AAQPS
Air Ambulance Quality and Patient Safety

Air Ambulance Quality and Patient Safety (AAQPS) Advisory Committee

December 12, 2024

CMS
CENTERS FOR MEDICARE & MEDICAID SERVICES

Federal Aviation Administration

Welcome

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- FACA Statement

Agenda

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Introduction and Background	10:00 - 10:30 AM
Overview of the Air Ambulance Industry	10:30 - 11:30 AM
Break	11:30 - 11:40 AM
Regulatory Environment	11:40 AM - 12:40 PM
Lunch	12:40 - 1:25 PM
Flight Safety Data and Best Practices	1:25 - 2:10 PM
Clinical Quality Environment	2:10 - 2:55 PM
Break	2:55 - 3:05 PM
Public Comments	3:05 - 3:25 PM
Flight Safety Discussion	3:25 - 3:55 PM
Clinical Standards Discussion	3:55 - 4:25 PM
Closing	4:25 - 4:50 PM

Introduction of Members

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HHS Designee

Jeff Richey, RN, MHA, FACHE

Executive Director, Airlift Northwest; Associate Administrator, University of Washington Medical Center

Healthcare Provider

William Hinckley, MD

Associate Professor, Emergency Medicine- University of Cincinnati

Accrediting Bodies Representative

Eileen Frazer, RN, CMTE

Executive Director & Founder of the Commission on Accreditation of Medical Transport Systems

HHS Additional Representative

Jason Clark

Senior Vice President of Field Operations, APOLLO MedFlight

HHS Additional Representative

Mark Gamber, MD

Chief Medical Officer, Alacura Medical Transport Management

Group Health Plans & Health Insurance Insurers

Jordan Pritzker, MD

Executive Regional Medical Director, Aetna

State Insurance Regulator

Grace Arnold

Commissioner, Commerce Department, Minnesota

Introduction of Members

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DOT Designee

Robert Reckert
Division Manager, FAA

DOT Appointee

Ben Clayton
Chief Executive Officer, LifeFlight Network

DOT Appointee

Jim Houser
President of the Center for Emergency Medicine of Western Pennsylvania, and CEO of STAT MedEvac

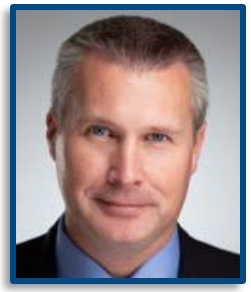
DOT Appointee

Thomas Judge
Founding Executive Director, LifeFlight of Maine

DOT Appointee

Paul Julander
Chief Operating Officer, PHI Health

DOT Appointee



Jason Quisling
Senior Vice President Flight Ops/Air Methods

Patient Advocacy Group

Col. Steven Coffee
Chief of Staff, National Security and Cofounder, Patient Safety U.S.

Overview of the AAQPS Committee

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- The No Surprises Act calls for the Department of Health and Human Services to establish an Advisory Committee to address the following topics in its deliberations and in a subsequent report to Congress:
  - Qualifications of different clinical capability levels and tiering of such levels
  - Patient safety and quality standards
  - Clinical triage criteria for air ambulances
  - Options for improving service reliability during poor weather, night conditions, or other adverse conditions
  - Differences between air ambulance vehicle types, services, and technologies, and other flight capability standards, and the impact of such differences on patient safety

AAQPS Overview

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Purpose:

- Review options to improve quality, patient safety, and clinical capability standards for each clinical capability of air ambulances.

Outcome:

- Define innovative approaches to improve quality, accessibility, affordability, and sustainability of air ambulance services for safe, quality healthcare.

Subcommittees and Committee Voting

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There will be two subcommittees that will inform the main committee:

Clinical Standards:

- Qualifications of different clinical capability levels and tiering of such levels
- Patient safety and quality standards
- Clinical triage criteria for air ambulances

Members:

- Committee members were selected from those who applied for the main committee.

Flight safety:

- Options for improving service reliability during poor weather, night conditions, or other adverse conditions
- Differences between air ambulance vehicle types, services, and technologies, and other flight capability standards, and the impact of such differences on patient safety

Members:

- DOT appointees on the main AAQPS committee will serve on the subcommittee.

The subcommittees will provide recommendations to the full Committee. The full Committee will aim to come to consensus on recommendations. If they are unable to reach consensus or time does not allow, the Committee will vote on recommendations.

Advisory Committee Meeting Schedules

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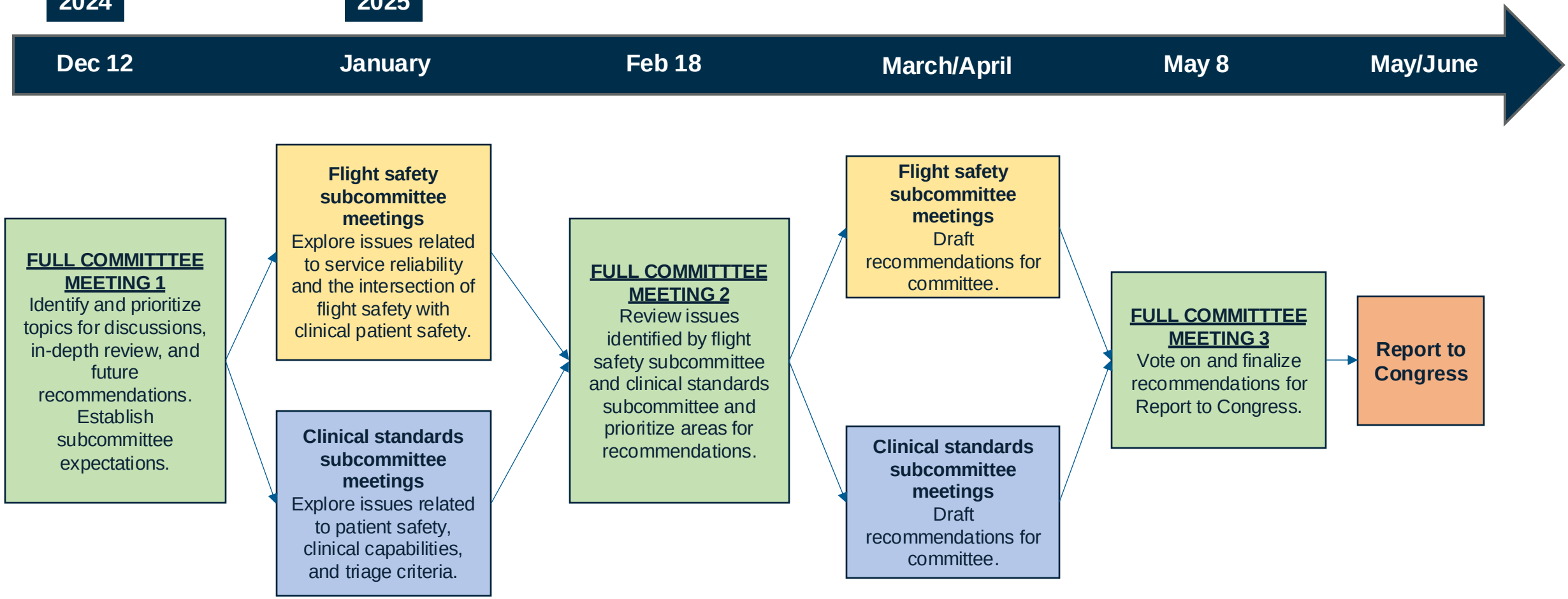

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Overview of the Air Ambulance Industry

Jana Williams, Association of Air Medical Services (AAMS), President and CEO

Jason Quisling, Air Methods, LLC, SVP Flight Operations and AirCom

Introduction to Air Ambulance

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Definition: Use of aircraft for medical transport

Types of aircraft: Rotor wing (helicopters) and fixed wing (airplanes)

Purpose: Began as rapid medical evacuation and evolved to rapid access to advanced care

Public Benefit: Over 86% of residents in rural areas have access to critical care air ambulance services within 20 minutes on avg.

Air Ambulance Services

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Scene Response: Directly at accident sites

Interfacility Transport: Moving critical care patients between healthcare facilities

Specialty care options (e.g., neonatal, balloon-pump, ECMO patients, etc.)

Organ team support

Disaster support (Hurricanes, Floods, Wildland fire, Earthquakes, and more)

Aircraft Types and Their Applications

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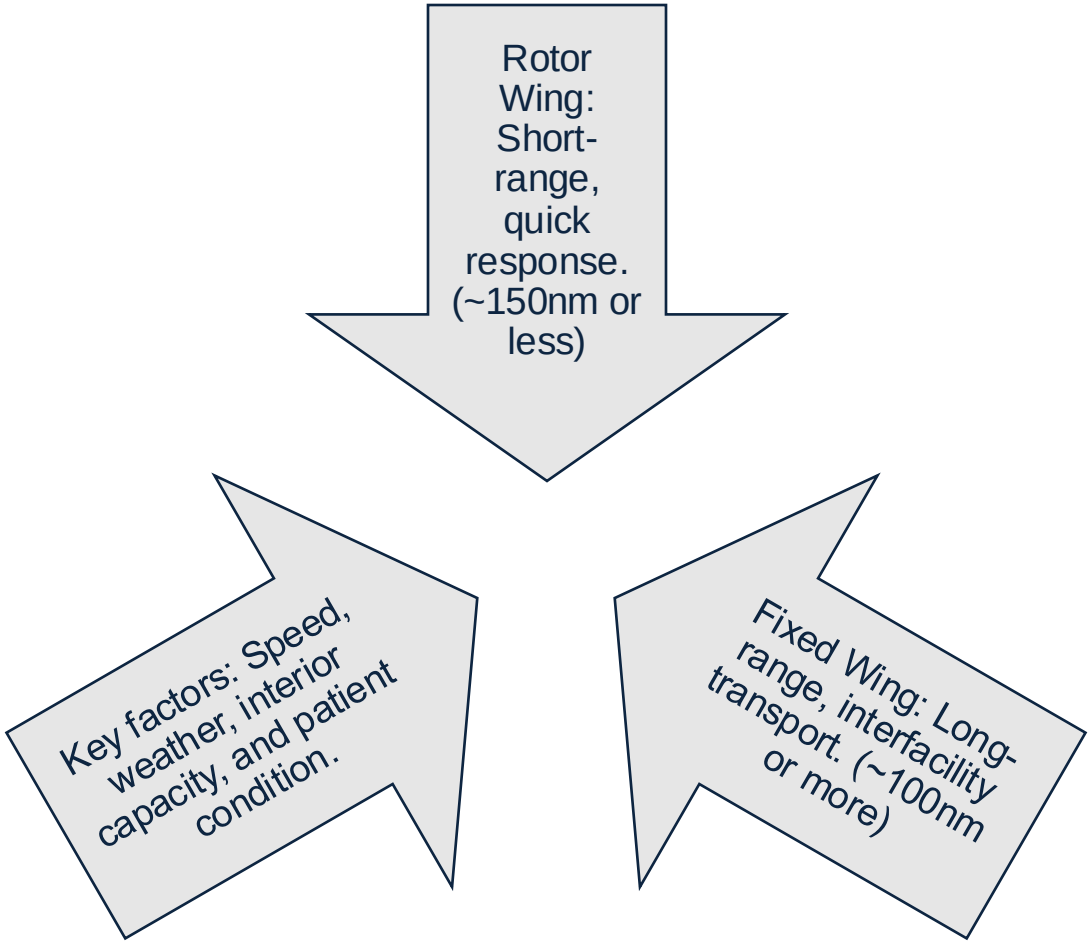

