The U.S. Experience with Waivers for Insulin-Treated Pilots

William D. Mills; Charles A. DeJohn; Mustafa Alaziz

INTRODUCTION: This study explores the U.S. experience with waivers for insulin treatment for third-class medical certificates. From 1997 through 2014, the Federal Aviation Administration (FAA) approved an estimated 1500 waivers for insulin-treated diabetes with a total of 450 active waivers as of December 31, 2014. These pilots were involved in 25 accidents, but none were attributed to medical issues.

METHODS: Data for the insulin waiver group and control group were obtained from the FAA's aeromedical certification system and matching accident data from the NTSB database. A logistic regression model comparing accidents in this group to the overall population of third-class certificate holders adjusted for gender, age, and flight times was performed. A novel technique for calculating accident rates was also employed.

RESULTS: No statistically significant association between waivers for insulin treatment and accident risk was found by logistic regression. The overall accident rate for pilots possessing an insulin waiver was 7.0 per 100,000 flight hours and an estimate for all third-class pilots was also 7.0 per 100,000 flight hours. Only 8% of waivers for insulin treatment were later terminated for adverse changes related to the applicant's diabetes. Of these pilots, 8% also had coronary artery disease severe enough to require its own waiver.

CONCLUSION: Taken together, these findings suggest that pilots holding special issuance waivers for insulin-treated diabetes are not detectably less safe than other airmen with third-class medical certificates and most are able to successfully comply with the FAA's stringent medical certification protocol for insulin treated diabetes.

KEYWORDS: diabetes, aviation safety, accident rate, special issuance, aeromedical certification.

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In recent times, the issue of aeromedical waivers for treatment with insulin has been a very controversial issue. The goal of this study was to explore the U.S. experience with special issuance (SI) waivers for insulin-treated diabetes mellitus (ITDM) for Federal Aviation Administration (FAA) third-class medical certification.

Prior to the 1990s, there was general agreement that use of insulin represented an unacceptable aeromedical risk of impairment from hypoglycemia as well as unacceptable risks from the common diabetic comorbidities such as cardiac disease, kidney disease, and retinopathy, which were also difficult conditions to waiver prior to that time. However, advances in glucose monitoring and new treatment options (such as insulin analogs and insulin pumps) during the 1990s greatly improved glycemic control, delayed related comorbidities, and reduced the frequency of hypoglycemic episodes. By late 1996, the FAA had empirically determined that a very select group of insulin-treated applicants could be safely waivered for third-class medical certification, allowing full private pilot operations within the borders of the United States.[6] This required a very benign medical history, rigorous evaluation and follow-up, and close monitoring of blood glucose before and during flight.

Canada had also began considering waivers for insulin-treated Class 4 pilots several years earlier, which permitted operations less than those of a full private pilot. Since then, other aeromedical certification authorities have issued some waivers for ITDM for recreational pilots, including the United Kingdom, Australia, and Israel.[29]

From the Civil Aerospace Medical Institute, Oklahoma City, OK, and Wright State University, Dayton, OH.

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Address correspondence to: William D. Mills, AAM-630, P.O. Box 25082, Oklahoma City, OK 73125; bill.mills@faa.gov.

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There have long been efforts by insulin-treated pilots and diabetes advocates to obtain aeromedical waivers for commercial pilots with ITDM. These efforts appear to have recently intensified and antidiscrimination laws in some countries have strengthened their argument.[1,35] This prospect has caused additional concern in the international aeromedical community beyond the already significant concern regarding insulin-treated recreational pilots.[16] In fact, a few certification authorities do approve waivers for some commercial pilots with ITDM who are limited to a multicrew environment. They include Canada, since 2001, and the United Kingdom, since 2012. The United States does not currently waiver insulin-treated commercial pilots, but if such a protocol was approved, it would likely be restricted to Class 2 certification (first officer), since the FAA is prohibited from placing a multicrew restriction on the Class I certification required for airline captains.[33] The European Society of Aerospace Medicine[26] and the American Diabetes Association[25] have recommended procedures for waiver of insulin-treated commercial pilots which are similar to the current FAA protocol outlined below.

