

Federal Aviation Administration

DOT/FAA/AM-15/5 Office of Aerospace Medicine Washington, DC 20591

Risk Assessment in the U.S. Pilot Population From 1983 to 2005: Diabetes Prevalence and Flight Safety

Paul B. Rogers Steven J.H. Véronneau Estrella M. Forster

Civil Aerospace Medical Institute Federal Aviation Administration Oklahoma City, OK 73125

March 2015

Final Report

NOTICE

This document is disseminated under the sponsorship of the U.S. Department of Transportation in the interest of information exchange. The United States Government assumes no liability for the contents thereof.

This publication and all Office of Aerospace Medicine technical reports are available in full-text from the Federal Aviation Administration website.

Technical Report Documentation Page

1. Report No.	Government Accession No.	Recipient's Catalog No.				
DOT/FAA/AM-15/5						
4 Title and Subtitle		5 Report Date				
	1. E 1002 2005	5. Report Date				
Risk Assessment in the U.S. Pilot Po	opulation From 1983-2005:	March 2015				
Diabetes Prevalence and Flight Safe	tv	6. Performing Organization Code				
7. Author(s)		8. Performing Organization Report No.				
Rogers PB Véronneau SJH Forster	EM					
	2112					
9. Fenoming Organization Name and Address	10. WOR OHILINO. (TRAIS)					
FAA Civil Aerospace Medical Instit	rute					
P.O. Box 25082	11. Contract or Grant No.					
Oklahoma City, OK 72125						
Okianoma City, OK 73125						
12. Sponsoring Agency name and Address		13. Type of Report and Period Covered				
Office of Aerospace Medicine						
Eaderal Aviation Administration						
800 Independence Ave., S.W.						
Washington DC 20591	14. Sponsoring Agency Code					
15. Supplemental Notes						
1						

16. Abstract

Introduction. A Scientific Information System developed at the Civil Aerospace Medical Institute (CAMI) has supported several studies of the U.S. civil pilot population. The CAMI Numerical Sciences Research Team used this unique data construct to examine the aeromedical and aviation safety aspects of diabetes. The prevalence of diabetes from 1983 through 2005 and its associated risk factor, obesity, was studied. Issues associated with the medical certification of aviators with diabetes and their relationships with accident risk were examined.

Methods. The Scientific Information System is a longitudinal dataset of the entire U.S. civil pilot population spanning the years 1983 through 2005. This paper discusses the parallel trends of Body Mass Index (BMI) and numbers of aviators with diabetes over a 23-year time frame. The information was stratified by gender and age groups. A count-based regression model was used to quantify safety risk posed by diabetic airmen.

Results. The number of airmen with diabetes in the U.S. active population of airmen has risen from 2,768 in 1983 to 10,806 in 2005. The increasing proportion of reported diabetes within the U.S. civil pilot population escalated to 1.6% and 0.5% for men and women, respectively, in 2005. Increasing median BMI is found to be on the rise from the early nineties through 2005. There was evidence that aviators with reported diabetes controlled by hypoglycemic medication and diabetes controlled by diet alone were at greater accident risk than aviators without these conditions. Examining the accident reports for airmen with diabetes controlled by insulin (Code No. 936) did not reveal any evidence that the diabetes condition played a role in the accident occurrence.

Discussion. It is clear that the epidemic of obesity and diabetes began in the early nineties within the U.S. civil pilot population. Increasing numbers of aviators with diabetes can be observed from 1983 through 2005. Diabetes controlled by hypoglycemic medication (Code No. 937) and diabetes controlled by diet (Code No. 935) were statistically associated with aviation accidents. Although associated with aviation accidents, the role of these two diabetes conditions was not a causal one but rather act as markers for a strata of high-risk airmen with multiple comorbid chronic conditions. Each of these comorbid conditions were not, by themselves, medically disqualifying but acted in combination to produce an airman marginally fit for flight.

combination to produce an annual marginary ne for ingite.							
17. Key Words		18. Distribution Statement					
Diabetes, U.S. Civil Pilot Popula	Document is available to the public						
Aviation Safety, Epidemiology,	Gender, Medical Class,	through the Internet:					
Age, Obesity, BMI, Flight Time,	www.faa.gov/go/oamtechreports						
Binomial, Regression, Scientific			-				
19. Security Classif. (of this report)	20. Security Classif. (of this page)	21.	No. of Pages	22. Price			
Unclassified	Unclassified		22				

Form DOT F 1700.7 (8-72)

Reproduction of completed page authorized

Contents

Risk Assessment in the U.S. Pilot Population From 1983-2005: Diabetes Prevalence and Flight Safety

1.0 Introduction	1
1.1 Background	1
2.0 Methods	2
2.1 Airmen Dataset	2
2.2 Accident Dataset	3
2.3 Variable Categorization and Classification	3
2.3.1 Body Mass Index	3
2.3.2 Effective Medical Class	4
2.3.3 Age	4
2.3.4 Total Flight Time	4
2.3.5 Gender	4
2.3.6 Diabetic Pathology Codes	4
2.4 Count-Based Regression Model	5
3.0 Results	6
3.1 Diabetes Prevalence	6
3.2 Trends in BMI	8
3.3 Quantifying Risk	8
3.4 Effective Medical Class	9
3.5 Age	0
3.6 BMI	.0
3.7 Gender	. 1
3.8 Flight Time	. 1
3.9 Diabetes	. 1
4.0 Discussion	.2
4.1 Prevalence of Diabetes and Obesity 1	2
4.2 Interpretation of Regression Results 1	2
4.2.1 BMI and Age 1	.2
4.2.2 Gender	2
4.2.3 Total Flight Time	2
4.2.4 Effective Medical Class 1	.2
4.2.5 Statistical Association of Diabetes Covariates With Accident Risk 1	3
5.0 Limitations	4
5.1 Identification of the Different Forms of Diabetes 1	.4
5.2 Misclassification	5
6.0 References	6
Appendix A. The Pathway of Model SelectionA	.1

RISK ASSESSMENT IN THE U.S. PILOT POPULATION FROM 1983-2005: DIABETES PREVALENCE AND FLIGHT SAFETY

If you know a thing only qualitatively, you know it more than vaguely. If you know it quantitatively – grasping some numerical measure that distinguishes it from an infinite number of other possibilities – you are beginning to know it deeply.

—Carl Sagan (Sagan, 1997)

1.0 INTRODUCTION

Are aviators with specific medical conditions or combination of conditions at greater risk of having an accident than aviators without these medical issues? This is a complex question that has been subject to much debate. Is it possible to quantify this risk and make the results available for practical use by managers and regulators? This study was conducted to do just that, by developing a method, through data reshaping and statistical modeling, to quantify the risk of an aircraft accident within diabetic airmen. We examined diabetes and obesity within the U.S. civil pilot population to determine if these conditions have any measurable effect on flight safety.

One of the major health issues within the United States is obesity and diabetes, a condition that has reached alarming proportions (Mokdad, Ford, Bowman, et al., 2003). Diabetes and obesity are not necessarily disqualifying conditions for obtaining an airman medical certificate. The prevalence of diabetes and obesity has increased in the U.S. general population, and the U.S. civil pilot population is a subset of this population. We conducted this study to see if these same trends for obesity and diabetes were reflected in the U.S. airman population and thus explore their effects on flight safety and the longevity of airmen with these conditions. That is, do these trends affect flight safety, and what are the implications within the aviator community? These are questions of interest to researchers, policy makers, and the aviation industry.

This study was an extension of the research published in *An Analysis of the U.S. Pilot Population from 1983-2005: Evaluating the Effects of Regulatory Change* (Rogers, Veronneau, Peterman, et al., 2009) and *Development of an Aeromedical Scientific Information System for Aviation Safety* (Peterman, Rogers, Veronneau, et al., 2008). From these publications, a 23-year longitudinal view of the U.S. civil pilot population was created and studied. In terms of overall numbers, the pilot population is declining and growing progressively older.