Organizational Models

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Hospital-Based Model: “Traditional Model” Integrated with hospitals as an aviation vendor

Community-Based Model: Independent and turn-key services covering larger/ rural areas

Alternate/Hybrid Models: Multiple stakeholders have critical participation with clear lines of delineation

Public Safety Model: Operated by government or public safety agencies

Regulatory Framework

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Federal Aviation Administration (FAA): Aircraft, maintenance, pilot certification and flight standards

Federal agencies such as DOT, DEA, OSHA, DOD and others control medications, licensure, and personnel safety requirements

State & Regional Authorities: Medical personnel and equipment standards and licensing

National Transportation Safety Board (NTSB): Accident investigation

Staffing Models

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Aviation staff:

- Pilots (single vs. dual pilot), maintenance technicians
- Certificate oversight and management teams

Clinical staff configurations:

- Nurse-paramedic, nurse-nurse, and nurse-physician teams

Specialty teams:

- Neonatal, pediatric, cardiac care, organ, and ECMO (extracorporeal membrane oxygenation)

Vehicle Selection Criteria

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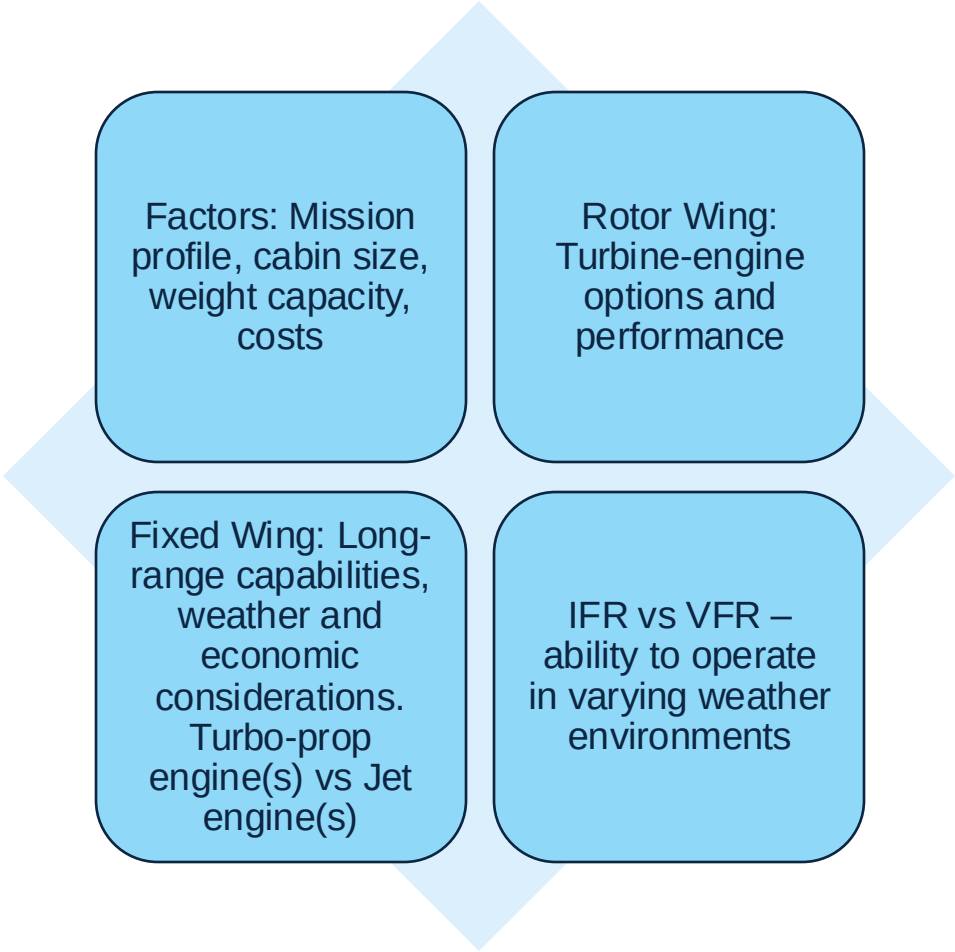

Safety Considerations

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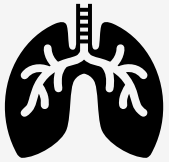

• Patient Safety: Handling critically ill patients in challenging environments

Altitude/ Temps/ Vibration/ Medical Interiors/ Medical oversight and training

• Provider Safety: Addressing risks to medical teams

Aircraft/ Technology/ PPE/ Infrastructure/ Training and Outreach

• Aviation Safety: Risk management systems (e.g., Safety Management Systems/ FAA collaboration)

Technology and Safety in Aircraft

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- Night Vision Goggles (NVG)
- Terrain Awareness Warning Systems (TAWS)
- Satellite tracking and weather systems
- Global Positioning System (GPS)
- Electronic Flight Bag (EFB)
- Pre-Flight Risk Analysis (PFRA)
- Operational Control Centers (Flight and Risk Monitoring)
- Communication Centers (Flight Following and coordination)
- Weather reporting infrastructure and access (Streaming wx or Radar)
- Traffic Avoidance Systems (TAS)
- Radio Altimeters

- Autopilot and Stability systems
- IFR capable aircraft
- Crash-resistant fuel systems
- Equipment mounts for medical devices and storage
- Med interiors and litter systems
- Energy attenuating seats/ landing gear
- Flotation systems and emergency equipment for overwater flights
- Wire strike protection systems
- Helmets and Fire-Resistant suits
- Multiple searchlights
- Bird resistant windows if possible
- Aircraft simulation training

Communication Centers

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-Relay info to pilot or medical crew

- Minute by minute flight following of team
- Coordinate team communication to external resources (i.e., – medical control, maintenance, etc.)

- Coordinate fuel/ ground transport/ multi-aircraft
- Coordinating scene responses and interfacility transfers

- Intake transport requests and coordinate with most appropriate asset/ agency
- Maintains transport record of flight

Clinical Education and Training

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- Flight nurses: Certified Flight Registered Nurse (CFRN)
- Paramedics: Certified Flight Paramedic (FP-C)
- Leadership training: Certified Medical Transport Executive (CMTE)

Key Challenges

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High operational fixed-costs	Regulatory complexities	Safety and training requirements
Safety and training investments	Aircraft equipment and availability – supply chain	Aircraft certification and STC support delays
Pre-hospital ground transport logistics and safety	Airport/ Heliport infrastructure	Operations at uncontrolled locations

Conclusion

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- Recap of AMS importance in emergency systems – especially for rural Americans
- Patient outcomes are greatly improved through critical care air transport
- Diverse operational and staffing models
- Emphasis on safety, technology, and education
- Mobile Critical Access “Beds”

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Questions?

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Committee Discussion

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Patient Perspective

Joshua Cools, Association of Critical Care Transport, Board Chair

The Why

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Association of Critical Care Transport (ACCT) – Mission, Vision and Values

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Patient Advocacy Association – filling the voice for patients in critical care transport (CCT) – ***ground and air***

- Mission – lead the critical care transport industry to ensure the best interests and needs of critically ill or injured patients are achieved
- Vision – to have a fully integrated, high quality critical care transport system that revolves around the needs of patients
- Values – safety, quality, advocacy, and integrity

About ACCT

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- The Association of Critical Care Transport (ACCT) is a grassroots organization of medical and aviation professionals committed to ensuring that critically ill and injured patients have access to the highest quality and safest levels of critical care transport systems possible.
- ACCT is leading the way by preserving and strengthening the integrity and viability of critical care transport. ACCT members have shared values and a commitment to advocating for the highest quality patient centered care via appropriate means of transport.
- ACCT is providing a voice for patients while fighting for system accountability at the policy and regulatory table.
- https://acctforpatients.org

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Advisory Committee on Air Ambulance Quality & Patient Safety

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- ACCT was instrumental in the NSA's establishment of AAQPS because **we must make the life-saving care we provide safer and accountable for quality and reliability**
- AAQPS Duties -- study and recommend:
  - Qualifications of different **clinical capability levels** and tiering of such levels
  - Patient safety and quality standards
  - Options for **improving service reliability** during poor weather, night conditions or other adverse conditions
  - Differences between air ambulance vehicle types, services and technolgies and other flight capability standards and the **impact of vehicle differences on patient safety**
  - **Clinical triage criteria** for air ambulances.

Air Ambulance Quality and Patient Safety Advisory Committee

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- AAQPS
  - Establish and convene an advisory committee for the purpose of reviewing options to establish **quality, patient safety**, and **clinical capability standards** for **each clinical capability level of air ambulances**
- Quality & Patient Safety
  - ACCT Critical Care Standards
  - CAMTS Accreditation
- Clinical capability standards for each clinical capability level of air ambulances
  - ACCT's introduction of tiered Air Ambulance Transport Services (AATS) with additional considerations of quality metrics

2000-2020: 87 Accidents, 239 Fatalities

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Patient safety: first, do no harm

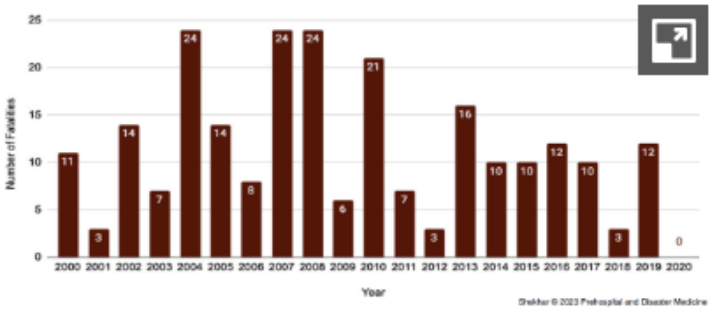

Figure 1. Air Medical Fatalities by Year (2000-2020).
Note: Figure 1 shows the number of air medical fatalities per year from 2000 through 2020. Years 2004, 2007, and 2008 were the deadliest, and the year 2020 was the least deadly.

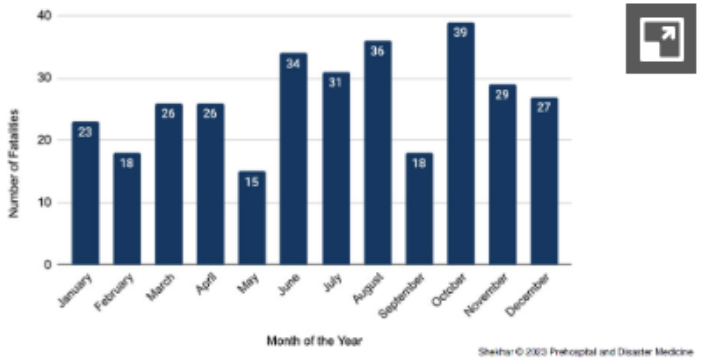

Figure 2. Air Medical Fatalities by Month (2000-2020).
Note: Figure 2 shows the number of fatalities based on the month the accident took place: October, August, and June were the deadliest months, and May, February, and September were the least deadly.

