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Blood glucose monitoring by insulin-treated pilots of commercial and private aircraft: An analysis of out-of-range values

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Abstract

Aim: To examine blood glucose measurements recorded as part of the diabetes protocol operated by the UK, Ireland and Austria, which allows commercial airline pilots with insulin-treated diabetes to fly.

Methods: An observational study was conducted in pilots with insulin-treated diabetes, granted medical certification to fly commercial or noncommercial aircraft, who recorded pre-flight and hourly in-flight blood glucose measurements. These values were correlated to a traffic light system (green 5.0 to 15.0 mmol/L; amber 4.0 to 4.9 mmol/L and 15.1 to 20.0 mmol/L; and red <4.0 mmol/L or >20.0 mmol/L) and studied for trends in glucose concentrations, time course within flight and any consequences. Pilot demographics were also analysed.

Results: Forty-four pilots (90%) recorded one or more blood glucose value outside the green range during the 7 years of the study. Pilot age, diabetes type and duration, and follow-up period were comparable among subgroups, and mean glycated haemoglobin did not differ before and after certification in a way which would indicate poorer glycaemic control in any subgroup. A total of 892 blood glucose values (2.31%) were outside the green range, with half reported in-flight at various time intervals. There were 48 (0.12%) low red range values recorded, 14 (0.04%) of which occurred in-flight; all but four were restored to within the green range by the time of the next measurement. Appropriate corrective action was taken for all out-of-range values, with no reports of pilot incapacitation from any cause.

Conclusions: The traffic light system appears effective in identifying and reducing the frequency and severity of out-of-range values.

KEYWORDS

clinical physiology, glycaemic control, hypoglycaemia, insulin therapy, observational study

1 | INTRODUCTION

People with diabetes who require treatment with insulin are usually precluded from safety-critical occupations because of the potential risk of hypoglycaemia, which can cause unpredictable incapacitation.[1,2] In addition, progressive microvascular and macrovascular diabetic complications, such as retinopathy or neuropathy, can compromise functional ability[2] and may impair pilot performance over time.[1] Before the 1990s, international aviation regulators considered that pilots with insulin-treated diabetes posed too great an aeromedical risk, so they were not licensed to fly commercial aircraft. Advances in insulin pharmacokinetics and delivery and in glucose monitoring technologies have allowed these policies to be challenged. While several countries issued aeromedical certification solely for leisure purposes,[1,3,4] it was not until 2002 that the first commercial pilot treated with insulin was certified to fly by the Canadian aviation authority.[1,3,4]

With the advice of an expert committee, the UK Civil Aviation Authority (CAA) created a protocol and started issuing class 1 medical certificates to insulin-treated commercial pilots in 2012.[5] In 2014, a joint protocol by the United Kingdom and Ireland was approved by the European Aviation Safety Agency (EASA) as a research project to certify insulin-treated pilots. Austria joined the protocol in 2016 with the approval of the EASA. The development and implementation of this protocol has been described previously.[6] The protocol involves documentation, collection of data and clinical oversight of all pilots with insulin-treated diabetes who apply for medical certificates used to validate commercial and private pilot's licences. All pilots are required to measure capillary blood glucose, obtained by fingerprick, before and during each flight, and to use a traffic light system of ranges to determine any further action.[6] The safety data from this cohort have been analysed and reported previously and represent the only systematic collection of such data from a safety-critical occupation that allows operatives treated with insulin.[7] In the present study we evaluated all recorded blood glucose measurements that were out of range to ascertain preceding and subsequent glucose concentrations, their time course during flight, and any consequences in order to be confident that the amber and red action ranges were appropriate to prevent any form of incapacity. In addition, the characteristics of pilots recording out-of-range results were examined.

2 | METHOD

Pilots with insulin-treated diabetes holding a class 1 medical certificate (required to validate a commercial pilot's licence) or a class 2 medical certificate (required to validate a private pilot's licence) must perform a series of capillary blood glucose measurements, obtained by fingerprick, using an ISO 9000-certified device. Pre-flight glucose measurements 1 hour before reporting for duty or 2 hours before commencing a flight are mandatory and must be repeated within 30 minutes before take-off to confirm that blood glucose is stable and within range. Once airborne, measurements must be performed every hour for the duration of the flight and within the 30 minutes before landing, with additional glucose testing if a pilot experiences symptoms that suggest a high or low blood glucose concentration.