All of the recommended and approved protocols known to the authors are reminiscent of the 1996 FAA protocol for private pilots. An overview of the initial and ongoing evaluation for the FAA ITDM protocol includes:[5]

- No recurrent episodes of hypoglycemia in the past 5 yr and none in the preceding 1 yr;
- Favorable treatment records;
- Verification of diabetes education and monitoring ability;
- Annual ophthalmology evaluation;
- For age 40 and up, a normal maximal exercise stress test initially then every 5 yr; and
- Quarterly endocrinology assessments with annual reports.

Requirements for monitoring before and during flight include:

- Must carry a recording glucometer and rapidly absorbable glucose snacks in 10-g portions.
- Measure blood glucose 30 min prior to flight. If blood glucose is:
    - $<100\ \mathrm{mg \cdot dl^{-1}}$, consume a glucose snack and check glucose level 30 min later;
    - Between 100 and 300 $\mathrm{mg \cdot dl^{-1}}$, flying is permissible;
    - $>300\ \mathrm{mg \cdot dl^{-1}}$, cancel flight.
- In-flight, measure glucose each hour and 30 min prior to landing. If glucose level is:
    - $<100\ \mathrm{mg \cdot dl^{-1}}$, a glucose snack is required;
    - Between 100 and 300 $\mathrm{mg \cdot dl^{-1}}$, continue flight;
    - $>300\ \mathrm{mg \cdot dl^{-1}}$, land as soon as possible.

There are U.S. aviation accidents known or suspected to be related to insulin use in pilots who were not in compliance with a valid SI for insulin treatment at the time [e.g., National Transportation Safety Board (NTSB) accident numbers ERA13FA388, CEN11FA259, DEN08LA096, and SEA04LA024]. The pilot in ERA13FA388 possessed a waiver for ITDM, but was using an unacceptable medication combination at the time of the accident which was not disclosed to the FAA. No U.S. aviation accidents were attributed to insulin-related issues in the cohort of pilots in compliance with a valid SI over the first 18 yr of this waiver program for ITDM. Note, however, that this cohort is relatively small, with proportionately small numbers of accidents, and that insulin-related impairment in an accident can be subtle and very difficult to identify.

There are no previously published studies that estimate the overall accident rate or attempt to quantitate the overall safety risk from insulin-treated pilots with valid waivers. However, the number of insulin-treated motor vehicle drivers worldwide is much larger and a significant body of literature addressing their safety outcomes is available. Much of the older literature is based on observational studies of highway accidents and has notable methodological limitations, including issues such as possible self-discontinuation of driving, smaller number of miles driven by insulin-treated drivers, and dependence on drivers' recall for accident counts.[12,15] The results are contradictory, with some studies showing no significant increased safety risk and other studies estimating an increased accident risk with insulin use. Several higher-quality studies suggest that the accident risk for drivers with type 1 diabetes could be about twice that of drivers without diabetes.[2,28] A more recent prospective U.S. study of 452 insulin-treated drivers counted minor mishaps, near misses, and episodes of hypoglycemia while driving as well as accidents.[2] In this study, 52% of the subjects reported at least one event over 12 mo and 5% reported six or more events. An experimental study by the same authors compared insulin-treated drivers with a history of a previous accident to a group with no accidents and demonstrated that the accident group had more difficulty recognizing hypoglycemia when it occurred.[3] Factors associated with increased risk of highway accidents included history of previous accidents, previous episodes of severe hypoglycemia, impaired awareness of hypoglycemia, and less frequent measurement of blood glucose prior to driving. Some drivers' license and diabetes authorities restrict driving for individuals with a recent history of severe hypoglycemia and have recommendations or requirements for insulin-treated drivers that are not as stringent as those for pilots, but do include glucose testing prior to and periodically while driving and the carrying of glucose "snacks" while driving.[13,31]

