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Design, Testing, and Implementation of the USAFSAM AMRAAM

RYAN S. MAYES, PHD, MPH
Deputy Chair
Department Of Aerospace Medicine
U.S. Air Force School of Aerospace Medicine

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Disclosure Information
Dr. Ryan Mayes

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Overview

- Background and Motivation
- Design and Development of the ACS Medical Risk Assessment and Airworthiness Matrix (AMRAAM)
- Use of the AMRAAM
- Validation of the AMRAAM
- Implementation of the AMRAAM and Lessons Learned

Aeromedical Consultation Service Medical Risk Assessment & Airworthiness Matrix (AMRAAM)

Version 1.0 CAO 28 Jun 2022

SEVERITY: Potential Duty-Specific Adverse Outcomes	LIKELIHOOD: FREQUENT (or continuous)	PROBABLE	OCCASIONAL	REMOTE	IMPROBABLE
	Likelihood of a Single Occurrence Per Year				
	Greater than 99%	60% to 99%	10% to 60%	1% to 10%	Less than 1%
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Risk Matrix Instructions

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ACCEPTABILITY

Initial Baseline Risk Assessment Level (Before Mitigation Measures Implemented)			
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Note 4: Risk assessment levels will be influenced by evolving medical event likelihoods over time and should be re-evaluated periodically.

Background: USAFSAM Aeromedical Consultation Service (ACS)

Mission: Keep flyers in the fight!

- To provide expert evaluation and risk assessment regarding the medical fitness of individuals for advanced aeromedical and operational duties
- To perform research that informs the development of aeromedical policy and Air Force medical standards
- And to provide aerospace and operational medicine education for the Air Force, the DoD and its international partners, through teaching, mentoring, and publication

- U.S. Air Force (USAF) aeromedical waiver evaluations
  - *2021: 2,255 cases; 90% return to flying status recommended*
- USAF pilot applicant exams
  - *2021: 1800 exams*
- USAF Aeromedical Waiver Guide
  - *~800 pages, 140+ chapters*
- Education
  - *Flight surgeons, physiologists, optometrists, int'l medical officers*
- Medical standards/policy consultation

Background: 1% Rule

- 1% Rule has long been a standard threshold for aerospace medical risk acceptance
- Despite its widespread use, there have been multiple criticisms of the 1% Rule
  - 1% only accounts for total incapacitation
  - Flight duration: 1% rule based on 1-hour sortie time
  - Critical phases of flight: 1% rule assumes that 10% of flight time would be critical
  - Impact of age on risk
- Functionally, ACS has used thresholds of 1-5% depending on crew position, severity, and other aeromedical or occupational considerations
- Why 1%?
  - Ultimately set to ~1/2 of all-cause fatal mishap rate (for large, civilian, jet transport aircraft in the UK in the 1970s-80s)
    - Mishap rate was >0.2 / 1M flying hours
    - Target fatal accident rate for aeromedical considerations: 0.1 / 1M flying hours

AMRAAM Motivation

- Challenges to aeromedical risk assessment
- Recognition of medical vs. line risk communication disconnect

- Aeromedical Risk Matrices (NATO-Ramstein Flight Medicine Summit 2019)

- Are we aligned with the US Air Force approach to risk assessment and risk communication?
  - *Are we systematically defining aeromedical events of concern and potential impact on flying safety, mission performance, and aircrew health?*
  - *Is appropriate risk tolerance framing our aeromedical waiver recommendations?*

- Update to ACS legacy risk assessment approach
  - *Utilize matrix to assess and communicate risk*
  - *Adopt airworthiness thresholds*

	Class 1 Medical Event	Class 2 Medical Event	Class 3 Medical Event	Class 4 Medical Event
	Minimal impact on mission	May 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
	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)
	Requires routine periodic medical follow-up	Requires medical attention	May require immediate medical attention	Requires immediate advanced medical care
PILOTS, COPILOTS				
Likely >2%/yr				
Possible 1-2%/yr				
Unlikely 0.5-1%/yr				
Highly unlikely <0.5%/yr				
NAVIGATORS, FLIGHT ENGINEER, FLIGHT CONTROLLERS				
Likely >2%/yr				
Possible 1-2%/yr				
Unlikely 0.5-1%/yr				
Highly unlikely <0.5%/yr				
FLIGHT ATTENDANTS LOADMASTERS				
Likely >2%/yr				
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Figure 3 Graduated risk matrices incorporating occupational role and differing classes of acceptable organisational risk for each aircrew category.

