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 HbA1c 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.

1University of Surrey, Guildford, U.K.
2Civil Aviation Authority, Crawley, West Sussex, U.K.
3Irish Aviation Authority, Dublin, Ireland
4Austro Control, Vienna, Austria
5The Queen’s Medical Research Institute, University of Edinburgh, Edinburgh, U.K.
6University of Portsmouth, Hants, U.K.
7Department of Oncology and Metabolism, University of Sheffield Medical School, Sheffield, U.K.
8Medical University Graz, Division of Endocrinology and Diabetology, Graz, Austria
9CRF-C University College Cork, HRB Clinical Research Facility Cork, Mercy University Hospital, Cork, Ireland
10Diabetes Research Group, Swansea University, Swansea, U.K.

Corresponding author: David L. Russell-Jones, davidrussell-jones@nhs.net

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Because people with insulin-treated diabetes are at risk for developing hypoglycemia, they have been barred from some “safety-critical” occupations, including flying commercial aircraft (1–3). Before the 1990s, it was widely accepted that insulin-treated diabetes was 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 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 practical.

Glycemic control was assessed on the basis of glycated hemoglobin (HbA1c) before certification, most recent HbA1c, 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 HbA1c before certification was 7.2% ([SD 0.89%] 55.0 mmol/mol [SD 9.74 mmol/mol]), and the final follow-up mean HbA1c was 7.2% ([SD 0.88%] 55.1 mmol/mol [SD 9.57 mmol/mol]). A comparison (paired t test) between the mean HbA1c 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
certification, had required photoocoagulation 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 red 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 subsequent reading 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>
<thead>
<tr>
<th>Table 1—Pilot demographics (n = 49)</th>
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<tbody>
<tr>
<td>Age, median years (IQR)</td>
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<tr>
<td>Sex</td>
</tr>
<tr>
<td>Male</td>
</tr>
<tr>
<td>Female</td>
</tr>
<tr>
<td>Pilot certificate class</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
</tr>
<tr>
<td>Type of diabetes</td>
</tr>
<tr>
<td>1</td>
</tr>
<tr>
<td>2</td>
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<tr>
<td>Duration of diabetes, median years, (IQR)</td>
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<tr>
<td>HbA1c before certification</td>
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<tr>
<td>Percentage (mean %)</td>
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<tr>
<td>Mean (SD), mmol/mol</td>
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<tr>
<td>Most recent (4.3 years after certification)</td>
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<tr>
<td>Percentage (mean %)</td>
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<tr>
<td>Mean (SD), mmol/mol</td>
</tr>
<tr>
<td>Retinopathy</td>
</tr>
<tr>
<td>None</td>
</tr>
<tr>
<td>Background retinopathy</td>
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<tr>
<td>Retinopathy/maculopathy</td>
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</table>

Data are n (%) unless otherwise indicated.
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 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 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

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

![Figure 1](image-url)
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

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).
Safety When Pilots With Diabetes Fly Aircraft

Diabetes control, as measured by HbA1c, any risk of hypoglycemia (3,9). The re-
within a higher range in order to avoid
medical notes. A copy of the log-
reviews by an independent medical ex-
ertoire readings at the six-month medical
of the recorded data. A copy of the log-
book and a download from the glucose

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 re-
results do not support such a premise. Diabetes control, as measured by HbA1c,
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 man-
age their diabetes with considerable
care. They are accustomed to frequently
monitoring instruments during flight and
had no problem accommodating addi-
tional glucose monitoring. In this study
they were able to successfully balance
close adherence to the protocol with
maintenance of excellent long-term gly-
cemic control. Another facet of the pro-
tocol that should be noted is the ongoing
surveillance for micro- and cardiovascu-
ar complications, which could adversely
affect flying skills. Clinical surveillance
has not identified the development of
any new clinically significant micro- or
macrovascular diabetes-related compli-
cations within the limited period of the
study.

Although several countries issue cer-
tificates to permit pilots to fly for leisure,
to our knowledge no studies have evalu-
ated the safety and the performance of
any of the existing protocols. A study
from Israel described the use of a dif-
ferent 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 per-
sonal 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 de-
vised 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, sub-
sequent 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 sug-
gested 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 in-
troduction 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 pro-
tocol, involving both commercial and
private pilots (clinical trial reg. no.
NCT04225455, clinicaltrials.gov). Further-
more, incorporating recent guidance con-
cerning recommended glucose ranges
obtained from CGM and including new
internationally agreed definitions of hy-
poglycemia 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 per-
suing 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 commer-
cial aircraft (19).

This study represents a systematic col-
lection 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 pro-
tocol 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 sim-
ilar safety protocols may be devised and
tested for this purpose.

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Novo Nordisk, Sanoﬁ, Abbott, Roche, and Merck
Sharp & Dohme. K.M.S. has served as a con-
tacted 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 Nor-
disk, Novartis, Pfizer, Sanoﬁ, and Laboratoires
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Control and has received research funding and
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traZeneca, Abbott, Amgen, Eli Lilly and Company,
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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 contacted as an independent advisor to the
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evaluated the results, and prepared the manuscrip-
collected clinical data and evaluated the manuscrip-
t. 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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