The traffic light system for blood glucose interpretation was used to determine acceptable and unacceptable blood glucose ranges and provide direction for appropriate corrective action where necessary (Appendix S1).[5,6] Glucose values between 5.0 and 15.0 mmol/L (90-270 mg/dL) are considered to be satisfactory and are coded green, with no action being required. Values between 4.0 and 4.9 mmol/L (72-89 mg/dL) and between 15.1 and 20.0 mmol/L (271-360 mg/dL) are coded amber to indicate caution and the potential need for intervention, and a glucose value of <4.0 mmol/L (<72 mg/dL) or >20.0 mmol/L (>360 mg/dL) is coded red and requires immediate action. A low value (<5.0 mmol/L; <90 mg/dL) requires the pilot to ingest 10 to 15 g of rapidly absorbed, fast-acting carbohydrate and to retest blood glucose after 30 minutes. A low red value <4.0 mmol/L (<72 mg/dL) also requires the pilot to demit flying operations to the co-pilot or, if flying solo, (private pilots only), to consider landing as soon as practicable. A pilot flying with other crew must wait for 45 minutes after the blood glucose has returned to within the green range before resuming duties. A blood glucose measurement >15.0 mmol/L (>270 mg/dL) in the high amber range requires the pilot to review their insulin dose schedule and planned carbohydrate intake. If the blood glucose level is in the high red range (>20.0 mmol/L; >360 mg/dL) the pilot must demit duties to the co-pilot or, if flying solo, consider landing as soon as is practicable.

The protocol also stipulates that all commercial pilots must brief their co-pilot about the testing regimen and the action required for out-of-range values before each flight. Every blood glucose measurement must be cross-checked with the co-pilot and read aloud to be captured by the cockpit voice recorder. The glucose readings and any action taken for out-of-range values must also be recorded in the pilot's flying hours logbook for compliance monitoring.

Each commercial pilot must undergo a medical review with a CAA Diabetes Specialist every 6 months (12 months for private pilots). During each assessment, the test glucose meter is reviewed against the logbook entries to ensure protocol compliance. Glycaemic control is evaluated using glycated haemoglobin (HbA1c), which is measured every 6 months, along with plasma lipids, urea and creatinine. An assessment of hypoglycaemia awareness is undertaken using the Gold score[8] and a recording of glucose level at which symptoms develop is made. A systems examination is also performed, including assessment for neuropathy using a 10-g monofilament. Blood pressure and weight are measured, and the results of annual retinal screening are reviewed.

All pre- and in-flight capillary blood glucose measurements obtained since the protocol commenced were transferred to an Excel spreadsheet and analysed using Microsoft Excel 2010 and SPSS statistics software version 25 (IBM) with each pilot's consent. Data are expressed either as mean and standard deviation (SD) or median and interquartile range (IQR), as indicated. Statistical significance is demonstrated using the *t*-test.

TABLE 1 Demographic details of all 49 pilots analysed in each blood glucose range subgroup

	Low red (<4.0 mmol/L [<72 mg/dL]), n = 15[a]	Low amber (4.0-4.9 mmol/L [72-89 mg/dL]), n = 39[b]	All green (5.0-15.0 mmol/L [90-270 mg/dL]), n = 5[c]	High amber (15.1-20.0 mmol/L [271-360 mg/dL]), n = 29[d]	High red (>20.0 mmol/L [>360 mg/dL]), n = 3[e]	All pilots, n = 49
Age, median years (IQR)	53 (46-57)	42 (34-54)	55 (52-58)	44 (34-56)	44 (37-44)	44 (34-56)
Sex						
Male, n (%)	15 (100)	38 (97)	4 (80%)	29 (100)	3 (100)	47 (96)
Female, n (%)	0	1 (3)	1 (20%)	0	0	2 (4)
Medical certificate						
Class 1, n (%)	13 (87)	27 (69)	1 (20%)	19 (66)	2 (67)	30 (61)
Class 2, n (%)	2 (13)	12 (31)	4 (80%)	10 (34)	1 (33)	19 (39)
Type of diabetes						
1, n (%)	13 (87)	33 (85)	3 (60%)	26 (90)	3 (100)	41 (84)
2, n (%)	2 (13)	6 (15)	2 (40%)	3 (10)	0	8 (16)
Diabetes duration[f], median years (IQR)	11.3 (8.6-15.0)	11.3 (6.8-14.4)	7.5 (7-14.9)	11.9 (8.6-16.8)	11.3 (10.1-11.6)	10.9 (7.3-14.9)
HbA1c mean						
Pre-certification, mmol/mol ± SD (%)	54.5 ± 9.6 (7.1%)	54.4 ± 8.8 (7.1%)	53.6 ± 8.7 (7.1%)	57.1 ± 10.4 (7.4%)	55.7 ± 7.4 (7.2%)	55.0 ± 9.74 (7.2%)
Post-certification, mmol/mol ± SD (%)	57.3 ± 9.2 (7.4%)	55.2 ± 9.7 (7.2%)	49.4 ± 7.4 (6.7%)	57.7 ± 9.8 (7.4%)	58.0 ± 7.5 (7.5%)	55.1 ± 9.57 (7.2%)
Paired *t*-test	0.2557	0.5387	0.1861	0.7217	0.1181	0.9606
Duration of follow-up, median years (IQR)	6.6 (5.0-6.8)	5.0 (2.7-6.7)	3.6 (1.6-3.7)	5.3 (2.9-6.7)	6.2 (5.6-6.4)	4.3 (7.3-14.9)

