



Assessing Cardiovascular Aeromedical Risk Beyond the 1% Rule

NATO Aviation Cardiology Working Group (RTG HFM-
251)

Gary Gray, MD, PhD, FRCPC

Canadian Forces Environmental Medical Establishment



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Gary Gray

I have no financial relationships to disclose

I will not discuss off-label and/or investigational drug use in my presentation



The 1% Rule



The risk of medical, in-flight incapacitation in pilots should be no greater than 1% per annum (for two pilot, civil aviation commercial operations)



Origins of the 1% rule



- 1973 Ian Anderson (Director of Civil Aviation Medicine Canada) presented a paper to ASMA
 - Accepted airworthiness targets at that time were approximately 1 aircraft accident per 10 million flying hours (10^7) hrs due to mechanical failure
 - Anderson proposed that pilot aeromedical failure could be assessed in the same way and provide an objective method of assessing fitness for medical certification



Origins of the 1% rule



- 1982 – First United Kingdom Workshop in Aviation Cardiology
 - Dr. Hugh Tunstall-Pedoe: “fatal accident rates in passenger aircraft can be compared directly with coronary heart attack rates in pilots”



- The workshop set a target for medical incapacitation as a cause of aircraft accidents at 1 in 1000 million flying hours (1 in 10^9) and used this target to develop the “1% rule” for acceptable risk for a fatal coronary event causing an aircraft accident
- European Heart Journal Vol 5, Supplement, 1984



The Aeromedical “1% rule”



- Assumptions
 - length of flights (1 hr)
 - critical flight periods (6 min),
 - dual pilot operations , and assumed the copilot could recover 99 times out of 100
- Equates to a medical event rate of 1% per year
 - 8760 hrs/yr $\sim 10^4$; 1/100 aircrew will have an event per year = $1/10^6$
 - Only 10% of flight time is flight safety critical; copilot can recover 99/100 = $1/10^9$
- Used by many aeromedical authorities to define the acceptable level of medical risk for aeromedical dispositions



Limitations of the 1% Rule



- Assumptions inherent in the 1% rule are not applicable in military air operations, nor in many civilian flying operations
- *Consequences* of medical events are assumed to be catastrophic/fatal. However, the consequences of medical events are likely to vary considerably depending on
 - The nature of the medical event
 - not all cardiac events are fatal nor are many medical events with aeromedical consequences eg asthma attacks, kidney stones, etc
 - The particular operation/mission
 - Compare a training mission with a critical military weapons delivery mission
 - Crewmember role
 - Compare a fighter pilot role with a flight surgeon role



1% Rule



- Excellent review of aeromedical risk and the 1% rule
 - Anthony Evans. Ernsting's Aviation Medicine, 4th edition, chapter 36



RISK MANAGEMENT



- Risk Management has now evolved into a formal discipline
- Wide application in a multitude of organizations
 - Financial, economic, political, military , space, aviation, aeromedical
- International Organization for Standardization – ISO/IEC Guide 73 – Risk Management
- Focus is on the identification and management of risk within any organizational context



