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Assessing Mortality Between the BasicMed Population and Third-Class Medically Certificated Pilots

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Report

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Abstract

Introduction

Because airmen seeking third-class medical certification and those declaring intention to fly under BasicMed differ in degree of medical observation and review, mortality and incapacitation differences are relevant to assess safety. In support of the Congressional requirement to review the efficacy and safety of BasicMed, we investigated differences in mortality between BasicMed and third-class medical certificate pilots.

Methods

We conducted a retrospective cohort study among pilot populations from May 2017 through December 2019. All BasicMed pilots within the first year of implementation were included in the study, and a random sample of third-class medical certificate holders was observed as a comparison group. Both groups were followed through December 2019. We collected mortality data from the U.S. Centers for Disease Control and Prevention for both groups and used Cox proportional hazards regression for data analyses, adjusting for age and Special Issuance (SI).

Results

A total of 29,248 BasicMed pilots were included in the study, and the same number of third-class airmen were randomly selected from the active third-class airmen population as the comparison group. Generally, BasicMed pilots had a lower risk of dying in nonmedically related deaths than the third-class group. When restricting the outcome to medically related deaths, BasicMed pilots had an overall age- and SI-adjusted 53% higher mortality risk than the third-class group. After adjustment for age and SI status, the mortality risk from suddenly incapacitating causes was three times higher among BasicMed airmen than third-class airmen. Further, risk of cancer-related deaths was two times higher among BasicMed airmen.

Discussion

The mortality data are generally unfavorable to BasicMed, likely because the BasicMed population is significantly older and more likely to have required an SI. However, the mortality risk remains elevated even when controlling for both age and SI. Absent Federal Aviation Administration oversight, mitigation of elevated risk of incapacitation and death is dependent upon the airman seeking regular medical care for their conditions.

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Introduction

One challenge for the pilot community has always been the burden of maintaining a medical certificate to fly. There have been arguments made both for and against the cost, time, and somewhat stringent medical policies the Federal Aviation Administration (FAA) imposes on pilots. Under the FAA Extension, Safety, and Security Act of 2016, Congress directed that pilots flying for personal purposes in certain aircraft categories be allowed to do so without maintaining a third-class medical certificate. The FAA implemented this directive through a program called "BasicMed" (Requirements for Operating Certain Small Aircraft Without a Medical Certificate, 2021; FAA, 2017). Since BasicMed became effective May 1, 2017, it has allowed many pilots to exercise private pilot privileges for flight operations that would have otherwise required a third-class certificate.

Consequently, with the inception of BasicMed, there has been a significant transition of third-class airmen, especially those with special issuances (SIs) and critical medical pathology codes, into BasicMed. While pilots come and go from the third-class certificated population routinely since BasicMed was enacted, the third-class group has declined by more than 20%, and the median age has decreased from 45.3 years to 37.9 years for these pilots, reversing a long-term aging trend in this population (Skaggs & Norris, 2021a).

Furthermore, pilots with medical conditions that require a medical certificate with an associated special issuance (SI) may become eligible to operate under BasicMed as long as they hold a valid medical certificate at least once under the FAA surveillance since 2006. This is a valuable incentive to pilots maintaining an SI; the number of active third-class airmen who possessed an SI to fly decreased from 7.7% before the implementation of BasicMed to 5.8% by the end of 2020. Percentages of third-class medical certificates with elevated-risk medical conditions have decreased by more than half in many cases since before BasicMed was implemented (Skaggs & Norris, 2021a). Many of the airmen with these medical conditions became alternatively certified through BasicMed.

BasicMed has had positive impacts, as well. Approximately 30,000 airmen have returned to flying status, slowing the long-term decline in numbers of general aviation airmen. Understanding the positive impact that BasicMed has had on the pilot community is important. Along with that understanding, assessing the safety impacts of BasicMed is critical in its early inception. Unfortunately, the medical information stream for an airman stops when an airman transitions from medical certification through the Office of Aerospace Medicine (AAM) under Part 67, to BasicMed, under Part 68. The FAA no longer has up-to-date medical data on those who declare their intent to fly BasicMed and become alternatively certificated.