1.1 Background

The prevalence of obesity and diabetes has increased within the United States over the last two decades. According to Mokdad et al. (2001), using the data from the Behavioral Risk Factor Surveillance System (BRFSS), these health conditions have reached epidemic proportions. In 2000, the prevalence of obesity had reached 19.8% among adults, an increase of 61% since 1991. This value equates to 38.8 million U.S. adults (19.6 million men

and 19.2 million women). Overweight (Body Mass Index >= 30 kg/m^2) men and women reached 65.5% and 47.6%, respectively, of the overall population. Diabetes has reached an all-time high of 7.3% of the U.S. population. If undiagnosed diabetes is considered, then it is likely that 10% of the U.S. population has this condition. In previous studies covering 1991-1998, every 1 kg (1kg = 2.2 lbs.) increase in average weight was associated with a 9% increase in diabetes prevalence. The average weight reported by U.S. adults increased by 0.5 kg from 1999-2000, and the prevalence of diagnosed diabetes increased by approximately 6% (Mokdad, Bowman, Ford, et al., 2001).

In a follow-up study published in 2003, Mokdad reported the trend towards increasing obesity was shown to continue. For the year 2001, the prevalence was reported at 20.9%; a 5.6% gain over the values reported for 2000 (Mokdad et al., 2003). The same trend was seen in reported diabetes over this same time frame: The overall prevalence increased from 7.3% in 2000 to 7.9% in 2001 (ibid.).

On December 23, 1996, the Federal Aviation Administration (FAA) modified its long-standing policy that disqualified all pilots who were insulin-dependent diabetics (FAA Pathology Code No. 936) from holding a medical certificate. Provisions were created to implement stringent policies that would make it possible for an insulin dependent aviator to hold a third-class medical certificate. The provisions came about due to the lobbying efforts of groups such as the American Diabetes Association (Greene, 1999). The policy change was controversial, and the American Association of Clinical Endocrinologists (AACE), along with some aviation medical examiners, opposed the decision (FAA 1996). Endocrinologists opposed these changes because the risks from the disease can never be eliminated. The Aerospace Medical Association (AsMA) also declined to endorse the new ruling (Mohler, 1997).

The current epidemic of obesity and subsequent rise of Type II diabetes will require that the aeromedical community, both civilian and military, understand how to prevent and recognize this disease (Steinkraus, Cayce, & Golding, 2003). It is of the utmost importance to recognize the symptoms of encroaching Type II diabetes mellitus. Aggressive therapy before onset is critical, as once the disease develops, the aviator will always be at risk of hypoglycemia. There is evidence that the risk of hypoglycemia increases over the duration of the disease (Steinkraus, Cayce, & Golding, 2003).

Diabetes mellitus was found to be one of the five major causes for the permanent grounding of U.S. Air Force pilots

between 1995-1999. Alon Grossman, using a hyperinsulinemic clamp technique, trained two Israeli Air Force aviators, recently diagnosed with Type I diabetes, to better recognize the onset of hypoglycemia and how to quickly manage it (Grossman, Barenboim, Azaria, et al., 2005). This technique successfully returned two Israeli Air Force aviators to active duty in multi-crew aircraft; they were followed 5 and 3 years with no hypoglycemic episodes. Grossman et al. concluded that it is possible to return insulintreated diabetics to the cockpit of multi-crew aircraft if they were provided a sufficient blood glucose-awareness training program. Another study of five Israeli Air Force aviators diagnosed with Type I diabetes reported using aggressive treatment to reduce their blood glucose levels (Carter, Azaria, & Goldstein, 2005). All five were successfully returned to active duty, although one later developed distal neuropathy, a permanent disability.

Heller and Nicholson (2006) argued that returning military aviators to the cockpit who are insulin dependent Type I diabetics, even in a multi-crew aircraft, is not feasible even if trained in a blood glucose awareness program. The management of the disease places an additional burden upon the airman and the rest of the crew. They contend that the onset of hypoglycemia will always be an unacceptable risk factor for the military aviator. Also, many patients who claim to recognize the onset of hypoglycemia fail to do so in a clinical setting (Heller & Nicholson, 2006).

It has also been established that diabetes is a risk factor for cardiovascular disease in older adults (Kengne & Patel, 2006). This is another condition that can lead to in-flight incapacitation. There are a number of additional risks that the diabetes condition imposes on the diabetic aviator. A description of the disease and a broad overview of its complications and associated risks to include hypoglycemia, impaired decision making, vision problems, cardiovascular issues within the aviation environment are summarized by Newman (Newman, 2005).

The current study focused on diabetes prevalence in the U.S. civil pilot population using FAA and National Transportation Safety Board's (NTSB's) databases to make this description possible. For the purposes of this research, an aviation accident was an event recorded in the NTSB's accident database or the FAA's Accident Incident Database System (AIDS).

2.0 METHODS

2.1 Airmen Dataset

The FAA's Scientific Information System (SIS) is a comprehensive aeromedical dataset constructed as prescribed by Holt (Holt, 2001). The SIS supports aeromedical researchers' efforts to describe parameters of interest from the U.S. airmen population. A better view of the effect of policy decisions on the U.S. civil pilot population can be gained with such studies. The SIS, a longitudinal dataset of the entire airman population, was created to view the prevalence of obesity and diabetes over a 23year period (1983-2005). The detailed methodology for piecing this data together is described by Peterman (2008). With such a view, each individual airman can be followed from the time he/she enters the airmen population until the time he/she exits

the population. Entry and exit from the airmen population is indicated with the receiving and expiration of an aviation medical certificate, respectively. The aeromedical exam information can be studied year to year for each individual airman. To be considered an active member of the pilot population, the airman had to pass a medical exam conducted by an FAA aviation medical examiner to obtain a first-, second-, or third-class medical certificate. In the Peterman et al. study, airmen who passed this medical exam are referred to as Active Airmen. This population, followed over 23 years, consisted of 2,390,296 distinct airmen. The relevant pathology codes, which are recorded from the aviator's medical exam (FAA Form 8500-8) were used to identify airmen with diabetes and cardiovascular conditions. The structured query language (SQL) algorithms that constructed this dataset used these pathology codes to track diabetic airmen over the study period. The FAA has no pathology code associated with weight conditions, but the height and weight of airmen are recorded at the time of their medical exam. We constructed and implemented an algorithm within the dataset to calculate the body mass index (BMI) of each airman at the time of his/her medical examination.

The FAA coded the various forms of diabetes within the airman's electronic medical record as disturbance of carbohydrate metabolism (Code No. 931), diabetes mellitus (Code No. 934), diabetes controlled by insulin (Code No. 936), diabetes insipidus (Code No. 938), diabetes controlled by hypoglycemic drugs (Code No. 937), and diabetes controlled by diet and exercise (Code No. 935). According to the FAA *Guide for Aviation Medical Examiners* for this time period, diabetes mellitus requiring insulin or other hypoglycemic medication was a disqualifying condition for all medical certificates under Title 14 of the Code of Federal Regulations (CFR) §67.113(a) (FAA, 2006). The latest edition of the *Guide for Aviation Medical Examiners* was released in September 2014 (FAA, 2014). A diabetic pilot on a hypoglycemic medication (937), other than insulin, was eligible for the consideration of a Special Issuance (SI) of a medical certificate.

Special Issuances are granted by the Federal Air Surgeon. A pilot classified as a diabetic on hypoglycemic medication can hold a first-, second-, or third-class medical certificate. The decision to certify the pilot is made on the basis of a report from the treating physicians. This report must contain information concerning the medication and its dosage, any side effects, and hypoglycemic episodes. The report must indicate if the diabetes is under control and provide the results of a glycosylated hemoglobin (HbA1c) test administered within the last 30 days prior to the FAA medical exam (FAA, 2014). The presence of any cardiovascular, neurological, renal, and/or ophthalmological disease must also be reported by the airman or his/her treating physician.

If the airman is certified, at a minimum, an annual followup evaluation by the treating physician must be accomplished regardless of the class of medical certificate (FAA, 2014). Disturbance of carbohydrate metabolism/hyperglycemia (Code No. 931) is considered a pre-diabetic condition. Airmen with diabetes controlled by diet and exercise alone (Code No. 935) are eligible for all classes of medical certificates as long as there is no associated illness that would be disqualifying. These conditions include cardiovascular, neurological, renal, and ophthalmologic disease. Diabetes insipidus (Code No. 938) was not tracked by the algorithm in the SIS since it frequently develops due to other reasons such as damaged kidneys or hypothalamus or pituitary injury associated with a tumor or stroke. Diabetes mellitus (934), a code no longer used in the electronic records of airmen, previously indicated that an airman was denied a medical certificate due to the diabetes condition. It is tracked in the SIS since many aviators were once denied a medical certificate due to their diabetes but were later able to improve their condition and hold a medical certificate.