[a]Fifteen of the 49 pilots recorded values in the low red range.
[b]Thirty-nine of the 49 pilots reported values in the low amber range.
[c]Five pilots reported no values outside of the desired green range.
[d]Twenty-nine of the pilots recorded readings in the high amber range.
[e]Three of the 49 pilots documented values in the high red range. Most pilots reported out-of-range values in more than one subcategory, so their demographic details were analysed in all relevant subgroups.
[f]Duration of diabetes from diagnosis to December 31, 2019.
Abbreviations: HbA1c, glycated haemoglobin; IQR, interquartile range.

For the purpose of this study the term "duty period" described the pre-flight window commencing 1 hour before a pilot reports for duty, or the 2 hours before take-off and the full duration of the flight until the aircraft has landed, for both commercial and private pilots.

3 | RESULTS

Data were collated from 49 pilots with insulin-treated diabetes, who had been issued with a class 1 or class 2 medical certificate between May 2012 and December 2019. All results are shown in Tables 1 and 2 and Figures 1 to 3. A total of 38 621 duty period capillary blood glucose values were recorded, with 37 729 readings (97.69%) being within the satisfactory green range of 5.0 to 15.0 mmol/L (90-270 mg/dL), while 892 values (2.31%) were outside the green range.

Forty-four (90%) of the 49 pilots recorded one or more blood glucose values outside the green range during the 7.5 years of the study. Fifteen pilots (31%) recorded values in the low red range (<4.0 mmol/L [<72 mg/dL]), 39 pilots (80%) reported low amber range values (4.0-4.9 mmol/L [72-89 mg/dL]), 29 pilots (59%) recorded high amber range values (15.1-20.0 mmol/L [271-360 mg/dL]) and three pilots (6%) documented one or more high red range readings (>20.0 mmol/L [>360 mg/dL]). All pilots who recorded low red values also reported values in the low amber range, and the three pilots who recorded high red readings also documented values in the high amber range. Nearly half of all pilots (49%) documented both high and low out-of-range values. Only five pilots reported having no values outside of the desired green range. Demographic data for all pilots reporting out-of-range measurements within each subcategory are shown in Table 1.

Across the four out-of-range subcategories most of the pilots had type 1 diabetes and held a class 1 medical certificate. No pilots with type 2 diabetes recorded a value >20.0 mmol/L (>360 mg/dL). The subgroup of pilots recording low red values had the highest percentage (87%) of pilots holding a class 1 medical certificate and the highest median (IQR) age of 53 (46-57) years. Diabetes duration and duration of follow-up were comparable between all four out-of-range

TABLE 2 Number of out-of-range measurements and frequency (%) with which they occurred for each of the specified blood glucose ranges in relation to the flight time

	Low red (<4.0 mmol/L), n (%)	Low amber (4.0-4.9 mmol/L), n (%)	High amber (15.1-20.0 mmol/L), n (%)	High red (>20.0 mmol/L), n (%)	Total out of range, n (%)
Total out-of-range values	48 (5.4)	550 (61.6)	288 (32.3)	6 (0.7)	892 (100)
Total pre-flight	34 (70.8)	291 (52.9)	119 (41.3)	4 (66.7)	448 (50.2)
<2 hours before take-off	24 (50.0)	152 (27.6)	48 (16.7)	2 (33.3)	226 (25.3)
<30 minutes before take-off	10 (20.8)	139 (25.3)	71 (24.7)	2 (33.3)	222 (24.9)
Total in-flight	14 (29.2)	259 (47.1)	169 (58.7)	2 (33.3)	444 (49.8)
Hour 1	4 (8.3)	98 (17.8)	46 (16)	0	148 (16.6)
Hour 2	1 (2.1)	45 (8.2)	27 (9.4)	0	73 (8.2)
Hour 3	2 (4.2)	18 (3.3)	14 (4.9)	0	34 (3.8)
Hour 4	2 (4.2)	14 (2.5)	7 (2.4)	0	23 (2.6)
Hour 5	0	7 (1.3)	2 (0.7)	0	9 (1.0)
Hour 6	1 (2.1)	5 (0.9)	3 (1.0)	0	9 (1.0)
Hour 7	0	1 (0.2)	4 (1.4)	0	5 (0.6)
Hour 8	0	0	1 (0.3)	0	1 (0.1)
Hour 9	0	0	0	0	0
Hour 10	0	0	1 (0.3)	0	1 (0.1)
Hour 11	0	1 (0.2)	0	0	1 (0.1)
Hour 12	0	0	0	0	0
Pre-landing	4 (8.3)	70 (12.7)	64 (22.2)	2 (33.3)	140 (15.7)

