

The U.S. Experience with Special Issuance Waivers

William D. Mills; Joshua T. Davis

- INTRODUCTION:** The special issuance (SI) waiver is the primary mechanism for U.S. pilots who do not meet FAA standards to obtain a medical certificate. About 34,000 pilots possess an SI waiver, but there is a large gap in knowledge of the relationship of SI waivers to aviation safety.
- METHODS:** All FAA pilot medical exams from 2002 through 2011 were matched to the National Transportation Safety Board accident database. The association of an SI waiver with accidents was explored using logistic regression models. Accident rates were also calculated using a novel technique based on pilots' reported flight times on their applications for medical certification.
- RESULTS:** For third-class flight exams overall, the presence of an SI waiver is associated with 8.7% lower odds of an accident than regular issuance exams. The calculated overall accident rate was 6.6 per 100,000 h. For the first and second-class exams, there was no significant association of SI waivers with safety for the overall group. The oldest and youngest pilots in the third-class group and the younger pilots in the first and second-class groups had somewhat elevated accident odds. The significance of these higher odds is uncertain, especially for the younger pilots who have a probable flight time bias.
- DISCUSSION:** The overall FAA program of special issuance waivers shows no detrimental effect on aviation accidents and enables a large number of pilots to safely continue their aviation pursuits in spite of failure to meet specific regulatory medical standards.
- KEYWORDS:** aeromedical, aviation medicine, accident rates, certification, pilot, epidemiology.

Mills WD, Davis JT. *The U.S. experience with special issuance waivers. Aerosp Med Hum Perform.* 2018; 89(10):905–911.

Determining whether a waiver should be approved for pilots who do not meet prescribed medical standards is one of the most important activities of aeromedical certification authorities. This is an area which directly impacts aviation safety and in which individual member nations of the International Civil Aviation Organization (ICAO) have fairly wide discretion.

The United States is a signatory of the 1944 Chicago Convention intended to harmonize international flight operations through actions of ICAO, which is a unit of the United Nations.⁶ Adherence to these standards has been ratified by 191 member states. ICAO standard 1.2.4.9 explicitly permits the issuance of medical waivers to pilots who do not meet the specific medical standards where “accredited medical conclusion indicates that in special circumstances the applicant’s failure to meet any requirement, whether numerical or otherwise, is such that exercise of the privileges of the license applied for is not likely to jeopardize flight safety.”⁵ It goes on to say that “the license is endorsed with any special limitation or limitations when the safe performance of the license holder’s duties is dependent on

compliance with such limitation.” ICAO’s “Manual of Civil Aviation Medicine” discusses many of the diseases of importance to flight safety but leaves fairly wide discretion as to when waivers should actually be approved.⁷

The primary mechanism for aeromedical waivers in the United States is the special issuance (SI) waiver. These waivers are based on a time-limited certificate with appropriate documentation of continued medical acceptability required to renew the certificate. About 36,467 (6.1%) of the 598,642 U.S. pilots required an SI waiver in 2010, but the SI rate is very age dependent with a much greater proportion of older pilots requiring an SI due to the strong correlation of disqualifying medical

From the Aeromedical Research Division, Civil Aerospace Medical Institute, Federal Aviation Administration, Oklahoma City, OK.

This manuscript was received for review in April 2018. It was accepted for publication in June 2018.

Address correspondence to: William D. Mills, Ph.D., Civil Aerospace Medical Institute, AAM-631, Bldg. 13, Room 155E, 6500 South MacArthur Blvd., Oklahoma City, OK 73169; bill.mills@faa.gov.

Reprint & Copyright © by the Aerospace Medical Association, Alexandria, VA.

DOI: <https://doi.org/10.3357/AMHP.5143.2018>

conditions with age.¹³ In 2010, the percent of pilots possessing an SI were:

- 1.1% for the 20- to 24-yr-old group,
- 1.8% for the 30- to 34-yr-olds,
- 4.0% for the 40- to 44-yr-olds,
- 7.6% for the 50- to 54-yr-olds,
- 13.9% for the 60- to 64-yr-old group, and
- 21.1% for those pilots ages 65 yr and older.¹³

The U.S. Federal Air Surgeon has granted waivers for some airmen who do not meet the medical certification standards since 1926 when issuance of medical certificates was adopted, but the early unstructured approach was poorly defined and left much to be desired. The modern special issuance procedures began in 1982 when Part 67 of the Federal Aviation Regulations (FARs) was modified to allow for special issuance of all medical conditions by the Federal Air Surgeon and included a provision for him to add functional limitations on medical certificates.⁴ Note that as the result of a court decision in 1980, the Federal Aviation Administration (FAA) is not allowed to place functional restrictions, such as “Valid Only When Serving as a Member of a Fully Qualified Two-Pilot Crew”, on first-class medical certificates, unlike the majority of ICAO signatories.²