Like pilots, in the U.K. insulin-treated drivers are required to report this condition to drivers' license authorities, which may result in driving restrictions. In one study, 43% did not disclose their insulin use to this authority, and 30% did not disclose this to their automobile insurers.[7]

The average type 1 diabetic patient experiences many episodes of asymptomatic hypoglycemia (glucose $< 70\ \mathrm{mg \cdot dl^{-1}}$), episodes of mild symptomatic hypoglycemia a couple of times a week, and episodes of severe hypoglycemia up to twice a year for insulin treatment less than 5 yr and over 3 times per year for insulin treatment for more than 15 yr.[4,14,32] For type 2 diabetic patients treated with insulin, the frequency of hypoglycemia is similar to that of type 1 when matched for duration of insulin treatment.[11] So, in type 2 ITDM, the incidence is fairly low during the first few years of insulin treatment, but approaches the frequency in type 1 diabetes after prolonged use of insulin.

In the general population of type I diabetics, about 20–25% have impaired awareness of hypoglycemia.[8,24] However, under the FAA protocol, the risk of in-flight hypoglycemia, even if impaired awareness is present, is substantially ameliorated by the requirement for blood glucose testing each hour. Studies of in-patient insulin treatment have shown that hourly monitoring is sufficient to avoid hypoglycemia.[9,30,34] The purpose of the current study was to explore the safety implications of waivers for ITDM in greater detail than previous efforts.[21]

METHODS

Study Population and Data Collection

This study was approved by the FAA Institutional Review Board. Aeromedical certification and waiver information for U.S. pilots is contained in the FAA's Document Imaging Workflow System (DIWS). The DIWS was designed as a point-of-service database and has significant limitations for research use. One of these limitations makes it difficult to determine which of the over 20 million stored physical examinations were issued with a waiver for a specific condition. This database was searched for insulin-treated applicants who had been approved for a SI waiver from the beginning of this program in late 1996 through December 2014. From about 1999 onward, these individuals could be reliably identified by a unique DIWS certificate restriction code for "Not Valid Outside the Borders of the U.S." This restriction code allowed for identification of a group of 1309 pilots approved for ITDM waivers. All subsequent analysis, except for an estimate of the total number of ITDM waivers approved, was carried out on this group. The estimate for the total number of individuals ever approved for an ITDM waiver was derived using issued exams with presence of the pathology code for "current" ITDM, which is somewhat less reliable. The number of applicants in the DIWS with a current code for ITDM having an issued medical certificate during the study period was 1522. For each of the 1309 pilots in the study group, data were extracted regarding their first and last waivered exams, reported total flight times, and descriptive data for those exams, and the average over all of each pilot's exams for the reported previous 6 mo flight time.

All pathology codes for each of the 1309 pilots were also extracted from DIWS for exploration of selected comorbid conditions. Information regarding all denied exams for these subjects was also extracted from DIWS to explore the reasons why waivers for ITDM were later terminated.

The NTSB maintains a database of U.S. aviation accidents. Each of the applicants identified with a waiver for ITDM was matched to the NTSB database to identify accidents that occurred while this SI was valid. Each accident was reviewed to determine whether insulin treatment was deemed to be related to the accident.

Data Analysis

A logistic regression model was used to determine odds ratios for the association of a waiver for ITDM with aircraft accidents. This technique has been successfully used with similar data sources to explore the association of other conditions with risk of aircraft accidents.[18–20] The outcome variable was the presence of an aircraft accident; the predictor variables included age, total and recent flight experience, and gender, in addition to the presence of a SI waiver for ITDM. The comparison group included all third-class certificate holders from 2005 to 2014. Odds ratios with 95% confidence intervals were calculated. A statistical significance level of $\alpha = 0.05$ was used.

Exploration of the association of factors of interest with aircraft accidents using logistic regression modeling, as described above, has been previously employed in a number of published studies.[17–20] However, the results are in terms of odds ratios, which are difficult to interpret in practical terms. A much more desirable measure of risk would be aircraft accident rates per 100,000 flight hours for each group. This study used a new approach to calculate the accident rates for this group of airmen with waivers for ITDM, as described below.

