Unfit Assessments of Class 1 Medical Certificate Holders

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INTRODUCTION: An aviation safety management system should consider and mitigate against all potential risks to flight safety. In addition to in-flight incapacitation, pilots falling below regulatory standards who are assessed as unfit may have represented a risk prior to that assessment. An analysis was undertaken of Class 1 certificate holders to determine factors correlated with unfit assessments.

METHODS: Fitness assessments of pre-existing Class 1 certificate holders following medical examinations (to EASA Part-MED standards) or between medicals were studied between 1 January 2016 and 31 December 2019. Assessments where the outcome was 'fit' (*N*= 99,406) were compared with those where the outcome was 'unfit' (*N*= 7925). Analyses for correlation between unfit assessments against age, declared coexisting medical conditions, and the number of days since last assessed as fit were undertaken using SPSS.

RESULTS: Unfit assessment likelihood and age were strongly correlated; there is, however, evidence for the 'healthy worker effect', with a fall in unfit assessments between 60–65 yr of age. There was no association between coexisting medical condition declaration and the likelihood of becoming unfit. The time interval between a fit and unfit assessment was significantly lower when comparing 20–60 and 61–63 yr old individuals.

DISCUSSION: The analysis of unfit assessments shows strong correlation with increasing age and the possible presence of the healthy worker effect among commercial pilots. The decreased time from a previous fit assessment to an unfit assessment supports the reduced certificate validity period of Class 1 applicants over 60 yr of age.

KEYWORDS: aeromedical certification, international aviation regulation, incapacitation risk, fitness to fly.

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The use of aeromedical certificatory-based assessment is intended to assure the fitness of the human component of a flight system. Applicants are assessed against a set of defined regulatory medical standards.[9,14] Prior to 31 December 2020, the United Kingdom was a member state of the European Aviation Safety Agency (EASA) and standards used by the UK Civil Aviation Authority to assess Class 1 certificate holders were aligned across all member states.[8]

As with any aviation system, it is possible that certificate holders may fall either temporarily or, in some cases, permanently below these standards, leading to certificate suspension. This is known as an unfit assessment. Pilots flying commercial air transport operations are required to undergo a Class 1 medical examination to assess fitness against these standards annually under the age of 60 and 6-monthly over the age of 60.[7] They may also be assessed as unfit at any time while holding certification.

Throughout the literature, there has been a strong focus on incapacitation prevention of pilots while in control of an aircraft, notably at critical phases of flight.[3] The 1% rule for multicrew commercial transport operations and its potential shortcomings have been well described.[10,21] The direct impact of an incapacitation event on aircraft safety is more readily apparent than an unfit assessment; it has rightfully, therefore, also been the greater priority for aviation regulators.

Despite these caveats, in line with ICAO Annex 19,[15] a mature aviation safety management system should seek to prospectively identify and mitigate all possible risks leading to an unsafe event, rather than solely react to events retrospectively.[5]

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The ability of an aviation regulator to predict a health-related safety issue is, therefore, of value, regardless of whether the prevented outcome was an unfit assessment or an incapacitation.

From an industry perspective the ability to predict unfit assessments can also inform workforce resiliency analysis and pastoral support for individual pilots. This recognizes the significant investment in training and resources for both individuals and at an organizational level.

Incapacitation events and unfit assessments are not synonymous, nor are they necessarily sequential. In fact, divergence between unfit assessments and incapacitation event rates may represent a system working optimally, with the presumption that an unfit assessment may have averted an incapacitation event.

Incapacitation attributable to medical causes may be prevented by screening those pilots who are at higher risk of conditions such as cardiovascular disease or cerebrovascular events;[13] however, there remain limits to how individualized a risk assessment can be.[12] Machine-learning prognostic models are becoming more common in many areas of clinical medicine,[19] but to date no equivalent has been developed to predict either incapacitation or unfit assessment rates in aviation medicine.