On December 23, 1996 an FAA policy change allowed insulindependent pilots who were diabetics (936) the opportunity to become eligible to hold a third-class medical certificate. No such provision was made for first- or second-class certification. To become eligible, airmen must successfully complete a rigorous set of medical tests and allow themselves to be monitored as to their diabetic condition. According to the FAA *Guide for Aviation Medical Examiners* (FAA, 2006), applicable to the time period of the study, the initial certification required that an applicant:

- Must not have had any more than two episodes of hypoglycemia in the last 5 years and none in the preceding year which resulted in loss of consciousness, seizure, impaired cognitive function or requiring intervention by another party, or occurring without warning (hypoglycemia unawareness).
- Copies of all medical records along with any accident or incident records relative to their diabetes conditions must be submitted.
- A comprehensive medical examination, along with the associated laboratory results by a physician that specializes in the treatment of diabetes, must be submitted.

To maintain their certificate, airmen who were issued thirdclass medical certificates must be evaluated every three months by their treating physician. The reports from this examining physician should confirm the absence or presence of eye disease on at least an annual basis. The airman must also report any hypoglycemic incidents, any involvement in accidents that resulted in serious injury, any change in their diabetic condition or the management thereof, and must cease all flying until cleared by the FAA. The airman must also agree to follow the rules concerning the monitoring and actions required for managing their glucose concentrations for each flight. Some of these actions are:

- One-half hour prior to flight, the airman must measure his or her blood glucose concentration. If it is less than 100 mg/ dl, the individual must ingest a glucose snack of not less than 10 gm and measure the concentration one-half hour later. If the concentrations are within 100 to 300 mg/dl, then flight operations may be undertaken. If less than 100 mg/dl, the process must be repeated; if over 300 mg/dl, the flight must be cancelled.
- One hour into the flight, at each successive hour, and within one-half hour of landing, the airman must measure his/her blood glucose concentration. If the concentration is less than 100 mg/dl, a 20- gm glucose snack should be taken. If

the concentration is 100-300 mg/dl, no action is required. If the concentration is greater than 300 mg/dl, the airman must land at the nearest suitable airport and may not resume flight until the glucose concentration can be maintained in the 100-300 mg/dl range.

For this study, the diabetic condition was considered a chronic disease that had no cure. Although some individuals improved their overall health and more effectively managed their diabetes-related problems, they were considered to be diabetics throughout their aeromedical history. The algorithm used this premise to calculate diabetes annual prevalence. Once an airman was diagnosed as diabetic, she/he was counted as a diabetic in subsequent years; this reasoning explained why a small number of insulin-dependent diabetics resided within the U.S. civil pilot population prior to the 1996 policy change that provided the opportunity to earn a third-class medical certificate. These individuals were insulin-dependent diabetics who improved their overall diabetes condition and later discontinued their use of insulin. The SIS algorithm identified the first exam where the individual was assigned any diabetes pathology code and carried this assignment forward. From the longitudinal data, we examined the prevalence of diabetes over this 23-year time frame, as well as other measures and demographics.

2.2 Accident Dataset

One of the greatest concerns regarding aviators with diabetes was an increased risk of accident due to incapacitation brought about by the disease or one of its complications. Complete accident data for the years 1983-2005 were obtained from the NTSB or AIDS databases; at times, the accident was recorded in both datasets, but the accident was only counted as a single occurrence. Algorithms within the SIS "tagged" the electronic records of an airman as an "*accident airman*" if he/she had one *or more* accidents in a given year. The purpose of this tag was to explore several factors, including: Age, Gender, BMI, Class of Medical Certificate, Diabetic Classification, and Flight Time.

We preferred to quantify any risk from these factors in terms of accident data with a count-based regression model. It is generally recognized that aviation accidents are rare events affecting roughly 1% of airmen. A properly constructed count-based regression method accommodates the modeling of rare outcomes. For ease of interpretation and to control for the effects of outliers, some of the previously mentioned factors were transformed into binary and ordinal variables.

2.3 Variable Categorization and Classification 2.3.1 Body Mass Index

BMI was initially a continuous variable calculated from the height and weight of airmen at the time of their medical exam. BMI was transformed into an ordinal variable and categorized as Underweight (< 18.5), Normal (18.5 – 24.9), Overweight (25.0 - 29.9) and Obese (\geq 30.0), according to the Centers for Disease Control and Prevention (CDC) classification for adults 20 years of age and older (CDC, 2010).

2.3.2 Effective Medical Class

The variable Effective Medical Class was created with three categories to represent first-, second-, and third-class medical certificate holders. Effective Medical Class captured the current medical certificate the airmen held at the end of each year; this may not be the same as the medical class issued to the airman at the time of their last medical exam. The class-level of an airman's medical certificate can, in effect, expire and revert to the next-lower medical class if not renewed at the appropriate time. For example, if an airman's first-class medical certificate was not renewed before the end of its validity period, it transformed to a second-class medical certificate for the remainder of the second-class validity period. Once the second-class validity period expired, it was considered a third-class medical certificate. If the airman held a third-class medical certificate and did not renew it before the expiration date, the airman became legally unable to fly and was no longer considered an Active Airman.

2.3.3 Age

The airman's age was initially stored as a continuous measure but transformed into categories. Age was divided into 16 to 25, 26 to 35, 36 to 45, 46 to 55, and 56+ year age groups. This methodology created five distinct categories of age groups. An individual airman moved through these different age categories if she/he remained in the U.S. civil pilot population for a number of years.

2.3.4 Total Flight Time

We intended to use the airman's reported flight time as a measure of the airman's flight experience. This was a self-reported value given at the time of the medical exam and recorded on the FAA Form 8500-8. It was usually considered a "guess" or "best estimate" by the airman. Within the electronic medical records, the variable "flight time" for many airmen had some extreme values and potential outliers. Therefore, flight time was transformed into a binary variable representing "experienced" and "inexperienced" aviators, based on House Resolution 5900, The Airline Safety and Federal Aviation Administration Extension Act of 2010 (H.R.5900 2010). Representing flight time as a binary variable reduced the influence of the outliers. Aviators with less than 1,500 flight hours were classified as "inexperienced," while those with 1,500 or more hours were classified as "experienced." These data were represented as a binary variable, with a "1" to indicate 1,500 or more flight hours and a "0" to indicate less than 1,500 flight hours.

2.3.5 Gender

Gender was converted to a binary variable with a "1" indicating male and "0" female. Overall, there were 2,176,095 (91%) distinct male and 214,201 (9%) distinct female airmen in the longitudinal dataset. This disproportionate population of males remained relatively constant over the study period.

2.3.6 Diabetic Pathology Codes

Due to the complex methods used in tracking the diabetes pathology codes through 23 years of data, an airman classified as diabetic remained so through the course of the study period. Subjects with diabetes insipidus (938) were excluded from classification as diabetic airmen, as this condition is not related to a glycemic condition. Diabetes controlled by diet (935), diabetes controlled by hypoglycemic medication (937), and disturbance of carbohydrate metabolism (931) were each represented as a binary variable, with a "1" or "0" indicating the presence or absence of the condition. Diabetes mellitus (934) and diabetes controlled by insulin (936) were not included in the Poisson regression due to inconsistent usage in pathology coding over the 23-year study period.

The pathology code for diabetes mellitus indicated disqualification, and its use was discontinued while policy changes allowed some aviators with diabetes controlled by insulin to appear in ever-increasing numbers from late 1996 forward. Further, the number of accident events for aviators with diabetes controlled by insulin was small enough to allow the examination of each accident individually. This analysis was performed to see if the NTSB accident investigation assigned the diabetes condition as an accident causal factor.

Some aviators were classified as having one or more of these diabetes conditions, creating an overlap, in terms of counts of airmen, among the diabetes variables. It became impossible to distinguish these path codes from one another as sometimes the path code for diabetes changed for individuals from exam to exam. For example, a subject may have been initially coded as a diabetic controlled by diet (935), then coded with diabetes controlled by hypoglycemic medication (937) on the subsequent exam, and then with the original pathology code of 935 on the third exam. It was not possible to determine if this change in diabetes pathology code represented a change in the treatment of the disease or if it was a coding error.