Shekhar AC, Blumen IJ. Fatal Air Medical Accidents in the United States (2000-2020). *Prehospital and Disaster Medicine*. 2023;38(2):259-263. doi:10.1017/S1049023X23000134

Air Medical Fatalities by Aircraft Category 2000-2020

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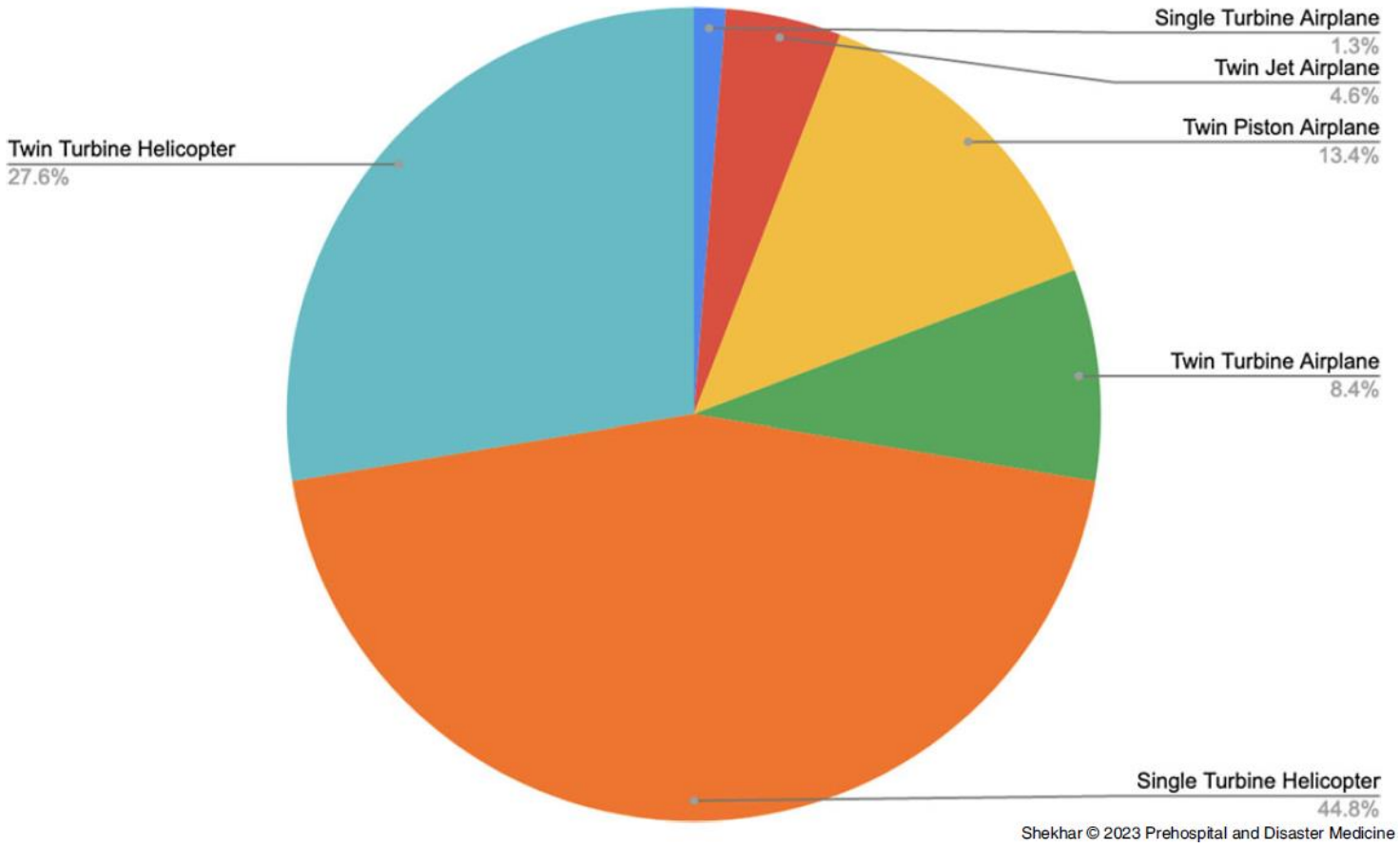

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What are the causes?

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Probable Causes of Fatal Air Medical Accidents (2000 – 2020)

Contributing Factor	% of Fatalities (n)
Human Factors	87.4 % (209)
Night	38.9 % (93)
Weather	35.6 % (85)
Mechanical Failure	17.2 % (41)

Shekhar AC, Blumen IJ. Fatal Air Medical Accidents in the United States (2000-2020). *Prehospital and Disaster Medicine*. 2023;38(2):259-263. doi:10.1017/S1049023X23000134

Variation of Medical Helicopter Capability in U.S. Fleet

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FACTORS AFFECTING AVIATION SAFETY/MEDICAL CAPABILITY

Volume * Reimbursement * Mission/Motive * State/Federal regulation

- Bell 407 GXi
- H 125
- AW119


- Bell 429
- Leonardo 109 SP
- H 145
- H 135


- S76D
- Bell 412 EPI
- EC155
- AS 365 N3


***Cost Range is for New Medically Equipped Aircraft- varies by model**

Cost: $3.9-4.4 million

- Single engine, VFR
- Single pilot
- Autopilot
- Single patient, 2 medical personnel
- Some have limited access to patient for medical procedures
- Limited weight carriage for certain medical equipment.
- Climate Control
- Provide neonatal transport and balloon pumps in some models

Cost: $6.8-8.7 million

- Twin engine, IFR
- 2 pilot capability
- 2 patient capability in some; 2-3 medical personnel
- Autopilot
- Longer range
- Climate control
- Some with limited access and some with full access to patient
- Higher critical care capability (e.g. balloon pumps)
- Specialty transport capability (e.g. specialized neonatal)

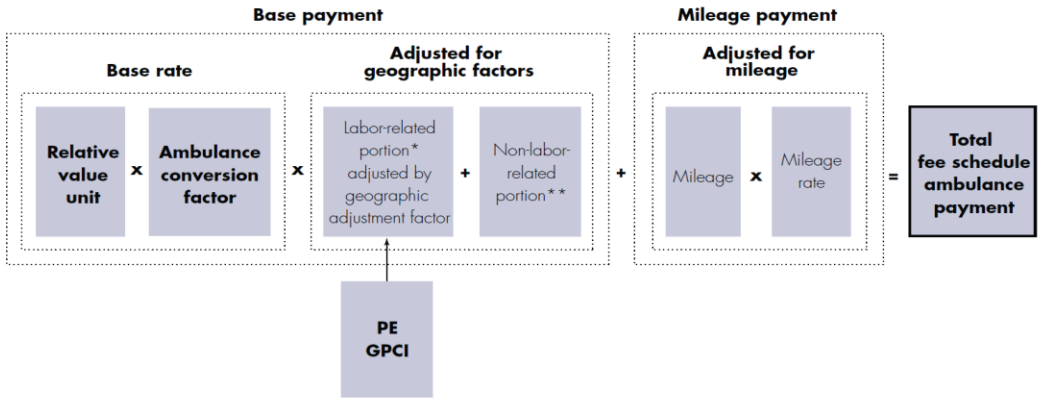
Cost: $11.4-15.8 million

- Twin engine, IFR
- 2 pilot capability
- Autopilot
- 2 patients, 4 medical personnel
- Climate Control
- Greatest distance capability without refueling
- Specialty transport capability (e.g. specialized neonatal)
- Higher critical care capability (e.g. balloon pumps)

No differentiation in Medicare Payment for:

- Higher acuity patients/clinical capability like ground RVUs
- Higher cost of aircraft needed for specialty transport patients and higher critical care capability
- Aviation safety investments beyond FAA minimums (e.g. IFR, NVGs, crash resistant fuel cells)
- No uncompensated care/DSH type payments
- Geographically isolated areas beyond rural add-on for air

Figure 1 Ambulance fee schedule equation



Note: PE (practice expense), GPCI (geographic practice cost index).
*The labor portion is 70 percent for ground ambulance transports and 50 percent for air ambulance transports.
**The non-labor portion is 30 percent for ground ambulance transports and 50 percent for air ambulance transports.

Table 1 Medicare ambulance service levels and conversion factors, 2019

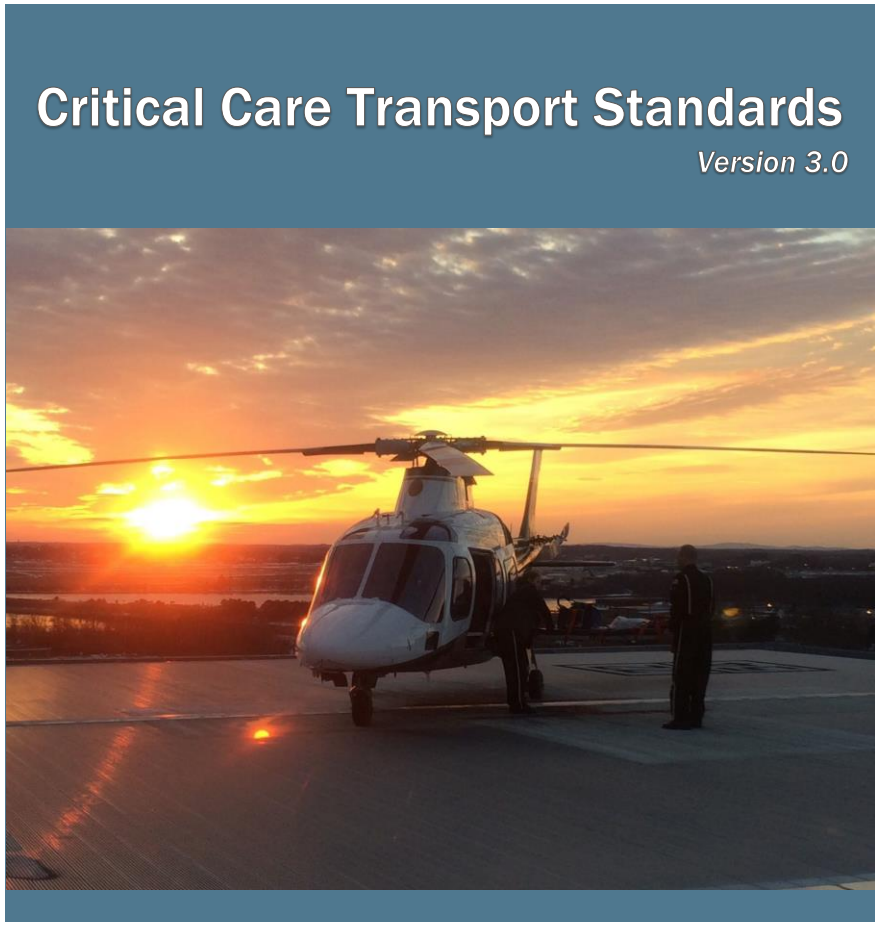
Ambulance service level	RVU	CF
Ground transports		
BLS nonemergency	1.00	$229.91
BLS emergency	1.60	$229.91
ALS nonemergency	1.20	$229.91
ALS emergency (level 1)	1.90	$229.91
ALS emergency (level 2)	2.75	$229.91
Specialty care transport	3.25	$229.91
Paramedic ALS intercept	1.75	$229.91
Air transports		
Fixed wing	1.00	$3,119.83
Rotary wing	1.00	$3,627.27

Note: RVU (relative value units), CF (conversion factor), BLS (basic life support), ALS (advanced life support).