subgroups. No statistical difference was found in mean HbA1c before certification and after an average of 4.3 years of follow-up in any of the subgroups, suggesting that no change in the quality of glycaemic control had occurred to account for the abnormal glucose values.

The five pilots who recorded all blood glucose values in the green range were older, with a median (IQR) age of 55 (52-58) years, had a significantly shorter median (IQR) duration of diabetes of only 7.5 (7-14.9) years, and a shorter median (IQR) period of follow-up, 3.6 (1.6-3.7) years.

All out-of-range values reported are shown in Table 2. The most common out-of-range values recorded were within the low amber range (61.6%), with a further third (32.3%) within the high amber range. There were 48 (5.4%) out-of-range values below 4.0 mmol/L (<72 mg/dL), that is, in the low red range, and only six (0.7%) values in the hyperglycaemic range, above 20.0 mmol/L (>360 mg/dL). Of the 892 out-of-range values documented, 50.2% were recorded within the pre-flight period, half of which (24.9%) occurred in the final 30 minutes before take-off. Figure 1 (Panels A-C) shows the serial measurements of blood glucose concentrations in individual pilots after an out-of-range value had been recorded within the final 30 minutes before take-off. Thirty-four (70.8%) of the 48 low red range values were recorded pre-flight, of which 10 (30%) were reported within the final 30 minutes before take-off. The lowest blood glucose concentration recorded during a duty period was 3.0 mmol/L (54 mg/dL). This occurred within the 2 hours before commencing flight; with corrective measures, blood glucose increased to 8.8 mmol/L (158 mg/dL) before take-off. With the exception of one pre-flight low red value which was corrected into the amber range, all were corrected to within the acceptable green range before take-off.

The 49.8% of out-of-range readings that were recorded in-flight occurred at various times during flight, as detailed in Table 2. One-third (33.3%) were reported during the first hour of the flight, with a further third (31.5%) recorded in the final 30 minutes of the flight (pre-landing). The flight duration was analysed for all 9189 flights. Just over half (51.8%) of the out-of-range values recorded in-flight occurred during short-haul flights of 3 hours or less and during private flying (3.0% of all short-haul flights); 31.8% were reported during medium-haul flights (3-6 hours; 15.0% of all medium-haul flights); and 16.4% were documented during long-haul flights of over 6 hours' duration (13.9% of all long-haul flights). Only 14 in-flight values were within the low red range. These were recorded within the first 6 hours of the flight (71.4%) or within 30 minutes before landing (28.6%). Four were reported on short-haul flights, six on medium-haul flights and four on long-haul flights. The lowest in-flight blood glucose concentration was 3.1 mmol/L (56 mg/dL), and this was recorded within 1 hour of take-off. Figure 2 (Panels A-C) displays the trends in blood glucose concentration before and after out-of-range values had been recorded in-flight.

Scrutiny of the 48 glucose values in the hypoglycaemic range ascertained that, despite a total of 550 low amber readings being documented, only three of the low red range values had directly followed a low amber value. Twenty-four were the first value recorded in the duty period. The remaining 21 all followed measurements within the green range value. All but four of the 48 low red

