55.1 (9.57)
Retinopathy	
None	36 (73)
Background retinopathy	12 (25)
Retinopathy/maculopathy	1 (2)

Data are n (%) unless otherwise indicated.

certification, had required photocoagulation for maculopathy in both eyes in 2012 and 2013 but still met the visual acuity standard required for flying.

Data were obtained from 9,189 flights accruing 22,078 flying hours. Of these, 8,036 flights (87.5%; range 3–1,126 flights) and 20,848 h (94.4%; range 13–3,161 h) had been flown by pilots with a class 1 medical certification. Pilots issued a class 2 medical certificate had flown 1,230 h (5.6%; range 3–293 h) over 1,153 flights (12.5%; range 3–541 flights).

Over the 7.5 years of the study, a total of 38,621 capillary blood glucose measurements had been recorded during the duty period. The results of all pre- and in-flight blood glucose measurements for pilots who had been issued a class 1 or class 2 medical certificate are shown in Table 2 and Fig. 1. Overall, 37,729 (97.69%) of all measurements were within the satisfactory green range. A total of 838 (2.17%) were within the cautionary amber range; of these, 550 (65.63% of amber values; 1.42% of all measurements) were low amber and 288 (34.37% of amber values; 0.75% of all measurements) were high amber. A total of 54 measurements (0.14%) were within the immediate-action red range; 48 (88.89% of red values; 0.12% of all measurements) within the low red range (indicating hypoglycemia); six (11.11% of red values; 0.02% of all measurements)

were within the high red range (indicating hyperglycemia).

A total of 15 pilots (31%) recorded blood glucose values in the low red range, 13 of whom (87%) had type 1 diabetes. Subanalysis of the 48 low red readings showed that 34 were recorded before flight, representing 0.21% of preflight measurements and 0.09% of all capillary blood glucose values recorded. Of these 34 low values, 25 were recorded by 10 pilots with a class 1 certificate and represent 0.17% of class 1 preflight capillary blood glucose measurements. The other nine values were recorded by two pilots with a class 2 medical certificate, representing 0.55% of class 2 preflight capillary blood glucose measurements.

Only 14 of the 48 low red values were recorded while in flight. This represents 0.07% of in-flight measurements and 0.04% of all capillary blood glucose values analyzed. A total of 13 of these values were recorded by eight class 1–certified pilots while flying commercial aircraft and one by a pilot with a class 2 certificate. These 14 measurements in the low glucose range represent 0.06% of in-flight low red measurements for each class. This equates to pilots having a blood glucose value <4.0 mmol/L (<72 mg/dL) during 0.16% of commercial flights over the study period. Five pilots recorded only a single low red

reading, two pilots each had two low red measurements, and a single pilot reported four values <4.0 mmol/L (<72 mg/dL). The individual who recorded four low red readings was responsible for accruing 3,161 flying hours over 1,126 separate flights—significantly more flying hours than any other pilot had accrued over the study period.

The 14 low red in-flight values were recorded at various stages of flight on 14 separate flights. These are represented with red asterisks in Fig. 1. The lowest capillary blood glucose recorded in flight was 3.1 mmol/L (56 mg/dL), and all the recorded episodes <4.0 mmol/L (<72 mg/dL) were self-treated. There were no episodes of severe hypoglycemia (requiring help for recovery).

Three pilots, all of whom had type 1 diabetes, had recorded high red readings. Subanalysis of the six high red measurements showed that four had been recorded before flight, representing 0.02% of preflight measurements and 0.01% of all capillary blood glucose measurements. Three of these values were recorded by a single pilot holding a class 1 certificate, and one was recorded by a class 2–certified pilot. Only two of the six high red values were recorded during flight: one by a class 1–certified pilot and one by a class 2–certified pilot (0.01% of all blood glucose values recorded). Both in-flight high red measurements were recorded during the 30 min before the flight landed. The highest recorded in-flight value was 21.1 mmol/L (380 mg/dL).