Source: CMS.

Source: From MedPAC Ambulance Payment Basics

ACCT's Critical Care Standards



- The need for a common understanding of high acuity, critical care transport and the development of acceptable practice standard is imperative for patients and referring/receiving providers. To address this, ACCT has developed a set of clinical standards for interfacility CCT, regardless of transport modality. These standards are in alignment with CAMTS and in some circumstances may extend beyond.
- In 2012, ACCT initiated an extensive, iterative process to work through all the elements of CCT. ACCT committed itself to the development of effective standards, focused on providing the highest quality of care to patients needing CCT. Version 3 was completed Oct 2022

Clinical Capability Standards for Air Ambulance Transport Services (AATS)

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- ACCT strongly believes that the No Surprises Act established the essential platform for a system that provides **reasonable reimbursement for the clinical and aviation services *actually provided*, promotes high quality and safe air transport services, and *appropriately differentiates* among the varying levels of clinical and aviation capability**.
- NSA's charge to establish varying levels of clinical capability is consistent with the National Academy of Medicine's vision for a regionalized emergency medical care system.

Clinical Capability Standards for AATS (cont.)

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- Two main factors for determining level of AATS: clinical capabilities and aircraft type
  - **Clinical capability** is determined by a number of factors, including the ability of the airframe and patient compartment to support varying levels of clinical care.
  - **Ambulance vehicle types**: Key features among rotor wing (the most predominant) aircraft for air medicine include the following relevant considerations for air ambulance mission profiles

Clinical Capability Levels 1-3

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Level 3: Flying Community ED

(i) **Aircraft flight environment** must maintain and have immediately available basic, advanced life-support and other supplies and equipment necessary to provide advanced emergency care

(ii) **Patient care compartment** is of sufficient size to carry and secure all necessary equipment and supplies, and accommodate 2 personnel needed to support the patient care requirements

(iii) **Equipment** includes ventilators and non-invasive ventilators, cardiac monitoring, & non-invasive monitoring as required by jurisdictional regulatory/licensing authority

(iv) **All BLS & ALS interventions** including advanced airway management, needle, thoracostomy, intraosseous placement, non-invasive CO2 monitoring; peripheral IV, waveform capnography

(v) **Sufficient onboard electrical power** to continuously support all required medical equipment & devices, and **sufficient fuel capacity** to minimize need to refuel with patient onboard

Level 2: Flying Advanced ED

(i) Aircraft handles **all age patients** and needed critical care equipment;

(ii) **Patient care compartment** is of sufficient size such that all medical personnel have access to patient's head, chest, abdomen, & pelvis while wearing installed seatbelts

(iii) **Equipment** includes invasive- monitoring (incl. hemodynamic, cardiac & neurological)

(iv) **Contains critical care formulary and medication infusion** with multiple IV pumps

(v) **Intervention capabilities** include rapid sequence induction, surgical airway, management of tube thoracotomy & central line, blood product infusion

(vi) Aircraft has **ability to blend medical air** for ventilatory support, **environmental control** capable of heating and cooling to address patient clinical needs and **onboard oxygen system** with reserve capacity based on the longest transport and highest flowrate for scope of care, service area

Level 1: Flying Tertiary ICU

(i) **Aircraft flight environment and equipment** are conducive to treat patients using **most recent evidenced-based treatment modalities in flight** without limitations in structural or electrical configurations to respond during flight to any patient status changes **comparable to ICU/ED**

(ii) **Patient care compartment** is of sufficient size that medical personnel have access to the treatment relative to patient condition

(iii) **Equipment** includes multimodality ventilators for all ages and invasive monitoring equipment including hemodynamic, cardiac & neurological

(iv) Can support **4 continuous infusions**

(v) **Invervention cabailities** including placing an endotracheal tube and central line, managing a cardiac assist & extracorporeal oxygenation device, performing tube thoracotomy, maintaining oxygenation and ventilation for all relevant ages, & performing point of care testing

(vi) Aircraft is able to secure **highly specialized intensive care equipment,** has gross operating weight and electrical capacity to support **at least 3 medical personnel** plus pilot

Clinical Capability Standards for AATS (cont.)

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- In addition to AATS structure, the following considerations are needed to evaluate tiered air medical services:
  - Quality and Patient Outcomes
    - We have provided a specific set of quality and outcome (QO) measures relevant to each clinical capability level that we recommend (GAMUT driven)
  - Patient Acuity and Complexity of Service
    - We have defined three patient acuity and service complexity levels
  - Medical Personnel Qualifications
    - We have delineated between Level I, II and III medical personnel, aligned with clinical capability levels

Quality & Patient Outcomes

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Level 3	Level 2	Level 1
	PATIENT SAFETY	
Sentinel Event Rate Medical Equipment Failure Rate Device Dislodgement Transport-Related Patient Injury Rate	Sentinel Event Rate Medical Equipment Failure Rate Device Dislodgement Transport-Related Patient Injury Rate **Blood transfusion reactions**	Sentinel Event Rate Medical Equipment Failure Rate Device Dislodgement Transport-Related Patient Injury Rate Blood transfusion reactions **Unintended Neonatal Hypothermia**
	OPERATIONS	
Average STEMI Scene Time	Average STEMI Scene Time	Average STEMI Scene Time
	CLINICAL OUTCOMES	
First Attempt ETI Success ETT Verification Glucose for AMS Hemorrhagic Shock Management	First Attempt ETI Success ETT Verification Glucose for AMS Hemorrhagic Shock Management **Ventilator Use Rates** **NPPV Failure Rates** **EtCO2 Monitoring** **Lung Protective Strategies**	First Attempt ETI Success ETT Verification Glucose for AMS Hemorrhagic Shock Management Ventilator Use Rates NPPV Failure Rates EtCO2 Monitoring Lung Protective Strategies **Dash 1A** **HIE Neonates with TTM** **HROB Seizure** **Hypertension** **Delivery Rates** **MCS Mortality Rates*** **MCS Adverse Event Rates***

* Indicates a non-GAMUT measure

Patient Acuity & Service Complexity

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Level 3

Patient has a **serious, emergent life and/or limb threatening medical condition** involving one organ system requiring close monitoring with ability to reassess and provide care above ALS care to include cardiac and trauma interventions during flight, that requires air transport.

Level 2

Patient has a **potentially life-threatening, involved, complex and critical medical or traumatic condition** involving more than one vital organ system requiring active treatment and resuscitation to stabilize for flight, with potential mortality and high morbidity but for treatment before and during transport to a higher level of care.

Level 1

Patient is **critically ill or injured with immediate life-threatening condition(s)** requiring sophisticated, specialized critical care, including active and ongoing resuscitation to stabilize before and during flight, with expected mortality and/or high morbidity but for treatment before and during transport to highest level of care**.**

Medical Personnel Qualifications

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Level 3

Emergency Care

Comparable to: Community Hospital ED

Level 2

Emergency Critical or Complex Care

Comparable to: Advanced ED stabilizing care or ICU transfer to definitive care

Level 1

Highly Specialized Intensive Care

Comparable to: A tertiary ICU

Ambulance Vehicle Type

Level 3

Operations Limitations Determined by OPS SPECS (tail and serial number) VFR

Level 2

Operations Limitations Determined by OPS SPECS (tail & serial #), Active IFR or VFR with autopilot, NVG

Level 1

Operations Limitations Determined by OPS SPECS (tail & serial #) Active IFR/VFR, 3 or more axis autopilot, NVG

Summary

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- ACCT has actively sought to define a tiered transport reimbursement structure that is in alignment with the capabilities of the transport vehicle, clinical scope of service and the clinical capabilities and training of the staff
- ACCT applauds the work of the AAQPS on an industry wide basis to establish long overdue clinical capability levels and improve patient safety
- We are happy to share our detailed work with the Committee as one of several potential building blocks for your discussion and consideration

Thank you

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- Thank you for the opportunity to present today. I'm happy to answer any questions you have from a patient advocacy perspective

Joshua Cools, Board Chair, ACCT

Joshua.cools@memorialhermann.org

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Committee Discussion

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Break

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Regulatory Environment

Federal Aviation and Air Ambulance Regulations

Federal Aviation Administration

Air Ambulance

- **Background:**
  - Transportation by aircraft of sick or injured persons may have originated during World War I when wounded were transported from battle fronts to field hospitals in an open cockpit biplane. Since that time, the transportation of patients needing medical attention has expanded into a significant industry operating modern aircraft equipped with state-of-the-art medical equipment carrying thousands of patients each year.
  - The Air Ambulance industry continues to expand. In response to the dynamic growth of this industry, the Federal Aviation Administration (FAA) has issued Federal Aviation Regulations, Orders, and Advisory Circulars (AC) to provide information and guidelines to assist Air Ambulance operators, other Title 14 of the Code of Federal Regulations (14 CFR) part 135 operators considering becoming an Air Ambulance operator and those considering new-startup Air Ambulance operations.

Air Ambulance

- **Definition:** An air ambulance is an aircraft equipped with medical equipment appropriate to the type of care required for the patient (Source: FAA Order 8900.1, Vol 3, Ch 18, § 3).

- **Air Ambulance Medical Services**
  - Hospital-to-hospital services account for two-thirds of air ambulance flights
  - Scene-to-hospital services account for one-third of air ambulance flights

Air Ambulance

- **Air Ambulance Aircraft**
  - An aircraft used in air ambulance operations. The aircraft must be equipped with at least medical oxygen, suction, and a stretcher, isolette, or other approved patient restraint/containment device. The aircraft need not be used exclusively as an air ambulance aircraft and the equipment need not be permanently installed.
- **Air Ambulance Operations**
  - (a) Air transportation of a person with a health condition that requires medical personnel as determined by a health care provider; or
  - (b) Holding out to the public as willing to provide air transportation to a person with a health condition that requires medical personnel as determined by a health care provider including, but not limited to, advertisement, solicitation, association with a hospital or medical care provider and
  - (c) Uses an air ambulance aircraft, either fixed wing or helicopter.
- **Medical Crewmember**
  - A person with medical training who is assigned to provide medical care and other crewmember duties related to the aviation operation during flight.