An unfit assessment occurs following expert assessment by a medical assessor working directly for an aviation regulator or is delegated to aviation medical examiners with varying degrees of regulatory oversight.[9] For many conditions, regulatory standards may explicitly indicate an unfit assessment should occur, but these do not cover all circumstances. When there is a degree of uncertainty about a health-related condition, it is possible that not all assessors will decide on the same fitness outcome. Developing validated predictive tools may help to standardize this process and reduce systematic noise.[20]

In order to categorize pilots at greater numerical risk of being assessed as unfit, this paper sought to identify the baseline risk of an unfit assessment being made on a per annum basis subcategorized by age and medical condition category. Furthermore, for those individuals assessed as unfit, the time interval which elapsed since their last successful Class 1 medical or fitness assessment was included.

Table I. MED160 Form Questions.

MEDICAL HISTORY CATEGORIES ON MED160 FORM	
Eye trouble/eye operation?	Spectacles and/or contact lenses ever worn?
Spectacle/contact lens prescription change since last medical?	Hay fever, other allergy?
Asthma, lung disease?	Heart or vascular trouble?
High or low blood pressure?	Kidney stone or blood in urine?
Diabetes, hormone disorder?	Stomach, liver, or intestinal trouble?
Deafness, ear disorder?	Nose, throat, or speech disorder?
Head injury or concussion?	Frequent or severe headaches?
Dizziness or fainting spells?	Unconsciousness for any reason?
Neurological disorders; stroke, epilepsy, seizure, paralysis, etc?	Psychological/psychiatric trouble of any sort?
Alcohol/drug/substance abuse?	Attempted suicide?
Motion sickness requiring medication?	Anemia/sickle cell trait/other blood disorders?
Malaria or other tropical disease?	A positive HIV test?
Sexually transmitted disease?	Admission to hospital?
Any other illness or injury?	Visit to medical practitioner since last examination?
Sleep apnea?	Musculoskeletal illness?
Refusal of life insurance?	Refusal of flying license/ATCO license?
Medical rejection from military service?	Award of pension or compensation for injury or illness?
Gynecological, menstrual problems?	Are you pregnant?
Family history of heart disease?	Family history of hypertension?
Family history of high cholesterol?	Family history of epilepsy?
Family history of mental illness?	Family history of diabetes?
Family history of tuberculosis?	Family history of allergy/asthma/ eczema?
Family history of inherited disorders?	

METHODS

The UK Civil Aviation Authority Medical Records System was searched for all EASA Class 1 medical examinations and all intermedical casework assessments conducted for anonymized applicants for which the UK Civil Aviation Authority was the state of license between 1 January 2016 and 31 December 2019. The assessments where a pre-existing certificate holder was assessed as 'fit' following either a medical examination or a casework assessment during this period are hereafter referred to as the fit assessment cohort.

All pre-existing certificate holders for whom a status of 'fit' was held at any point during this period and who underwent an assessment where the outcome was subsequently changed to either 'unfit', 'deferred', or 'deceased' were included (hereafter all referred to as the 'unfit' assessment cohort).

Those who underwent a Class 1 initial medical and those who changed their State of License Issue within the study period were excluded; this was done in order to ensure all individuals had an equitable opportunity of becoming unfit during the 4-yr period and avoid a bias toward those who entered the pool of applicants later. Data were purged to exclude fitness assessment changes which were started but not completed. Assessments for any individual which occurred when they were over the age of 65 were excluded in line with restrictions on commercial air transport flight crew licensing as per ICAO Annex 1.[14]

The overall rate of an unfit assessment likelihood for 5-yr age groupings was calculated based on all recorded instances in the retrieved data. The correlation and variance between age and unfit rates was calculated using linear regression analysis. Additionally, at the time of the medical, applicants must declare past medical history by means of ticking 'yes' or 'no' to 46 system groupings as shown in **Table I**. The frequency with which the fit and unfit cohorts answered 'yes' at the time of their previous medical to each of the 46 boxes was compared using a Chi-squared test to assess if any specific past medical history grouping was associated with an increased likelihood of becoming unfit.