As an additional indication of safety hazards, applicants granted a waiver for insulin treatment that was later terminated were reviewed to determine the reason for the withdrawal and its degree of hazard to flight safety. The DIWS was also queried to determine the proportion of pilots granted an SI for insulin treatment who were also afflicted by selected comorbidities. For these calculations and the descriptive data, the subject pilots were limited to the 1309 individuals reliably identified by the unique restriction code which came into general use around 1999.

The accident rate was calculated using the number of accidents divided by the number of flight hours of exposure. The number of exposure flight hours was calculated as the product of the time each pilot possessed a valid insulin waiver and their average annual flight time, as described below.

For all subject pilots, the time exposed to accident risk was taken as the time from the first SI exam for insulin treatment to the last certificate expiration date, 2 yr past the last exam date, or the end of the study period (December 31, 2014), whichever was shortest. Only accidents that occurred while pilots had a valid SI for insulin treatment were counted. A correction factor to adjust for any breaks in certification between the first and last exams was calculated from the product of the total number of exams and the duration of the validity for each exam divided by the time between the first and last exams. This value turned out to be under 0.9 in less than 2% of the cases. Most pilots with a waiver for ITDM obtained flight exams more often than required in order to obtain maximum Aerospace Medical Examiner assistance when renewing their SI.

Average annual flight time for each pilot with more than one exam during the study period was calculated from the difference between the pilot's reported total flight time on the first and last waivered exams. In addition, it was also calculated from the average of the previous 6 mo reported flight time for each applicant's exams during the time the pilot held a valid insulin waiver.

For purposes of calculating accident rates, an annual flight time of 35 h derived from the above method was assigned where necessary. This included applicants whose reported values were clearly in error or extremely unlikely, applicants with only one exam, and those with missing data on applications for a medical certificate. Annual flight times of 35 h were assigned for calculations involving total time, previous 6-mo flight time, or both, for 720 subjects. This included 647 with only one exam and 73 with missing or clearly erroneous data. It was noted that a decrease in the assigned annual flight times of 5 h would decrease the overall sum of exposure hours by less than 3% for both total flight time and previous 6-mo flight time calculations.

The total number of flight hours contributed to the study by each pilot was calculated as the product of the average annual flight time and the exposure time described above. This was calculated separately for the flight time derived from the reported total time and that obtained from the average of the reported time for the previous 6 mo over all exams during the study period. Using the reported total flight times resulted in a total of 285,928 exposure hours, and using the average reported 6-mo flight times gave 284,221 exposure hours.

The overall accident rate for pilots holding a valid SI medical certificate for insulin treatment was calculated using the exposure times from both the total time reports and the reports of previous 6-mo flight times. A less refined, but similar, technique was used to calculate a rough accident rate for all third-class applicants from January 1, 2005, through December 31, 2014. This estimation does not compensate for gaps in certification, which would tend to underestimate the true accident rate. It also does not account for all of the issues with reported flight times, which would have an unknown effect on the calculated accident rate. Overall general aviation accident rates and accident rates for personal flying were also calculated using NTSB data.

Descriptive statistics and logistic regression were performed using SPSS version 21 (IBM, Armonk, NY) and proportions were analyzed using Minitab version 17 (Minitab, Inc., State College, PA). Power calculations were performed using G*Power version 3.1.9.2 (Heinrich-Heine-Universität, Düsseldorf, Germany).

RESULTS

Since the beginning of the FAA program for special issuance of medical certificates for applicants with insulin-treated diabetes in late 1996 until December 31, 2014, an estimated 1500 SIs have been granted. The number of annually approved SIs increased to a maximum of 126 in 1999 and 108 in 2000, but after this early surge of applicants, the annual number of new SIs has been remarkably consistent with a mean of 70 (SD of 9.0). As of December 31, 2014, approximately 450 applicants possessed a valid SI for insulin treatment with previous numbers in the same range.[21]