Rotorcraft vs. Fixed-Wing

- Approximately 70% of air ambulances in the United States are rotorcraft
- Used primarily for scene calls and short-distance hospital-to-hospital transportation
- The flights do not always operate under the direction of an air traffic controller (ATC)

Rotorcraft vs. Fixed-Wing

- The remaining air ambulances in the United States are fixed-wing aircraft
- Fixed-wing air ambulances are primarily used for long-distance hospital-to-hospital transportation
- These aircraft typically operate under IFR within the NAS
- Fixed-wing aircraft are more structured and encounter fewer regulatory ambiguities
- Airplane air ambulance operations do not differ significantly from other types of airplane air carrier operations

Air Transportation Division Operations Group

- 135 Flight Operations Section - The Part 135 Air Carrier Operations Branch is responsible for the development and maintenance of policy and guidance related to certification and operations conducted under 14 CFR Part 135.
- This includes fixed wing, powered-lift, and rotary wing aircraft conducting part 135 commuter, on-demand, and cargo operations.
- This branch also develops and maintains Operations Specifications (OpSpecs) along with the associated policy and guidance materials that enable the wide-ranging types of operations conducted under part 135.
- **NOTE:** The policy and guidance related to training and checking of airmen for part 135 falls under the purview of the Air Carrier Training Systems and Voluntary Safety Programs Branch.

Regulatory Structure

- Statutes
- FARs
  - **Part 91**- General Operating and Flight Rules
  - **Part 135** - Operating Requirements: Commuter and on Demand Operations and Rules Governing Persons on Board such aircraft
    - Subpart L - Helicopter Air Ambulance Equipment, Operations, and Training Requirements
  - **Part 23** - Airworthiness Standards: Normal Category Airplanes
  - **Part 25** - Airworthiness Standards: Transport Category Airplanes
  - **Part 27** - Airworthiness Standards: Normal Category Rotorcraft
  - **Part 29** - Airworthiness Standards: Transport Category Rotorcraft

Helicopter Air Ambulance

- **§ 135.601 Applicability and definitions.**
- (a) Applicability. This subpart prescribes the requirements applicable to each certificate holder conducting helicopter air ambulance operations.
- (b) Definitions. For purposes of this subpart, the following definitions apply:
  - (1) Helicopter air ambulance operation means a flight, or sequence of flights, with a patient or medical personnel on board, for the purpose of medical transportation, by a part 135 certificate holder authorized by the Administrator to conduct helicopter air ambulance operations. A helicopter air ambulance operation includes, but is not limited to—
    - (i) Flights conducted to position the helicopter at the site at which a patient or donor organ will be picked up.
    - (ii) Flights conducted to reposition the helicopter after completing the patient, or donor organ transport.
    - (iii) Flights initiated for the transport of a patient or donor organ that are terminated due to weather or other reasons.
  - (2) Medical personnel means a person or persons with medical training, including but not limited to flight physicians, flight nurses, or flight paramedics, who are carried aboard a helicopter during helicopter air ambulance operations in order to provide medical care.

Helicopter Air Ambulance

- Orders
  - **8900.1** Flight Standards Information Management System
    - A021Helicopter Air Ambulance (HAA) Operations
    - A024 Air Ambulance Operations – Airplane
    - 8900.1 - Volume 3, Chapter 18, Section 7
      - Part H Helicopter Terminal Instrument Procedures and Airport Authorizations and Limitations

Operational Safety

- Advisory Circulars & Guidance
  - AC 135-14B - Helicopter Air Ambulance Operations
  - AC 135-15 - Emergency Medical Service/Airplane
  - AC 120-96A - Operations Control Center (OCC) for Helicopter Air Ambulance (HAA) Operations
  - AC 150/5390-2D - Heliport Design
  - AIM – Aeronautical Information Manual
  - AIM Helicopter Operations (Chapter 10)
  - Helicopter Flying Handbook
  - Instrument Flying Handbook
- Information for Operators (InFO)
- Safety Alert for Operators (SAFO)

2023 Helicopter Air Ambulance Operations

2023 Helicopter Air Ambulance flight hours: 528,312

1315	129,586	143281	287906	170961	1177	97	528312.6	8188.7	226218	385366
Number of Aircraft	**Scene Acc**	**Scene Dec**	**Int-Fac Acc**	**Int-Fac Dec**	**Organ Acc**	**Organ Dec**	**HAA Hours**	**IFR Hrs**	**Night Hours**	**Patients Xported**

Helicopter Operations Industry Partners

- Vertical Aviation International (VAI)
- Air Medical Operators Association (AMOA)
- Association of Air Medical Services (AAMS)
- United States Helicopter Safety Team (USHST)

New Rules Affecting Air Ambulance Operations

- FARs
  - PART 5-Safety Management Systems (SMS) released April 26, 2024
    - Applicability - Any person that holds or applies for a certificate issued under part 119 authorizing the person to conduct operations under part 121, 135 or any person that holds or applies for a Letter of Authorization issued under 91.147.
    - A formal, top-down, organization-wide approach to managing safety risk and assuring the effectiveness of safety risk controls. It includes systematic procedures, practices, and policies for the management of safety risk.
    - A program that evaluates risk and creates mitigation to the associated risk. The program allows operators to evaluate the overall safety health of the organization.

New Rules Effecting Air Ambulance Operations

- Safety Management Systems (SMS) released April 26, 2024
  - Within part 5, an SMS must include the following four components:
    - Safety Policy
    - Safety Risk Management
    - Safety Assurance
    - Safety Promotion
  - During the implementation period (May 28, 2024 - May 28, 2027) a certificate holder or Air Tour operator will submit a declaration of compliance in a form and manner acceptable to the FAA.
  - Submitting a declaration of compliance to the FAA serves as evidence that the organization has developed and implemented an SMS meeting all the applicable requirements of part 5.

Federal Aviation and Air Ambulance Regulations

Questions?

AAQPS
Air Ambulance Quality and Patient Safety

State EMS Perspective
Joseph House, NASEMSO

CMS Perspectives on Patient Safety and Possible Application to Air Ambulance Transport

Air Ambulance Quality and Patient Safety Federal Advisory Committee Meeting #1
December 12, 2024

Ron Kline, MD
Chief Medical Officer
Quality Measurement and Value Based Incentives Group
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services

Speaker Conflict of Interest Statement

Ron Kline, MD
Chief Medical Officer, Quality Measurement & Value-Based Incentives Group – Centers for Medicare & Medicaid Services

Dr. Kline has no relevant financial relationships with ineligible companies to disclose.

Why Does CMS Measure Quality?

- Every successful organization measures the quality and safety of its products or services to remain successful
- Retail enterprises measure the quality of the products they purchase from manufacturers to ensure customer satisfaction
- Customers comment on the quality of the products and services they purchase

- Healthcare is no different
- CMS is a payer of healthcare services
- Americans are consumers of healthcare services

Why Does CMS Measure Quality? (2)

- Can't improve what you can't measure
- A method to understand performance
- Key part of ongoing continuous quality improvement and PDSA
- Linkage to payment programs
- Consumer Awareness and Action – spurs provider improvement

- Current CMS Portfolio
  - Approximately 500 measures in active use
    - *Not the only measures used in most organizations*
  - Over 2000 in CMS Measures Inventory
  - Moving toward more digital, outcome and patient reported measures

CMS Quality Levers

- Payment Policy
- Conditions of Participation
- Survey and Certification
- Quality Improvement Organization Network
- Coverage Analysis Group
- Clinician Engagement
- Quality Measures
- Value Based Programs (payment and public reporting)
- Extensive Stakeholder Engagement

How do we Measure Quality?

- **Structural Measures – the attributes of settings in which care is provided. This includes material and human resources and organizational structure.**

- **Process Measures – what is actually done in providing and receiving care. It includes both patient and provider activities in making a diagnosis and recommending or implementing treatment.**

- **Outcome Measures – the effects of care on the health status of patients and populations. Improvements in patient behavior and satisfaction with care are included in the definition of health status.**

From Donabedian (JAMA, 1986)

CMS Quality Incentives Programs

Hospital	Clinician and Other	Post Acute Care and Other
Hospital Inpatient Quality Reporting	MIPS – Merit Based Incentive Program	Expanded SNF VBP*
Hospital Readmissions Reduction	MSSP/ACO MIPS	Hospice Quality Reporting
Hospital Value Based Purchasing	CMMI/APN and Model Programs	Home Care Quality Reporting
Hospital Acquired Conditions	Support Act – eRx of Opioids*	Inpatient Rehabilitation Facility
Hospital Promoting Interoperability	Hospital Stars (plus other Stars)	Long Term Care Hospital
Cancer Exempt Hospital	ESRD Quality Improvement	Medicaid Adult Core Set
Inpatient Psychiatric Hospital	Rural Emergency Hospital*	Medicaid Child Core Set
Hospital Outpatient	Home Health VBP (model)*	Marketplace Quality Reporting
Ambulatory Surgery Program	SNF Quality Reporting/NH Stars	Medicare C&D Stars Rating

Red font connotes pay for PERFORMANCE; others are pay for REPORTING *new program

CMS Care Compare Programs (Stars Programs)

- Clinician Ratings
- Home Health Star Ratings
- Home Health CAHPS Star Ratings
- Hospice CAHPS Star Ratings
- Dialysis Star Ratings (Quality and Patient Survey [CAHPS])
- Hospital Star Ratings (Overall and Patient Survey [CAHPS])
- Nursing Home Star Ratings (Overall, Health Inspection, Staffing, and Quality)

Measure Development and Implementation

Measure Submission

January—May 2024:

Developers submit measures through the Measure Submissions for CMS Consideration Entry/ Review Information Tool (MERIT)

MUC List Development

June—November 2024:

Review of the Measure Submissions for CMS Consideration List by CMS, HHS, and OMB

PRMR

December 2024—January 2025:

Process to seek broad, represent-ative input on the Measure Submissions List with recommend-ations posted February 1

Rulemaking

2025:

Notices of Proposed Rulemaking (NPRM) publish

Final Rules Publish

Implementation

Collection may begin as early as 2026 with reporting 1-2 years after collection

Digital Transformation

- An important element of the CMS National Quality Strategy
- A path towards decreasing clinician burden in quality measurement
- Challenges
  - Agreeing on common metrics and data elements
  - Broad FHIR implementation requires IT infrastructure investment across the health care continuum
  - Modification of existing measurements into digital form
- Goals
  - FHIR expansion
  - Implementation of USCDI (US Core Data for Interoperability)
  - USCDI+ build out to create interoperable data elements for measurement for multiple medical indications (e.g., Public Health, Maternal Health, Quality, Cancer, Behavioral Health,

Electronic Quality Measures minimize administrative burden (and cost)

Table 3. Estimated Total and Per-Metric Person-Hours and Personnel Costs by Type of Quality Metric at a Large Academic Medical Center in Maryland

Metric type	Unique metrics	Person-hours per year	Person-hours per metric per year	Personnel cost per year (certainty interval), $[a]	Personnel cost per metric per year (certainty interval), $
Claims-based	96	80 218	836	3 605 144.01 (2 377 146.05-7 601 599.78)	37 553.58 (24 761.94-79 183.33)
Chart-abstracted	26	17 975	691	880 653.76 (545 462.54-1 648 438.78)	33 871.30 (20 979.33-63 401.49)
Electronic	4	159	40	7606.31 (4401.77-16 836.27)	1901.58 (1100.44-4209.07)
Survey or direct reporting from patients or staff	32	59	2	8622.89 (3878.16-16 777.35)	269.47 (121.19-524.29)
Summative[b]	4				
Uncategorized[c]		10 068		536 191.31 (327 491.74-1 241 080.24)	
Total		108 478		5 038 218.28 (3 258 380.27-10 524 732.43)	

[a] These data exclude vendor fees for the 2018 calendar year, which totaled $602 730.66, as detailed in the text. All dollar amounts are inflation-adjusted to 2022 USD using the US city-average Consumer Price Index (Bureau of Labor Statistics).