Research in the program's early years becomes critical because the medical data within the AAM databases will become more outdated over the years. However, health impacts accumulate slowly, making any safety issues more challenging to detect in that same period. Most medical studies within the FAA focus on the demographics of each pilot population and how that may relate to accident rates and differences in autopsy findings within each group. However, another outcome that has not been measured frequently is mortality. The U.S. Centers for Disease

Control and Prevention (CDC) comprehensively captures information on U.S. deaths, including causes. Government research agencies can access this data for the populations they study within criteria stated by the CDC. In support of the requirement of the FAA Extension, Safety, and Security Act of 2016 to assess and report on the efficacy and safety of BasicMed implementation, we explored the association between pilots' decisions to fly under BasicMed or third-class certification and subsequent mortality. We investigated differences in death between the pilot population who register for BasicMed and those who maintain third-class medical certification.

Methods

Study Design and Population Sources

The purpose of this project was to explore differences between exercising BasicMed and third-class certification options to fly and the subsequent risk of death. We conducted a retrospective cohort study among the BasicMed and third-class pilot populations from May 2017 through December 2019. We used data available from the FAA's Document Imaging Workflow System (DIWS), the Airmen Registry database, and the National Death Index supplied by the CDC. We investigated differences in death between the pilot population who obtained their BasicMed application and those who maintained third-class medical certification. The FAA institutional review board approved the study design (protocol #202011).

Exposure Assessment

All pilots who declared intention to operate under BasicMed between May 1, 2017, and April 30, 2018, were included in the study as the primary exposure group. This encompassed all BasicMed airmen during the first year of implementation. In addition to these pilots, a random sample of issued third-class pilots active during the same period, who never opted to operate under BasicMed as of October 2020, was observed as a comparison group. Both groups were followed through December 2019, a 20- to 32-month period.

The primary exposure variable originated from DIWS and Airmen Registry. The binary exposure variable of flying "BasicMed" (yes/no) came from a unique number obtained from the Airmen Registry database and was linked to each pilot's most recent medical certificate in the DIWS database. Those in the comparison group originated from active airmen who were issued a third-class medical certificate during the one-year period. Most private pilots need to hold at least a third-class medical certificate to fly if they are not flying under the new BasicMed rules. The validity period of this type of certificate is five years if the pilot is under age 40 or two years if the person is age 40 or older. This group represents the closest comparison to the BasicMed pilot population where the FAA still obtains current medical and demographic information and, thus, is the source population of BasicMed pilots.

Covariate Assessment

Skaggs and Norris (2021b) reported that the age distribution in pilots flying BasicMed is older than the general pilot population, and BasicMed pilots are more likely to have required an SI to obtain a medical certificate. In the past, when baseline characteristics of participants in cohort

studies have been imbalanced, researchers have occasionally employed a matching technique where each exposure is paired to one or more unexposed individuals in the study. While many case-control studies employ individual matching between cases and controls to increase statistical efficiency, matching in a cohort study is rarely used. In rare cases, matching certain variables in a cohort study would eliminate the need to adjust for our matching confounders during analysis. However, with the potential for any censored data in the study that may cause an imbalance in data collection between the two groups, the consequence of matching becomes less statistically efficient and still requires accounting for the confounder in analysis (Rothman et al., 2008). Thus, we decided not to match our exposed and unexposed groups on any factor and instead control for confounding in the analyses.

We collected age and presence of an SI from the pilots' most recent medical exams in DIWS as the two covariates measured at the study's baseline start time. Age was examined as a continuous variable and then categorized as appropriate. To determine if age should be evaluated continuously, we needed to test the log hazard-linear assumption in the model. Therefore, we grouped age into bins and plotted against the estimated log hazard plot. While age was approximately linear in the log hazard, extreme observations influenced the pattern, especially in the younger ages. Therefore, we repeated analyses for all models using both a continuous and categorical variable for age. We did not observe any meaningful differences in the magnitude and direction of the outcomes, and therefore, age was ultimately categorized into quintiles based on the distribution of the comparison group.