Appropriate action was taken by the pilots for all out-of-range measurements. In particular, rapidly absorbed carbohydrate was ingested by the pilots in order to correct all low readings, and no adverse events were reported. Of the 48 low red readings, 39 (81%) were within the satisfactory green range by the time of the next measurement, and 5 (10%) were within the cautionary amber range at the subsequent reading before being restored to within the green range. Four (8%) were recorded within the 30-min period before landing, so after carbohydrate was ingested no subsequent blood glucose readings were recorded during that duty period. In relation to the six high red measurements, one reading was within the satisfactory green range by the subsequent reading, two readings were recorded

Table 2—Total, preflight, and in-flight capillary blood glucose measurements for all 49 pilots (classes 1 2), recorded between May 2012 and December 2019

Capillary glucose, mmol/L	Measurements, n (%)
Total	
<4.0	48 (0.12)
4.0–4.9	550 (1.42)
5.0–15.0	37,729 (97.69)
15.1–20.0	288 (0.75)
>20.0	6 (0.02)
Total	38,621 (100)
Preflight	
<4.0	34 (0.21)
4.0–4.9	291 (1.78)
5.0–15.0	15,918 (97.26)
15.1–20.0	119 (0.73)
>20.0	4 (0.02)
Total	16,366 (100)
In flight	
<4.0	14 (0.07)
4.0–4.9	259 (1.16)
5.0–15.0	21,811 (98.00)
15.1–20.0	169 (0.76)
>20.0	2 (0.01)
Total	22,255 (100)
Outside of green range (<5.0 or >15.0)	892 (2.31)
Within amber range (4.0–4.9 or 15.1–20.0)	838 (2.17)
Preflight	410 (1.06)
In flight	428 (1.11)
Within red range (<4.0 or >20.0)	54 (0.14)
Preflight	38 (0.10)
In flight	16 (0.04)

Fig. 2. The out-of-range readings decreased from 5.7% in 2013 to 1.2% in 2019. The greatest annual decline observed was in the percentage of low amber readings, which fell from 5.0% in 2013 to 0.7% in 2019. High amber values, which initially were 0.3% in 2013, increased to 1.1% in 2014 before falling thereafter to 0.5% in 2019. Low red readings were relatively unchanged (0.2% in 2013 and 0.1% in 2019), and high red values were completely absent by 2017. After 2016, no capillary blood glucose measurements above 20.0 mmol/L (360 mg/dL) were recorded by pilots, either before or during flight.

CONCLUSIONS

Because of the potentially devastating consequences of an accident involving a commercial aircraft conveying passengers, air travel requires strict measures to ensure a very high standard of safety. Pilots of commercial airplanes are therefore subjected to rigorous medical screening and review, and they are debarred from flying because of the presence of some medical disorders, which until recently included insulin-treated diabetes. The main risk is the potential for developing hypoglycemia, but complications of diabetes could also interfere with flying performance. Following the policy of Canada to allow pilots with insulin-treated diabetes to fly commercial aircraft, the U.K. CAA began issuing class 1 medical certificates to such pilots in 2012, on the basis of a protocol for safe

during the same preflight duty and the pilot’s blood glucose had returned to the green range by the first in-flight recording, and two were obtained within the 30 min before landing the aircraft. One preflight high red value in a class 2–certified pilot was caused by the pilot

inadvertently consuming a drink containing a high sugar content. None of the pilots were incapacitated for any reason during the 22,078 flying hours.

Data were analyzed for each year of the study. The results per year of all out-of-range measurements are shown in