One problem in generating the counts of airmen for the three diabetic covariates (931, 935, 937) for inclusion in the countbased regression model was that of overlapping counts. That is, airmen who had multiple diabetic pathology codes contributed to the overall counts for more than one diabetes covariate. A coding system was implemented to prevent overlapping counts of the three diabetes covariates. The method for calculating the counts for each of the covariates representing diabetes was hierarchical based on degrees of disease severity. Disturbance of carbohydrate metabolism was considered a pre-diabetic condition (931) and was considered less severe than diabetes controlled by diet (935) and hypoglycemic medication (937). Diabetes controlled by diet (935) was considered a lesser degree of the disease than diabetes controlled by hypoglycemic medication (937). This approach meant that an electronic airmen medical record tagged as a diabetic airman with multiple codes was only counted once towards the diabetes code considered the most severe. For example, if an airman in the year 1998 was tagged as a diabetic airman and had two pathology codes (say, codes 931 and 937), then that airman contributed to the counts of diabetes controlled by hypoglycemic medication (937) and not towards disturbance of carbohydrate metabolism (931). If this same airman, in the year 2002, was no longer on hypoglycemic medication (937) but had diabetes controlled by diet (935), this airman still contributed to the counts of diabetes controlled by hypoglycemic medication (937) and not towards diabetes controlled by diet (935). In other words, an airman was always counted towards the greatest degree of diabetes severity the airman at one time experienced and was never allowed to be counted towards a lesser severity of diabetes pathology code.

2.4 Count-Based Regression Model

Aviation accidents are rare in the National Airspace System and have been decreasing over time. Initially, as the data in the SIS was longitudinal and allowed the tracking of individual pilots, a Generalized Estimating Equation (GEE), with accidents represented as a binary dependent variable, was to be used to quantify risk relative to selected covariates of interest. The rarity of the outcome, in GEE, created problems with the variances of the regression coefficients, so this method was abandoned. GEE models with binary outcomes underestimate the variance of the regression coefficients when the outcome is rare (King & Zeng 2001; Hardin 2003).

A Poisson count-based model was then used to accommodate rare events and provide estimates of risks in terms of incidence rate ratios (IRR). The units of these ratios were measured in number of accident events in person-years. One of the unique assumptions of the Poisson model is that the mean and variance are considered equal. This was a drawback in that our data were typically overdispersed (the variance was greater than the mean). We intended to address this overdispersion in the Poisson model with the dispersion statistic, which adjusts the standard errors of the regression coefficients. In the Poisson model, the factors of interest were restricted to Year, Gender, Age, Flight Time, BMI, and Diabetes code. Diabetes was represented by the three covariates (931, 935, and 937). This methodology generated results for each factor, adjusting for all other covariates in the model.

In Poisson regression, the outcome, or dependent variable, must be count-based. The independent variables may be countbased, or some other data type may be used. To accommodate this requirement, the longitudinal data were reshaped into categories based upon the counts of accident airmen. Structuring the data in this manner allowed the analyst to examine the numbers of accident airmen for a given *covariate pattern*. A covariate pattern can be envisaged as the configurations created by the unique combinations of all the independent factors in the regression model. There were a total of 10,465 observations (covariate patterns) in the dataset constructed from these counts. At a significance level (α) of 0.05 and using an incidence rate ratio of 1.40 as an effect size, then with a base response rate of 1% these values resulted in an estimate of statistical power at 85% (Signorini, 1991).

Another predictor in the Poisson model, the *offset*, or exposure, does not have a regression coefficient to be estimated. The offset represents the denominator, or total number of airmen in a particular category or covariate pattern. The need to include this offset was to calculate incident rate ratios within the Poisson regression model. Our initial Poisson regression model equation, omitting interaction terms, appeared as follows (see Equation 2.0, below).

All analyses were performed in Statistical Analysis Software (SAS) version 9.3. The level of significance for all tests was set at 0.05 (α).

$$Log [Count (Accident Airmen)] = \beta_0 + \beta_1 * (Year) + \beta_2 * (Medical Class) + \beta_3 * (Age) + \beta_4 * (BMI) + \beta_5 * (Gender) + \beta_6 * (Flight Time) + \beta_7 * (Diabetes 931) + \beta_8 * (Diabetes 935) + \beta_9 * (Diabetes 937) + log (Offset)$$

$$(2.0)$$

3.0 RESULTS

3.1 Diabetes Prevalence

The prevalence of diabetes was found to be on the increase from the mid-1990s through 2005 (Figure 1). Expressed as a population percentage, the minimum was 0.31% in 1983 and increased to a maximum of 1.57% in 2005. When considering gender, the overall trend was one of increased prevalence of diabetes over time for both sexes. The proportion of men was greater and increased more quickly after 1991 (Figure 2). By the year 2005, the difference between men and women, expressed as a percentage, was 1.17%; thus, diabetes appeared to be three times more prevalent within male U.S. civil pilots than in female pilots. Figure 3 provides another view of how diabetes prevalence has changed from 1983 to 2005 by age category. It is clear that the U.S. civil pilot population has undergone a transformation in terms of numbers of airmen with diabetes, as expected, due primarily to the obesity epidemic.



Figure 1. Number of diabetics in the U.S. civil pilot population.



Figure 2. Diabetes proportion of pilot population by gender.



Figure 3. Population pyramid of pilots with any form of diabetes, excluding diabetes insipidus by age category (Years 1983 vs. 2005).

3.2 Trends in BMI

The BMI of airmen, a factor frequently associated with diabetes determined at their medical exam, showed an upward trend over the study years. In Figures 4 and 5, the median BMI (and weight) for the overall U.S. civil pilot population increased over the study period. BMI appeared to dip in 1989; this was a biased year populated primarily by the surviving medical exams from younger pilots posted to the FAA Document Information Workflow System (DIWS) (Rogers et al., 2009). That is, in 1989, only the electronic medical records requiring no physician review (primarily younger pilots) for the year 1989 were stored in DIWS. Analyzing BMI by gender and age displayed a similar story for women, although the differences in median BMI (Figures 4 and

5) were smaller than those of men. Median BMI appeared to increase consistently over the study years, but the slope of those changes increased more steeply in the early 1990s.

3.3 Quantifying Risk

A Poisson regression model was initially selected for the analysis of data in this study. Due to the characteristics and complexities of the dataset, a Negative Binomial (NB) methodology, employing a robust, or "sandwich" variance estimator, was later adopted. The pathway of model selection is important, and a large part of this research, but due to its length and statistical intricacy, has been moved to Appendix A for readers interested in the mathematical details.



Figure 4. Median female BMI adjusted for age.



Figure 5. Median male BMI adjusted for age.

The NB regression results, consisting of only the significant main effects, are given in Table I. A selection of the NB regression coefficient estimates from Table I was converted to incidence rate ratios for easier interpretation of the analysis and presented in Table II, along with their confidence intervals. Conversion to incidence rate ratios allowed a comparison between the various categories within each specific factor of interest.

Table I indicates that the results of the NB regression revealed that the covariates Year, Effective Medical Class, Age, BMI, Gender, Diabetes Controlled by Diet (Code No. 935), Diabetes Controlled by Hypoglycemic Medication (Code No. 937), and Total Flight Time were all statistically associated with an accident/incident. The regression coefficient for airmen with pre-diabetes symptoms (931) was not statistically associated with such an adverse event (Z = -0.94, p-value = 0.3452).

3.4 Effective Medical Class

The results for Effective Medical Class showed that when third-class was used as the reference group, first-and second-class resulted in incidence rate ratios of 1.42 and 1.75, respectively, (Table II). That is, first-and second-class medical certificate holders showed to be at a greater risk of being classified as an accident

Table I. Negative binomial regression results. The reference group is the group to which all other categories are compared. For example, the ordinal variable, BMI, gives the results for the Underweight, Normal, and Overweight groups, as compared to the Obese group.