Finally, the unfit cohort was further subcategorized by age of the pilot against the mean time interval from the point at

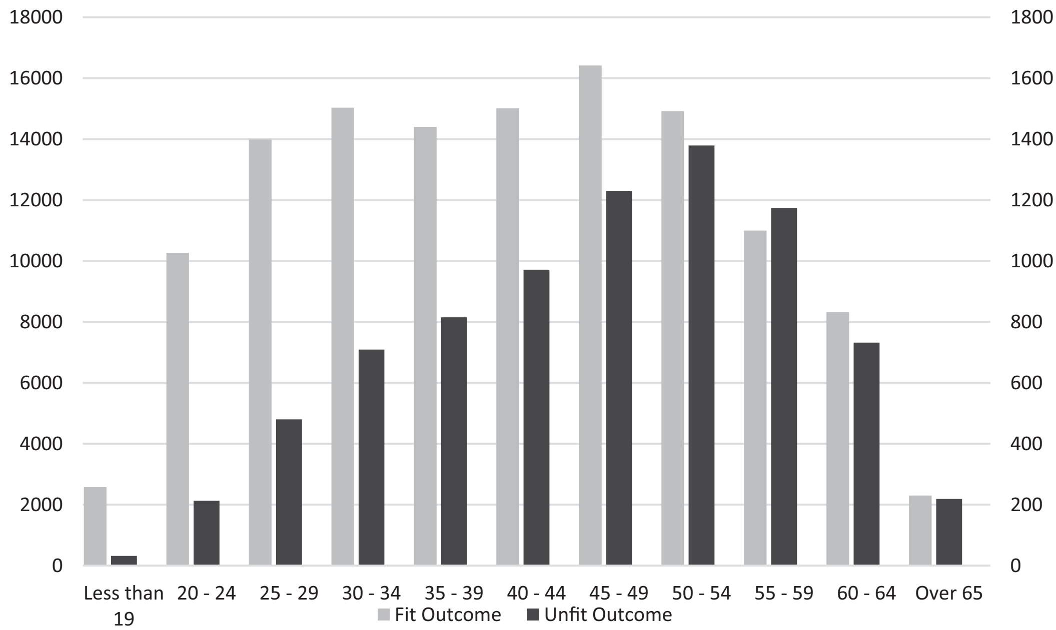

Fig. 1. Age Distribution of fit (1000s) and unfit (100s) Assessments.

which a fit assessment was undertaken until a subsequent unfit assessment occurred. Analysis for significant differences in the mean number of days until an unfit period against age was undertaken using a one-way ANOVA. Post hoc analysis was then undertaken to determine which ages were significantly different. This measure may be considered as analogous to a 'time to failure'. Both fit and unfit assessments on individuals below 19 yr were removed from this specific analysis due to small sample sizes in the unfit cohort with extreme variances.

Statistical analysis was undertaken using IBM SPSS version 26. The study was discussed with King's College London Research Ethics Committee, who confirmed as records were anonymized at the time of retrieval, no formal ethical approval was required.

RESULTS

The fit cohort over the period 1 January 2016 to 31 December 2019 was 99,406 or an average of 24,851 per annum. Following the exclusions due to State of License Issue changes, incomplete entries, or those over 65 yr of age, this left 93,813 assessments in the fit cohort and 7925 assessments in the unfit cohort.

The median age of the fit cohort was 42 and of the unfit cohort was 43. Using Kolmogorov-Smirnov testing, the distribution of the fit cohort was confirmed to be parametric (skew: 0.025) and the unfit cohorts nonparametric (skew: 0.220). This reflects the increased rates of unfit assessments in those who are older as shown in **Fig. 1**.

Pearson bivariate correlation showed that age and the likelihood of an unfit assessment are strongly correlated (r = 0.93, $P < 0.001$). Linear regression R^2 value was 0.871, showing that 87.1% of the variance in rates can be explained by change in age alone. The hypothesized healthy worker effect is likely to become particularly pronounced within the age 60–65 grouping and this is estimated to contribute to the fall in the unfit assessment rate as shown in **Table II**. This was not calculated, however, due to the inability to control for employment or contractual retirements.