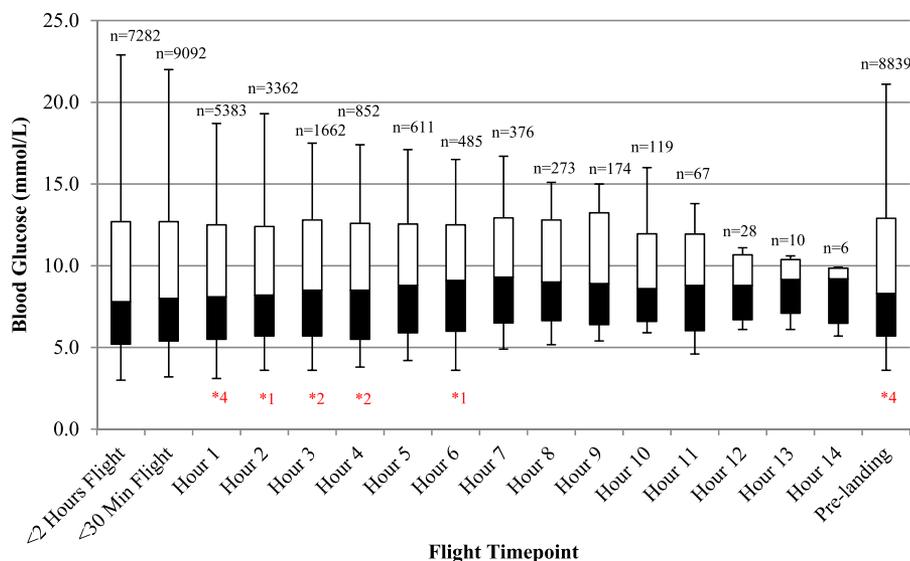


Figure 1—Pre- and in-flight blood glucose measurements for all pilots. Whiskers indicate the maximum (top) and minimum (bottom) values. The boxes show values in the 5th to 50th percentiles (black) and the 50th to 95th percentiles (white). *The number of in-flight low red values.

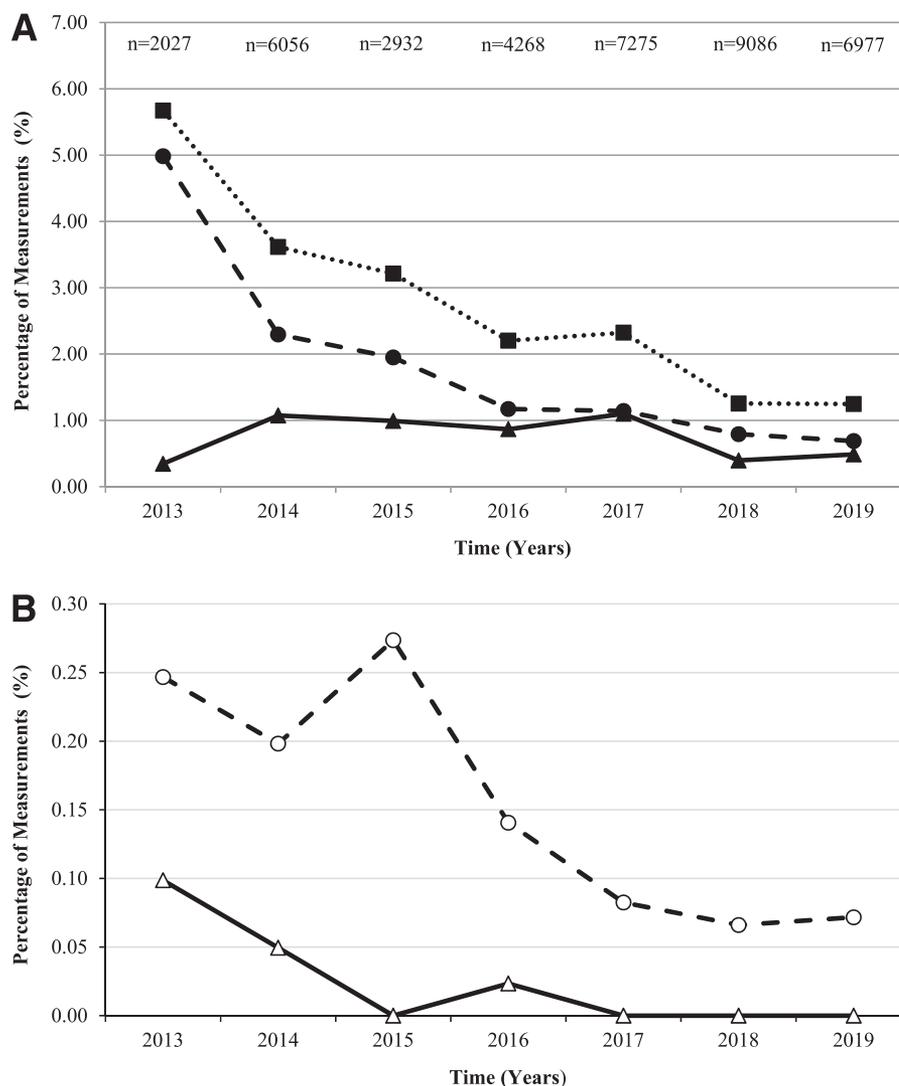


Figure 2—A: Overall rate of readers outside of the green range for all pilots per year (dotted line with black squares), and the rates of low amber values (4.0–4.9 mmol/L) (dashed line with black circles) and high amber values (15.1–20.0 mmol/L) (solid line with black triangles). B: Rates of values in the red range: low (<4.0 mmol/L) (dashed line with white circles) and high (>20.0 mmol/L) (solid line with white triangles).