Outcome Assessment

For the study pilots who had not renewed BasicMed requirements or their medical certificate after December 2019, we requested CDC's National Death Index (NDI) to determine if they had become deceased by the end of the study period. For a fee per airman per year, the CDC's NDI program linked our airmen to any potential matches of people in their system who could have died during the study period along with their causes of death. We provided the CDC with the first name, middle name, social security number, gender, state of residence, and date of birth to enable the search. They returned a password-protected compact disc containing the search results.

Mortality data were analyzed by cause of death. We individually reviewed each cause of death and grouped them into the following categories: total deaths, nonmedically related deaths, and medically related deaths. Within the nonmedically related death category, we further defined additional subgroups consisting of aircraft-related, motor vehicle-related, accidental, and suicide deaths. Within the medically related death category, subgroups were cardiac-related (excluding myocardial infarctions [MIs]), sudden incapacitation (due to stroke or MI), cancer-related, and all other medically related deaths. Two AAM physicians examined and verified each cause of death to ensure they were all within the correct categories described above.

Statistical Analysis

We performed power calculations using Power Analysis and Sample Size software version 13 (NCSS, Statistical Software, LLC, Kaysville, Utah) (2014). To determine the power of our retrospective cohort design, we assumed an alpha of 0.05 and a proportion of deaths from 0.01 to

0.1. This range of proportions is based on life tables that demonstrate that people who live to age 45 to 50 (i.e., the median age of our source population) have an approximately 96% to 98% chance of surviving five more years (Arias, 2011). After applying the exclusion and selection criteria to the datasets, given the approximately 30,000 pilots that legally flew through the BasicMed option the first year, we selected an equal proportion of pilots who were issued a valid medical certificate during the same period. To account for the unknown influence of adding other covariates into the model, we examined a range of assumptions for the R-squared values representing the magnitude of the association when the exposure is regressed on other independent variables from 0.0 to 0.8. Based on these parameters, we would have 90% power to detect even the most minimal associations in our multivariate models.

Statistical analyses were conducted using SAS v.9.4 (SAS Institute, Inc., Cary, NC). We used Cox proportional hazards models to estimate the hazard rate for death with 95% confidence intervals (95% CI). We checked the assumption of proportional hazards graphically, with a log minus log plot of the cumulative hazard function for each variable. In each instance, the curves were parallel, indicating no violation in the assumption. Because BasicMed pilots tend to be older and more likely to suffer from conditions requiring an SI, the decision was made a priori to keep both covariates in each model for consistency. We also evaluated whether effect modification was present in the model by examining whether any interactions had a p-value less than 0.05. When interactions were observed, we reported results separately for each stratum of the significant effect modifier. We explored the cause of death in broad categories to determine if the outcome categories differed between groups. Finally, we calculated deaths per 1,000 person-years for each group to examine absolute risk.

Results

A total of 29,248 pilots declared intention to operate under BasicMed between May 1, 2017, and April 30, 2018. The same number of third-class pilots were randomly selected from the active third-class pilot population who had never exercised BasicMed privileges. However, we removed 1,265 international pilots (25 BasicMed, 1,240 third-class) from the analysis because NDI does not capture international deaths. Removing these international pilots did not significantly alter the mean age or study outcomes.

The average and median age of the BasicMed pilots was 63.3 and 64.6 years, respectively. For the third-class group, the mean and median age was only 48.1 and 50.7 years. While 30.9% percent of the BasicMed group held an SI, only 9.3% of the third-class group held an SI.