The current form of FAR Part 67, dating from 1996, changed the “Special Issuance of Medical Certificates” section from Part 67.19 to Part 67.401 and clarified authorizations, time limits, and terminations of these waivers. It also included a new section for the Statement of Demonstrated Ability (SODA) waiver, which is used for conditions that are permanent and not expected to change. SODAs usually require a one-time evaluation that frequently includes a medical flight test by an FAA aviation safety inspector. Less than 2% of U.S. pilots possess a SODA and these waivers are not addressed in this study.

Most U.S. medical certification is carried out by the FAA’s Aerospace Medical Certification Division (AMCD), which is located at the Civil Aerospace Medical Institute (CAMI) in Oklahoma City. Additional cases are evaluated by the nine Regional Flight Surgeon’s offices and the Federal Air Surgeon’s office. Our data showed that from 2002 through 2011, the FAA processed an average of 414,972 applications per year and, of these, an average of 25,000 (6.0%) were special issuances.

The U.S. aeromedical certification protocols for SI waivers are well defined for most common conditions and have evolved over time in response to advances in predictive medical knowledge. There are general guidelines that can be applied to uncommon medical conditions to help guide the professional judgment of AMCD’s aerospace medicine physicians and an appropriate medical specialist with aeromedical experience may be consulted if the certification decision is still unclear. The FAA maintains panels of cardiologists and neurologists who meet periodically at CAMI to review the most difficult cases in these two important specialties. A number of the protocols for SI of specific medical conditions are publicly available online in the Guide for Aviation Medical Examiners.³

Note that advances in medical knowledge and years of favorable aeromedical experience have resulted in reassigning a

number of medical conditions from requiring a formal SI with a time-limited certificate to a well-defined evaluation that, if favorably reviewed by the Aeromedical Examiner (AME), allows for the AME to issue a regular certificate with no time limitation, but with a specified reevaluation at the next regular flight exam. This program, known as “Conditions AMEs Can Issue” (CACI), was started in 2013, so does not impact this study, which ends after 2011. CACI currently includes 18 conditions that previously required an SI waiver and reduces the number of applicants who need these waivers. The certification criteria for all CACI conditions are available online.¹² The prototypical condition for CACI was the long-standing protocol for medication-treated hypertension, which allows for regular issuance by the AME if periodic evaluations are favorable. There were 64,434 (10.8%) such pilots in 2010.³

Background

There is very little existing information from previous analytical studies available regarding the safety impact of U.S. special issuance waivers, or any other aeromedical waivers for that matter. Our online search using the key words [Aerospace Medicine or Aeromedical or Aviation Medicine] AND [Waiver] returned 61 articles. Only two of these articles were analytical studies of the relationship of waivers to aviation accident risk.

One of the studies was published in 2016 and addressed the accident experience of U.S. pilots holding a special issuance for insulin-treated diabetes.¹⁰ We found that a special issuance for insulin-treated diabetes was not associated with increased risk of accident when adjusted for age, gender, and flight times. The other study, published in 2002, explored the association of waiver status in U.S. naval aviators with mishaps during 1992 to 1999.¹⁵ This study included 234 pilots in the accident group. The author found no association between waivers and serious mishaps. The U.S. Navy waiver protocols are in general much more restrictive than the corresponding FAA protocols.¹⁴ Our current study aimed to contribute to this large gap in knowledge regarding the safety of U.S. special issuance waivers.

METHODS

This study was approved in advance 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) and includes over 21,000,000 examinations for over 3,583,000 applicants. For each examination, this database includes demographic data, medical history and physical exam data, medical conditions assigned by the FAA, and detailed certification actions. The application for medical exam also asks the applicant to self-report his pilot-in-command (PIC) flying hours for the past 6 mo and his total PIC hours. While self-reported flying hours are requested, the application can be successfully submitted with blanks for these fields, so missing data was an issue for the flight time variables. DIWS also has no restrictions on values entered for flight hours, dates, and other data. We queried all 4,149,726 exams (representing

1,093,443 pilots) contained in the DIWS from a period of stable data, 1/1/2002 to 12/31/2011, for presence or absence of a special issuance waiver. The majority of recent SI protocols are similar to those used during this time period. We collected applicant ID number and exam ID number, exam date, gender, age at exam, height, weight, self-reported 6-mo and total flight hours for this exam and the subsequent exam (if any), exam expiration date, and class issued code into an encrypted data file.