Negative Binomial Regression Results Using Sandwich Estimator Standard Errors							
Parameter	Estimate	Standard Error	95% Confidence Limits		Z-Score	p-Value	
Year	-0.0321	0.0012	-0.0345	-0.0298	-26.71	<.0001	
Effective Medical Class							
First	0.3490	0.0222	0.3055	0.3926	15.71	<.0001	
Second	0.5617	0.0157	0.5309	0.5925	35.76	<.0001	
Third	0.0000	0.0000	0.0000	0.0000	Referer	ice Group	
Age – Years							
16-25	-0.1802	0.0355	-0.2497	-0.1107	-5.08	<.0001	
26-35	-0.1843	0.0235	-0.2497	-0.1383	-7.85	<.0001	
36-45	-0.2231	0.0209	-0.2640	-0.1821	-10.68	<.0001	
46-55	-0.0824	0.0208	-0.1232	-0.0417	-3.97	<.0001	
56+	0.0000	0.0000	0.0000	0.0000	Reference Group		
BMI							
Underweight	-0.2787	0.0508	-0.3783	-0.1791	-5.49	<.0001	
Normal	-0.0923	0.0197	-0.1308	-0.0538	-4.70	<.0001	
Overweight	-0.0374	0.0189	-0.0744	-0.0004	-1.98	0.0473	
Obese	0.0000	0.0000	0.0000	0.0000	Reference Group		
Gender	0.3014	0.0236	0.2551	0.3476	12.77	<.0001	
Total Flight Time	0.7196	0.0166	0.6871	0.7521	43.41	<.0001	
Diabetes 935	0.1645	0.0515	0.0636	0.2654	3.20	0.0014	
Diabetes 937	0.2456	0.0597	0.1286	0.3626	4.11	<.0001	

airman than effective third-class medical certificate holders. This classification did not consider type of flying operation, as this would have required a case-by-case review of every accident.

3.5 Age

The results for Age indicated a mixed result regarding accident risk. The age category of 56+ years was set as the reference group, as this was the oldest age category in this study. This group, when compared to airmen in the 16 to 25 and the 26-35 year age groups, had a 20% (IRR = 1.20) greater risk of being classified as an accident airman (Table II). The incidence rate ratios changed to 1.25,

and 1.09 when compared with the 36-45 and 46-55 age groups, respectively. The safest age category was the 36-45 year age category, while the 16-25 and 26-35 age categories were the next safest.

3.6 BMI

A gradient of risk existed for BMI. Comparing the Obese (reference) group to the Normal and Underweight categories resulted in IRRs of 1.10, and 1.32, respectively (Table II). The Obese group was at 4% greater risk (IRR = 1.04) than the overweight group. As BMI increased, so did the risk of the airman becoming an accident airman.

Table II. Selected Table I estimates converted to incidence rate ratios (IRR).

Covariate	IRR	95% Confidence Limits		
A Year versus one later Year	1.0326	1.0302	1.0351	
Medical Class				
First versus Third	1.4177	1.3573	1.4807	
Second versus Third	1.7537	1.7005	1.8085	
Age - 56+				
56+ versus 16-25	1.1975	1.1170	1.2837	
56+ versus 26-35	1.2024	1.1483	1.2591	
56+ versus 36-45	1.2500	1.1998	1.3022	
56+ versus 46-55	1.0858	1.0425	1.1311	
BMI				
Obese versus Underweight	1.3214	1.1962	1.4598	
Obese versus Normal	1.0967	1.0552	1.1399	
Obese versus Overweight	1.0381	1.0004	1.0773	
Gender (Female is Reference group.)	1.3518	1.2907	1.4158	
Total Flight Time (Inexperienced is Reference group.)	2.0536	1.9879	2.1215	
Diabetes Controlled by Diet (935) (Airmen without this condition are the reference group.)	1.1788	1.0656	1.3040	
Diabetes Controlled by Hypoglycemic Medication (937) (Airmen without this condition are the reference group.)	1.2784	1.1372	1.4371	

3.7 Gender

The outcome for Gender indicated that males were at greater risk than females in terms of accident risks. Males were at a 35% (IRR = 1.35) greater risk than females of becoming an accident airmen (Table II).

3.8 Flight Time

Aviators with over 1,500 hours of flying time presented twice the risk of an accident or incident than a lower flight time pilot without regard for type of flying operation.

3.9 Diabetes

The regression coefficient representing Diabetes Controlled by Diet (Code No. 935) was statistically associated with a higher risk of an accident. These airmen had an 18% (IRR = 1.18) greater risk when compared to airmen without this pathology code. Diabetes controlled by hypoglycemic medication (937) was also statistically associated with a higher risk of accident. These airmen had a 28% greater risk (IRR = 1.28) of an accident than airmen without this pathology code (Table II). Insulin-dependent diabetic aviators were not included in the regression model, as they were not allowed to hold an aviation medical certificate until late 1996. Therefore, they were not a part of the U.S. civil pilot population over all 23 years of the study and were not represented in the years before 1996.

The number of NTSB events involving insulin-dependent airmen from 1997-2005 was only 18. The NTSB accident reports were examined for the cause of each accident. There were no medically related accidents (incapacitation, diabetes); all but one incident, which was mechanical (not pilot-related), were human factors-related. All flights were conducted by male pilots under Title 14 CFR Part 91 (general operations) as personal trips. Two of these accidents resulted in fatalities; one resulted in non-fatal injuries, while 15 resulted in no injuries. Seventeen of these accident flights were conducted under Visual Flight Rules (VFR) operations. One flight was operating under Instrument Flight Rules (IFR) conditions. Table III lists the outcome of these accidents, as well as the time and result of the airman's last aviation medical examination.

Table III. Eighteen accidents involving insulin-dependent diabetic pilots and the outcome of their last aviation medical examination.

	Year of			
Year of	Airman's Last		Accident	
Accident	Medical Exam	Outcome of Medical Exam	Injuries	NTSB Number
1998	2001	Denied due to medical reasons.	Uninjured	NYC99LA016
1999	1999	Issued	Uninjured	MIA99LA090
1999	1998	Issued prior fatal	Fatal	FTW99FA211
1999	2002	Issued	Uninjured	SEA00LA009
1999	2001	Issued	Uninjured	NYC00LA041
2000	2006	Issued	Uninjured	FTW00LA092
2000	2009	Converted to sport pilot	Uninjured	DEN00LA058
2000	1998	Issued	Uninjured	FTW00LA122
2000	2012	Not issued	Serious	ATL00LA060
		AME denial due to failure to		
2001	2004	provide information	Uninjured	CHI01LA153
2002	2001	Issued prior fatal	Fatal	FTW02FA087
2002	2011	Issued	Uninjured	DEN02LA059
2003	2005	Issued	Uninjured	ATL04LA034
2003	2003	Issued	Uninjured	NYC04CA031
2004	2013	Issued	Uninjured	DEN04LA042
2004	2012	Issued	Uninjured	DEN04CA054
2004	2003	Issued	Uninjured	SEA04LA072
2005	2013	Issued	Uninjured	ATL05CA080

4.0 DISCUSSION

4.1 Prevalence of Diabetes and Obesity

Examining the U.S. civil pilot population over the 23-year study period revealed that this community also experienced the diabetes and obesity epidemic as in the U.S. general population (Rogers et al., 2009). Overall, the U.S. civil pilot population declined in numbers and increased in median age. As the population aged, chronic conditions such as diabetes and obesity were becoming more prevalent. The percentages of diabetics observed in this study (Figure 2) were much smaller than those of the U.S. general population and were probably due to the "healthy worker" effect attributed to the medical certification process. The "healthy worker" effect limited this study to those airmen who maintained a minimum standard of health that allowed them to hold an aviation medical certificate.

Using the SIS to examine the distribution of diabetes and obesity within our defined population showed that the prevalence of diabetes and elevated BMI has been increasing over time. Furthermore, we were able to identify the exact time periods (1994 onward) when the rates of obesity and diabetes began to increase. When the last year of the study period was examined, it showed the greatest number and prevalence of diabetes. This study showed that the aviator community is not immune to the obesity epidemic, as median BMI has increased greatly over time (Figures 4 and 5). Obesity was associated with a number of other medical conditions such as high blood pressure and cardiovascular disease; other studies have demonstrated that aviators are not isolated from these effects (Bryman & Mills, 2007). While the diabetic condition can be hidden or remain undiscovered, excessive BMI is difficult to hide. As Bryman and Mills pointed out, BMI is a comorbid condition for many other medical conditions in the aviation population (ibid).

In the present study, we observed that pilots with diabetes were also much more likely to have a cardiovascular condition and/or hypertension requiring medication. A combination of these other medical conditions may have contributed to the overall probability of having an accident.