Gray G, et al. Heart 2018;105:s9–s16. doi:10.1136/heartjnl-2018-313052

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Development of ACS Risk Matrix

Risk Assessment

- DoD Safety and Occupational Health Program (DoDD 6055.01)
  - *Structured risk management process*
  - *All DoD operations and tasks*
- U.S. Air Force Risk Management (AFI 90-802)
- U.S. Air Force Risk Management Guidelines and Tools (DAFPAM 90-803)
  - *Risk assessment matrix*
- USAF Mishap Prevention Program (AFI 91-202)
  - *Safety risk assessment*
  - *Flight surgeon as human systems integration consultant*

Airworthiness

- Department of Defense Airworthiness Policy (DoDD 5030.61)
  - *Airworthiness: aircraft's suitability for safe flight*
  - *System operators must be qualified by the service*
- DoD Standard Practice: System Safety (MIL-STD-882E)
  - *System safety methodology – encourages use by occupational health professionals*
- U.S. Air Force Airworthiness (AFI 62-601)
  - *Defines airworthiness program*
- Airworthiness Risk Assessment and Acceptance (U.S. Air Force Airworthiness Bulletin 150B)
  - *Defines the process for assessing and accepting the risk of mishap associated with a hazard*
  - *Establishes acceptable probability levels for occurrence of mishap per flight hour or sortie*

Table 4: USAF Airworthiness Risk Assessment Matrix[10]

USAF Airworthiness Risk Assessment Matrix			Severity Category			
Probability Level	Probability per FH or Sortie	Freq per 100K FH or 100K Sorties	Catastrophic (1)	Critical (2)	Marginal (3)	Negligible (4)
Frequent (A)	$10^{-3} \leq$ Prob	100 ≤ Freq	1	3	7	13
Probable (B)	$10^{-4} \leq$ Prob < 10^{-3}	10 ≤ Freq < 100	2	5	9	16
Occasional (C)	$10^{-5} \leq$ Prob < 10^{-4}	1 ≤ Freq < 10	4	6	11	18
Remote (D)	$10^{-6} \leq$ Prob < 10^{-5}	0.1 ≤ Freq < 1	8	10	14	19
Improbable (E)	0 < Prob < 10^{-6}	0 < Freq < 0.1	12	15	17	20
Eliminated (F)	Prob = 0	Freq = 0	Eliminated			

High	RAC = 1 - 5	Medium	RAC = 10 – 17
Serious	RAC = 6 – 9	Low	RAC = 18 – 20

U.S. Air Force Airworthiness Bulletin 150B (30 September 2020)

ACS Risk Assessment Matrix

- Likelihood of aeromedical event
  - *Columns*
  - *Aeromedically relevant clinical events*
- Severity of outcome
  - *Rows*
  - *Adverse operational outcomes*
    - *Mission*
    - *System*
    - *Health*
- **Risk = Likelihood x Severity**
- Weighted risk scores
- Risk assessment levels
  - *Range of risk scores*

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Where is the 1% rule?

- Likelihood of sudden incapacitation less than 1%/year
  - Likelihood category: Improbable
  - Severity category: Catastrophic

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AMRAAM Utilization – Stepwise Approach