The National Transportation Safety Board (NTSB) maintains a database of U.S. aviation accidents.¹¹ Each of the 4,149,726 exams was matched to the NTSB database to identify any accidents that occurred while that exam was valid for pilot duties. We matched these exams to 15,683 accidents. We collected accident date, type of flying (Part 91-General Aviation, 121-Air Carrier, 135-Commuter, etc.), and whether the accident involved fatalities for each matching accident.

For analyzing the association of SI waivers with aviation accidents, the natural and most useful study units were the individual exams. Use of exams captured all of the available data and allowed for the most straightforward and accurate calculation of accident rates and associations of special issuance waivers with accident odds. The more intuitive approach using individual pilots as the datapoints is problematic due to changes over the 10-yr study period in consistency of annual flying hours, class of exam, and type of flight operations as well as lapses in exams, and many pilots' requirement for SI waivers for only part of the study period. Many special issuance exams are shorter in duration than a regular issuance exam since their certificates are time-limited and either may not be renewed or may be renewed in conjunction with a new exam for convenience. So the proportion of SI exams for a parameter is usually higher than the proportion of pilots. This does not affect our accident rate calculations and was accounted for in the logistic regression models by use of exam length as a covariate. We provide the number of pilots represented by a group of exams where this is helpful.

We employed logistic regression models to determine odds ratios (ORs) for the association of a special issuance waiver with aircraft accidents. This technique has been successfully used previously to explore the association of other conditions with risk of aircraft accidents using similar data sources.^{2,8,10} The outcome variable was occurrence of an aircraft accident and the predictor variables included age, total and recent flight experience, gender, body mass index (BMI), and certificate duration in addition to the presence of an SI waiver. A great advantage of logistic regression modeling is the ability to remove the confounding effects of the covariates. We calculated odds ratios with 95% confidence intervals. Since a unit size of one for the quantitative predictor variables would result in miniscule ORs, a unit size of 10 yr was used for age, 25 h for recent flight time, and 1000 h for total flight time in order to scale the ORs to be more understandable.

Logistic regression modeling is an established and valuable technique for exploring the adjusted association of multiple predictor variables with the odds of an outcome variable.

However, these models produce their results in terms of odds ratios that are difficult to intuitively appreciate. So we felt it would be very desirable to also present actual accident rates per 100,000 flying hours in the SI exams vs regular issuance exams. We stratified by age groups to account for this important confounder.

Our study used a novel technique to calculate accident rates for the SI and non-SI exams using the flight times that pilots self-report on their applications for aeromedical certification. We calculated the accident rate per 100,000 flying hours using the number of accidents occurring during the valid period of the exams of interest (detailed below) divided by the sum of the flight hours of exposure for the same exams times 100,000. The number of flight hours for each exam was calculated as the product of the length of time the exam was valid and the mean annual flight time for that exam calculated from the pilot's self-reported flight times as described below.

For each exam the valid time period was determined from the exam date to the shortest of either the statutory exam validity, any added expiration date, the date of a subsequent exam, or the end of the study period on 12/31/2011. For each exam, we calculated the number of flight hours during its valid period using both of the following techniques, where the self-reported data exists:

- Difference in self-reported total flight time between the study exam and the subsequent exam.
- Sum of the self-reported previous 6-mo flight times for this exam and the subsequent exam (or double the value when data for only one of the exams was present) to represent 1 yr multiplied by the length of the valid period for the exam.

The total number of flight hours contributed to the study by each group was calculated as the sum of all the individual flight times from those exams. We calculated this separately for the flight time derived from the reported total time and that obtained from the reported time for the previous 6 mo. Accident rates published by the NTSB are a widely used benchmark for U.S. civilian aircraft safety and were used for comparison with our calculated rates.

The group of 3rd-class certificate holders is really a different population than those holding 1st and 2nd class certificates due to the relationship between their flight hours and accidents. We examined these two groups separately. The private pilots' accidents matched with their reported flight hours. However, the 1st and 2nd-class pilots obtain the vast majority of their flight hours in commercial flying, but had 72% of their accidents during private-pilot type flight operations (6073 of 8445 accidents). We were unable to determine the flight hours for personal flying for the commercial pilots to enable meaningful calculation of these accident rates. We did, however, define a group of established commercial pilots and used their commercial accidents to estimate some of these rates.

