

The 1% rule

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Centrum voor Mens en Luchtvaart, Soesterberg



Potentiële belangenverstrengeling	Geen
Voor bijeenkomst mogelijk relevante relaties met bedrijven	n.v.t.
Sponsoring of onderzoeksgeld Honorarium of andere (financiële) vergoeding Aandeelhouder Andere relatie, namelijk ...	CardioExpert BV



Cardiovascular risk assessment

- 1 % rule
 - geschiedenis
 - achtergrond
 - 1% anno 2025
 - andere risicomodellen



the 1 % rule: the problem

August 16, 2023: A LATAM Airlines pilot passed away mid-flight on a scheduled Miami-Santiago route, leading to an emergency diversion to Panama City. Captain Ivan Andaur, 56, year, became unwell and left the flight deck to go to the bathroom. However, Capt Andaur collapsed while in the bathroom, and emergency assistance was subsequently provided by other crew members.



June 8, 2024: An Egyptian pilot passed away mid-flight while steering the aircraft from Cairo to Taif, Saudi Arabia. Captain Hassan Youssef Adas, the flight commander, died after suffering a medical emergency during flight NE130, the pilot was in his late thirties, unmarried, and had been experiencing health issues related to obesity and its complications.



October 10, 2024: The Turkish Airlines flight from Seattle to Istanbul was diverted to New York after the man lost consciousness shortly after take-off. Its pilot died on board. Airbus A350's crew tried to revive the 59-year-old after he lost consciousness, but he was confirmed dead before the plane landed. A spokesperson said he had no known prior health problems.



Historical perspective

1944: convention on International Civil Aviation, Chicago

1947: International Civil Aviation Organisation (ICAO)
first regulations Aviation Medicine

1974: ICAO Manual of Civil Aviation Medicine

1985: second edition of the manual (cardiovascular)



The ICAO cardio vascular standards (1987)

- 6.3.2.5 The applicant shall not possess any abnormality of the heart, congenital or acquired, which is likely to interfere with the safe exercise of the applicant's licence and rating privileges. A history of proven myocardial infarction shall be disqualifying.
- Note. — Such commonly occurring conditions as respiratory arrhythmia, occasional extrasystoles which disappear on exercise, increase of pulse rate from excitement or exercise, or a slow pulse not associated with auriculo-ventricular dissociation may be regarded as being within 'normal' limits.
- 6.3.2.5.1 Electrocardiography shall form part of the heart examination for the first issue of a licence and shall be included in reexaminations of applicants between the ages of 30 and 40 no less frequently than every two years, and thereafter no less frequently than annually.
- Note 1. — The purpose of routine electrocardiography is case finding. It does not provide sufficient evidence to justify disqualification without further thorough cardiovascular investigation. Note 2. — Guidance on resting and exercise electrocardiography is published in the ICAO Manual of Civil Aviation Medicine (Doc 8984-AN 1895).
- 6.3.2.6 The systolic and diastolic blood pressure shall be within normal limits.
- Note 1. — The use of drugs for control of high blood pressure is disqualifying, except for those drugs the use of which, according to accredited medical conclusion, is compatible with the safe exercise of the applicant's licence and rating privileges. Note 2. — Extensive guidance on the subject is published in the ICAO Manual of Civil Aviation Medicine (Doc 8984-AN1895)
- 6.3.2.7 There shall be no significant functional or structural abnormality of the circulatory tree



Hugh Tunstall-Pedoe



Cardiologist

**Professor of epidemiology,
Dundee, Scotland**

**Many epidemiologic studies on risk
factors for coronary heart disease.**

1984:

**Risk of a coronary heart attack in the normal
population and how it might be modified in flyers".**

European Heart Journal 5 (Suppl A): 43-9. doi:10.1093/eurheartj/5.suppl_A.43.

1988:

Acceptable cardiovascular risk in aircrew.

Introduction. European Heart Journal 9 (Suppl G): 9-11. doi:10.1093/eurheartj/9.suppl_G.9

The concept of risk . European Heart Journal 9 (Suppl G): 13-15.