Chi-squared testing found no association between a 'yes' response and an applicant being in the fit [$\chi^2(2) \geq 1890$, $P = 0.243$] or unfit [$\chi^2(2) \geq 1440$, $P = 0.271$] groups for any of the 46 system groupings. It would therefore not be possible to use this as a predictive screening factor at the time of the medical. This is likely explained by the heterogenous nature of the categories, accounting for conditions with a broad mixture of risks.

There was a statistically significant difference between unfit age groups as determined by one-way ANOVA [$F(46, 9343) = 5.443$, $P \leq 0.001$]. A Tukey post hoc test revealed that the number of days until an unfit assessment became significant between groups ages 20–60 and groups ages 61–63 ($P \leq 0.05$), as shown in **Fig. 2**. The correlation between certificate validity changing to 6 mo after age 60 and the likelihood of an unfit assessment is discussed further below.

Table II. Rate of Unfit Assessments (Per Annum).

AGE	RATE
Less than 20	0.84%
21–25	0.86%
26–30	1.28%
31–35	1.56%
36–40	1.99%
41–45	2.05%
46–50	2.54%
51–55	2.91%
56–60	3.38%
61–65	2.49%

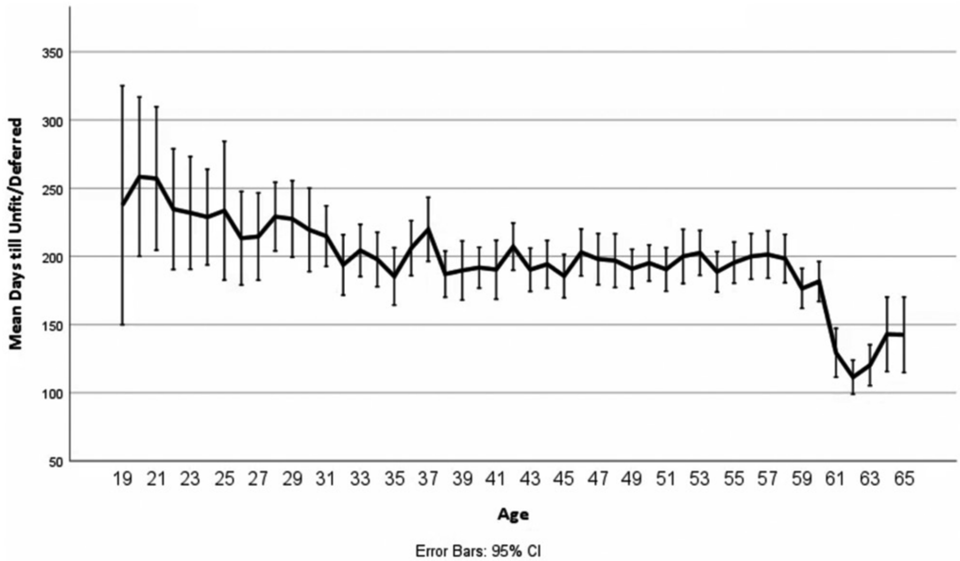

Fig. 2. Mean Days Until Unfit Assessment (Error Bars: 95% Confidence Intervals).

DISCUSSION

In its broadest sense, the key aviation safety role of regulatory aeromedical assessment is the ability to identify an individual who may be at greater risk of incapacitation and implement a suitable risk mitigation strategy.[10] While the primary end point in risk assessment is normally incapacitation while in control of an aircraft, not all instances of incapacitation are registered formally via recognized routes such as via the Mandatory Occurrence Reports System.[6]

Furthermore, the ability to predict future incapacitation is usually reliant on population level data for cohorts which may not share similar characteristics to commercial pilots, who are typically younger, fitter, and more socioeconomically successful than the general population.[13] All cause, vascular, and malignant standardized-mortality data for commercial pilots are all correspondingly lower.[1,18] Predictive risk scores used in clinical practice may overestimate the likelihood of events with the potential for incapacitation.