Descriptive statistics, logistic regression, and Chi-squared testing were performed using SPSS version 21 (IBM, Armonk, NY). We used a statistical significance level of $\alpha = 0.05$.

RESULTS

Over the 10-yr period from 1/1/2002 to 12/31/2011 the FAA received 4,149,726 medical exams from 1,093,443 unique individuals. Of these applicants, 320,727 submitted only 1 exam during this time period. The FAA issued 4,072,660 valid medical certificates to 1,051,388 pilots. Of these certificates, 249,995 (6.1% of issued exams) were issued with a special issuance waiver. This included 69,453 unique pilots (6.6% of issued individuals) who were approved for one or more special issuance waivers.

For the analysis of 3rd-class exams, we restricted age at exam to 16 to 100 yr old, flight time for the last 6 mo was limited to no more than 600 h, and total flight times were limited to no more than 40,000 h for these tables. This is because of a small number of probable reporting errors that would significantly distort the results. The total number of issued 3rd-class exams during this period was 1,236,086 to 584,662 different pilots. The restrictions above removed 3003 (0.2%) exams and 2448 (0.4%) pilots from the third-class group, leaving 1,233,083 exams and 582,214 pilots.

Table I compares demographics between exams with a special issuance and a regular issuance for 3rd-class applications. Missing data in this 3rd-class group includes 43,940 (3.6%) exams missing the reported past 6-mo flight time, and 31,230 (2.5%) missing the reported total flight time.

The overall crude accident OR for pilots with a special issuance was not significant, with OR = 0.956 (95% CI = 0.878 to 1.041) and $P = 0.296$. But this lack of association between presence of an SI and accidents is misleading due to confounding. For example, the pilots with SI exams were significantly older, which is a risk factor for accidents.^{1,9,10} We adjusted for the effect of age and several other confounders using logistic regression. For this model, we removed applications for which the past 6-mo flight time question was left blank and also for those where it was left blank on the subsequent exam if one existed. This removed those exams for which recent flight time could just not be assessed and matches the population used in the accident rate analysis below. This model included 1,032,486 (83.7%) of the exams with 5853 accidents and gives the results displayed in **Table II**.

Table I. Descriptive Statistics for All 3rd Class Exams.

	REGULAR	SI	P-VALUE
Age (yr, mean)	47.7	61.0	< 0.001
Gender (% female)	6.6	3.2	< 0.001
BMI (mean)	27.5	28.1	< 0.001
Total Flight Time (h, median)	250.0	720.0	< 0.001
Past 6 mo (h, median)	10.0	11.0	< 0.001
Exam Time (yr, median)	2.02	1.07	< 0.001
Accidents	5881	610	0.731
Number Exams	1,118,727	114,356	(SI = 9.3%)
Number Pilots	552,868	29,346	(SI = 5.0%)

SI: special issuance.

Age between 16 to 100; previous 6-mo flight time no more than 600 h and total flight times no more than 40,000 h.

Table II. Results of Logistic Regression Model for 3rd-Class Accidents.

PREDICTOR VARIABLE IN MODEL	95% CONFIDENCE		
	ODDS RATIO	INTERVAL	P-VALUE
Special issuance waiver	0.913	0.836–0.998	0.045
Age (per 10 yr)	1.304	1.275–1.334	< 0.001
Gender (compared to Male)	0.826	0.721–0.945	0.005
BMI (per 10 units)	1.029	0.969–1.093	0.355
Total Flight Hours (per 1000 h)	0.996	0.988–1.004	0.285
6-mo Flight Time (per 25 h)	1.158	1.147–1.169	< 0.001
Exam Duration (per yr)	1.470	1.418–1.523	< 0.001

Results for each predictor variable are adjusted for the effect of the other predictor variables.

Units for continuous covariates were chosen to improve clarity.

These findings show that the presence of an SI is protective against accidents, with this group having 8.7% lower odds of accident than exams without a special issuance. It also shows that increasing age is an accident risk, with 30.4% greater accident odds ratio for each 10 yr, and that female pilots have 17.4% lower odds of an accident. Both of these findings agree with previous studies.^{1,9,10} Exam duration is a measure of exposure to accidents and, as expected, longer duration was associated with increased odds of accident, as it was for all of the models in this study. Reported flight time in the last 6 mo is also associated with odds of an accident with 15.8% increased odds for every 25 h. The 6-mo flight time measures both exposure to risk and recent experience. The OR for increasing total flying time suggested a minimal protective effect but was not statistically significant ($P = 0.285$). This would be a measure of overall flying experience. BMI had no significant association with accidents. If only significant covariates are retained in the above model, the results are very similar. When this model was constructed without the above restriction on past 6-mo flight times, it included 1,188,197 (96.4%) of the exams with 6361 accidents and gave very similar results, except the effect of an SI was a little more protective (OR = 0.878, 95% CI = 0.804 to 0.958, $P = 0.003$).