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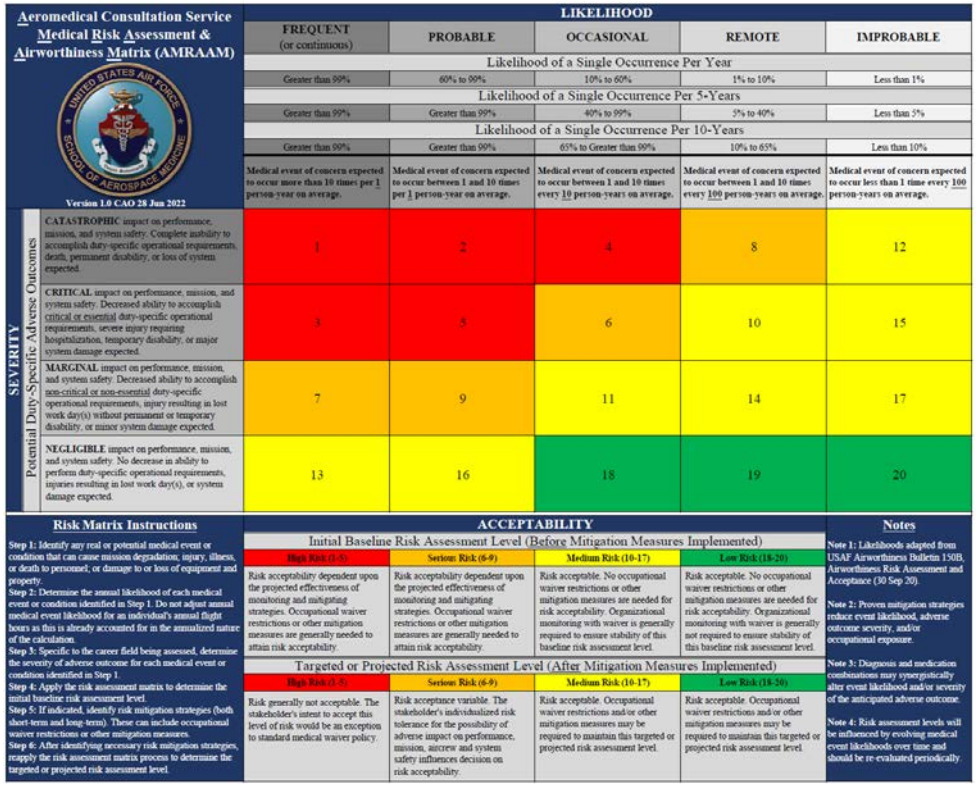
- 3) **Specific to the career field being assessed**, determine **severity** of adverse outcomes for **each** medical event or condition.
- 4) Apply risk assessment matrix to determine **initial baseline risk assessment** level.
- 5) If indicated, identify **risk mitigation strategies** (such as occupational restrictions).
- 6) After identifying necessary risk mitigation strategies, reapply risk assessment matrix process to determine the **targeted/projected risk assessment level**.
- Overall risk score is the highest score.

Steps 1 & 2

Step 3

Step 4



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Potential Duty-Specific Adverse Outcomes: CATASTROPHIC impact on performance, mission, and system safety. Complete inability to accomplish duty-specific operational requirements, death, permanent disability, or loss of system expected.	1	2	4	8	12
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ACCEPTABILITY

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Steps 5 & 6

AMRAAM: Likelihood

- Annualized probability ranges per flight hour for airworthiness
  - Some slight rounding for ease of use (generally rounded up)
- Also expressed in 5- and 10-year intervals, events per patient-year
- Translates to medical literature
- Columns differ by an order of magnitude

USAF Airworthiness Risk Assessment Matrix		
Probability Level	Probability per FH or Sortie	Freq per 100K FH or 100K Sorties
Frequent (A)	$10^{-3} \leq$ Prob	100 ≤ Freq
Probable (B)	$10^{-4} \leq$ Prob < 10^{-3}	10 ≤ Freq < 100
Occasional (C)	$10^{-5} \leq$ Prob < 10^{-4}	1 ≤ Freq < 10
Remote (D)	$10^{-6} \leq$ Prob < 10^{-5}	0.1 ≤ Freq < 1
Improbable (E)	0 < Prob < 10^{-6}	0 < Freq < 0.1
Eliminated (F)	Prob = 0	Freq = 0

U.S. Air Force Airworthiness Bulletin 150B, Table 4 (30 September 2020)