Women accounted for 3.7% of the ITDM waivers, compared to 7.3% of all third-class certificates, as of December 31, 2013.[27] The applicants' average age when the SI for insulin treatment was first issued was 46.2 yr old (SE = 15.5 yr), with a median age of 47.3. There were 10% who were less than 25, 25% were less than 35, 25% were older than 58, and 10% were older than 66. This compares to an average age of 43.3 (SE = 16.8) and a median of 41.0 for all third-class applicants in 2013.[27]

The average body mass index (BMI) of ITDM pilots was in the slightly overweight range at 27.8 (SE = 4.8) with median of 27.1. This compares to an average BMI of 27.1 (SE = 4.4) and a median of 26.5 for all third-class applicants in 2013.[27] The BMI distribution was unimodal and offered little assistance in differentiating type 1 diabetes. However, 75% of these applicants were in the obese range (BMI > 30) and 12 applicants (0.9%) were in the underweight range (BMI < 18.5).

The median total flight time for these applicants at the initial SI was 100 h, with 25% having 3 h or less and 25% having more than 800 h. About 45% (585) of these pilots reported less than 60 h of flight time. Of the 507 applicants with no previous flight exam in the study period, 95% reported less than 60 h and 85% had less than 20 h.

The median annual flight time calculated using the difference in reported total flight time on the first and last exams with valid SI was 34 h/yr or 38 h/yr if values of zero are excluded. Annual flight time using the applicant's average reported flight times for the previous 6 mo showed a median time of 36 h/yr when first-time applicants and subjects with only one exam are excluded. Annual flight times between the first-ever flight exam and the second exam for the 144 pilots having these data available showed the median for the difference in reported total times to be 33 h. Using the previous 6-mo time from the second exam gives a median of 34 h annual flight time. The distribution of all of these annual flight times is highly skewed to the right, so the means were not a useful measure of central tendency. Using the reported total flight times resulted in 285,928 exposure hours for the study period and using the average reported 6-mo flight times gave 284,221 exposure hours.

The 1309 insulin-treated pilots in the study group maintained their SI for a median of 3 yr, with 25% maintaining their SI for 2 yr or less, and 25% complying with their SI for over 6.5 yr and 5% for over 15 yr. Approximately 180 pilots (13%) have maintained their SI for 10 yr or more. The longest SI has been valid for all 18 yr in this study period and is still active.

In the study group of 1309 pilots 20 accidents occurred and an additional 5 accidents occurred in pilots holding a valid waiver for ITDM who were not members of the study group (**Table I**). Accidents in the first four columns occurred in the study group and the last column has other accidents involving a valid ITDM waiver. None of these accidents was attributed to the pilots' insulin treatment. These accidents were responsible for four fatalities, five serious injuries, and one minor injury.

To assess accident risk, a logistic regression model was performed using the combined set of 1309 applicants with waivers for ITDM and the overall group of third-class certificate holders from 2005 through 2014. The model contains 5552 total

Table I. NTSB Number and Injuries for ITDM Pilot Accidents.

FTW02FA087	ERA13LA360	ERA14CA307	ERA13LA311	ATL00LA060
2 Fatal	1 Minor	None	None	2 Serious
CEN14FA506	ERA13LA151	WPR12CA425	CEN12CA031	NYC00LA041
1 Fatal	None	None	None	None
ERA11FA258	ATL05CA080	ANC08CA091	ERA13CA207	FTW00LA092
1 Fatal	None	None	None	None
CHI06LA087	DEN04LA042	NYC04CA031	ATL04LA034	DEN00LA058
2 Serious	None	None	None	None
CEN09LA318	DEN02LA059	DEN04CA054	SEA04LA072	SEA00LA009
1 Serious	None	None	None	None

The 20 accidents in the first four columns occurred in the study group and the last column shows five other accidents involving pilots with a valid insulin-treated diabetes mellitus (ITDM) waiver who were not in the study group. (NTSB Number, Injuries).

accidents, 1040 fatal accidents, and 577,030 pilots. The presence of an accident was the outcome variable. Predictor variables included whether the pilot possessed a valid waiver for ITDM, gender, age (per 10 yr), reported total flight time (per 1000 flight hours), and reported flight time in the previous 6 mo (per 25 h). The accident odds ratio for an ITDM waiver adjusted for the other predictor variables was not statistically significant ($P = 0.15$), with an odds ratio = 1.39 (95% CI 0.88–2.20). This model has a power of 80% to detect an odds ratio of 1.7 between ITDM waiver and accident rate.