We also constructed logistic regression models separately for a young age group, the oldest age group, and the remainder to look for associations in the former groups that may be obscured in the overall model. The results for the odds ratio for the association of special issuance certificates with accidents were as follows: 20–29 yr, OR 2.73 (95% CI 1.19–6.27, $P = 0.018$); 30–69 yr, OR 0.84 (95% CI 0.76–0.94, $P = 0.002$); and 70 and over, OR 1.25 (95% CI 1.06–1.48, $P = 0.009$).

Models for the 30–39 yr group and the 60–69 yr group gave odds ratios similar to the larger 30–69 yr group. The young and old groups above showed a significantly increased accident odds ratio for special issuance exams. The large middle group shows a stronger protective effect, with SI exams having a 16% lower accident odds ratio. We are concerned that this model for the younger group may be biased by a higher proportion of first time exams in which reported flight times may be much less than actual hours flown, as discussed below, which would elevate this OR. If so, we have no way to correct for this bias, but the OR is high enough that further investigation is warranted. The 6-mo flight time restriction also removes many first and

only exams so this group is underrepresented in this and the following 3rd-class analyses.

The logistic regression analyses above have the advantage of adjusting for several confounders when modeling the association of a special issuance with the odds of an accident for these groups. However, these models produce their results in terms of odds ratios, which are difficult to intuitively appreciate. So we felt it would be very desirable to also express these effects directly in terms of accident rates per 100,000 flying hours. Calculating the flight time denominator for these accident rate calculations can be accomplished using the pilot reported past 6-mo or total flight times using two different techniques as discussed in the Methods section. The difference in total flight times has the potential to be more precise since the 6-mo times reflect only part of the exam duration or reflect retrospective flying. However, the missing data in the reported total flight times resulted in 424,677 (34%) exams for which flight time cannot be calculated, which makes it likely that this group is not representative of the overall group of 3rd-class certificate holders. Flight time based on reported past 6-mo time was not available for 185,246 (15%) exams due to missing data.

Calculation of accident rates using flight hours derived from reported total flight times included 720,463 exams and 3448 accidents, with 38 fatal accidents representing 287,545 pilots. The sum of flight hours using this method is 135,744,998, so the accident rate is 2.54 per 100,000 h with a fatal accident rate of 0.028 per 100,000 h.

Repeating this calculation using flight hours derived from reported past 6-mo flight times included 1,041,931 exams and 5906 accidents with 1150 fatal accidents for 389,875 pilots. The sum of flight hours was 89,035,946 h, so this method gave an accident rate of 6.63 per 100,000 h with a fatal accident rate of 1.29 per 100,000 h.

It is disappointing that calculations using reported total flight times yielded such unrealistic rates, but one consequence of this approach was to exclude many exams and accidents that are associated with smaller flight times due to the requirement for reported total flight times for both that exam and the subsequent exam. This appears to have had a large negative effect on the calculated rate. The general aviation accident rates published by the NTSB for 2002 through 2011 averaged 6.78 per 100,000 flight hours, with an average fatal rate of 1.28 per 100,000 h, which is very close to the 6.63 per 100,000 h and fatal accident rate of 1.29 obtained here using the reported 6-mo times.¹¹ We used the flight times derived from the reported past 6-mo flight times for the analysis below. Even though we expect that both the NTSB rate and our rate have large margins of error, it is reassuring that the published NTSB rates are so similar to our calculated rates using reported 6-mo flight time.

Repeating these accident rate calculations separately for regular issuance and special issuance exams within 10-yr age groups gave the results below. These are accident rates (fatal rates in parentheses) per 100,000 h using flight hours derived from reported past 6-mo flight times: 20–29 yr, regular 2.99 (0.41), SI 7.23 (--); 30–39 yr, regular 4.72 (0.65), SI 3.23 (--); 40–49 yr, regular 6.01 (1.13), SI 6.10 (1.20); 50–59 yr, regular

7.05 (1.41), SI 6.27 (1.38); 60–69 yr, regular 8.42 (1.91), SI 8.25 (1.43); 70–79 yr, regular 9.76 (1.93), SI 11.55 (2.65); and 80–89 yr, regular 9.93 (2.38), SI 14.62 (--). Where there were fewer than 10 accidents, the rates are designated (--).