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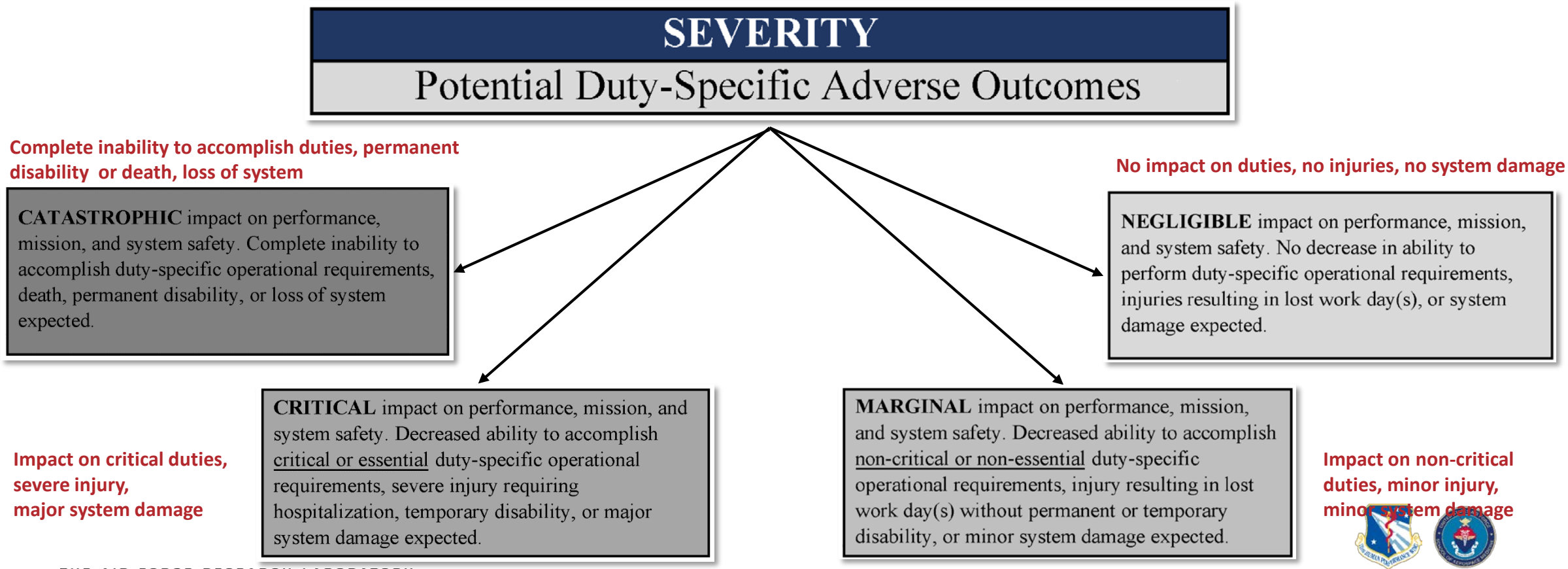
AMRAAM: Levels of Severity

- Impact on system safety (human health/system damage)
- Impact on performance and mission (ability to accomplish duty-specific operational requirements)



AMRAAM: Risk Assessment Levels and Acceptability

- Weighted risk scores, risk assessment levels
  - *Line of the Air Force (stakeholder) thresholds*
- Risk assessment levels correlate with need for mitigation
  - Flying waiver, occupational restrictions, close monitoring, etc.
- Pre-mitigation ("before") and post-mitigation ("after") levels

1	2	4	8	12
3	5	6	10	15
7	9	11	14	17
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Utilization of the AMRAAM – Clinical Example

Case Presentation: 22 y/o transport pilot with 2 episodes of spontaneous pneumothorax (PTX), 1 year s/p VATS with mechanical pleurodesis, normal chest CT (no underlying parynchemal abnormalities)

1. Medical event of aeromedical concern: recurrence of PTX in flight
2. Likelihood: Occasional to probable -- Without definitive treatment, risk of a third PTX is >20-50% (risk is highest within in the first year).
3. Severity: Critical to Catastrophic (injury and mission)
4. Baseline Risk Level: with no treatment, serious to high risk, which needs to be mitigated for waiver eligibility
5. Risk Mitigation: definitive treatment such as with VATS mechanical pleurodesis; note that if flyer declines treatment, then can mitigate with restriction from manned aviation (i.e., RPA-only); may still recur at ground level, but since not at altitude, would probably be marginal to critical rather than critical to catastrophic
6. Post-Mitigation Risk Level: When >1 year out, good recovery from pleurodesis, and no other risk factors for recurrence such as abnormal lungs, risk of recurrence estimated to be <1% per year → recommend unrestricted waiver

Aeromedical Consultation Service Medical Risk Assessment & Airworthiness Matrix (AMRAAM)

Version 1.0 CAO 28 Jun 2022

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Validation of the AMRAAM: Methods

- Compare AMRAAM to ACS legacy model for aeromedical disposition
- Cases from 1 Jan 2019 through 31 Dec 2019 timeframe (occurred prior to AMRAAM development)