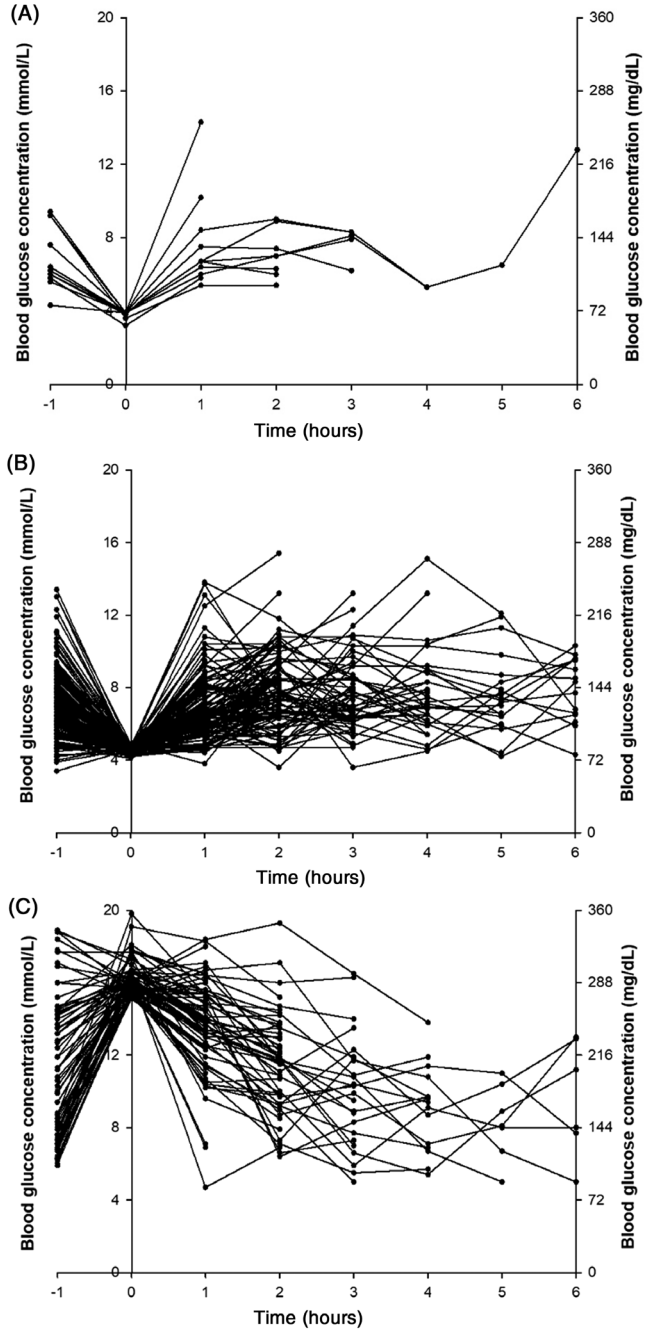

FIGURE 1 Scatter graphs showing serial capillary blood glucose concentrations after those recorded in the 30 minutes before the flight: (A) a low red value (<4.0 mmol/L); (B) a low amber value (4.0-4.9 mmol/L); and (C) a high amber value (15.1-20.0 mmol/L)