Overall, the unadjusted risk of death was 2.48 times (95% CI 2.04, 3.01) higher in BasicMed pilots than the third-class pilots. However, after adjusting for age and SI status, the risk of all-cause mortality was not significantly different between the two groups (hazard ratio [HR]=1.15; 95% CI 0.94, 1.42). Table 1 displays the categories of cause of death between the two groups, adjusted for age and SI. Generally, BasicMed pilots had a lower risk of nonmedically related mortality than the third-class group (HR=0.60; 95% CI 0.41, 0.88), but due to the presence of interaction in the model, these results were stratified by SI status. For those BasicMed pilots who did not have an SI at their baseline exam, the risk of nonmedically related mortality was 53%

lower than the third-class group (95% CI 0.30, 0.73). However, for those BasicMed pilots who possessed an SI at baseline exam, the risk of nonmedically related mortality trended towards the other direction, although not statistically significant (HR=2.75; 95% CI 0.65, 11.68).

When we restricted the outcome to medically related deaths, BasicMed pilots had an overall age- and SI-adjusted 53% higher mortality risk than the third-class group (HR=1.53; 95% CI 1.18, 1.98). Because stroke and MI cause of deaths would usually present with sudden incapacitation, we also examined pilots with a stroke- or MI-related death to use as a proxy category for conditions causing sudden medical incapacitation resulting in death. After adjustment for age and SI status, the mortality risk from suddenly incapacitating causes was three times higher among BasicMed pilots than third-class pilots (HR=3.03; 95% CI 1.17, 7.84). Further, the risk of cancer-related deaths was two times higher among BasicMed pilots than third-class pilots (HR=2.05, 95% CI 1.35-3.10).

After demonstrating the relative risks of each group to be significantly different after adjustment for age and SI, an examination of the unadjusted death rates was warranted to understand the magnitude of difference. Medically related mortality among BasicMed pilots was 4.72 deaths per 1,000 person-years (95% CI 4.21, 5.28), and among third-class pilots, it was 1.26 (95% CI 1.00, 1.58). Mortality due to stroke or MI among BasicMed pilots was 0.59 deaths per 1,000 person-years (95% CI 0.42, 0.81), and among third-class pilots, it was 0.08 (95% CI 0.03, 0.19). Mortality due to cancer among BasicMed pilots was 2.28 deaths per 1,000 person-years (95% CI 1.93, 2.68), and among third-class pilots, it was 0.46 (95% CI 0.31 - 0.66). Overall, mortality among BasicMed pilots was 5.68 per 1,000 person-years versus 2.26 among third-class pilots.

These rates can be placed in context by comparison to the U.S. general population, but only per 1,000 persons, not person-year statistics. The 2019 U.S. general population death rate was 8.78 per 1,000 persons (MacroTrends, LLC, 2021). Third-class airmen had more favorable mortality, with 4.93 deaths per 1,000 airmen. BasicMed airmen had less favorable mortality with 12.76 deaths per 1,000 airmen, but these comparisons cannot be adjusted for age and SI.