Inclusion Criteria

- Pilot (manned aircraft)
- Completed disposition
  - Medically Qualified
  - Unrestricted Wavier
  - Restricted Waiver
  - Disqualified

Exclusion Criteria

- Pilots (unmanned aircraft) and other aircrew
- Incomplete disposition
  - Case return
  - Continue Duties Not Including Flying (DNIF)

N=100

- 130 in-person evaluations
  - Cases randomized
  - N = 50 cases (6 cases excluded)
- 523 virtual reviews
  - Cases randomized
  - N = 50 (25 cases excluded)
- 100 cases were de-identified and disposition masked

Validation of the AMRAAM: Methods

- AMRAAM administrative case flow mirrored legacy case flow process
  - In-person case: specialist(s) review followed by case conference with all specialties
  - Virtual review: specialist(s) review, then consultation with aerospace medicine specialist
- AMRAAM Disposition Recommendation: same options as legacy disposition
  - Medically Qualified
  - Unrestricted Waiver
  - Restricted Waiver
  - Disqualified
- Polychoric Correlation to compare legacy and AMRAAM disposition
  - Compares two ordinal variables, interpreted same as Pearson correlation

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Validation of the AMRAAM: Results

- One case discarded because it did not meet inclusion criteria.

- 88/99 cases had the same outcomes with AMRAAM and legacy process
  - AMRAAM disposition showed strong agreement with legacy dispositions, with ρ*= 0.9424 (p<<0.0001).

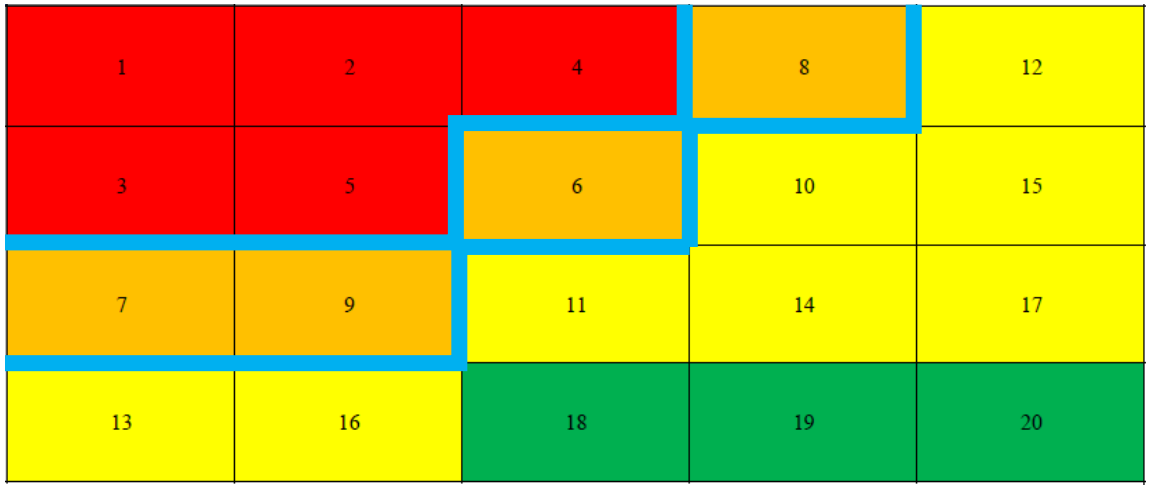
- 11/99 case had different outcomes with AMRAAM and legacy process
  - **8 cases were less restrictive with the AMRAAM**
    - 2/8 due to policy changes over time
    - 6/8 functionally significant change due to AMRAAM
  - **3 cases were more restrictive with the AMRAAM**
    - 1/3 not a functional difference
    - 2/3 functionally significant change due to AMRAAM
  - The difference is statistically significant
    - (Pearson G^2 p=0.034)

		AMRAAM Disposition				
		Qualified	Unrestricted Waiver	Restricted Waiver	Disqualified	Total
Legacy Disposition	Qualified	3 (100%)	0	0	0	3
	Unrestricted Waiver	2 * (2.8%)	67 (94.4%)	1 † (1.4%)	1 ‡ (1.4%)	71
	Restricted Waiver	0	5 (25%)	15 § (75%)	0	20
	Disqualified	0	0	0	5 (100%)	5
Total		5 (5.1%)	72 (72.7%)	16 (16.2%)	6 (6.1%)	99