flying. The outcomes of U.K. pilots with insulin-treated diabetes who received a certificate from May 2012 until March 2015 were reported in 2017 (8). Since adoption of the protocol by Ireland and Austria, it now forms part of the European ARA.MED 330 protocol under the auspices and guidance of the European Aviation Safety Agency. This study has extended the initial assessment (8) by collecting a much larger quantity of data on glucose monitoring by insulin-treated pilots in relation to flying. No episodes of incapacitation or any safety problems were reported during the 7.5 years of the study, and the protocol was shown to be feasible, practical, and easily understood by copilots. The application of a “traffic light” system has alerted pilots

when to take preventive action to avoid any impairment in performance and decision making resulting from unduly high or low glucose values. To our knowledge, this study also represents the systematic collection of the largest amount of blood glucose data from among a cohort of people with insulin-treated diabetes undertaking an important safety-critical occupation. This protocol may be transferable to those in other safety-critical occupations, such as bus drivers and maritime workers.

The negative impact of hypo- and hyperglycemia on cognitive and motor functions and on mood is well documented (10–13). Mental efficiency and speed of performance are rapidly reduced at both extremes of blood glucose

(10–13), and cognitive performance becomes impaired at a blood glucose level of 2.6–3.0 mmol/L (47–54 mg/dL) and above 15.0 mmol/L (270 mg/dL) (10–13). Although blood glucose at or below 3.0 mmol/L (54 mg/dL), which is now the accepted international definition of hypoglycemia (14), would be very likely to have an adverse effect on flying skills and performance, some degree of cognitive impairment could commence at values above this, so 4.0 mmol/L (72 mg/dL) was chosen as the threshold for intervention (8). The data presented in this study indicated a very small percentage of readings outside the satisfactory green range (2.3%), with the lowest in-flight blood glucose measurement being 3.1 mmol/L (56 mg/dL) and the

highest, 21.1 mmol/L (380 mg/dL). Scrutiny of the data found that appropriate action had been taken by the pilots for all out-of-range measurements, which were corrected into the safety zone.

Although the study depended on accuracy of reporting by individual pilots, all in-flight blood glucose values recorded were verified by the copilot, who would not usually be known to the first pilot, and were spoken into the flight voice recorder. Both pre- and in-flight results documented in the flight logbooks were verified against the pilot's blood glucose meter readings at the six-month medical reviews by an independent medical examiner in order to ensure the accuracy of the recorded data. A copy of the logbook and a download from the glucose meter are retained in the pilot's aviation medical notes.

There were concerns that pilots might allow their blood glucose to remain within a higher range in order to avoid any risk of hypoglycemia (3,9). The results do not support such a premise. Diabetes control, as measured by HbA_{1c}, did not deteriorate over the period of the study, which had a mean follow-up period of 4.3 years from certification. As a group, pilots are highly trained and well motivated, and they generally manage their diabetes with considerable care. They are accustomed to frequently monitoring instruments during flight and had no problem accommodating additional glucose monitoring. In this study they were able to successfully balance close adherence to the protocol with maintenance of excellent long-term glycemic control. Another facet of the protocol that should be noted is the ongoing surveillance for micro- and cardiovascular complications, which could adversely affect flying skills. Clinical surveillance has not identified the development of any new clinically significant micro- or macrovascular diabetes-related complications within the limited period of the study.

Although several countries issue certificates to permit pilots to fly for leisure, to our knowledge no studies have evaluated the safety and the performance of any of the existing protocols. A study from Israel described the use of a different self-monitoring protocol by five military aviators, who measured blood glucose half an hour before takeoff and every 2 h on long flights, but neither out-

of-range levels nor whether any remedial action was required were reported (15). Similarly, results from insulin-treated pilots certified to fly commercially in Canada have been reported only as personal abstracts at aeromedical meetings; to our knowledge no formal evaluation of blood glucose levels, nor the frequency of out-of-range values, has been published (5,16).