Table 1

Cause of Death Among BasicMed and Third-Class Pilots

Cause of Death Categories	BasicMed N=29,223 (%)	Third-Class ^a N=27,982 (%)	Adjusted HR and 95% CI ^b
Total Deaths			
Yes	373 (1.28)	138 ^c (0.49)	1.15 (0.94, 1.42)
No	28,250 (98.72)	27,844 (99.51)	
<i>Nonmedically Related Deaths</i>			
Aircraft-Related			
Yes	36 (0.12)	36 (0.13)	0.52 (0.32, 0.86)
No	29,187 (99.88)	27,946 (99.87)	
Motor Vehicle-Related			
Yes	7 (0.02)	10 (0.04)	0.67 (0.22, 2.00)
No	29,216 (99.98)	27,972 (99.96)	
Accidental/Elemental			
Yes	9 (0.03)	4 (0.01)	1.10 (0.31, 3.90)
No	29,214 (99.97)	27,978 (99.99)	
Suicide			
Yes	11 (0.04)	10 (0.04)	0.65 (0.26, 1.63)
No	29,212 (99.96)	27,972 (99.96)	
Total Nonmedically Related			
Yes	63 (0.22)	60 (0.21)	0.60 (0.41, 0.88)^d
No	29,160 (99.78)	27,922 (99.79)	
<i>Medically Related Deaths</i>			
Cardiac-Related (excluding MIs)			
Yes	54 (0.18)	29 (0.10)	0.74 (0.46, 1.19)
No	29,169 (99.82)	27,953 (99.90)	
Sudden Incapacitation (Stroke/MI)			
Yes	39 (0.13)	5 (0.02)	3.03 (1.17, 7.84)
No	29,184 (99.87)	27,977 (99.98)	
Cancer-Related			
Yes	150 (0.51)	28 (0.10)	2.05 (1.35, 3.10)
No	29,073 (99.49)	27,954 (99.90)	
All Other-Medical			
Yes	67 (0.23)	15 (0.05)	1.51 (0.85, 2.69)
No	29,156 (99.77)	27,967 (99.95)	
Total Medically Related			
Yes	310 (1.06)	77 (0.28)	1.53 (1.18, 1.98)
No	28,913 (98.94)	27,905 (99.72)	

Note: Significant HR are in bold. CI = confidence interval; HR = hazard ratio; MI = myocardial infarction; SI = Special Issuance.

^aThird-Class group is the referent exposure group

^bHazard ratios and 95% CIs from Cox proportional hazard model, adjusted for age and SI

^cOne death was excluded from total third-class deaths when calculating nonmedically and medically related death totals due to "unknown cause of death."

^dInteraction with group and SI status (further information provided in text).

Discussion

The goal of medical certification is to prevent incapacitation during the valid period of certification. Because airmen maintaining third-class medical certification and those declaring intention to fly under BasicMed differ in degree of medical observation and review, incapacitation differences are relevant to assess the impact on aviation safety. For BasicMed airmen and third-class airmen who do not renew their certification, incapacitating health outcomes are unobservable to the FAA. However, the CDC collects U.S. deaths and their causes, and these data are available for research purposes through the NDI. Therefore, we investigated differences in mortality between the pilot population who declared intention to fly under BasicMed and those who maintained third-class medical certification.

Overall, the mortality data are unfavorable to BasicMed, and our results may be summarized as follows:

- On average, BasicMed pilots are older than pilots maintaining third-class certification and the pre-implementation third-class population.
- BasicMed airmen are much more likely to have required an SI. Referencing the meaning and purpose of an SI, this reflects a potentially elevated risk of incapacitation among the BasicMed population in the context of reduced FAA oversight. Mitigation is dependent upon airmen seeking regular care by primary and specialist physicians.
- When restricted to medically related death, BasicMed airmen had an age- and SI-adjusted 53% higher mortality risk over the study period than airmen who maintained third-class certification.
- BasicMed airmen had an age- and SI-adjusted risk of death from stroke or MI three times that of airmen who maintained third-class certification. These conditions are likely to cause sudden incapacitation.
- BasicMed airmen had an age- and SI-adjusted risk of death from cancer twice that of airmen who maintained third-class certification.

The mortality results in this study are consistent with past research and have two potential explanations, both likely valid for a portion of the cases. Mills and Greenhaw (2019) found that SIs were associated with 33% lower odds of death while holding a medical certificate and 35% increased odds of death within four years after the expiration of a medical certificate. Skaggs and Norris (2015) found a similar effect in a case-control study examining aircraft accidents. In the current study, for BasicMed pilots who had an SI at baseline exam, the risk of nonmedically related mortality trended toward an increase in the risk of overall nonmedically related death compared with third-class pilots (although the difference was not significant). For medically related deaths, the mortality risk was higher in BasicMed pilots while controlling for age and SI. The protective trend during active AAM medical surveillance demonstrated in past studies seems to disappear with the transition to BasicMed for medically and nonmedically related death in general.