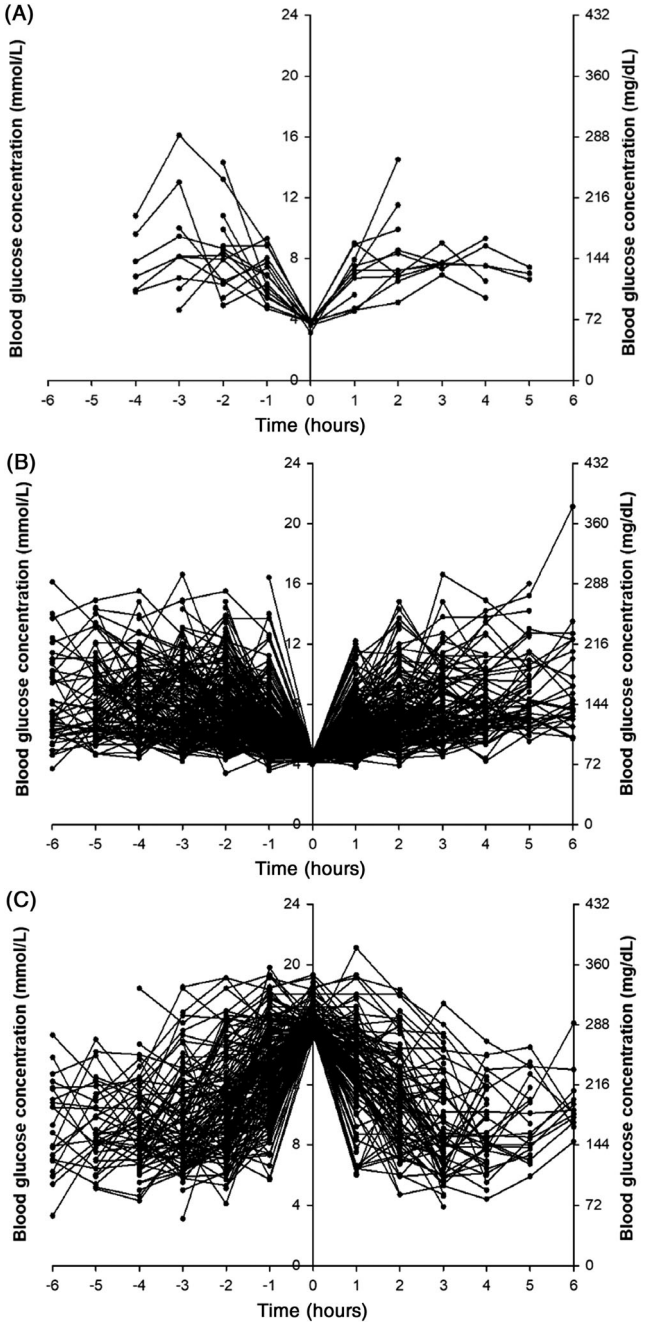

FIGURE 2 Scatter graphs showing capillary blood glucose concentrations recorded in flight before and after: (A) a low red value (<4.0 mmol/L), (B) a low amber value (4.0-4.9 mmol/L), and (C) a high amber value (15.1-20.0 mmol/L)

values were corrected satisfactorily to within the green range by the time of the next measurement. Four other low red glucose values increased to within the low amber range before entering the safe green range. Only six blood glucose values in the high red hyperglycaemic range were recorded throughout the study period. Four occurred within the 2-hour pre-flight period, two of which were within 30 minutes before take-off. The two in-flight high red readings were both recorded within the 30 minutes before landing, one on a short-haul flight and the other on a medium-haul flight.

The rates of change in mean blood glucose concentrations, before and after low red range values, and low amber range values, were analysed and are shown in Figure 3. Blood glucose concentrations were observed to have fallen more rapidly and from a higher concentration before a low red value than before a low amber reading. An unpaired *t*-test found a statistically significant difference in the decline of the mean glucose concentration in the final hour before the out-of-range reading was recorded ($P = 0.0143$). The recovery was also more rapid after a low red range value and reached a higher

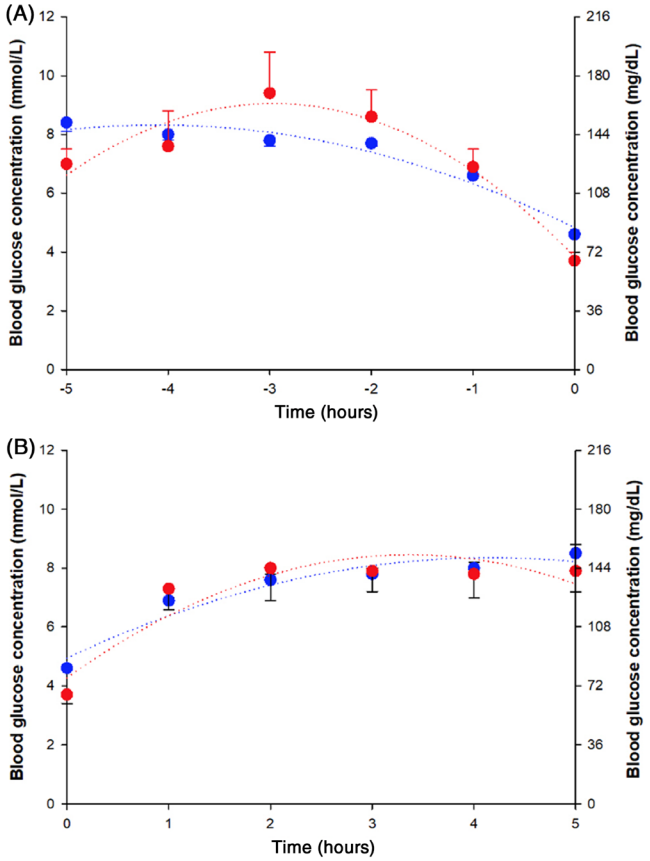

FIGURE 3 Rate of fall (A) and recovery (B) in mean blood glucose concentration in relation to a low red range value (<4.0 mmol/L; red) or a low amber range value (4.0-4.9 mmol/L; blue) recorded anytime during the duty period with polynomial trend lines and error bars

blood glucose concentration after 2 hours than after correcting a low amber glucose value. A statistically significant difference was observed in the speed of recovery of the mean blood glucose concentration within the first hour after recording a low red value compared to recovery from a low amber value ($P = 0.0003$). No statistical differences were found either in the rates of fall or of recovery of the mean blood glucose concentrations for earlier or later time periods.

Appropriate corrective action was taken by all pilots for all out-of-range blood glucose concentrations that were recorded, and no episodes of pilot incapacitation (from any cause) were reported.