The 1 % rule : Problem: “acute incapacitation”

**the predicted annual medical (cardiological) event rate
which, if exceeded, should exclude a professional
airman from flying a multi-crew aircraft.**



Michael Joy



Cardiologist to the UK Civil Aviation Authority (CAA)

Travelling Professor to the International Civil Aviation Organisation (ICAO)

Visiting Professor in Clinical Cardiology at Surrey University.

1984

Introduction and summary of principle conclusions to the First U.K. Workshop in Aviation Cardiology. Eur Heart J 1984; 5 (Suppl A): 1-7.

1988

A risk orientated approach to the problems of cardiovascular certification in aircrew: summary of principal conclusions of the Second U.K. Workshop in Aviation Cardiology European Heart Journal, Volume 9, Issue suppl G., Pages 1-8, https://doi.org/10.1093/eurheartj/9.suppl_G.1

1992

Introduction and summary of principal conclusions to the first European workshop in aviation cardiology. European Heart Journal, Volume 13, Issue suppl H, 1, Pages 1-9, https://doi.org/10.1093/eurheartj/13.suppl_H.11992

Cardiological aspects of aviation safety — the new European perspective. European Heart Journal (1992) 13, (Supplement H), 21-26

Start JAR-FCL

1999

Introduction and summary of principal conclusions of the Second European Workshop in Aviation Cardiology. European Heart Journal Supplements : Journal of the European Society of Cardiology [01 Apr 1999, 1 Suppl D:D1-12]



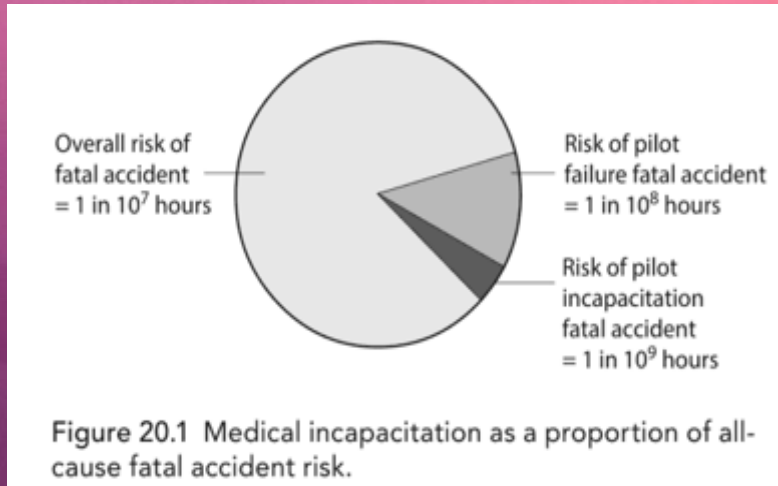


1 % rule: risk expressed as number of accidents per time unit (hours)

- Tunstall-Pedoe
- Based opinion on 1979 cardiac mortality statistics
- UK fatal accident rate at the time was
 - 1×10^{-6} flights (multicrew)
 - 1×10^{-5} flights (single pilot)



1 % rule



Catastrophe defined as event involving loss of an aircraft and/or fatalities should not occur more often than 1 per 10 million = 1×10^{-7}

Single component failure should not account for more than 10% of accidents

✈️ Aircrew regarded as a single component

Single cause within each component should not account for more than 10% of accidents

✈️ Medical regarded as a single cause

maximal acceptable incidence of medical incapacitation (per pilot):

$$1/10^{-7} \times 10^{-1} \times 10^{-1} = 1/10^{-9} \text{ pilot flying hours}$$

Step 1: from machine to man (woman/ x)