The accident rate for all ages was 6.49 per 100,000 h for regular issuance and 8.23 per 100,000 h for SI, which was significant ($P < 0.001$) due to the confounding effect of age. This confounding effect is reduced by the above age stratification and only the 20–29 yr group showed a statistically significant ($P = 0.042$) difference between regular issuance and SI, with the oldest two groups coming close ($P = 0.060$ and $P = 0.055$.) The trend for increasing accident rates with age was significant ($P < 0.001$).

These higher accident rates for younger and older special issuance pilots agree with the pattern of the odds ratios modeled above. As for the logistic regression models, a measurement bias is a possible issue in the 20 to 29 yr group as detailed in the Discussion section. So, we feel this result is not sufficient to confirm the effect of a special issuance in this group. But the elevated point estimates in both the young and old groups deserve further investigation.

The overall analysis of 1st and 2nd-class exams used the same age and flight hour limitations as for the 3rd-class exams above. In order to obtain accidents more congruent with flight times, we also explored a subgroup with characteristics typical of established commercial pilots. These pilots held an airline transport pilot (ATP) rating, were 23–65 yr old, and had reported at least 200 h in the past 6 mo and at least 1500 h of total flight time.

Table III compares demographics between exams with a special issuance and a regular issuance for all 1st & 2nd-class applications and also for the ATP group. In the overall 1st and 2nd-class group only 1.9% of the exams were missing past 6-mo flight time and 1.5% were missing total flight time. The difference between regular issuance and SI in both the overall 1st/2nd-class group and the ATP group were statistically significant ($P < 0.05$) for age, gender, BMI, and flight times, but not for accidents.

A logistic regression model for commercial accidents in the overall 1st and 2nd-class group adjusted for the confounding variables tabulated below included 2,755,550 (98%) of the exams, with 2418 accidents, and gave the results displayed in **Table IV**.

Table III. Descriptive Statistics for Overall Commercial and Those with ATP.

	REGULAR	SI	REG. ATP	SI ATP
Age (yr, mean)	44.5	52.9	47.1	53.5
Gender (% female)	4.3	3.1	3.3	2.6
BMI (mean)	27.1	28.4	27.2	28.3
Total Fit Time (h, median)	6600	10,000	9641	12,600
Past 6-mo (h, median)	200.0	150.0	300	200
Exam Time (yr, median)	0.68	0.53	0.51	0.51
Accidents	8372	380	2756	180
Number Exams	2489,987	125,405	1732,117	96,263
Number Pilots	437,711	23,362	156,527	13,829

SI: special issuance; ATP: airline transport pilot.

Age between 16 to 100; previous 6-mo flight time no more than 600 h and total flight times no more than 40,000 h.

Table IV. Results of Logistic Regression Model for All 1st & 2nd-Class Exams.

PREDICTOR VARIABLE IN MODEL	95% CONFIDENCE		
	ODDS RATIO	INTERVAL	P-VALUE
Special Issuance Waiver	1.011	0.825 1.238	0.919
Age (per 10 yr)	1.076	1.028 1.126	0.002
Gender (compared to Male)	0.719	0.569 0.909	0.006
BMI (per 10 units)	1.044	1.024 1.064	<0.001
Total Flight Hours (per 1000 h)	0.996	0.987 1.004	0.289
6-Mo Flight Time (per 25 h)	1.071	1.064 1.079	<0.001
Exam Duration (per yr)	1.466	1.399 1.536	<0.001

Results for each predictor variable are adjusted for the effect of the other predictor variables.

Units for continuous covariates were chosen to improve clarity.

This model showed no association of special issuance waivers with accidents for the overall 1st and 2nd-class group. The association of gender and past 6-mo flight hours was significant and similar to that found in the 3rd-class group. Increasing age was also a risk factor, with a 7.6% increase in accident odds for every 10 yr, which is a smaller effect than for the 3rd-class group. Exam duration will always be significant in these models as discussed under 3rd-class.

The logistic regression for the ATP group included 1,080,644 (99.2%) of the exams, with 798 commercial accidents, and was significant only for both flight times, which were very small effects. Logistic regression models of the ATP group were also constructed separately for a young age group, the oldest age group, and the remainder to look for associations in the former groups that may be obscured in the overall model. We found: 23–35 yr, OR 2.854 (95% CI 1.052–7.744, $P = 0.040$); 36–55 yr, OR 0.972 (95% CI 0.580–1.628, $P = 0.913$); and 56–65 yr, OR 1.130 (95% CI 0.603–2.155, $P = 0.704$).