A similar logistic regression model was carried out on the combined set of applicants with waiver for ITDM and overall third-class certificates for fatal accidents. The association between ITDM waivers and fatal accidents was also not statistically significant, with $P = 0.816$, but an 80% power of detection would require an odds ratio of 2.7 for this model. The odds ratios for the other covariates are in the same general range as displayed in **Table II**.

The results for the other covariants show that accident risk increased with increasing age and was higher for male gender, which agrees with previous findings.[17,19,20] Coefficients for total and last 6 mo flight times were positive and statistically significant in the overall accident model, but the odds ratios were too small to be of practical significance.

The fit of the models was rejected by Hosmer and Lemeshow testing; however, our intention was only to test for an association between ITDM waiver and accidents with adjustment for potential confounders, rather than for any kind of predictive use. Thus, model fit is not critical for this purpose.

In an effort to obtain a more useful measure of accident risk, accident rates per 100,000 flight hours for the airmen with valid ITDM waivers were estimated using the airmen's reported flight hours obtained from DIWS. Using the technique described in "Methods" with the estimated denominator exposure hours from reported total flight times gives 20 accidents with 285,928 exposure hours for an overall accident rate of 7.00 per 100,000 h (95% CI 4.3 to 10.8) and a fatal accident rate of 1.05 per 100,000 h (95% CI 0.2 to 3.1). Using the estimates from the average reported previous 6-mo flight times (284,221 h) gives an accident rate of 7.04 per 100,000 h (95% CI 4.3 to 10.9) and a fatal accident rate of 1.06 (95% CI 0.2 to 3.1). Note that there were only three fatal accidents in this group, so those confidence intervals are very wide.

Using a less refined but similar technique to calculate a rough accident rate from January 1, 2005, through December 31, 2014, for all third-class applicants with available data resulted in 77,204,433 exposure hours and 5406 accidents, for an accident rate of 7.00 per 100,000 flight hours (95% CI = 6.82 to 7.19). This estimation did not compensate for gaps in certification or other issues with reported flight times, but the result is not statistically different from the rates calculated for the pilots with waivers for ITDM ($z = -0.00$, $P = 0.996$). There were 1037 fatal accidents in this group, which gives an estimated fatal accident rate of 1.34 per 100,000 flight hours (95% CI = 1.26 to 1.43), which is also not statistically different from the pilots with ITDM waivers ($z = -0.48$, $P = 0.628$). The power to detect a difference of 5 per 100,000 flight hours in the overall accidents rates and a difference of 3.3 per 100,000 in the fatal rate is about 80%.

Using NTSB published data from the period 1997 thru 2013 (minus 2011, for which data are not available) shows 388,128,000 general aviation flight hours with 26,317 total accidents and 4968 fatal accidents.[23] This gives an overall general aviation accident rate of 6.78 per 100,000 (95% CI 6.70 to 6.86) flight hours and a fatal accident rate of 1.28 per 100,000 flight hours (95% CI 1.24 to 1.32). This is not statistically different than the ITDM group for total accidents ($z = -0.139$, $P = 0.89$) or for fatal accidents ($z = 0.345$, $P = 0.73$). Most of the insulin-treated pilots would have likely been engaged in personal flying and available NTSB data for 2003 through 2012 (minus 2011) shows 81,583,236 personal flying hours with 9385 accidents, 1927 of which were fatal. This results in an overall rate of 11.50 per 100,000 flight hours (95% CI 11.27 to 11.74) and a fatal rate of 2.36 per 100,000 h (95% CI 2.26 to 2.47).[22] It is important to note that the NTSB rates are calculated using flight hours obtained from a survey to owners addressing aircraft usage, so these values are not directly comparable to the rates calculated in this study from pilots' self-reported flight time. The NTSB calculations are presented as another comparison; however, it would not be valid to conclude that the ITDM pilots have a lower accident rate based on the NTSB rates.