Risk Management Process





Risk Assessment



Risk = Likelihood x Consequence

Risk Assessment Triplet

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



Risk Matrices



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



4 x 4 Risk Matrix



Increasing severity of consequence
should an event occur



Increasing
probability of
an event occurring





Generic Aeromedical Risk Matrix



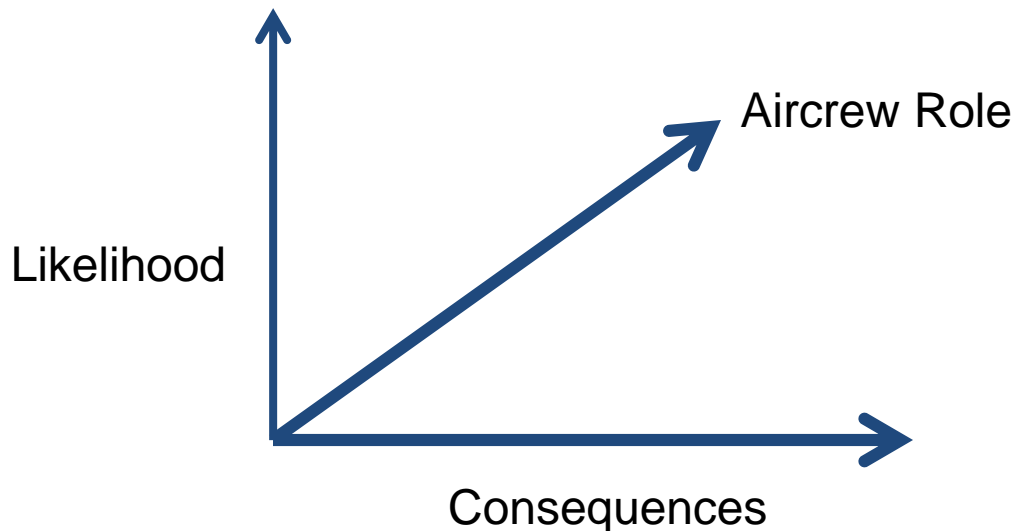
	Level 1 Medical Event	Level 2 Medical Event	Level 3 Medical Event	Level 4 Medical Event
Performance →	May result in a deleterious effect on the health of the individual aircrew but minimal effect on performance	Aircrew able to continue duties with minor to moderate performance compromise.	Major decrement 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



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





Aircrew Role: The Third Dimension



- All aircrew have a defined operational role but not all aircrew roles have equal effects on mission outcome and flight safety
- Aeromedical risk assessment should include the mission/flight safety impact of a medical event through aircrew roles
- This requires a series of risk matrices stratified for aircrew roles/responsibilities



RCAF Aircrew Roles



- Stratification by Aircrew Roles

CATEGORY	AIRCREW
CAT 1	<ul style="list-style-type: none">• Pilots – Fighters, Tac Hel, Maritime RW, SAR RW, Pre-Wings Instructor• SAR Techs
CAT 2	<ul style="list-style-type: none">• Pilots – Transport, Maritime Patrol, Post-Wings Instructor
CAT 3	<ul style="list-style-type: none">• Non-Pilot Group A Aircrew ACSO, FE, AESOp, MS, FTE, LM, AEC, ACOp (DCP), AMTO, Aeromed Tech, UAV Tier 1/2 Op
CAT 4	<ul style="list-style-type: none">• Group B Aircrew Flight Surgeon, Flight Nurse, Flight Med Tech, Flight Steward, Flight Attendant, AWACS/ATIS, UAV Payload Ops



3D RISK MATRICES



- Three dimensional model of risk matrices that incorporates
 - Likelihood (rows)
 - Consequences (columns)
 - Aircrew role (series of matrices)

 **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

CAT 1 - PILOTS-Fighter, Tac Hel, MRW, SAR RW, Ab Initio instructors. SAR Techs

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

CAT 2 - PILOTS - Transport, MFW, Post-Wings Instructors

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

CAT 3 - Non-Pilot Group A Aircrew

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

CAT 4 - Group B Aircrew

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



Case



- 49 year old Air Force transport pilot
 - History –Family history of coronary disease; dyslipidemia; mild controlled hypertension; smoker; irregular exercise
 - 100kg, BMI 30.9, WC 104cm, BP 144/90
 - TC/HDL 6.49/0.82, LDL 5.0, TG 2.20, hs-CRP 3.5, A1C 5.8
 - Reynold's Risk Score 30% for a cardiac event in the next decade



Case



- Exercise stress echo negative for ischemia
 - VO2 max 8 METS
- CT coronary artery calcium score 476 Agatson units
- Coronary angiogram – 40% LAD stenosis, 25% D1 stenosis, 35% RCA stenosis
- Risk for a coronary event
 - ~ 1% per year based on CACS (Rozanski et al, JACC)
 - ~ 1.1% per year based on angiographic data with aggregate stenosis of 100 (USAF data).