The 1 % rule

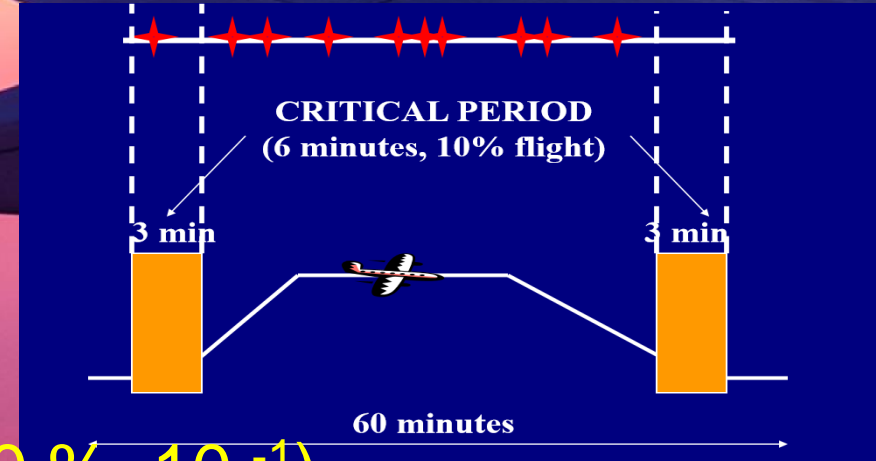
- Assumptions:

- length of flights (1 hr)
- critical flight periods (6 min= 10 %, 10^{-1})
- dual pilot operations
- and assumed the co-pilot could recover 99 times out of 100

(failed : 1 %= 10^{-2})

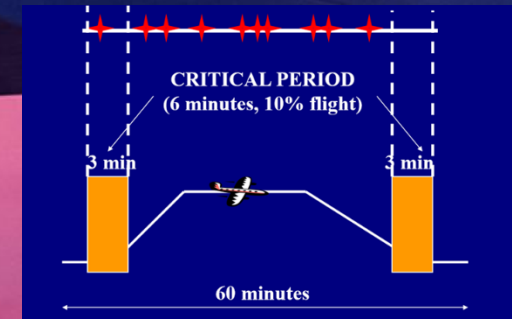
Chapman 1984: 400 simulator studies. 1 unsuccessful handover during critical phase of flight

Bennet 1988: Proposed realistic unsuccessful handover rate of 1 in 100 emergencies .
Allowed for aircrew in simulator anticipating emergencies



The 1 % rule

- Threshold: $1 \times 10^{-7} \times 10^{-1} \times 10^{-1} = 10 \times 10^{-9}$
- This is risk per “flying hours”
- How to get from “flying year” to “life year” ?
- The calculations can be re-written as if a pilot flies all year round (1 life year = 1 flight year)
- The flying itself does not influence the cardia events, they occur “at random”.
- 1 year has about 10.000 hours = 10^4 hours ($24 \times 365 = 9760$ hours)
- The **threshold** then becomes: $1 \times 10^{-9} \times 10^4 = 1 \times 10^{-5}$ flightyears (= 1 / 100.000)



The 1 % rule

- The vulnerable period in a one hour flight is $10\% = 0,1 = 10^{-1}$
- The chance that a second pilot can take over in the vulnerable period is 99/100, so the chance of a failure is 1 %, $= 0,01 = 10^{-2}$
- The maximal acceptable medical risk (= incapacitating medical events) =
- threshold (y) / vulnerable period x change of failure of takeover =
- $10^{-5} / 10^{-1} \times 10^{-2} = 10^{-2}$ events per year = 1%/ y. (= Cardiac risk)
- It is strictly *not about mortality*, but about ***incapacitating events***.



The 1 % rule

What medical risks should we worry about?

- CHD by itself is the biggest single cause of death in the UK in pilot age population
- The main forms of CVD are CHD and stroke; just under half of CVD deaths are from CHD (46%) and around a quarter are from stroke (26%)
- Other heart diseases caused 16% of all CVD deaths, and were mainly due to pulmonary heart diseases, heart failure and atrial fibrillation



The 1 % rule

What about other causes?