4.2 Interpretation of Regression Results

Quantifying risk from the diabetes condition in regard to flight safety involved the use of an NB regression model. The NB regression results provided evidence of excess hazard in aviator diabetics controlled by hypoglycemic medication (937) and diabetes controlled by diet (935) in terms of accident risk.

Age, Gender, BMI, Year, and Medical Class were other factors that contributed significantly to airmen having an NTSB or AIDS event. These factors may or may not be causal in nature. The negative regression coefficient for the covariate Year revealed that the risk of having an accident decreased over time. This result matched the NTSB data in this same time period. The reason for this decrease was attributed to the declining airmen population.

4.2.1 BMI and Age

BMI and Age indicated an association of increasing risk for the obese older aviator. These two risk factors for chronic disease conditions were associated with an increased risk of accident. BMI was a covariate that revealed more about an individual's health and its relationship to risk in aviation. The gradient of risk for BMI was clear; an increase in this factor directly associated with an increase in accident occurrence.

The NB regression results for Age indicated that the magnitude of risk took on a nonlinear relationship in this category. The values of the IRRs in Table II indicated that the 36-45 age groups were least prone to accidents. This may be due to an optimal combination of cognitive function and overall experience where experience is defined as training, balanced exposure to the flight environment, and familiarity with flight gear. Airmen in the oldest age category (56+) were at greater risk than those in any other group. This finding may be due to cognitive issues related to the aging process, or because older airmen have been "exposed" to the hazards of flying longer than younger pilots.

BMI and Age may not be directly causal in most aviation accidents, but it identifies a pilot who may be at higher risk of suffering from cognitive issues or incapacitation.

4.2.2 Gender

Female gender may be a protective factor, as men were found to be 35% (IRR = 1.35) times more likely to be involved in an accident. The reason for this difference is unknown. It may be that women are safer pilots just as they are safer drivers (Baker, Lamb, Grabowski, et al., 2001). It may also be the case that in geographic locations where the risk of having an accident was higher, women were underrepresented in the aviation community such as the state of Alaska. However, the geographic location of pilots or accidents was not examined in this study.

4.2.3 Total Flight Time

Flight time was statistically associated with accident occurrence. Airmen with flight times of 1,500 hours or more appeared at twice the risk of an accident. This effect is expected due to increased exposure to the overall hazards of the environment. Flight time was believed to perhaps offer a protective effect for new pilots, where safety improved as time in the air was gained, but at some point, this seemingly protective effect diminished. Beyond a certain number of hours, increased flight time turns to increased risk with prolonged exposure to a hazardous environment (Booze, 1977). The number of hours differs on an individual basis and the type of flying being performed.

4.2.4 Effective Medical Class

Effective Medical Class was included as a variable in this study since it was believed to be a surrogate for the type of flying the airmen intended to pursue. The type of flying is classified under the Federal Aviation Regulations (FAR), as defined in Title 14 of the Code of Federal Regulations. For example, an airman holding a third-class medical was believed to have an interest in aviation as a private pilot, while those in the first- and second-class categories may have a commercial interest. If this assumption were true, then the results of our study indicated that airmen issued a first- or second-class medical certificate, relative to airmen holding a third-class medical certificate, were at greater risk of an accident. We found that airmen maintaining a second-class certificate were 1.75 times more likely to be involved in an accident than an airman keeping a third-class certificate. Airmen retaining a first-class medical certificate were 1.42 times more likely to be involved in an accident than an airman issued a third-class medical certificate. Therefore, the class of medical cannot be a surrogate for the type of flight operations intended by the airmen, as commercial accidents were extremely rare when compared to general aviation. This study found numerous examples of airmen involved in general aviation who pursued a more stringent class of medical than that required, relative to their occupation as stated in their records.

4.2.5 Statistical Association of Diabetes Covariates With Accident Risk

There was evidence that pilots with diabetes controlled by diet and diabetes controlled by hypoglycemic medication were at greater accident risk than airmen without these conditions. Airmen with diabetes controlled by diet were at an 18% increased risk of having an accident, while airmen with diabetes controlled by hypoglycemic medication were at a 28% greater risk. Although these conditions were statistically associated with the counts of accident airmen, it does not mean that the conditions were directly causal. The reason for an accident can be very complex and includes a number of other factors such as mechanical issues, human factors, time of day, weather conditions, and medications. It was hypothesized in this research that diabetes controlled by hypoglycemic medication and diet acted as a "marker" for a strata of airmen that tended to be suffering from multiple conditions brought about by chronic illness and at greater jeopardy of cognitive decline. That is, any aeromedical risks posed by diabetes may come from a number of its comorbidities such as cardiovascular disease and/or hypertension. It was this combination of conditions that made these a higher risk group in terms of aviation accidents. These multiple conditions may have led to cognitive decline or incapacitation, which would not necessarily be discovered in the post-accident investigation. Each of these conditions, considered individually, may not be disqualifying for the afflicted aviator but, in combination, produce a pilot who was marginally fit for flight.

The year 2005 was the last year of this study and had the greatest prevalence of pilots with a diabetic condition. For this particular year, prevalence odds ratios were used to describe the risk, in terms of having a comorbid cardiovascular condition, for aviators with diabetes. Stratifying the airmen population in this year by age, using 46 years as the threshold, we found that age was a confounding factor when assessing the relationship of cardiovascular disease and diabetes (Figure 6). Age 46 was chosen, based on Figure 3, which demonstrated the large increase in diabetes beginning at the 46 to 55 age category. Men and women less than 46 have odds ratios eight times greater than non-diabetics for having a cardiovascular condition, given that they have presented with diabetes. After 46 years of age, the association was reduced to four times as great as non-diabetic aviators. This effect was due to the increased prevalence of cardiovascular disease in the general population as it aged.



Figure 6. Stratified prevalence odds ratios for a cardiovascular condition given diabetes by age and gender in the year 2005.



Figure 7. Stratified prevalence odds ratios for hypertension controlled by medicatio and a cardiovascular condition given diabetes by age and gender in the year 2005.

The prevalence odds ratio of having hypertension requiring medication given an aviator has presented with diabetes is given in Figure 7. There were only seven females under 46 with hypertension requiring medication and diabetes for the year 2005. With such a small group, the prevalence odds ratio is subject to a wider degree of variation.

In addition to cardiovascular disease and hypertension, the diabetic pilot is also at greater risk of stroke, obesity, kidney disease, and cognitive decline. These conditions can contribute to the occurrence of an aviation accident through either pilot incapacitation or actions, influenced by the disease, manifested as human factor errors.

Given the extent of increasing obesity and diabetes prevalence in our society, mandating an effective screening test specifically for diabetes at the time of the FAA medical exam is recommended. Such a test is justifiable not only from a flight safety viewpoint — the possibility of hypoglycemia-related loss of consciousness — but also in terms of helping the pre-diabetic aviators take charge of their health and avoid the comorbidities that arise later.

Aviators with diabetes controlled by insulin were not examined in the NB regression model. Instead, there were so few outcomes that a review of each accident was performed. Upon examining each NTSB accident record (18 total), there was no indication that the disease contributed to any of the accidents. All were general aviation accidents attributed to pilot error. Commissioning a new study taking into account the years since 2005 would allow a closer look at these rare events.

5.0 LIMITATIONS

5.1 Identification of the Different Forms of Diabetes

One limitation of this study included our inability to distinguish between type I and type II diabetes, because there is no FAA pathology code that clearly distinguishes these conditions. Over time, many diabetic airmen were assigned multiple diabetic pathology codes in terms of the disease's treatment recorded in their FAA medical record. The multiplicity of diabetic codes and the evolution of the disease over time made it difficult for the SIS algorithm to address this complexity. That is, the disease pathology codes often overlapped over the course of a pilot's aeromedical history, and it was difficult to determine which code or combinations of codes were valid for a specific point in time in that pilot's history. As previously discussed, this overlap of airmen in the diabetes groupings necessitated establishing a hierarchy of diabetes covariates based on the severity of the disease. This hierarchy allowed the grouping of airmen into a single category. Diabetes was most likely underreported within the aviation community since it is up to the pilot to report the condition. FAA Form 8500-8 requests the pilot to provide information regarding whether or not he/she has been diagnosed with this disease. The pilot provides a simple Yes/No response and the system relies on the veracity of this response. Too often, diabetic pilots were discovered by post-accident investigation (e.g., the diabetic condition was known or unknown to the pilot), but there was no record of the condition in the FAA medical record.