Case



- Temporarily grounded. Intensive life-style modification with diet, exercise, smoking cessation and treatment with statin for six months
 - Repeat labs – TC/HDL = 5.1/1.0, LDL 2.0, TG 0.90, FBG 5.2, A1C 5.5
 - Improved aerobic capacity at 10 METS
- Revised risk estimate now 0.5-1.0% per year

Medical Risk Matrix: Cat 2

Pilots- Transport, MFW, Post-wings Instructor

	Level 1 Medical Event	Level 2 Medical Event	Level 3 Medical Event	Level 4 Medical Event
	Likely to 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	Likely to result in a mission abort or compromised effectiveness	Likely to 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
Likely $\geq 2\%$				
Possible $\geq 1\% < 2\%$			ACS	
Unlikely $< 1\% \geq 0.5\%$				MI, SCD
Highly unlikely $< 0.5\%$				




Risk-based Decision Analysis

- Low risk – acceptable for unrestricted aircrew duties
- Moderate risk – Requires agency discussion and disposition re disposition
- High risk – unsuitable for aircrew duties
-

Medical Risk Matrix: Cat 1 Pilots- Fighter, Tac Hel, SAR RW, MRW, Pre-Wings Instructor, SAR Techs

	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
Likely $\geq 2\%$				
Possible $\geq 1\% < 2\%$			ACS	
Unlikely $< 1\% \geq 0.5\%$				MI, SCD
Highly unlikely $< 0.5\%$				

Risk-based Decision Analysis

-  Low risk – acceptable for unrestricted aircrew duties
-  Moderate risk – Requires AUMB discussion and disposition re A3
-  High risk – unsuitable for aircrew duties



Summary



- Aeromedical risk assessment has evolved beyond the 1% rule
- Aeromedical risk can be quantitatively conceptualized using three dimension risk matrices which include
 - the probability that a medical event will occur
 - the consequences of a medical event
 - the specific role of the aircrew.
- The acceptable level of risk (ie the colour of the boxes) is an agency/organizational decision
- Risk matrices are only a tool to help conceptualize risk in the process of making aeromedical decisions, and should not be used to provide “cookie cutter” aeromedical decisions. Shortcomings include
 - Large confidence intervals in assessing the risk of medical events
 - Consequences of medical events may vary considerably for any particular condition



QUESTIONS?



Case 2



- 43 year old airline pilot mildly aware of an irregular heart action, no lightheadedness or other untoward symptoms
- Goes to the Emergency Department – ECG shows atrial fibrillation, ventricular rate 90-100
- Normal cardiac function on echo
- Spontaneously reverts to sinus rhythm in ED
- Reports a similar sensation 3 years before on vacation which disappeared after a couple of hours



Case 2



- Investigations
 - Echocardiogram – normal
 - Exercise stress test – normal, VO₂ max 10 METs, no arrhythmias
 - Holter monitor – rare PAC, no arrhythmias
 - Thyroid function normal



Case 2



- Recurrent atrial fibrillation with normal cardiac function
- Risk of recurrence is in the range 4-5% per year or higher
- CHADS2Vasc risk for thromboembolism < 1%/yr



Commercial Pilots



Level 1 Medical Event	Level 2 Medical Event	Level 3 Medical Event	Level 4 Medical Event
Likely to 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	Likely to result in a mission abort or compromised effectiveness	Likely to 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

Likely $\geq 2\%$	Afib Recurrence Risk			
Possible $\geq 1\% < 2\%$				
Unlikely $< 1\% \geq 0.5\%$			Stroke Risk	
Highly unlikely $< 0.5\%$				

Risk-based Decision Analysis

- Low risk – acceptable for A1
- Moderate risk – Requires agency discussion and disposition re disposition
- High risk – unsuitable for A1 or A3 duties
-