- 1% rule deals with **predictable** incapacitation risk
- **Unpredictable**, short lived risk such as GI upset predominate in actual in flight incapacitation events
- Current all cause incapacitation annual rate has been estimated at 2.4% (0.12% in flight)
- (Evans CAA 2002)

In pilot age population, cardiovascular disease predominates predictable risks

New unprovoked seizure risk 0.05% per annum



1% rule:

Grounding of Pilots: Medical Reasons and Recommendations for Prevention

Ries Simons; René Maire; Alwin Van Drongelen; Pierre Valk

Simons R, Maire R, Van Drongelen A, Valk P. Grounding of pilots: medical reasons and recommendations for prevention. *Aerosp Med Hum Perform.* 2021; 92(12):950–955.

Period 2013-2017; 82,435 cases; 50,101 Class 1 examinations and 32,334 Class 2 grounded : 1724 cases (2.1%).

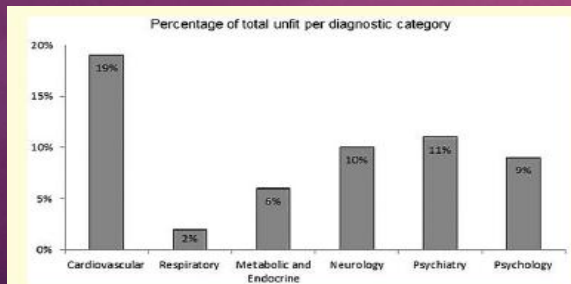


Fig. 1. Relative contribution of the diagnostic categories to the total number of unfit cases (N = 1724; pooled data of Class 1 and 2).

Table II. The Relative Contribution of the Most Frequent Diagnostic Categories Causing Unfitness to the Total Number of Unfitness Cases Per Age Group.

AGE (YR)	CARDIOVASCULAR	RESPIRATORY	METABOLIC ENDOCRINE	NEUROLOGY	PSYCHIATRY	PSYCHOLOGY
20–40	8%	3%	4%	7%	15%	20%
41–50	13%	1%	4%	11%	14%	8%
51–60	21%	2%	6%	10%	10%	4%
61–65	28%	2%	13%	11%	8%	2%
>65	48%	0%	6%	13%	2%	1%

Cardiovascular conditions are the most frequent reason for unfitness in the older age groups, with 21% (517 cases) in the 51–60 group, 28% (151 cases) in the 61–65 group, and 48% (195 cases) in those beyond 65 yr of age



The 1 % rule: challenges*

- Modern flight last on average 2hrs. Would permit a 2% rule
- Vulnerable period of 2x 3 minutes = $6/120 = 0,05 = 5 \times 10^{-2}$
- medical risk = $10^{-5} / 5 \times 10^{-2} \times 10^{-2} = 10^{-5} / 5 \times 10^{-4} = 0,1/5 = 0,02$
= **2 %**
- Less time is actually safety critical than the model allows.
- Issue is safe altitude on take off, not time
- 1,500ft (480 m) proposed, reached at 1 min
- Would permit 3 % rule (4 of 120 mins total flight)
 $10^{-5} / 3,3 \times 10^{-2} \times 10^{-2} = 0,1 / 3,3 = 0,03 =$ **3 %**

The 1 % rule: challenges

- Increased automation (eg autoland) makes taking control in safety critical period more likely. Risk of failure in 1 in 200 proposed ($1/200 = 0,005 = 5 \times 10^{-3}$)
- Would permit a $10^{-5} / 3 \times 10^{-2} \times 5 \times 10^{-3} = 1 / 15 = 0,06 = 6\%$ rule
- Comparable with engineering standard for annual in-flight shut down rate of modern engines (5.8%)
- Risk of 2 aircrew both with 1% individual risk both being incapacitated in critical phase is 1×10^{-12} . Could permit 2 OML to fly together



The 1 % rule: beyond class 1

- Private Flying:
- Assumptions:
 - Flight duration 1 hour
 - Single pilot
 - No one to take over when the pilot is incapacitated
 - No “vulnerable phase”, the whole flight is “vulnerable”



The 1 % rule

- The 1 % rule is a useful model to calculate the maximum permitted cardiovascular risk given an agreed upon threshold for air accidents, but
- The assumptions are made in the 1980ies, and aviation and aviation medicine has changes since
- With different assumptions one might accept a higher cardiovascular risk, with the same degree of aviation safety



The 1 % rule: evolving concepts

Risk Assessment

Risk = Likelihood x Consequence

Risk Assessment Triplet

- What can go wrong?
- How likely is it to occur?
- What is the consequence?