From this perspective, it is not surprising to find an elevated risk of medical-cause mortality among BasicMed pilots. The level of surveillance decreased with the expiration of their SI and third-class certificates. Concerning explanations, first, older BasicMed pilots and those previously issued an SI might have been more advanced in progressive conditions at the time of

BasicMed implementation. This interpretation might be supported by approximately 30,000 pilots returning from inactive status. They might have become inactive rather than pursue a third-class renewal that they expected would be denied. Second, older BasicMed pilots and those previously issued an SI may not have received the same level of care for their conditions after declaring for BasicMed. This may be supported by the knowledge that SI provisions for some of these conditions require higher levels of care than community standards.

However, increased risk of medically related death among BasicMed airmen within 32 months of implementation was an unexpected finding (see Limitations). For third-class airmen under age 40, we may not have observed a return exam for some or even most; their certificates are valid for five years. For third-class airmen over age 40, we are unlikely to have observed more than one return exam for most airmen. Nevertheless, we find a 53% increased risk of medical-related mortality among the BasicMed airmen. This suggests that most of what we have captured is the risk of preexisting conditions among the cohort. If the risks associated with decreased surveillance are significant, mortality differences will be exacerbated. This is a strong argument for continued research on BasicMed. It may be that the initial cohort was unique, fought for the legislation, and were motivated to make use of it. As time passes, younger and healthier pilots may take advantage of BasicMed, reducing the population mortality risk. However, if we have yet to capture the effects of reduced medical surveillance, increased BasicMed mortality is unlikely to decrease.

Strengths and Limitations

To date, this is the first epidemiologic study to assess risk between the BasicMed population and mortality outcomes. The use of survival analysis accounts for varying amounts of follow-up time in the different years of the pilots' deaths. It also accounts for the censored data at the completion of the study period. It allows us to model hazard ratios from a population of airmen about whom we know little and assess a more accurate estimate of risk by controlling for known confounders.

This study is not extremely useful in quantifying the risk of fatal aircraft- or motor vehicle-related accidents, as we have no data on how much each group flies/drives compared with the other. However, this analysis is unique because it allowed us to assess the risk of general mortality in the group of pilots who chose to fly via BasicMed compared with those who did not, which cannot be assessed by using any other currently available datasets due to lack of information on exposure time.

While the study has considerable strengths, we have identified a few limitations as well. First, the potential for misclassification exists due to the timing of the most recent medical examinations for each pilot in the system. Although our data for the third-class medical certificate airman group will be current, the data from medical certificates for the BasicMed group may be more than a decade old. Potentially relevant changes in the medical histories of pilots could happen between the time of the last medical examination and death or the end of the study period. However, preliminary reports demonstrate that the median time from the last medical certificate exam for the initial BasicMed pilot group was 2.5 years, which is relatively recent for the majority of the pilots in this group (Mills, 2018). Second, the cause of death data come from information on death certificates, which introduces variability according to the

various physicians inputting such data. Therefore, some of the causes of deaths we received from the NDI data might be more of an underlying cause of death than an immediate cause of death.

Furthermore, the approximately 2.5-year maximum follow-up period for this study severely limits our ability to evaluate deaths on a longer timeline accurately and limits the number of deaths available to study. However, it is telling that BasicMed pilots are at a higher risk of dying of medically related causes regardless of age and SI status, even after a few years of surveillance.

The results of this study should facilitate future research into the safety of BasicMed. Based on these results, BasicMed airmen appear to have a greater risk of dying a medically related death. The BasicMed population is significantly older and much more likely to possess an SI. Without FAA oversight for many of these pilots opting to fly via BasicMed, we may see an increased risk of incapacitation. In reviewing BasicMed safety, the results of this study are unfavorable to the risk of incapacitation for BasicMed pilots. However, this overall mortality risk should not be extrapolated to assume a higher risk of an aircraft accident, as the exposure time in the cockpit is not something we can assess at this time.

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