5.2 Misclassification

Some pilots who were coded as diabetic on their electronic medical record may have been assigned to that code in error, e.g., typos, erroneous or incomplete information. That is, they may have had diabetes but were assigned an incorrect diabetes pathology code. For example, the pilot may have diabetes controlled by insulin and yet was mistakenly coded as having diabetes controlled by hypoglycemic medication. It is also possible that there were pilots with some form of diabetes who were not classified with any diabetes pathology code.

The methods and rules for the handling and coding of electronic medical records have changed over the 23 years of the study. Related to the latter issue, is this study's SIS-derived database algorithm used to identify diabetic airmen. For example, insulin-dependent airmen, once identified (and therefore coded) as such, remained as such – regardless of whether or not their condition changed (improved or otherwise). The reasons for this approach in the construction of the algorithm included the need to address the apparent failure to record the continued presence of the disease or the nature of its treatment (diet/exercise, medications, insulin) in the coding of subsequent medical exams for any particular pilot.

For example, if a diabetes pathology code appeared in the electronic medical records for an airman but was missing in a subsequent record and reappeared in an even later record, it was not possible to discern the rationale for these changes and inconsistencies (i.e., improvement/deterioration of the condition, change in treatment modality, omission error, etc.). Reducing or eliminating misclassification bias would involve a case-by-case review of not only the pilot population classified as diabetic but also of a fairly large sample of the pilot population classified as non-diabetic to assess the rate of misclassification either way. Perhaps enough misclassification of diabetes within the electronic medical records masked or distorted the association between the disease and risk of aviation accidents.

Diabetes remained hidden or undiscovered for many airmen. Flight physicals for any class of medical exam did not involve clinical laboratory tests, unless the pilot reported a diabetic condition on the FAA Form 8500-8 that would prompt these tests or glucometer readings to assess glucose levels. It was, therefore, possible that many aviators were unaware, or simply did not report their diabetic conditions. According to the Guide for Aviation Medical Examiners, "A blood glucose determination is not a routine part of the FAA medical evaluation for any class of medical certificate. However, the examination does include a routine urinalysis" (FAA 2006). The urinalysis, as part of the medical certificate examination is performed to determine the presence of glucose in the urine (glycosuria), ketones, protein, and blood, all of which can be accomplished with urine test strips. The FAA online Form 8500-8 asks if the urinalysis is normal or abnormal and has a place to record glucose and protein values reported by interpretation of the test strip. Trace or 1+

proteinuria, without a history of renal disease, is not a reason for denial but is to be explored during the AME's interview with the applicant. If glycosuria is not due to carbohydrate intolerance, the medical certificate may be issued.

Per the *Guide for Aviation Medical Examiners*, the diagnosis of diabetes can currently be made at lower blood levels than in the past (140 mg/dl). Fasting plasma glucose levels greater than 126 mg/dl, or 200 mg/dl two hours after a 75g oral glucose load are sufficient to clinically diagnose diabetes mellitus. A blood test for evidence of elevated blood sugar levels over a period of several months is the level of glycosylated hemoglobin (HbA1C). When it is at or above 6.5%, the diagnosis of diabetes could be considered. The renal threshold for blood glucose is that value of blood glucose that can be reabsorbed within the kidney as part of its filtration system. When the threshold is exceeded, glucose that would otherwise be reabsorbed is not reabsorbed by the kidneys and it thus appears in the urine. This threshold is approximately 160-180 mg/dl.

Thus, one can see that a medical certificate applicant might not present with glycosuria, since the renal threshold has not been exceeded, but may still be considered a diabetic. Sometimes asymptomatic diabetics will be identified by glycosuria via urinalysis, which is why the urinalysis is still part of the medical certificate application physical exam. Control of diabetes using urine glucose determinations is not of clinical use due to the high renal threshold for glucose, compared to the relatively moderate blood glucose that defines diabetes. These limitations probably contribute to the likely underreporting of diabetes in the U.S. civil pilot population.

There was no way to gauge the degree of this underreporting, or its existence, except through forensic toxicology reports. Discovery of diabetic medications or paraphernalia at the accident site or through other accident investigation processes such as family interviews sometimes revealed the diabetes condition. For example, accident investigations utilized the CAMI Forensic Toxicology Research Laboratory's analysis of biological samples from fatally injured pilots. These samples were tested for various drugs, alcohol, toxins, and other substances. Fluids, including blood, vitreous, and urine were also analyzed for glucose. The FAA reported findings for the 1998-2005 period, addressed glucose levels in accident pilots greater than 125 mg/dl in vitreous fluids and greater than 100 mg/dl in urine. During this period, the FAA laboratory received 2,487 samples from fatally injured pilots. Of these, 1,335 samples were tested for glucose levels. The study reported a considerable number of pilots with elevated glucose levels, indicating their possible diabetic condition, though no medical history of such a condition was present in their FAA medical records (Botch, Chaturvedi, Canfield, & Forster, 2008). Finally, there may be other factors, unaccounted for in this study, which acted as confounders between the risk of accident and the independent factors considered in the analysis.

6.0 REFERENCES

- Baker, S.P., Lamb, M.W., Grabowski, J.G., et al. (2001). Characteristics of General Aviation Crashes Involving Mature Male and Female Pilots. *Aviation Space and Environmental Medicine* 72(5): 447-452.
- Booze, C.F. (1977). An Epidemiologic Investigation of Occupation, Age, and Exposure in General Aviation Accidents (Report No. DOT/FAA/ AM-77/10). Washington, DC: Federal Aviation Administration Office of Aviation Medicine.
- Botch, S.R., Chaturvedi, A.K., Canfield, D.V., and Forster, E. M. (2008). Vitreous Fluid and/or Urine Glucose Concentrations in 1,335 Civil Aviation Accident Pilot Fatalities (Report No. DOT/FAA/AM-08/11). Federal Aviation Administration Office of Aerospace Medicine.
- Bryman, D.A. and Mills, W. (2007). Co-Morbid Conditions in Overweight and Obese Airmen: Trends and Aeromedical Implications. *Aviation Space and Environmental Medicine* 78: 702-705.
- Carter, D., Azaria, B., and Goldstein, L. (2005). Diabetes Mellitus Type I in Five Military Aviators: Flying with Insulin. *Aviation Space and Environmental Medicine* 76: 861-862.
- CDC. (2010). *Healthy Weight*. Retrieved 16 October 2014 from: http://www.cdc.gov/healthyweight/assessing/bmi/adult_bmi/index.html
- FAA. (1996). Special Issuance of Third-Class Airmen Medical Certificates to Insulin-Treated Diabetic Airman Applicants. *Federal Register* 61(226).
- FAA. (2006). Guide for Aviation Medical Examiners. Federal Aviation Administration Office of Aerospace Medicine. Retrieved 21 April 2008 from: http://www.faa.gov/about/office_org/ headquarters_offices/avs/offices/aam/ame/guide/
- FAA. (2014). *Guide for Aviation Medical Examiners*. Federal Aviation Administration Office of Aerospace Medicine. Retrieved 16 October 2014 from: http://www.faa.gov/go/ameguide/
- Greene, M.A. (1999). The Age of Legal Advocacy for Diabetes. *Diabetes Spectrum* 12(4).
- Grossman, A., Barenboim, E., Azaria, B., et al. (2005). Blood Glucose Awareness Training Helps Return Insulin-Treated Aviators to the Cockpit. *Aviation Space and Environmental Medicine* 76: 586-588.
- H.R.5900 (2010). Airline Safety and Federal Aviation Administration Extension Act of 2010. H.R. 5900.
- Hardin, J.W. (2003). The Sandwich Estimate of Variance. *Maximum Likelihood Estimation of Misspecified Models: Twenty Years Later* 17: 45-74.

- Heller, S.R. and Nicholson, A.N. (2006). Aircrew and Type I Diabetes Mellitus. *Aviation Space and Environmental Medicine* 77: 456-458.
- Hilbe, J.M. (2014). *Modeling Count Data*. New York, NY: Cambridge University Press.

Holt, R.W. (2001). *Scientific Information Systems*. Burlington, VT: Ashgate.