4 | DISCUSSION

To ensure the highest safety standards, the aviation industry has developed a multitude of safety measures, which include repeated assessment of a pilot's medical fitness to confirm functional ability and estimate incapacity risk. Some medical disorders prohibit pilots from obtaining a medical certificate to validate a pilot's licence and, until recently, this included insulin-treated diabetes, primarily because of the potential risks associated with hypoglycaemia. Hypoglycaemia is the most common side effect of insulin therapy and the principal barrier to achieving optimal glycaemic control.[9,10] A commonly used classification established in the American Diabetes Association/European Association for the Study of Diabetes position statement defines hypoglycaemia as a plasma glucose of less than 3.0 mmol/L (<54 mg/dL, level 2),[11] while 3.9 mmol/L (<70 mg/dL, level 1) is designated as an alert level at which patients should take avoiding action to prevent progression to clinically significant hypoglycaemia.[11] Severe hypoglycaemia (level 3) is defined by the inability to self-treat and is characterized by the development of neuroglycopenia, which causes impairment of cognitive function with complex and speed-dependent tasks being affected most.[12] Although most studies have focused on hypoglycaemia, high blood glucose can also be associated with impaired reaction time.[12-15] Any impairment in decision-making and the ability to perform tasks with speed and precision would have an adverse effect on a pilot's flying performance, which could have very serious consequences. The purpose of the traffic light system used in the European protocol is to alert pilots as to when to take corrective action to avoid any risk of developing cognitive impairment and mood change resulting both from unduly low[12] and high blood glucose concentrations.[13-15]

The present study found that only 48 (0.12%) of 38 621 blood glucose values, which were recorded over more than 7 years, were within the low red, hypoglycaemic range, while 550 (1.42%) were within the low amber range. Analysis of the low red measurements showed that only three of the 48 values directly followed a low amber value, and all but four were corrected to a glucose concentration within the desired green range by the time of the next glucose measurement. The four other values had increased to within the low amber range before being restored to the safety of the green range. This supports the view that traffic light graduation, which requires action to be taken for amber (noncritical) blood glucose levels, is highly effective and contributed to the very low number of potential safety-critical values that were recorded.

Furthermore, over two-thirds of the low red values occurred in the pre-flight period and, after corrective action, all except one had returned to within the desired green range before the flight. This step in the protocol that requires two pre-flight measurements to be performed, allows sufficient time for pilots to take corrective action to ensure that their blood glucose is within the acceptable green range before take-off. Because the pre-flight screening process was effective, no pilot had to be excluded from duty.

A further observation was that the rates of decline and recovery of blood glucose following out-of-range readings were greater with red than with amber values. While this may reflect a greater urgency of the pilot to correct an abnormal reading, this does not explain the steeper rate of glycaemic descent observed with low red readings.

Demographic details of pilots across all subgroups reporting out-of-range readings were similar. Mean HbA1c concentrations ranged from 54.4 to 57.1 mmol/mol (7.1% to 7.4%) pre-certification and from 55.2 to 58.0 mmol/mol (7.2% to 7.5%) post-certification, after an average follow-up period of 4.3 years, indicating that no significant difference in glycaemic control had occurred in the pilots in each group.

The certification of pilots with insulin-treated diabetes is enabled through Part ARA.MED.330 of the European Union Aircrew Regulation. The protocol was approved by the EASA and permits insulin-treated pilots to fly, providing they meet certain criteria. As well as demonstrating strict glycaemic control, pilots must have intact hypoglycaemia awareness, which is assessed at each pilot's 6-monthly medical review. Impaired hypoglycaemia awareness is characterized by a diminished ability to detect the onset of hypoglycaemia with evidence of the loss or delayed onset of autonomic warning symptoms, thereby increasing the risk of neuroglycopenia and progression to severe hypoglycaemia.[16] It affects 20% to 25% of people with type 1 diabetes[8,16,17] and up to 10% with insulin-treated type 2 diabetes,[18,19] and can also be associated with strict glycaemic control.[17] Impaired hypoglycaemia awareness increases the risk of severe hypoglycaemia (level 3) sixfold in people with type 1 diabetes[8,17] and up to 17-fold in people with type 2 diabetes requiring insulin.[18] There were no reports of impaired awareness of hypoglycaemia and external assistance was not required by any pilot to treat hypoglycaemia.