* Both cases were impacted by a policy change, the AMRAAM and legacy dispositions were in accordance with aeromedical policy at the time of review; the policy changed in between legacy and AMRAAM dispositions.
† The legacy disposition was not in accordance with aeromedical policy at the time of the legacy disposition recommendation.
‡ The legacy disposition was not in accordance with aeromedical policy at the time of the legacy disposition recommendation.
§ Compared to the legacy disposition, 1 restricted waiver was less restrictive with the AMRAAM disposition, and 1 restricted waiver was more restrictive with the AMRAAM disposition.

Validation of the AMRAAM: Discussion

- AMRAAM model provides consistent results and has similar outcomes compared to the legacy model.
- AMRAAM dispositions were generally less restrictive when different from legacy model.
  - Potential for more aircrew to be returned to duty and minimize occupational restrictions.
- Helpful in determining risk acceptability for controversial cases.



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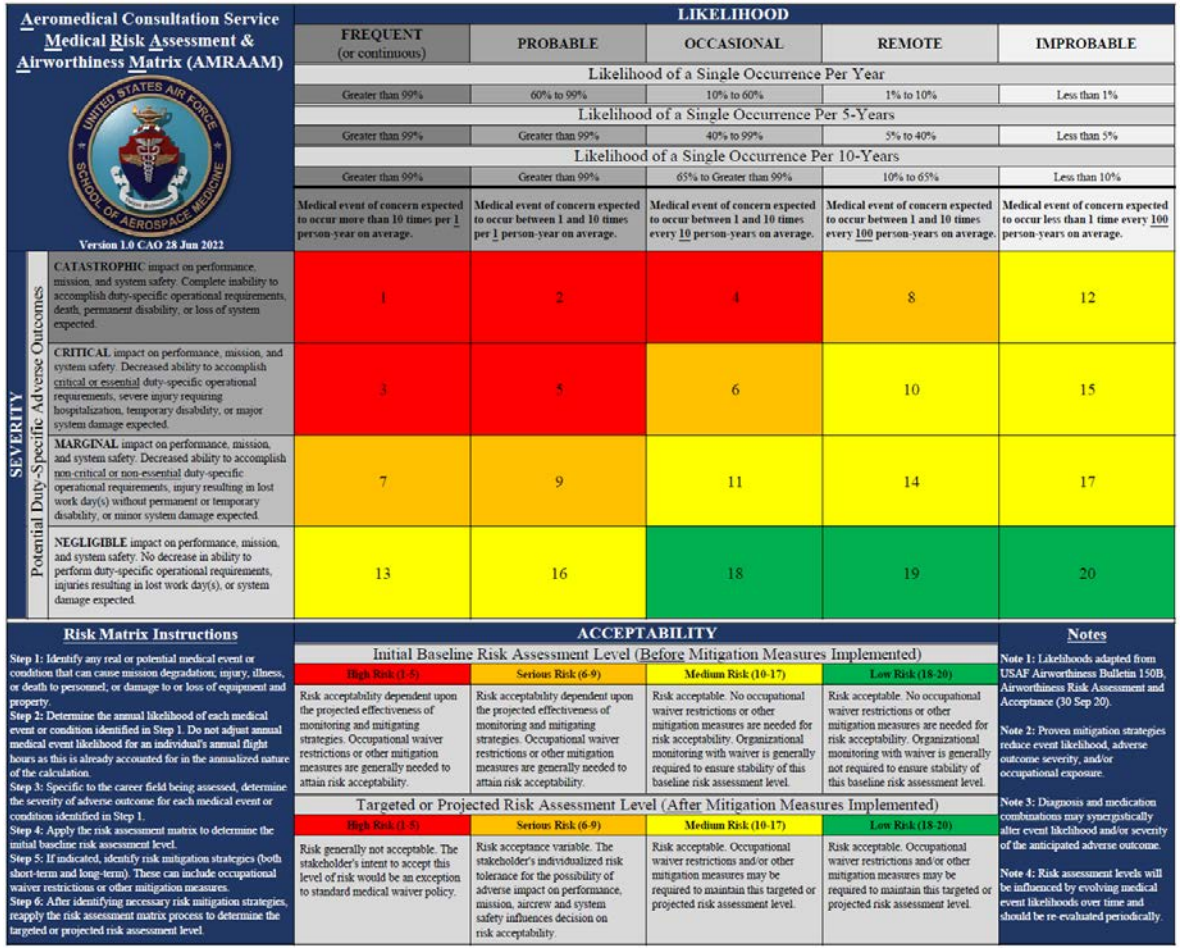
AMRAAM Implementation and Lessons Learned