The 1 % rule: evolving concepts

A Risk Matrix*

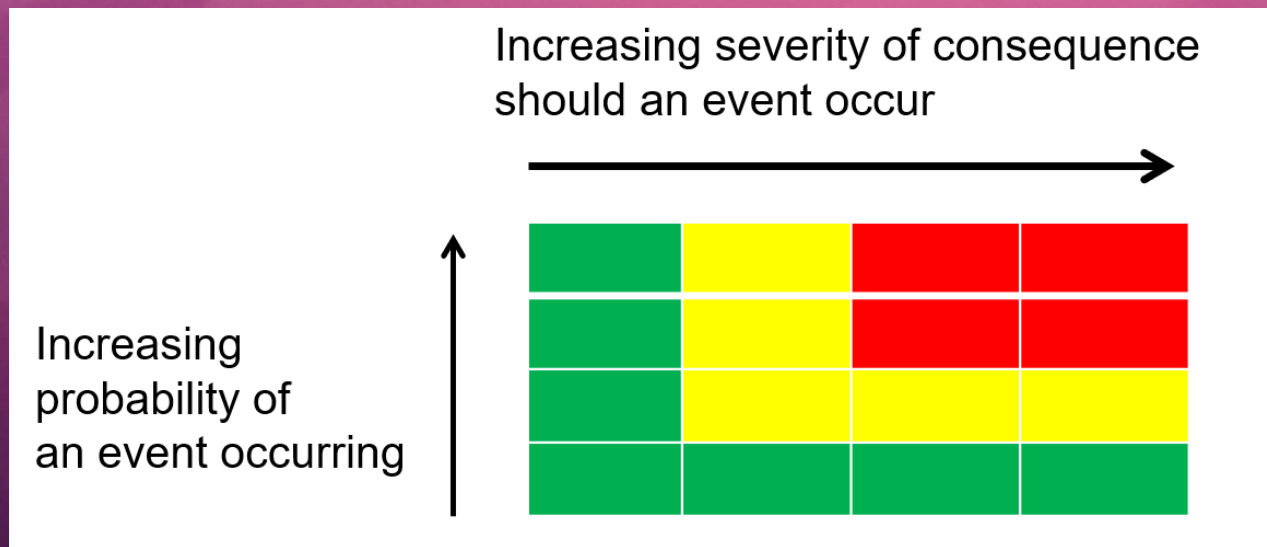
- Is a table that has several categories of likelihood for rows (probability of event occurring) and several categories of consequences of events for columns
- Partitions hazards into distinct categories corresponding to different levels of risk in the matrix cells (often colour coded)
- Provides an approximate, qualitative representation of quantitative risks



* Gary Gray, MD, PhD, FRCPC, Canadian Forces Environmental Medical Establishment

The 1 % rule: evolving concepts

4x4 Risk Matrix



The 1 % rule: evolving concepts: generic aeromedical risk matrix

	Level 1 Medical Event	Level 2 Medical Event	Level 3 Medical Event	Level 4 Medical Event
Performance →	May result in a deleterious effect on the health of the individual aircrew but minimal effect on performance	Aircrew able to continue duties with minor to moderate performance compromise.	Major decrement in performance	Total acute incapacitation (may include sudden death)
Mission →	Minimal impact on mission	May result in a mission abort or compromised effectiveness	May result in a flight safety hazard or compromise	Likely to result in a flight safety critical event
Medical →	Requires routine periodic medical follow-up	Requires medical attention	May require immediate medical attention	Requires immediate advanced medical care

Likely $\geq 2\%$				
Possible $\geq 1\% < 2\%$				
Unlikely $< 1\% \geq 0.5\%$				
Highly unlikely $< 0.5\%$				