[b] Because summative metrics (eg, Centers for Medicare & Medicaid Services star rating) are higher-level metrics formed by combinations of other metrics for which time was already counted, summative metrics did not have time or personnel cost attributed, but were retained in reporting for completeness and because they are widely recognized.

[c] Some respondents were unable to categorize their time by metric type and chose to report their time as "uncategorized."

JAMA. 2023;329(21):1840-1847. doi:10.1001/jama.2023.7271

Patient Safety

- **25% of Medicare beneficiaries experienced harm (e.g., adverse events and temporary harm events) during an acute care hospitalization in 2018. 43% were deemed to have been preventable (medication errors, pressure ulcers, infection)**

  HHS OIG Report, 2022

- **Patient Safety is a Biden – Harris Administration priority – PCAST Report**

- **CMS is focusing on patient safety as an important domain in quality measurement – Patient Safety Structural Measure in HIQR Program**

Patient Safety Structural Measure (FY25)

Attestation Domain	Intent
Domain 1: Leadership Commitment to Eliminating Preventable Harm	Senior leadership and governing board must be accountable for patient safety outcomes and ensure that patient safety is the highest priority for the hospital. The governing board must oversee safety activities and hold organizational leadership accountable for outcomes.
Domain 2: Strategic Planning & Organizational Policy	Hospitals must use strategic planning and organizational policies to demonstrate safety as a core value. Continual process improvement with the goal of zero preventable harm.
Domain 3: Culture of Safety & Learning Health Systems	Hospitals must integrate a suite of evidence-based practices and protocols that are fundamental to cultivating a hospital culture that prioritizes safety and establishes a learning system both within and across hospitals.
Domain 4: Accountability & Transparency	There must exist a culture that promotes event reporting without fear or hesitation and promotes safety data collection and analysis with the free flow of information.
Domain 5: Patient & Family Engagement	Hospitals must engage patients, families, and caregivers as co-producers of safety and health through meaningful involvement in safety activities, quality improvement, and oversight.

Proposal: Progressive Increase in the Number of Mandatory eCQMs

Reporting Period/ Payment Determination	Total # of eCQMs Reported	eCQMs Required to Be Reported
CY 2024/FY 2026 and CY 2025/FY 2027	Six	• Three self-selected eCQMs; and • Safe Use of Opioids - Concurrent Prescribing eCQM; and • Cesarean Birth eCQM; and • Severe Obstetric Complications eCQM
CY 2026/FY 2028	Nine	• Three self-selected eCQMs; and • Safe Use of Opioids - Concurrent Prescribing eCQM; and • Cesarean Birth eCQM; and • Severe Obstetric Complications eCQM; and • Hospital Harm - Severe Hyperglycemia eCQM; and • Hospital Harm - Severe Hypoglycemia eCQM; and • Hospital Harm - Opioid-Related Adverse Events eCQM
CY 2027/FY 2029 (and for subsequent years)	Eleven	• Three self-selected eCQMs; and • Safe Use of Opioids - Concurrent Prescribing eCQM; and • Cesarean Birth eCQM; and • Severe Obstetric Complications eCQM; and • Hospital Harm - Severe Hyperglycemia eCQM; and • Hospital Harm - Severe Hypoglycemia eCQM; and • Hospital Harm - Opioid-Related Adverse Events eCQM; and • Hospital Harm - Pressure Injury eCQM; and • Hospital Harm - Acute Kidney Injury eCQM

Possible First Steps for Air Ambulance Transport Quality Measurement

- **Structural Measure** – Ensuring that all necessary equipment and properly trained personnel are available during medical air transport.

- This would have to be appropriately tiered for different intensity and complexity levels of medical air transport.

Possible First Steps for Air Ambulance Transport Quality Measurement (2)

- **Process Measures** - ???
- What consensus clinical activities exist that the medical air transport community agrees are important for achieving the best outcomes
- Can be classified by patient type (e.g., pediatrics, cardiac, sepsis, trauma, etc.)

Possible First Steps for Air Ambulance Transport Quality Measurement (3)

- **Outcome Measure** – All cause mortality during air transport
- **Outcome Measure** – Preventable complications that occur during air transport
- This would have to be appropriately **risk-adjusted** for different intensity and complexity levels of medical air transport.

Thank you

Questions and Discussion

Ronald.Kline@cms.hhs.gov

AAQPS
Air Ambulance Quality and Patient Safety

Committee Discussion

AAQPS
Air Ambulance Quality and Patient Safety

Lunch

AAQPS
Air Ambulance Quality and Patient Safety

Flight Safety Data and Best Practices

Air Ambulance Industry Accident Data & Analysis

Lee Roskop, Aircraft Certification, Operational Safety Branch

Federal Aviation Administration

Overview

- HAA Flight Hours
- HAA Accident Metrics
- U.S. Helicopter Safety Team (USHST) Analysis Data
- NTSB Findings from HAA Accidents
- USHST Initiatives Related to HAA

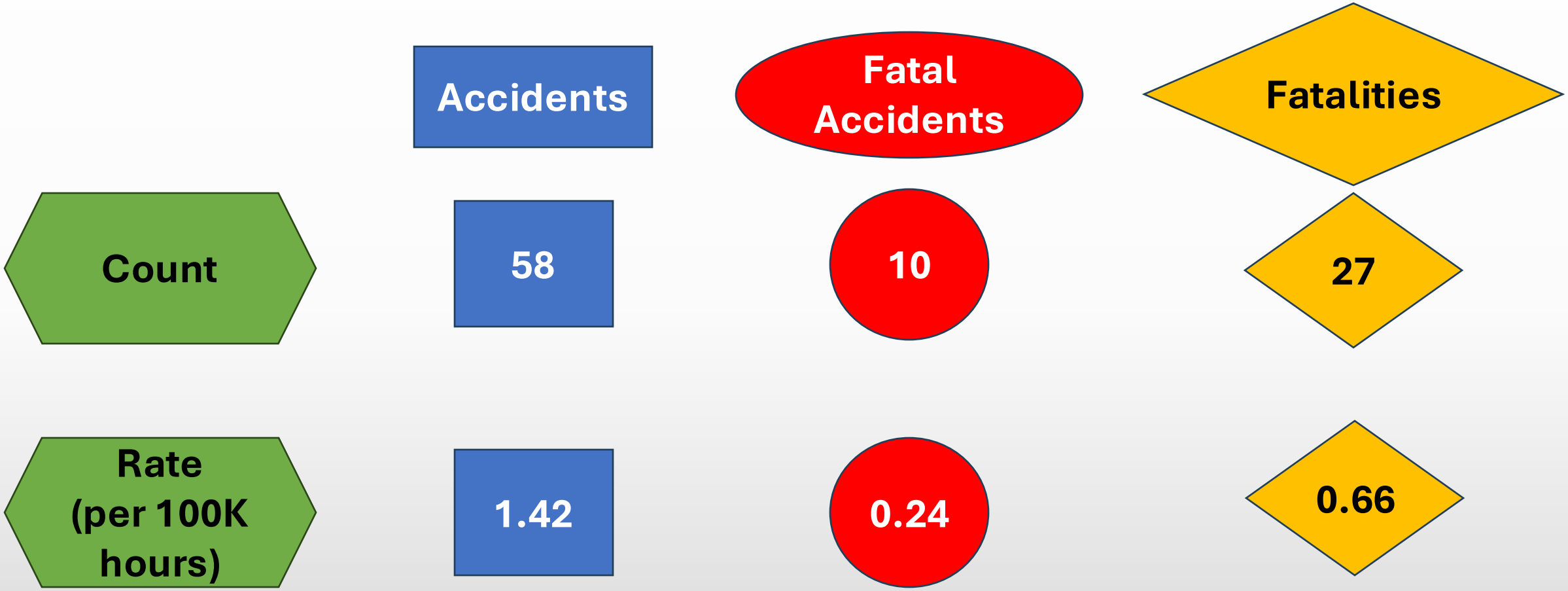
HAA Part 135 Flight Hours

- As a segment of **overall** U.S. helicopter flight hours:
  - On average, **16%** of hours since 2016
  - Increasing share over last 8 years:
    14% in 2016, up to **19%** in 2023
  - Ranked in top three helicopter industry segments each year for hours flown

- As a segment of **Part 135** U.S. helicopter flight hours:
  - On average, **52%** of hours since 2016
  - About **3 times** higher than any other U.S. helicopter Part 135 industry segment
  - Increasing share over last 8 years:
    44% in 2016, up to **67%** in 2023