Again, we found a significantly elevated accident OR for the youngest age group, which would benefit from further research to determine why this is the case. We believe possible information bias due to under-representations of flight times is much less of a threat for this young ATP group due to the lack of first-time exams. However, it is likely that this younger group is involved in higher risk flight operations such as instruction or air taxi than the older pilots.

Calculation of accident rates for the 1st & 2nd-class group can provide further information regarding the effect of a special issuance on safety in different age groups. Due to the discordance between accident numbers and flight hours in the overall group as discussed above, meaningful accident rates could only be calculated for the ATP group using only commercial accidents that should correspond more closely with their reported flight times.

As in the 3rd-class group, use of total flight time data for calculation of accident rates was unsatisfactory and reported past 6-mo flight times in the ATP group were expected to be much more reliable than for the 3rd-class group. We assume the vast majority of these flight hours were for airline operations. This data included 1,079,952 exams with 798 accidents. The accident rate per 100,000 h for the special issuance group was 0.196 compared to 0.165 for regular issuance. These rates were not significantly different ($P = 0.975$). Our confidence in this technique

for accident rate calculations was further bolstered by its close agreement with the published NTSB rates for U.S. airline accidents, which was 0.189 per 100,000 h for this time period.¹¹

Accident rates per 100,000 flight hours for five age strata from 23 yr old to 65 yr old were also calculated for this group. There was no statistically significant difference between the regular issuance and special issuance rates in any of the age groups. And we observed no trend of increasing risk with age in this ATP group.

DISCUSSION

This study was carried out on a very large pilot population consisting of 1,051,388 U.S. pilots who were issued medical certificates based on 4,072,660 flight exams from 1/1/2002 to 12/31/2011. The pilots with special issuance were significantly older, with a smaller proportion of women, larger total flight time, and slightly larger BMI than the regular issuance pilots. Annual flight time for the SI pilots was larger for pilots with 3rd-class certificates and smaller for 1st and 2nd-class holders.

We explored the association of special issuance certificates with accident odds using logistic regression modeling which was adjusted for age, gender, total flight time, flight time in previous 6 mo, BMI, and exam duration to remove the effect of confounding by these variables. We also calculated accident rates directly using a novel technique based on pilots' self-reported flight hours from the applications for a medical certificate.

For the overall 3rd-class group, logistic regression modeling showed the special issuance group had 8.7% lower odds of an accident than the regular issuance group. As found in previous studies, increasing age was associated with higher accident odds, women had lower accident odds than men, and higher recent flight time (exposure) was associated with increased accident odds. When stratified by age, the youngest and oldest groups showed a significantly increased accident odds ratio for special issuance exams. We are not confident about the younger pilots' findings due to a possible data bias, explained below, which could result in underreported flight time for this group. If so, this would contribute to elevation of both this calculated OR and the accident rates below for younger pilots.

Calculated accident rates for the overall 3rd-class group were 6.63 per 100,000 flight hours (1.29 for fatal accidents), which agrees closely with published NTSB rates for general aviation. When calculated for 10-yr age groups, accident rates showed the expected increase with age and special issuance accident rates were lower for the 40 to 69 yr group, but higher for the youngest and oldest groups.

The overall group of 1st and 2nd-class exams and a group with characteristics representative of established commercial pilots was also explored. Our logistic regression model found no significant association of an SI with accident odds in either of these groups or in age-stratified subgroups. As in the 3rd-class models, age, gender, and 6-mo flight time were significant and in the same direction. For the ATP group, the logistic

regression model was only significant for flight times and these were very small effects.

The most significant limitations of this study were the amount of missing DIWS data for flight hours and the difficulty accounting for flight hours for some types of exams such as pilots with only one exam during the study period. We are concerned that some exams may also be biased toward smaller flight times due to the reported flight times not being representative of flying activity during the entire exam period. For example, first and only exams are valid for up to 5 yr for pilots under 40 yr old, but the reported flight times only represented activity prior to that first exam. This is a disproportionate issue for younger pilots, which may well bias their flight times to be too small and, thus, accident odds and rates may both be elevated. This bias should not affect the ATP group, but this group of younger pilots may be involved in higher risk flight operations. The missing flight-hour data also causes some groups not to be well represented in the exams available for our analysis. However, we do believe that the similar findings from multiple analysis allows for estimates that are more reliable regarding the association of SI waivers with aviation accidents.