Table II. Results of Logistic Regression Model for All Accidents.

PREDICTOR VARIABLE IN MODEL	ODDS RATIO	95% CONFIDENCE INTERVAL	*P*
ITDM Waiver	1.393	0.884–2.195	0.153
Age (per 10 yr)	1.424	1.398–1.450	<0.001
Gender (compared to Female)	1.327	1.164–1.513	<0.001
Total Flight Hours (per 1000 h)	1.008	1.001–1.014	0.026
Flight Time 6 Month (per 25 h)	1.034	1.029–1.040	<0.001

Result for each predictor variable is adjusted for the effect of the other predictor variables. ITDM: insulin-treated diabetes mellitus.

Adverse events for the group of 1309 pilots with waivers for ITDM were also explored. They submitted a total of 5656 exams during the study period with 753 of these exams having a FAA code indicating denial of the medical certificate. Pilots were able to qualify for a new SI during the study period in 583 of these cases. This left 170 applicants whose waivers were terminated and were not recertified prior to December 31, 2014. These 170 terminated waivers were reviewed to determine the reasons for the denial, with the following results:

- Hypoglycemic events: 13;
- Inadequate control of HbA1c: 19;
- Coronary artery disease complications: 17;
- Other diabetic complications (kidney, eye, etc.): 11;
- Other disqualifying conditions: 23;
- Disqualifying medications: 37;
- Failure to provide requested information: 50.

Several of these pilots were withdrawn for multiple disqualifying issues and only the most serious of these is counted above.

Our cohort of 1309 applicants approved for waivers for ITDM were matched to selected comorbid conditions using the legacy FAA pathology codes. Pathology codes for coronary artery disease (CAD), hypertension, and diabetes treated with oral medications are specific, but codes for retinopathy, renal disease, and neuropathy also included some diseases not related to diabetes.

- Pathology codes for significant CAD were found for 110 (8.4%) of these pilots. A total of 26% of the pilots over 62 yr of age with waivers for ITDM (55 of 215) also required waivers for significant coronary artery disease.
- “Retinal disease” (155, 11.4%) or “miscellaneous eye conditions” (88, 6.7%) were found in 16.9% of these pilots.
- Hypertension treated with medications was found in 529 (40.4%) of these pilots.
- The pathology code for renal disease was present in 66 (5.0%).
- The pathology code for neuralgia or neuropathy was found in 50 (3.8%); and
- The pathology code for diabetes treated with oral medications was found in 365 (27.9%) of these pilots, suggesting that they were controlled on oral medications for a time but eventually required insulin for control.

DISCUSSION

The FAA has granted third-class SI waivers for ITDM to an estimated 1500 applicants from the start of this program in December 1996 to December 31, 2014, at which time there were about 450 active waivers. A reliable study group of 1309 of these pilots was found to be fairly similar to the overall group of third-class pilots for BMI and annual flight hours with a slightly older age distribution. When first approved for an ITDM waiver, about half were already experienced pilots and about half were learning to fly. Median annual flight hours were similar to the overall group of third-class applicants at about 35 h/yr. Those pilots with ITDM maintained their waivers a median of 3 yr, with 13% holding their SI for more than 10 yr.

This group is small for purposes of a safety study, but is the largest cohort of pilots waivered for ITDM ever studied. For pilots holding a valid SI for ITDM, 25 aircraft accidents were identified and while most of these accidents were due to pilot error, none was determined by the NTSB to involve the pilot’s medical condition. Of those accidents, 18 produced no injuries and the other 7 were responsible for 4 fatalities, 5 serious injuries, and 1 minor injury.

A logistic regression model was carried out on the combined set of applicants with waiver for ITDM and all other third-class applicants to explore any association of waiver for ITDM with aircraft accidents. No statistically significant association was detected ($P = 0.15$) and the calculated overall accident odds ratio for presence of an ITDM waiver was 1.39 (95% CI 0.88–2.20).