23% increase in HAA Part 135 flight hours from 2016 through 2023

HAA Part 135 Accident Metrics, 2016 – 2024*



*2024 numbers for January – October only

HAA Part 135 Accident Metrics, 2016 – 2024*

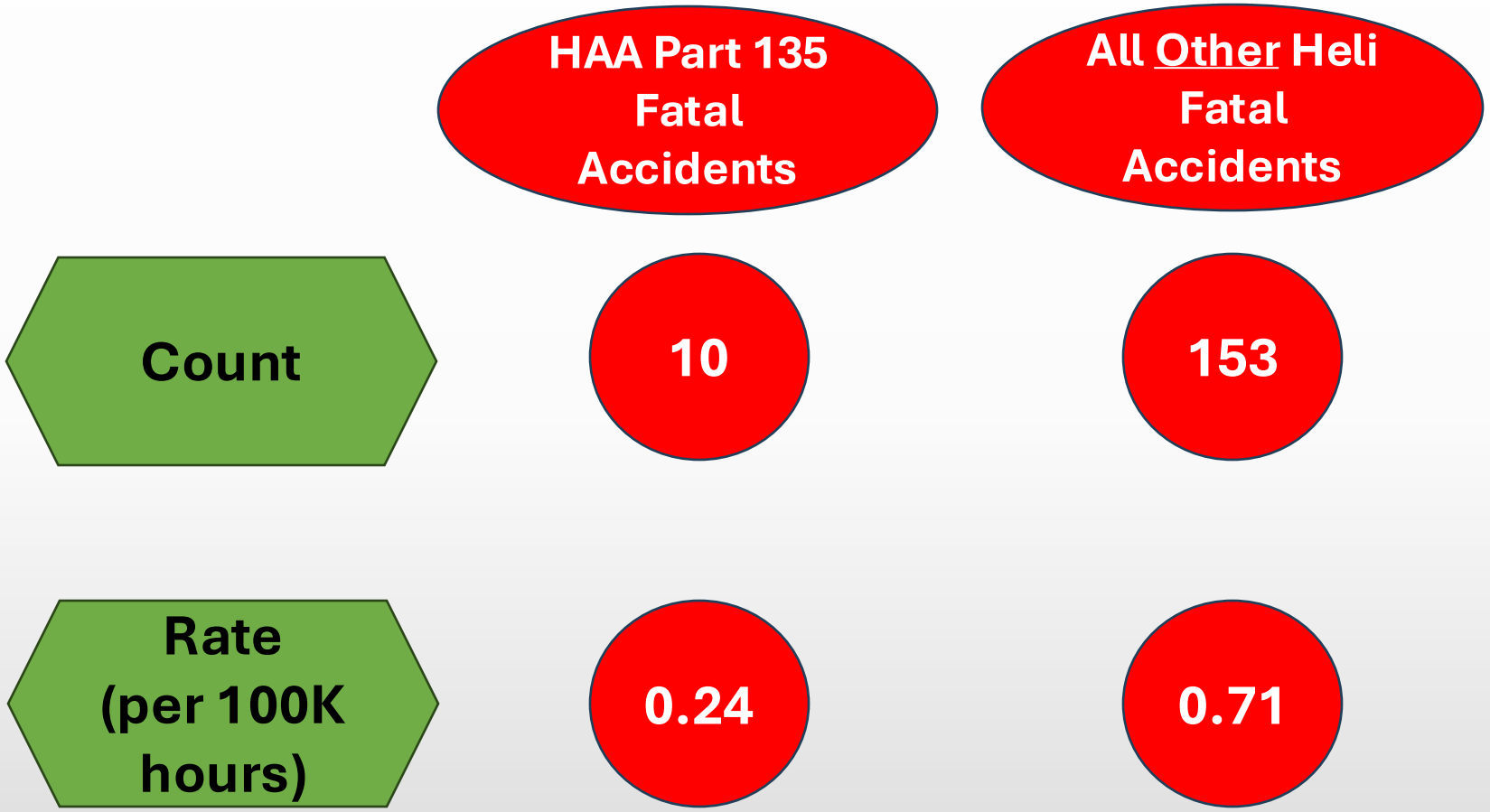
	HAA Part 135 Accidents	All Other Heli Accidents
Count	58	904
Rate (per 100K hours)	1.42	4.19

*2024 numbers for January – October only

HAA Part 135 Observations

- **6%** of 962 U.S. heli accidents
- Rate ≈ **3 times lower** than the rest of U.S. heli industry
- **Best** Year (count & rate): **2020**
  Count = **3**, Rate = **0.7**
- **Worst** Year (count & rate): **2022**
  Count = **12**, Rate = **2.8**

HAA Part 135 Accident Metrics, 2016 – 2024*



*2024 numbers for January – October only

HAA Part 135 Observations

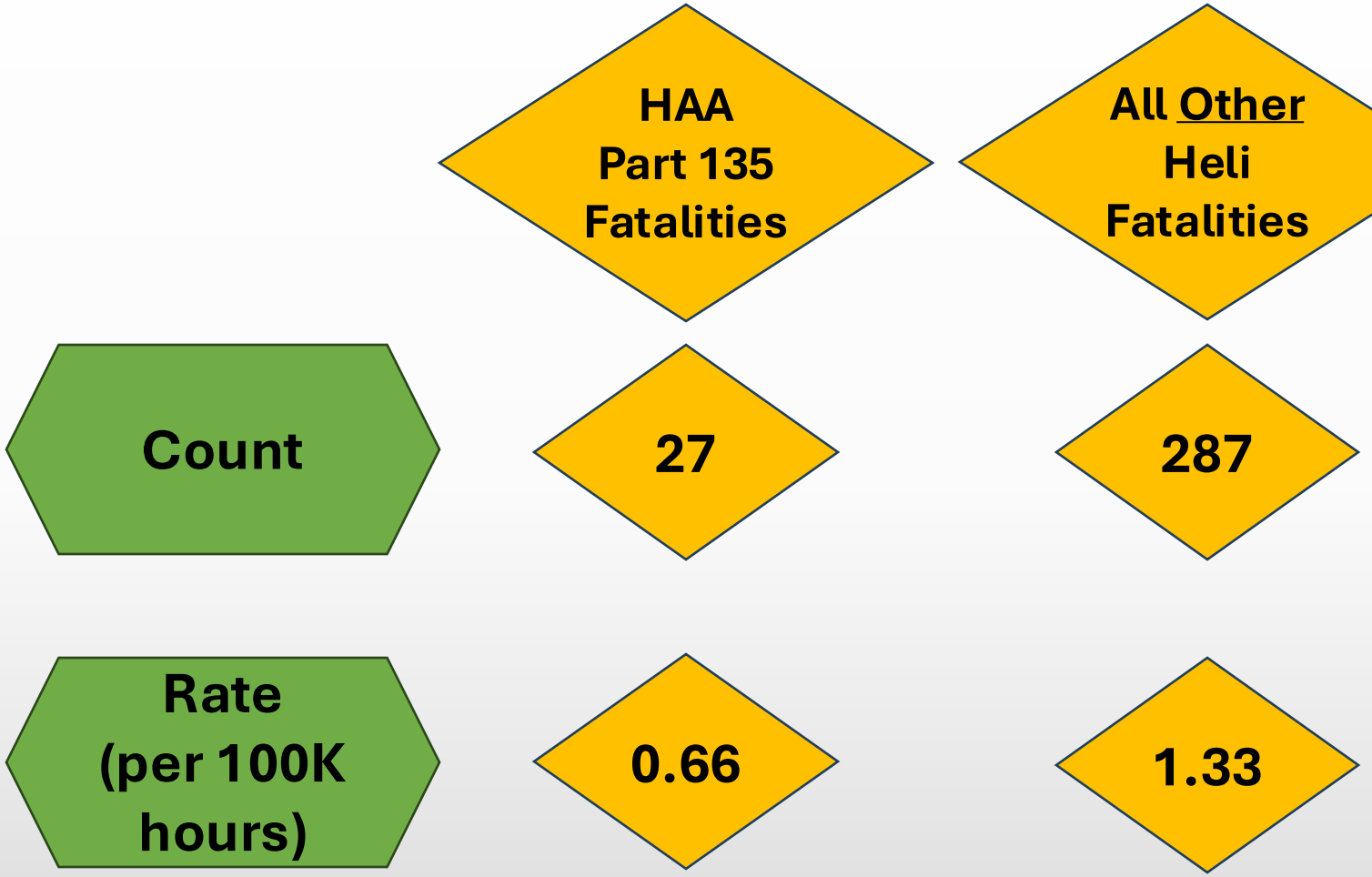
- **6%** of 163 U.S. heli **fatal** accidents
- Rate ≈ **3 times lower** than the rest of U.S. heli industry
- **Best** Years (count & rate):

  2018, 2020, 2021, 2022

  Count = **0,** Rate = **0**
- **Worst** Year (count & rate): **2019**

  Count = **3**, Rate = **0.70**

HAA Part 135 Accident Metrics, 2016 – 2024*



*2024 numbers for January – October only

HAA Part 135 Observations

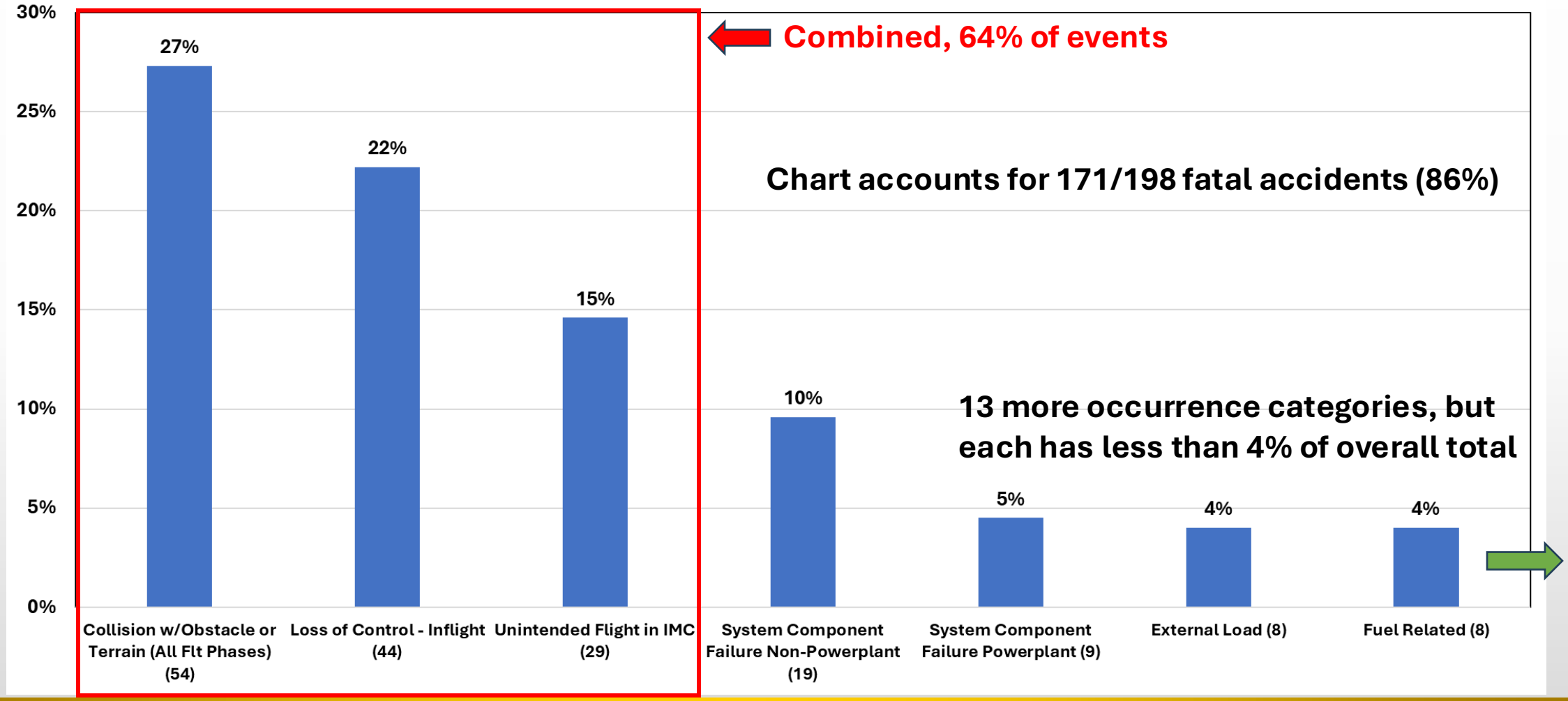
- **9%** of 314 U.S. heli **fatalities**
- Rate ≈ **2 times lower** than the rest of U.S. heli industry
- **Best** Years (count & rate):

