Assessing Cardiovascular Aeromedical Risk Beyond the 1% Rule

NATO Aviation Cardiology Working Group (RTG HFM-251)

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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 ~ 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
- Focus is on the identification and management of risk within any organizational context
Risk Management Process

1. Agency Level Risk Management Program
   *Define Acceptable Level of Risk*

2. Identify Risks
   *Diseases/Medical Events*

3. Analyse Risks
   *Assess the probability and consequences of a medical event*

4. Evaluate Risks
   *Compare with Defined Acceptable Level*

5. Modify Risks and reassess
Risk Assessment

Risk = Likelihood x Consequence

Risk Assessment Triplet

• What can go wrong?
• How likely is it to occur?
• What is the consequence?
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.
Increasing severity of consequence should an event occur

Increasing probability of an event occurring
# Generic Aeromedical Risk Matrix

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

<table>
<thead>
<tr>
<th>CATEGORY</th>
<th>AIRCREW</th>
</tr>
</thead>
<tbody>
<tr>
<td>CAT 1</td>
<td>• Pilots – Fighters, Tac Hel, Maritime RW, SAR RW, Pre-Wings Instructor • SAR Techs</td>
</tr>
<tr>
<td>CAT 2</td>
<td>• Pilots – Transport, Maritime Patrol, Post-Wings Instructor</td>
</tr>
<tr>
<td>CAT 3</td>
<td>• Non-Pilot Group A Aircrew ACSO, FE, AESOp, MS, FTE, LM, AEC, ACOp (DCP), AMTO, Aeromed Tech, UAV Tier 1/2 Op</td>
</tr>
</tbody>
</table>
3D RISK MATRICES

• Three dimensional model of risk matrices that incorporates
  – Likelihood (rows)
  – Consequences (columns)
  – Aircrew role (series of matrices)
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**CAT 1 - PILOTS-Fighter, Tac Hel, MRW, SAR RW, Ab Initio instructors. SAR Techs**

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

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<tr>
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**CAT 3 - Non-Pilot Group A Aircrew**

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<tr>
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**CAT 4 - Group B Aircrew**

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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

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<td>Suitable for unrestricted aircrew duties</td>
<td>Requires agency discussion and disposition re disposition</td>
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## 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**
- May result in a deleterious effect on the health of the individual aircrew but minimal effect on performance

**Level 2 Medical Event**
- Aircrew able to continue duties with minor to moderate performance compromise.

**Level 3 Medical Event**
- Major decrement in performance

**Level 4 Medical Event**
- Total acute incapacitation (may include sudden death)

**Likely ≥ 2%**
- Likely ≥ 2%

**Possible ≥ 1% <2%**
- Possible ≥ 1% <2%

**Unlikely <1% ≥ 0.5%**
- Unlikely <1% ≥ 0.5%

**Highly unlikely <0.5%**
- 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

### Event Levels
- **Level 1 Medical Event**
  - May result in a deleterious effect on the health of the individual aircrew but minimal effect on performance
  - Requires routine periodic medical follow-up
  - Likely ≥ 2%

- **Level 2 Medical Event**
  - Aircrew able to continue duties with minor to moderate performance compromise.
  - Requires medical attention
  - Possible ≥ 1% <2%

- **Level 3 Medical Event**
  - Major decrement in performance
  - May require immediate medical attention
  - Unlikely <1% ≥ 0.5%

- **Level 4 Medical Event**
  - Total acute incapacitation (may include sudden death)
  - Requires immediate advanced medical care
  - Highly unlikely <0.5%

### Event Descriptions
- **Level 1 Medical Event**
  - May result in a deleterious effect on the health of the individual aircrew but minimal effect on performance
  - Requires routine periodic medical follow-up
- **Level 2 Medical Event**
  - May result in a mission abort or compromised effectiveness
  - Requires medical attention
- **Level 3 Medical Event**
  - May result in a flight safety hazard or compromise
  - May require immediate medical attention
- **Level 4 Medical Event**
  - Likely to result in a flight safety critical event
  - Requires immediate advanced medical care
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
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

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| Likely ≥ 2% | Afib Recurrence Risk | | |
| Possible ≥ 1% <2% | | | |
| Unlikely <1% ≥ 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