In addition, a novel technique to directly estimate the accident rate for the ITDM pilots resulted in an overall accident rate of 7.0 per 100,000 flight hours, with a rate for fatal accidents of 1.1 per 100,000 h. Using a similar technique to calculate a rough estimate for the overall accident rate for all third-class applicants from 2005 to 2014 also gave a result of 7.0 per 100,000 flight hours and a fatal accident rate of 1.3 per 100,000 flight hours. These rates fall between the rates published by the NTSB for all of general aviation (6.8 per 100,000 h overall, with 1.3 per 100,000 h for fatal accidents) and that for personal flying (11.5 per 100,000 h overall, with 2.4 per 100,000 h for fatal accidents). The methodology used in this study is quite different from that for the NTSB calculations, so the rates are not directly comparable. In any case, none of our data suggest that pilots with ITDM waivers are less safe than other airman holding third-class medical certificates.

The reasons that waivers granted for ITDM were later terminated by the FAA and not reissued were also explored. The waivers for ITDM were withdrawn at some point on 58% of the 5656 exams for the study group of 1309 pilots and were not reinstated during the study period for 170 (13%) of those pilots. Not counting waivers terminated for failure to provide required information and for conditions not related to diabetes, there were 107 terminations (8% of the study group of 1309) for adverse changes related to ITDM that were not reinstated. This included 13 that were terminated due to hypoglycemic events and 17 for complications of coronary artery disease. This demonstrates that a significant number of these pilots had adverse developments in their ITDM or comorbidities that resulted in termination of their waivers, but most pilots who had difficulty continuously complying with the requirements of the ITDM protocol were able to succeed in having their ITDM waivers reinstated.

All individuals with ITDM are at increased risk for a number of complications which are also hazards to flight safety. For example, CAD, which also requires a waiver for at least 50% stenosis of a coronary artery, was found in 110 (8.4%) of the ITDM study group. It has been demonstrated that even in

ITDM patients with no history of CAD, their risk for a new cardiac event is similar to non-ITDM patients who do have a history of a myocardial infarction.[10] The FAA protocol addresses this risk with the requirement for an initial exercise stress test for applicants over 40 yr old, with repeat testing every 5 yr. The FAA protocol also provides for close surveillance of other significant ITDM comorbidities with quarterly endocrinology follow-up.

Studies of automobile drivers show that insulin treatment does represent a transportation safety hazard. The results of this study suggest that the FAA protocol for third-class ITDM waivers ameliorates this risk and appears to be an acceptable balance between maintaining aviation safety and permitting these individuals to fly as a private pilot. This study is based on relatively small numbers, so continued monitoring of these airmen is recommended.

Finally, the favorable findings for this cohort of third-class ITDM pilots should not be directly extrapolated to the waiver of commercial pilots with ITDM. Differences would include inability to delay a flight or to end a flight prematurely if glucose readings are too high. Irregular flight schedules, sleep schedules, exercise, and meals may complicate insulin management and increase the probability of a protocol deviation that could disrupt a flight or cause an unsafe condition. In addition, the third-class cohort did suffer a number of adverse events that terminated their SI and could have adversely impacted safety had they occurred during flight.

The major limitations impacting this study included the relatively small number of individuals and accident outcomes in the study group, which limited the precision of the analysis. There was also the difficulty determining flight times from pilots' total and previous 6-mo flight times on the application for a medical certificate, dependence on pilots self-reporting for this data, and our inability to accurately adjust for gaps in certification during the study period. It would be helpful to repeat this study when larger numbers of ITDM pilots are available and techniques for calculating the flight hours of exposure have been further refined.

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Authors and affiliations: William D. Mills, M.D., Ph.D., and Charles DeJohn, D.O., M.P.H., Civil Aerospace Medical Institute, Federal Aviation Administration, Oklahoma City, OK, and Mustafa Alaziz, M.B.B.S., M.S., Wright State University, Dayton, OH.

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