- AMRAAM: high value as a communication tool
- Overall, ad-hoc modifications to 1% rule well-calibrated based on AMRAAM outcomes
- For aeromedical reviewers, systematic and separation of likelihood, severity, and aeromedical events of concern helpful
  - When AMRAAM differs from legacy dispositions, it is generally less restrictive
    - Often due to high severity but very low likelihood
- Biggest challenge: systematically implementing stepwise approach
  - Avoid pre-conceived notion / snap judgment



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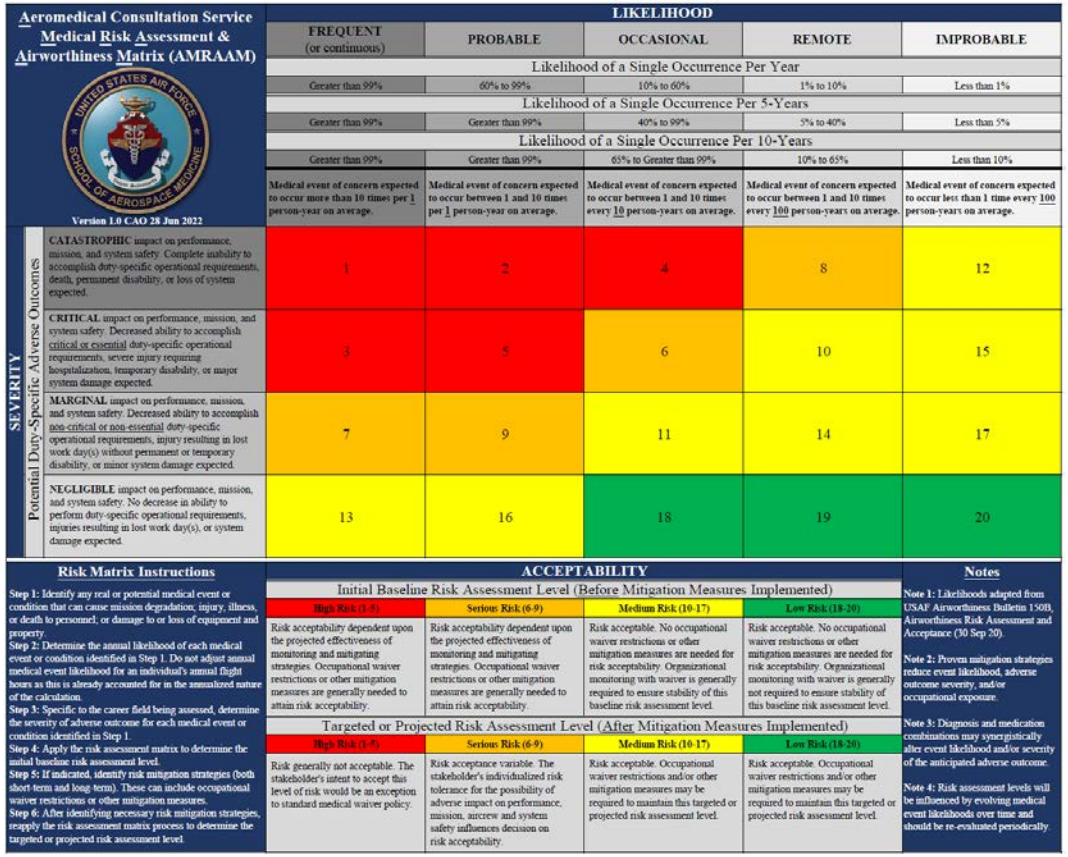
Considerations for non-USAF use of AMRAAM