When the current protocol was devised in 2010 in the U.K., it was decided that noninvasive continuous glucose monitoring (CGM) was not sufficiently accurate and could not be relied on to meet safety standards (7). However, subsequent trials of real-time CGM devices have demonstrated that their usage leads to an increase in the time in range and reduces the number and severity of hypoglycemia episodes, and the time spent in hypo- and hyperglycemia (6,17). This technology has been suggested as being applicable for use by pilots on the flight deck (6,17). Many of the pilots in this study were using CGM devices in addition to finger sticks to test blood samples during duty periods, as stipulated by the protocol. This may partly explain why the number of out-of-range values and the variability of glucose levels during flight have declined considerably since the widespread introduction and availability of noninvasive CGM systems. Further research on the use of real-time CGM during flying is desirable, and CGM is being formally evaluated in parallel to the current protocol, involving both commercial and private pilots (clinical trial reg. no. NCT04225455, clinicaltrials.gov). Furthermore, incorporating recent guidance concerning recommended glucose ranges obtained from CGM and including new internationally agreed definitions of hypoglycemia could lead to modifications of the current protocol, which is based on monitoring glucose by using meters (18). Proof of the value of CGM technology could play a fundamental role in persuading aviation authorities worldwide to adopt more flexible licensing policies for pilots with insulin-treated diabetes. The U.S. Federal Aviation Authority has recently acknowledged the value of CGM in this context and has announced that the U.S., like Canada, the U.K., Ireland, and Austria, will now allow pilots with insulin-treated diabetes to fly commercial aircraft (19).

This study represents a systematic collection of what is to our knowledge the most extensive data set from people with diabetes treated with insulin who work in a "safety-critical" occupation, on which future protocols may be based. The protocol for insulin-treated pilots that is currently being used by the U.K., Ireland, and Austria is practical and feasible to operate and has performed well, with no reports of pilot incapacitation during flights. These data should help to inform the debate about whether people with insulin-treated diabetes can perform some safety-critical occupations, and similar safety protocols may be devised and tested for this purpose.

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Duality of Interest. B.M.F. has served as a member of an expert panel of the U.K. Civil Aviation Authority (CAA) and has received honoraria for lectures from Eli Lilly and Company, Novo Nordisk, Sanofi, Abbott, Roche, and Merck Sharp & Dohme. K.M.S. has served as a contracted medical consultant (clinical assessments) and independent advisor to the U.K. CAA, and has previously served on specialist advisory boards for Abbott, GlaxoSmithKline, Merck, Novo Nordisk, Novartis, Pfizer, Sanofi, and Laboratoires Servier. S.R.H. has served as a member of an expert panel of the U.K. CAA; has consulted for Novo Nordisk, Eli Lilly and Company, and Zealand Pharma (for which his institution has received remuneration); and has served on speaker panels for Novo Nordisk and AstraZeneca (for which he has received personal remuneration). G.K. is contracted as an independent advisor to Austro Control and has received research funding and speaker and advisory board honoraria from AstraZeneca, Abbott, Amgen, Eli Lilly and Company, Novartis, Novo Nordisk, and Sanofi. 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, Mundipharma, and Sanofi. D.L.R.-J. is contracted as an independent advisor to the U.K. CAA and has received research funding and advisory board honoraria from AstraZeneca, Dexcom, Eli Lilly and Company, Novartis, Novo Nordisk, and Sanofi. No other potential conflicts of interest relevant to this article were reported.

Author Contributions. G.L.G. and J.L.H. designed the study, collected and analyzed data, evaluated the results, and prepared the manuscript. S.J.M., E.J.H., T.P.G., V.H., G.K., and G.A.R. collected clinical data and evaluated the manuscript. B.M.F., K.M.S., and S.R.H. interpreted and evaluated clinical data and prepared the manuscript. D.L.R.-J. designed the study, collected clinical data,

analyzed data, and prepared and evaluated the manuscript. D.L.R.-J. is the guarantor of this work and, as such, had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

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