It is therefore suggested that an analysis of unfit assessments can serve as a useful adjunct to the primary aeromedical assessment process. As the number of unfit assessments is much greater than incapacitation events, it may also be more sensitive to subtle changes in pilot health over the course of a career. On an individual level this may also be a more practically useful metric, helping to inform targeted interventions by aviation medicine clinicians (medical assessor/aviation medical examiners), employers, and peer support programs. This would tie in with recent EASA regulatory amendments that require all commercial air transport operators to provide access to peer support programs for their pilots.[4]

It is not possible to determine if any of the individuals who underwent an unfit assessment would have otherwise presented with an in-flight incapacitation; a prospective paired cohort study may help in determining this among the pilot population. Intuitively there is likely to be a degree of overlap based on previous study data.[11]

Extrapolation of a future risk of incapacitation from pre-existing disease, even when a well-established link exists, can be inaccurate over short time frames. For example, while hypertension is a significant risk factor for a primary cardiac event, the ability to predict the timing of a future event using antecedent risk factors remains imprecise with wide confidence intervals.[2] Additionally, the Tower Hamlets study from which the original 1% rule was derived showed that not all myocardial events are necessarily incapacitating, evidenced by the fact that approximately 50% of individuals delayed calling a doctor for 2 h after the onset of their symptoms.[22] The overall rate of unfit assessments at 2.1% for all age groups was notably lower than in other previously studied data of 4.5% per annum;[11] the reasons for this are unclear, but may reflect general improvements in population health since 2004.

Unfortunately, a significant number of the medical record system entries are incomplete or have free text entered, which makes further interpretation of the data time-intensive and was, therefore, outside the scope of this study. Attempted analysis of chronic health conditions based into systems against unfit assessment rates was also made difficult by the way data is collected at the time of the medical. Cardiological illness includes very common and treatable conditions such as hypertension, which on a frequency basis will tend to outnumber more serious conditions with a higher risk of being unfit. This perhaps explains the failure to find a significant correlation between the declaration of a health condition and the likelihood of an unfit assessment.

The results of this study are intended to have value for employers beyond those simply pertaining to the risk of incapacitation. Knowledge of the likelihood of an unfit period, during which time a pilot is unable to operate commercially, may help with workforce planning and to implement measures to support pilots who have become aeromedically unfit.[16] While the specific impact of the 'healthy worker effect' on the data was not fully assessed, there is a statistically significant increase in the rate of becoming unfit until age 60, which does not continue between 60–65 as might be expected.[17] The impact of chronic health conditions in those approaching retirement age is an area of suggested further study.

There is, however, a significant decrease in the time interval until an unfit assessment occurs after the age of 60, relative to the rest of the pilot cohort. Further exploration of why these two seemingly contradictory trends occur is needed. From a policy perspective, current regulations (both EASA and UK Part-MED) include increased oversight frequency with 6-monthly certificate validity following the first medical after this point.[7] The data are therefore broadly supportive of this; however, the correlation of increased medical oversight and a decreased time interval until being made unfit may be bidirectional. The evidence for extending Class 1 certificate validity beyond 65 yr of age for commercial air transport operations was not studied in these data.

In conclusion, the age of a pilot is significantly correlated with the likelihood of an unfit assessment. Due to the broad groupings of medical comorbidities declared at the time of the Class 1 medical examination, no correlation was found with the likelihood of an unfit assessment. There is evidence of a healthy-worker effect among commercial pilots. The data findings of this study are intended to act toward further data-driven algorithmic risk modeling. A prospective study would be required to better determine if there is a correlation between unfit periods and incapacitation.