Risk-based Decision Analysis

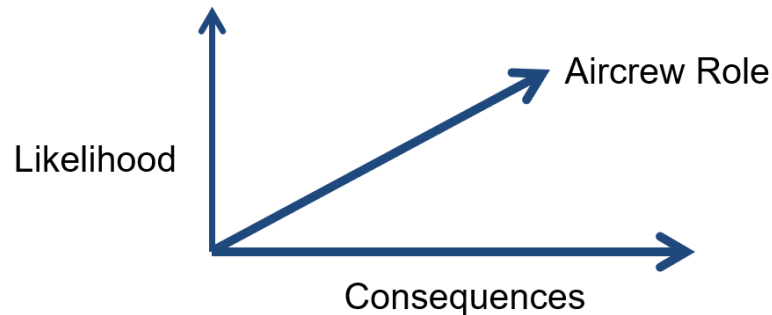
- Low risk – likely acceptable
- Moderate risk – Requires aeromedical board-level discussion for disposition
- High risk – unlikely to be suitable for aircrew duties



The 1 % rule: evolving concepts

Aircrew Role: The Third Dimension

- Acceptable risk for a medical event also varies with the aircrew role
- Aeromedical risk assessment modelling should include this variable



■ Low aeromedical risk

■ Moderate risk

■ High aeromedical risk

	Level 1 Medical Event	Level 2 Medical Event	Level 3 Medical Event	Level 4 Medical Event
	May result in a deleterious effect on the health of the individual aircrew but minimal effect on performance	Aircrew able to continue duties with minor to moderate performance compromise.	Major decrement in performance	Total acute incapacitation (may include sudden death)
	Minimal impact on mission	May result in a mission abort or compromised effectiveness	May result in a flight safety hazard or compromise	Likely to result in a flight safety critical event
	Requires routine periodic medical follow-up	Requires medical attention	May require immediate medical attention	Requires immediate advanced medical care
ATPL				
Likely $\geq 2\%$				
Possible $\geq 1\% < 2\%$				
Unlikely $< 1\% \geq 0.5\%$				
Highly unlikely $< 0.5\%$				
CPL				
Likely $\geq 2\%$				
Possible $\geq 1\% < 2\%$				
Unlikely $< 1\% \geq 0.5\%$				
Highly unlikely $< 0.5\%$				
PPL				
Likely $\geq 2\%$				
Possible $\geq 1\% < 2\%$				
Unlikely $< 1\% \geq 0.5\%$				
Highly unlikely $< 0.5\%$				
LAPL				
Likely $\geq 2\%$				
Possible $\geq 1\% < 2\%$				
Unlikely $< 1\% \geq 0.5\%$				
Highly unlikely $< 0.5\%$				



1 % rule

Cardiovascular Risk Assessment in Pilots

Andrew Mulloy; Andreas Wielgosz

Mulloy A, Wielgosz A. *Cardiovascular risk assessment in pilots*. *Aerosp Med Hum Perform*. 2019; 90(8):730–734.

Risk of Harm in flight

$RoH = TD \times V \times SCI \times Ac$

RoH: acceptable accident rate

TD: time spent flying over a given time period

V: type of airplane

SCI: cardiac event rate

Ac: probability that an event will result in injury/ fatality



1 % rule: risk of harm formula

$$\text{AAR} \times \text{OR} \times \text{MR} = \text{M} \times \text{CFD}/\text{AFD} \times \text{FHR}$$

AAR: acceptable yearly flight accident rate

10^{-7}

OR: acceptable proportion pilot-related

10^{-1}

MR: acceptable proportion medical

10^{-1}

M: annual pilot incapacitation (mortality, event rate)

?