In conclusion, FAA special issuance procedures did not appear to be a safety risk overall and enabled many pilots to greatly extend their flying careers. In fact, they were associated with significantly lower odds of an accident in the 3rd-class certificate holders overall with no effect on risk for 1st and 2nd-class pilots. Analysis stratified by age showed increased accident odds for special issuances in the oldest and youngest age groups, but lack of consistent statistical significance in the older group and the possibility of bias in the data for the younger group does not permit confirmation of this. It would be interesting and useful to explore which medical conditions (using FAA pathology codes) may be associated with higher accident risk in the oldest and youngest pilot groups, and how they interact with the presence of a special issuance. This is beyond the scope of this study and is recommended for future research.

ACKNOWLEDGMENTS

Authors and affiliations: William D. Mills, M.D., Ph.D. (Epidemiology), Civil Aerospace Medical Institute, and Joshua T. Davis, Ph.D. (Biophysics), M.S. (Physics), Venesco LLC, Oklahoma City, OK.

REFERENCES

1. Bazargan M, Guzhva VS. Impact of gender, age and experience of pilots on general aviation accidents. *Accid Anal Prev*. 2011; 43(3):962–970.
2. Delta Air Lines, Inc v. United States, et al., 490 F. Supp. 907 (N.D. Ga. 1980). [Accessed July 2018]. Available from: <http://law.justia.com/cases/federal/district-courts/FSupp/490/907/1905311/>.
3. FAA Office of Aerospace Medicine. Guide for Aviation Medical Examiners. 2017. [Accessed July 2018]. Available from: https://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/.
4. Federal Aviation Administration. Revision of Medical Standards and Certification Procedures and Duration of Medical Certificates, Federal Register Doc No: 94-26047. 1994; 59(203). [Accessed July 2018]. Available from: <https://www.gpo.gov/fdsys/pkg/FR-1994-10-21/html/94-26047.htm>.
5. International Civil Aviation Organization. Annex 1 - Personnel Licensing, 11th Ed. Montréal: ICAO; 2011:1-10. [Accessed July 2018]. Available from http://web.shgm.gov.tr/documents/sivilhavacilik/files/pdf/saglik_birimi/mevzuat/ICAO_Annex%201-ed11.pdf.
6. International Civil Aviation Organization. Convention on International Civil Aviation, Document 7300. Montréal: ICAO; 1944. [Accessed July 2018]. Available from <https://www.icao.int/publications/Pages/doc7300.aspx>.
7. International Civil Aviation Organization. Manual of Civil Aviation Medicine, 3rd Ed. 2012 ed. Montréal: ICAO; 2012:I-3-3. [Accessed July 2018]. Available from <https://www.icao.int/publications/pages/publication.aspx?docnum=8984>.
8. McFadden KL. DWI convictions linked to a higher risk of alcohol-related aircraft accidents. *Hum Factors*. 2002; 44(4):522–529.
9. Mills WD. The association of aviator's health conditions, age, gender, and flight hours with aircraft accidents and incidents [Dissertation.] 2005. [Accessed July 2018]. Available from: <http://birdlibrary.ouhsc.edu/MODX/epub/Dissertations/Mills-William-Douglas.pdf>.
10. Mills WD, DeJohn CA, Alaziz M. The U.S. experience with waivers for insulin-treated pilots. *Aerosp Med Hum Perform*. 2017; 88(1):34–41.
11. National Transportation Safety Board. Aviation Accident Database & Synopses. Washington, DC; 2017 [8/28/2017]. [Accessed July 2018]. Available from: <https://app.ntsb.gov/avdata>.
12. Office of Aerospace Medicine. CACI Conditions, Guide for Aviation Medical Examiners. 2017. [Accessed July 2018]. Available from: http://www.faa.gov/about/office_org/headquarters_offices/avs/offices/aam/ame/guide/certification_ws/.
13. Skaggs V, Norris A, Johnson R. 2010 Aerospace Medical Certification Statistical Handbook. Washington (DC): FAA; 2012. [Accessed July 2018]. Available from: http://www.faa.gov/data_research/research/med_humanfacs/oamtechreports/2010s/media/201203.pdf.
14. U.S. Navy. Aeromedical Reference and Waiver Guide. Pensacola (FL): U.S. Navy; 2016. [Accessed July 2018]. Available from: <http://www.med.navy.mil/sites/nmotc/nami/arwg/Pages/AeromedicalReferenceandWaiverGuide.aspx>.
15. Weber DK. Aeromedical waiver status in U.S. Naval aviators involved in Class A mishaps. *Aviat Space Environ Med*. 2002; 73(8):791–797.