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REFERENCES

1. Blettner M, Zeeb H, Auvinen A, Ballard TJ, Caldora M, et al. Mortality from cancer and other causes among male airline cockpit crew in Europe. Int J Cancer. 2003; 106(6):946–952.
2. Bonifonte A, Ayer T, Veledar E, Clark A, Wilson PW. Antecedent blood pressure as a predictor of cardiovascular disease. J Am Soc Hypertens. 2015; 9(9):690–696.e1.
3. Chapman PJ. The consequences of in-flight incapacitation in civil aviation. Aviat Space Environ Med. 1984; 55(6):497–500.
4. Civil Aviation Authority. CAP1695: pilot support programme – guidance for commercial air transport (CAT) operators. [Accessed 2021 Feb. 24; Withdrawn 13 July 2021]. Available from https://publicapps.caa.co.uk/modalapplication.aspx?appid=11&mode=detail&id=8659
5. Civil Aviation Authority. CAP 795: safety management systems (SMS) guidance for organisations. [Accessed 2021 Jul. 30]. Available from https://publicapps.caa.co.uk/docs/33/CAP795_SMS_guidance_to_organisations.pdf.
6. Civil Aviation Authority. Mandatory occurrence reporting system code. [Accessed 2021 Feb. 4]. Available from https://www.caa.co.uk/Our-work/Make-a-report-or-complaint/MOR/The-MORs-code/.
7. Civil Aviation Authority. Medical certificate table of validity periods for examinations and tests. Version 9.0. Crawley, West Sussex (UK): Civil Aviation Authority; April 2019.
8. European Aviation Safety Agency. Brexit. [Accessed 2021 Jul. 30]. Available at: https://www.easa.europa.eu/brexit.
9. European Commission. Regulation (EU) No 1178/2011 of 3 November 2011 laying down technical requirements and administrative procedures related to civil aviation aircrew pursuant to Regulation (EC) No 216/2008 of the European Parliament and of the Council Text with EEA relevance. OJ L 311, 25.11. Brussels (Belgium): European Commission; 2011: 1–193.
10. Evans ADB. Aeromedical risk: a numerical approach. In: Gradwell D, Rainford DJ, editors. Ernsting's aviation and space medicine, 5th ed. Boca Raton (FL): CRC Press; 2016: 373–383.
11. Evans S, Radcliffe SA. The annual incapacitation rate of commercial pilots. Aviat Space Environ Med. 2012; 83(1):42–49.
12. Hippisley-Cox J, Coupland C, Brindle P. Development and validation of QRISK3 risk prediction algorithms to estimate future risk of cardiovascular disease: prospective cohort study. BMJ. 2017; 357: j2099.
13. Huster KM, Müller A, Prohn MJ, Nowak D, Herbig B. Medical risks in older pilots: a systematic review on incapacitation and age. Int Arch Occup Environ Health. 2014; 87(6):567–578.
14. International Civil Aviation Organization. Annex 1: personnel licensing. Edition 13. Montreal (Canada): ICAO; July 2020.
15. International Civil Aviation Organization. Annex 19: safety management. Edition 2. Montreal (Canada): ICAO; July 2016.
16. International Federation of Air Line Pilots' Associations. Pilot assistance manual, 1st ed. Montreal (Canada): IFALPA; March 2018.
17. Kirkeleit J, Riise T, Bjørge T, Christiani DC. The healthy worker effect in cancer incidence studies. Am J Epidemiol. 2013; 177(11):1218–1224.
18. Mills WD, Greenhaw RM. Association of medical certification factors with all-cause mortality in U.S. aviators. Aerosp Med Hum Perform. 2019; 90(11):938–944.
19. Shah P, Kendall F, Khozin S, Goosen R, Hu J, et al. Artificial intelligence and machine learning in clinical development: a translational perspective. NPJ Digit Med. 2019; 2(1):69.
20. Thammasitboon S, Cutrer WB. Diagnostic decision-making and strategies to improve diagnosis. Curr Probl Pediatr Adolesc Health Care. 2013; 43(9):232–241.
21. Tunstall-Pedoe H.Risk of a coronary heart attack in the normal population and how it might be modified in flyers. Eur Heart J. 1984; 5(Suppl. A):43–49.
22. Tunstall-Pedoe H, Clayton D, Morris JN, Brigden W, McDonald L. Coronary heart attacks in East London. Lancet. 1975; 2(7940):833–838.