CFD: critical flight duration

10^{-1}

AFD: average total flight duration

1

FHR: anticipated rate of failure to hand over at incapacitation

10^{-2}

$$10^{-7} \times 10^{-1} \times 10^{-1} = \text{M} \times 10^{-1} \times 10^{-2}$$

$$\text{M} = 1 / 10^6 = 1 / 100 = 0,01 = 1 \% / \text{year}$$



The 1 % rule: beyond class 1

- Accident rate: 1 : 40.000 flying hours =
- 1: 25×10^6 flying hours = 1: 25×10^2 flying years = 4×10^{-4}
- Fatal incidence rate because of medical causes: 4 %
- $4 \times 10^{-4} = \text{cardiac risk} \times 0.04 = \text{cardiac risk} \times 4 \times 10^{-2}$
- Cardiac risk = $1 \times 10^{-2} / y = 1 \%$



the 1 % rule: beyond class 1

- $AAR \times OR \times MR = M \times CFD/AFD \times FHR$

- AAR: acceptable yearly flight accident rate: 1: 40.000 flying hours 25×10^{-6}
- OR: acceptable proportion pilot-related 10^{-1}
- MR: acceptable proportion medical : 4 % 4×10^{-2}
- M: annual pilot incapacitation (mortality, event rate) ?
- CFD: critical flight duration 1
- AFD: average total flight duration 1
- FHR: anticipated rate of failure to hand over at incapacitation 1

- $M = 25 \times 10^{-6} \times 10^{-1} \times 4 \times 10^{-2} = 10^2 \times 10^{-9} = 1 / 10^6 = 1 / 10^2 = 0,01 = 1 \% / \text{year}$



1 % rule: policy

- The NATO HFM-251 Occupational Cardiology in Military Aircrew
- 2018: series of 9 articles in Heart (free access)



The challenge of asymptomatic coronary artery disease in aircrew; detecting plaque before the accident

Gary Gray,¹ Eddie D Davenport,² Dennis Bron,³ Rienk Rienks,⁴ Joanna d'Arcy,⁵ Norbert Guettler,⁶ Olivier Manen,⁷ Thomas Syburra,⁸ Edward D Nicol⁵

- Gray G, et al. Heart 2019;105:s17–s24. doi:10.1136/heartjnl-2018-313053
- Exercise tests are not apt to detect CAD properly in asymptomatic patients.
- Coronary Ca score and Coronary CT angio are.

Table 5 Event rates for revascularisation, myocardial infarction and sudden cardiac death (SCD) with various coronary calcium scores in over 32 months in 1153 patients, median age 58 (± 10) years³⁰

CAC	0	1–9	10–99	100–399	400–1000	>1000
Number	249	51	202	263	212	112
Revascularisation/MI/SCD	3	0	6	8	17	12
Annual event rate (%)	0.45	0	1.11	1.14	3.00	4.01