During the 7.5 years of observation of the protocol the frequency of out-of-range readings declined.[7] These data have previously been discussed in detail[7] and may reflect better care, including additional education and enhanced insulin replacement regimens, leading to improved self-care, as well as increased experience with the in-flight glucose monitoring schedule. Another likely contributing factor is the increasing use of noninvasive continuous and flash glucose monitoring devices amongst pilots. The use of continuous glucose monitoring (CGM) and flash glucose monitoring devices has been shown to reduce the frequency and severity of hypoglycaemia and increase time in the normoglycaemic range.[20-23] Employing such a device in the cockpit provides the pilot with access to instant single glucose values and glucose trends, which guide treatment decisions and enable the pilot to make subtle insulin adjustments in order to avoid undesirable high and low glucose concentrations.[24] Some systems forecast rapidly rising or falling glycaemic trends and enable the pilot to take corrective action while their glucose concentration is still within the satisfactory green range. The use of CGM technology has yet to be proven within the hypobaric environment of an aircraft cockpit. Demonstration of its efficacy could help to persuade aviation authorities around the world to adopt the policy of the United States Federal Aviation Authority, which has allowed pilots with insulin-treated diabetes using CGM to fly commercial aircraft since November 2019.[25]

The present study included a detailed examination of all out-of-range blood glucose levels that were recorded by pilots with insulin-treated diabetes before and during flight, within the operational protocol. This protocol allows insulin-treated pilots to fly commercial and private aircraft safely, and functions consistently in the safety-critical environment of the cockpit. The glucose profiles and actions following out-of-range results suggest the current protocol is fit for purpose and support its continued application for insulin-treated pilots. In particular, the traffic light rules that demand action at non-safety-critical levels appear to prevent and reduce the frequency of significantly out-of-range values. This protocol and concept may be applicable to other safety-critical environments from which people with insulin-treated diabetes have historically been precluded because of the perceived risk of hypoglycaemia.

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CONFLICT OF INTEREST

G.L.G. is a clinical fellow in Diabetes and Endocrinology affiliated with the University of Surrey and has no conflict of interest. B.M.F. has served as a member of an expert panel of the UK CAA, on advisory boards for Eli Lilly, and Zucara Pharmaceuticals and has received honoraria for lectures from Lilly, Novo Nordisk, Sanofi, Abbott, and MSD. J.L.H. is a radiology registrar affiliated with the University of Surrey and has no conflict of interest. E.J.H. is contracted to the UK Civil Aviation Authority and has no conflict of interest. S.J.M. is contracted to the UK Civil Aviation Authority and has no conflict of interest. K.M.S. has served as a contracted Medical Consultant (clinical assessments) and independent advisor to the UK Civil Aviation Authority (CAA). S.R.H. has served as a member of an expert panel of the UK CAA, provides consultancy for Novo Nordisk, Eli Lilly, Zealand Pharma, for which his institution receives remuneration, and serves on speaker panels for Novo Nordisk and Astra Zeneca, for which he receives personal remuneration. G.K. is contracted as an independent advisor to Austro Control and has received research funding, speaker and advisory board honoraria from Astra Zeneca, Amgen, Boehringer-Ingelheim, Lilly, Novo Nordisk, and Sanofi. V.H. is contracted to Austro Control and has no conflict of interest. T.P.G. is a medical assessor with the Irish Aviation Authority and has no conflict of interest. D.M. is a medical assessor with the Irish 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, Mundipharma and Sanofi. D.L.R.-J. is contracted as an independent advisor to the UK Civil Aviation Authority (CAA), and has received research funding and advisory board honoraria from Astra Zeneca, Dexcom, Lilly, Novartis, Novo Nordisk, and Sano.

AUTHORS CONTRIBUTIONS

G.L.G. and D.L.R.-J. were responsible for the study design, collection of clinical data, data analysis, evaluation of the results, as well as preparation and evaluation of the manuscript. J.L.H. was responsible for data collection, data analysis, evaluation of results and evaluation of the manuscript. E.J.H., S.J.M., G.K., V.H., T.P.G., D.M. and G.A.R. were responsible for collection of clinical data and evaluation of the manuscript. B.M.F., S.R.H. and K.M.S. were responsible for interpretation and evaluation of clinical data and preparation and evaluation of the manuscript. All authors have approved the final version of the manuscript.

PEER REVIEW

The peer review history for this article is available at https://publons.com/publon/10.1111/dom.14471.

DATA AVAILABILITY STATEMENT

The data that support the findings of this study are held by the UK Civil Aviation Authority, Irish Aviation Authority and Austrocontrol. Restrictions apply to the availability of these data, which were used under license for this study. Data are available from DavidRussell-Jones@nhs.net with the permission of all relevant aviation authorities.

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SUPPORTING INFORMATION

Additional supporting information may be found online in the Supporting Information section at the end of this article.

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