- Kengne, A.P. and Patel, A. (2006). How Important is Diabetes as a Risk Factor for Cardiovascular and Other Diseases in Older Adults? *PLoS Medicine* 3(10): e424 0001-0002.
- King, G. and Zeng, L. (2001). Logistic Regression in Rare Events Data. *Political Analysis* 9: 137-163.
- Mohler, S.R. (1997). New FAA Medical Standards Revise Vision, Hearing, Insulin-treated Diabetic Provisions. *Flight Safety Foundation: Human Factors & Aviation Medicine* 44(2).
- Mokdad, A., Bowman, B., Ford, E., et al. (2001). The Continuing Epidemics of Obesity and Diabetes in the United States. *The Journal of the American Medical Association* 286(10): 1195-1200.
- Mokdad, A., Ford, E., Bowman, B., et al. (2003). Prevalence of Obesity, Diabetes, and Obesity-Related Health Risk Factors, 2001. *The Journal of the American Medical Association* 289(1): 76-79.
- Newman, D.G. (2005). *Diabetes Mellitus and its Effect* on Pilot Performance and Flight Safety: A Review, Australian Transport Safety Bureau. B2005: 22.
- Peterman, C.L., Rogers, P.B., Veronneau, S.J.H., et al. (2008). Development of an Aeromedical Scientific Information System for Aviation Safety (Report No. DOT/FAA/AM-08/01). Washington, DC: Federal Aviation Office of Aerospace Medicine.
- Rogers, P.B., Veronneau, S.J.H., Peterman, C.L., et al. (2009). An Analysis of the U.S. Pilot Population From 1983-2005: Evaluating the Effects of Regulatory Change (Report No. DOT/FAA/AM-09/9). Federal Aviation Administration Office of Aerospace Medicine.
- Sagan, C. (1997). Billions & Billions: Thoughts on Life and Death at the Brink of the Millenium. New York, NY: Random House.
- Signorini, D. (1991). Sample Size for Poisson Regression. *Biometrika* 78(2): 446-450.
- Steinkraus, L.W., Cayce, W. and Golding, A. (2003). Diabetes Mellitus Type 2 in Aviators: A Preventable Disease. Aviation Space and Environmental Medicine 74: 1091-1101.
- Vuong, Q. (1989). Likelihood Ratio Tests for Model Selection and Non-Nested Hypotheses. *Econometrica* 57(2): 307-333.

APPENDIX A The Pathway of Model Selection

A.1 Model Assumptions and Selection

A Poisson regression model is frequently employed when the dependent variable consists of count data. This was the approach initially adopted for this study. Equation 2.0 describes the outcome variable in terms of the log counts of accident airmen. The Poisson distribution can be defined in terms of a single parameter (λ) as:

$$f(\mathbf{k};\lambda) = \frac{e^{-\lambda}\lambda^k}{k!}, \quad k = 0, 1, 2, \dots$$

One of the fundamental assumptions in Poisson regression is that the mean and variance is equal; that is $\lambda = \mu$ is a necessary condition for producing valid standard errors for the regression coefficients. Slight departures from this assumption can be compensated with the use of a dispersion statistic used to scale the standard errors (Hilbe 2014). A test of this supposition revealed a fundamental problem; the data produced a mean of 9.49 and a variance of 927.34 for the dependent variable. That is, the variance was almost 100 times greater than the mean (Table A1). The assumption of an equal mean and variance is violated in this case. When the variance is greater than the mean in a count-based model, it is said to be overdispersed. Furthermore, there were an excessive number of categories with zero accident airmen in the data, to the effect that the median was zero. It is probable that the excessive zero observations were one source of overdispersion. With a mean of 9.49, the probability of a Poisson probability mass function producing a category of zero events is 7.5604×10^{-5} . Given that $\lambda = 9.49$, a dataset with 10,465 observations would be expected to have a single category of observations with a zero number of events; this dataset currently has 6,754 observations with a zero number of accident airmen. The dataset can thus be considered inflated with an excess number of zero event observations. The basic assumptions essential to the use of a Poisson-based regression methodology did not hold in this situation.

Ν	Mean	Variance	Std. Dev.	Min.	Max.	Median
10,465	9.49	927.34	30.45	0	328	0

Table A1. Descriptive statistics for the dependent variable - counts of accident airmen.

Hence, we used an alternative to a Poisson regression that is based on the Negative Binomial (NB) distribution. The NB model has the same distributional assumptions and advantages as the Poisson, with the exception of a more flexible variance. The variance is still a function of the mean and can be described as: $V(\mu) = \mu + k\mu^2$ where k is a dispersion parameter estimated from the data. It allows the modeling of a wider range of variability than one based on the Poisson distribution. Although the NB adjusts for overdispersion, the production of excess zero observations still needed to be addressed.

A Zero-Inflated Negative Binomial (ZINB) can be employed to model and explain excess zero counts separately from the rest of the count data and adjust for overdispersion (Hilbe, 2014). The philosophy behind a Zero-Inflated count-based model is that there is a separate process producing an excess of categories with zero events from that of producing the event of interest. For example, in our dataset, the combination of categories with zero events can be thought of as being populated with small groups of airmen that perform little to no flying and therefore generate no accident airmen. These groups of airmen are different from those who fly frequently. A ZINB model then produces two sets of results, one representing the process producing accident airmen and another for that producing the excess zeroes. Therefore, a ZINB regression model was built using the same factors as the Poisson model to describe the accident airmen process, while the total number of airmen in each category of observations was used to separately model the excess zeroes. To determine which model (NB or ZINB) was best suited for these data, we employed the Vuong Closeness test (Vuong 1989). The Vuong test is a likelihood ratio test that can determine which model is closer to the "true" model. The hypothesis tested was:

 H_0 : The NB and ZINB models are equally close to the true model.

 H_A : One model is closer to the true model.

The Vuong test favored the NB model as being closer to the "true" model. As such, this was the regression model used to explore the relationships between the factors of interest and accident airmen.

The NB model, like the Poisson, relied upon the assumption of independent observations. Plotting the predicted model means versus standardized Pearson residuals supported this assumption, although there were signs in the range of zero means that there may have been some correlation present. As a result, the sandwich estimate of variance was used within the NB model. This sandwich, or "robust" estimator, gives an accurate estimate of the regression coefficient variances when the data are not independent. Unaccounted for correlation produces invalid regression coefficient standard errors. If the data were truly independent then the

sandwich estimator will give the same result as the model-based estimator of variance. To invoke the sandwich estimator in SAS, using the GENMOD procedure, the SAS REPEATED option was employed as if the data were correlated. This permitted the use of the sandwich estimator in the NB model with presumed independent data and explains why the test statistics in Table I are given as Z-scores, as opposed to the usual χ^2 values. Producing test statistics in terms of Z-scores did not change any of the estimated regression coefficients or the results of the tests for significance (Hilbe 2014).

The NB regression model was constructed in a stepwise backwards approach using the same factors of interest described for the initial Poisson model. That is, all covariates were added to the model at the same time, and the least significant covariate was eliminated at each iteration of the model, with interaction terms being removed before the main effects. It was plausible to expect an interaction between diabetes and the factors of BMI, Age, and Gender. A check for interaction between all three diabetes covariates and these three factors resulted in no statistically significant interaction terms.

Multicollinearity is a condition that is frequently encountered with the modeling of chronic conditions that occur with advancing age. It becomes difficult to disentangle the effects of diabetes and other covariates as, they frequently occur as people grow older. As chronic conditions become more prevalent in the aging U.S. civil pilot population, multicollinearity becomes a major roadblock in the statistical analysis (i.e., linear regression) of medical factors related to these conditions. There were no observed signs of collinearity/multicollinearity between these factors when expressed as categorical variables.

A.2 Model Fit

Although it was determined via the Vuong Likelihood-Ratio test that the NB model was better than the ZINB for these particular data, it informed nothing in terms of model fit. A test for the model fitness was performed using the deviance, a measure of the statistical distance between our model and one which is saturated. A saturated model is one that has as many estimated parameters as there are data points therefore; it perfectly fits the data. The deviance is asymptotically distributed as a χ^2 statistic. This allows for a simple test to determine if the model fits the data. The hypothesis tested was:

> H_0 : The NB model is a good fit to the data. H_4 : The NB model is not a good fit to the data.

The test produced a Chi-Square test statistic; ($\chi^2 = 64, 448.67$) with roughly 10,400 degrees of freedom which renders a very high p-value of 0.999. The hypothesis that the NB model is a good fit to the data was not rejected.