1 % rule: policy

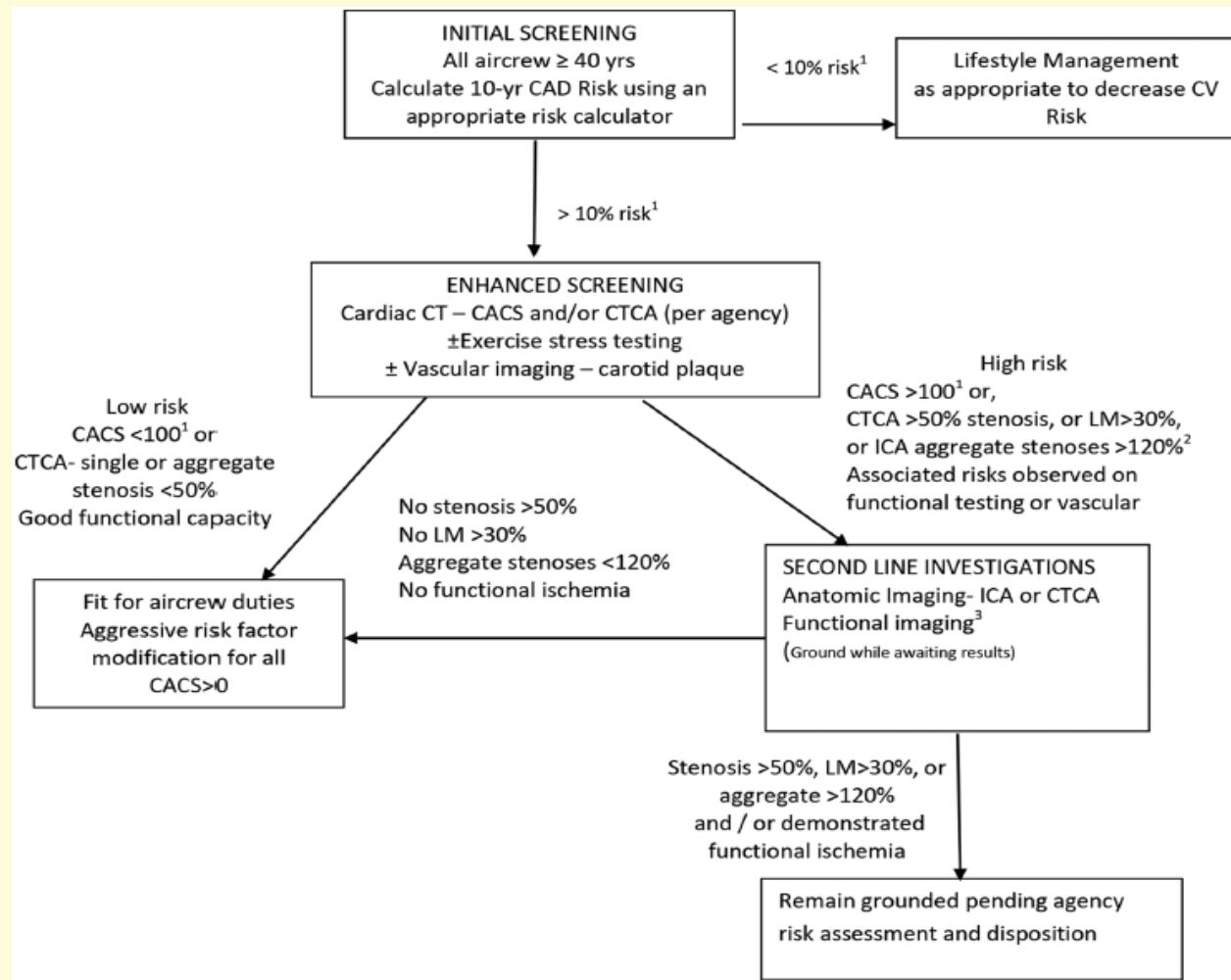


Figure 1 HFM-251 generic screening and evaluation algorithm (Adapted from DeJohn *et al* [1]). (1) This algorithm should be modified/revised for use by specific agencies as required. (2) Aggregate stenosis is the sum of quantified stenoses found on invasive coronary angiography (ICA). Adapted from Davenport *et al* [53]) (3) Functional imaging refers to stress myocardial function (eg, MUGA), stress nuclear perfusion studies stress echocardiography or perfusion CMR. Functional imaging should be performed based on the results of anatomical imaging studies and/or clinical decision. CAD, coronary artery disease; CACS, Coronary Artery Calcium Score; CTCA, CT coronary angiography; MUGA, multigated acquisition.



1% rule

- Take home message
 - risk assessment without a reference ("threshold") is useless
 - the threshold should be determined by the assessing body (government, professional (medical) organisations, etc)
 - the 1 % rule is a useful framework for risk assessment
 - however, one should consider adaptations according to the current state of aviation



1 % rule

Thank you for your attention!

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06-51248975



<https://www.bing.com/videos/riverview/relatedvideo?q=+self+driving+car+crashes&mid=2C93911E72AE1FDB75BB2C93911E72AE1FDB75BB&mmscn=stvo&FORM=VRDGAR>

<https://www.bing.com/videos/riverview/relatedvideo?q=%20self%20driving%20car%20crashes&mid=D96C6C9BF0B519EB883CD96C6C9BF0B519EB883C&ajaxhist=0>

the 1 % rule





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