- Interest in AMRAAM for non-USAF applications from several aeromedical bodies since May 2022 rollout
- Basic construct of AMRAAM likely to translate well to non-USAF applications
  - Consistent with modern risk assessment approaches
  - Transparent; de-mystifies aeromedical decision-making and/or recommendations
- Specific definitions within AMRAAM may not translate 1:1 outside of USAF.
- AMRAAM derived directly from USAF Airworthiness standards. If considering adopting AMRAAM for non-USAF usage, USAFSAM ACS recommends examination of 4 specific areas:
  1. Likelihood categories
     - May need to tailor the ranges for non-USAF application
  2. Severity Definitions
     - Higher likely variability than likelihood, depending on application (military/civilian, passenger/non-passenger, single/dual piloted, etc.)
  3. Risk thresholds
     - Risk tolerance may vary between USAF and non-USAF applications
  4. Order of weighted scores (1-20).
     - Likelihood generally weighted higher than severity on the AMRAAM

AMRAAM Summary

- Concepts of airworthiness and “system safety” applied to the human in the air system
- Clarifies stakeholder thresholds
- Annualizes likelihood for ease of use by medical professionals
- Single-page tool adaptable to any USAF platform or set of aerospace operational duties
- Provides framework that standardizes risk assessment across medical conditions
- Facilitates more precise assessment of ambiguous and/or complex cases
- Enhances aeromedical risk communication



Aeromedical Consultation Service Medical Risk Assessment & Airworthiness Matrix (AMRAAM)

Version 1.0 CAO 28 Jun 2022

SEVERITY: Potential Duty-Specific Adverse Outcomes	LIKELIHOOD: FREQUENT (or continuous)	PROBABLE	OCCASIONAL	REMOTE	IMPROBABLE
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Questions?

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Limitations

- Generalizability
  - Likelihood thresholds and severity scales informed by USAF standards
  - Study results may not reflect all USAF aircrew waiver dispositions
    - Pilots (other aircrew excluded)
    - ACS generally reviews more complex cases
    - Results informed by multidisciplinary and specialty input
- Recall Bias
  - Cases used for the study were dispositioned using legacy model between 1 Jan – 31 Dec 2019
  - Mitigated by de-identifiying case and masking legacy disposition recommendation
- Observation Bias
  - ACS providers participated in the AMRAAM development
- Medical standard and policy changes
  - Mitigated by selecting cases dispositioned in 2019

Methods cont.

- In-Person Evaluations (n=50)
  - De-identified case data
- ACS specialist reviewed case
  - Identified medical events of concern
  - Determined likelihood of occurrence
  - Selected outcome severity
- Interdisciplinary review
  - Aerospace medicine specialist
  - Representation from other specialties
- Risk Score finalized after discussion
  - Disposition Recommendation
  - MQ, UR, RW, DQ

- Remote Reviews (n=50)
  - De-identified case data
- ACS specialist reviewed case
  - Identified medical events of concern
  - Determined likelihood of occurrence
  - Selected outcome severity
- Interdisciplinary review
  - Aerospace medicine specialist
- Risk Score finalized after discussion
  - Disposition Recommendation
  - MQ, UR, RW, DQ

United States Air Force Airworthiness Bulletin 150B, 30 Sep 2020

Table 4: USAF Airworthiness Risk Assessment Matrix[10]

USAF Airworthiness Risk Assessment Matrix			Severity Category			
Probability Level	Probability per FH or Sortie	Freq per 100K FH or 100K Sorties	Catastrophic (1)	Critical (2)	Marginal (3)	Negligible (4)
Frequent (A)	$10^{-3} \leq$ Prob	100 ≤ Freq	1	3	7	13
Probable (B)	$10^{-4} \leq$ Prob $< 10^{-3}$	10 ≤ Freq < 100	2	5	9	16
Occasional (C)	$10^{-5} \leq$ Prob $< 10^{-4}$	1 ≤ Freq < 10	4	6	11	18
Remote (D)	$10^{-6} \leq$ Prob $< 10^{-5}$	0.1 ≤ Freq < 1	8	10	14	19
Improbable (E)	0 < Prob $< 10^{-6}$	0 < Freq < 0.1	12	15	17	20
Eliminated (F)	Prob = 0	Freq = 0	Eliminated			

High	RAC = 1 - 5	**Medium**	RAC = 10 – 17
Serious	RAC = 6 – 9	**Low**	RAC = 18 – 20