  2018, 2020, 2021, 2022

  Count = **0,** Rate = **0**
- **Worst** Year (count & rate): **2017**

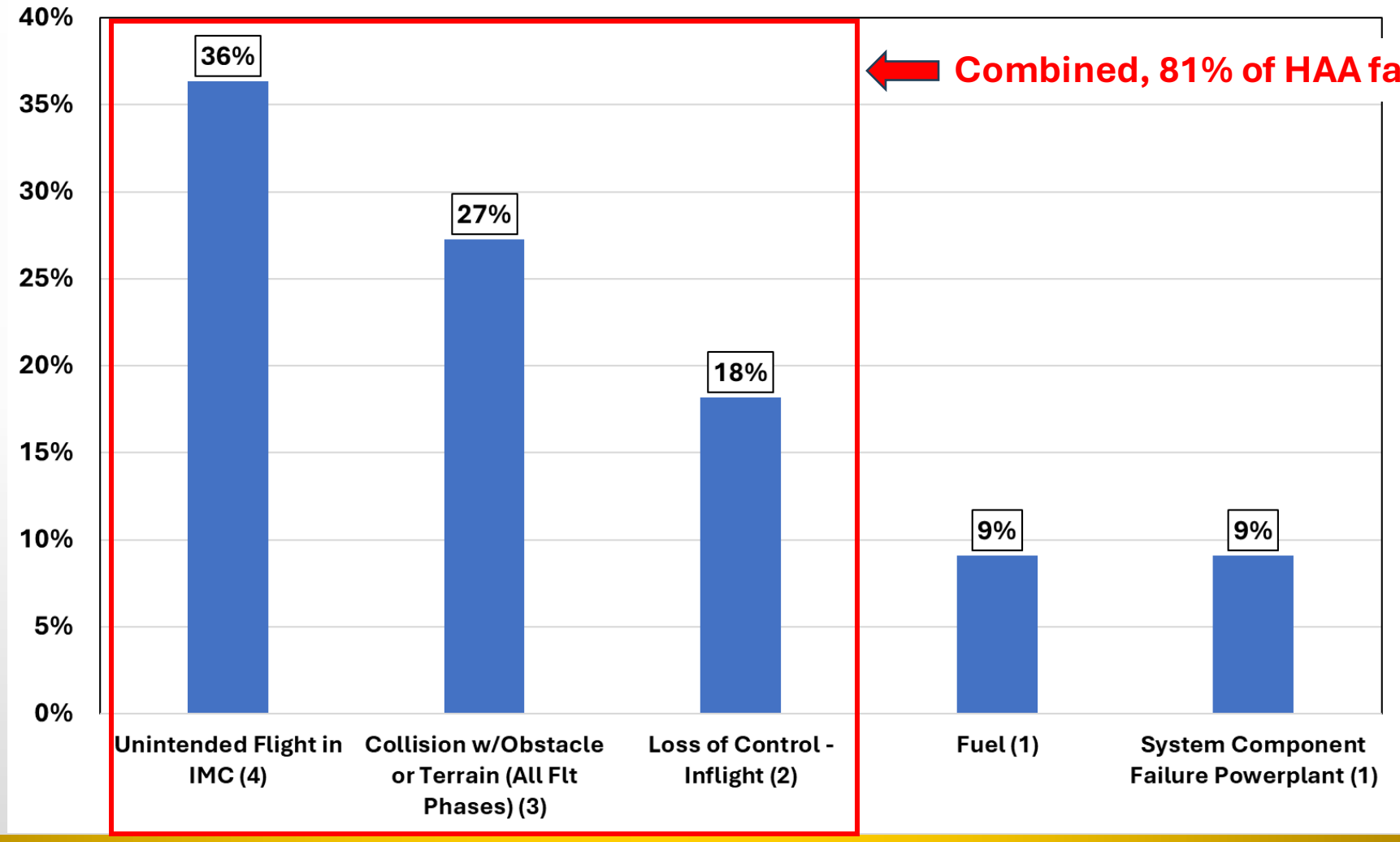
  Count = **7**, Rate = **1.63**

USHST Occurrence Categories
All Helicopter Fatal Accidents, 2009-2018



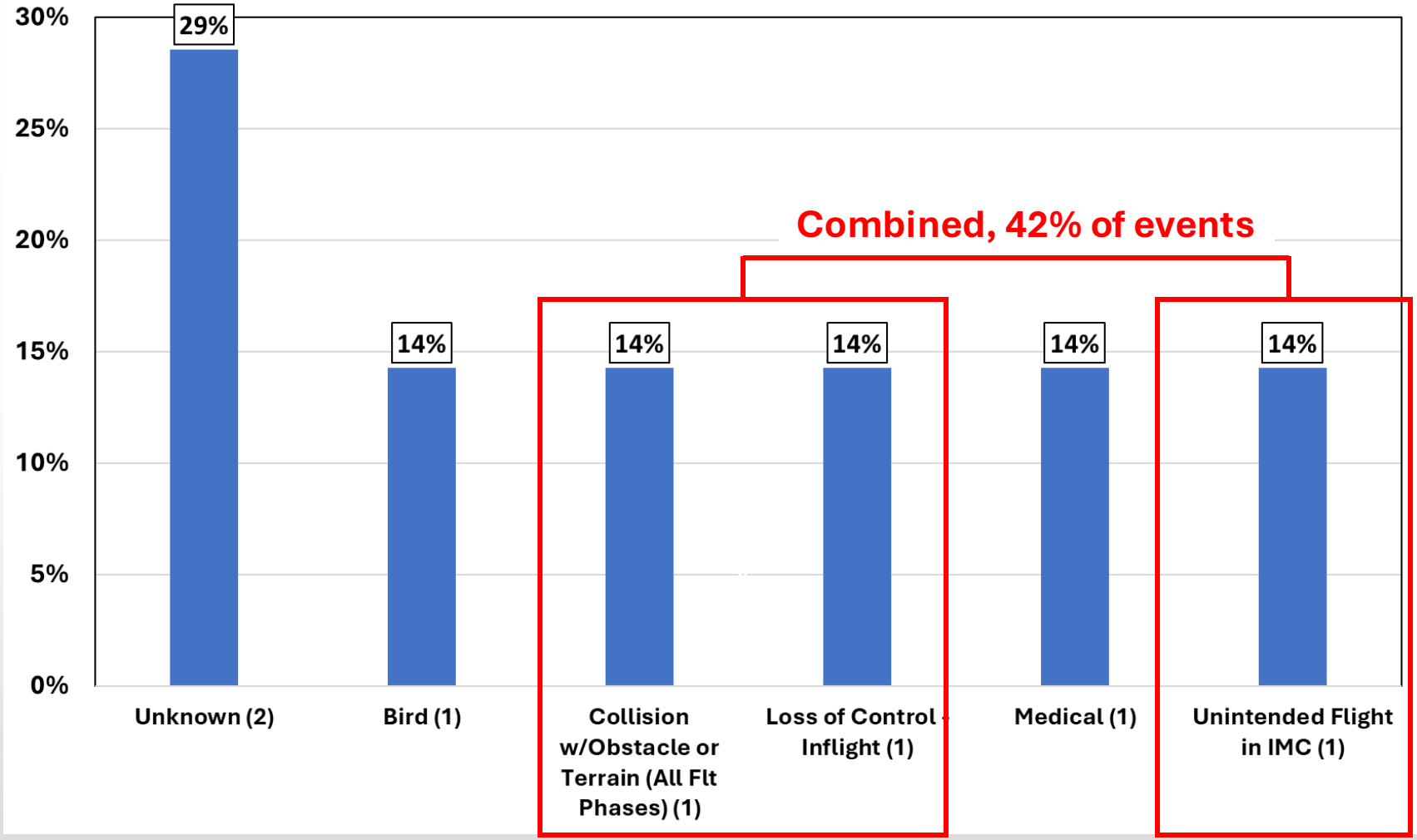
Federal Aviation Administration

USHST Occurrence Categories
HAA Part 135, Fatal Accidents, 2009-2018



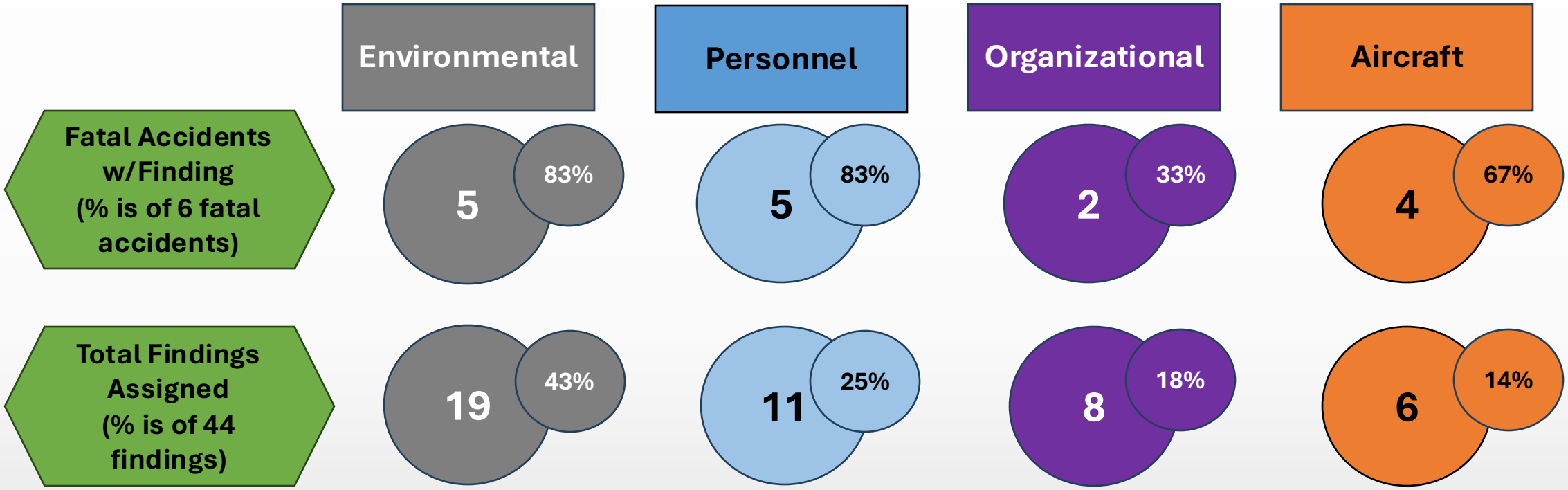
Federal Aviation Administration

USHST Occurrence Categories
HAA Part 135, Fatal Accidents, 2019-2024



Federal Aviation Administration

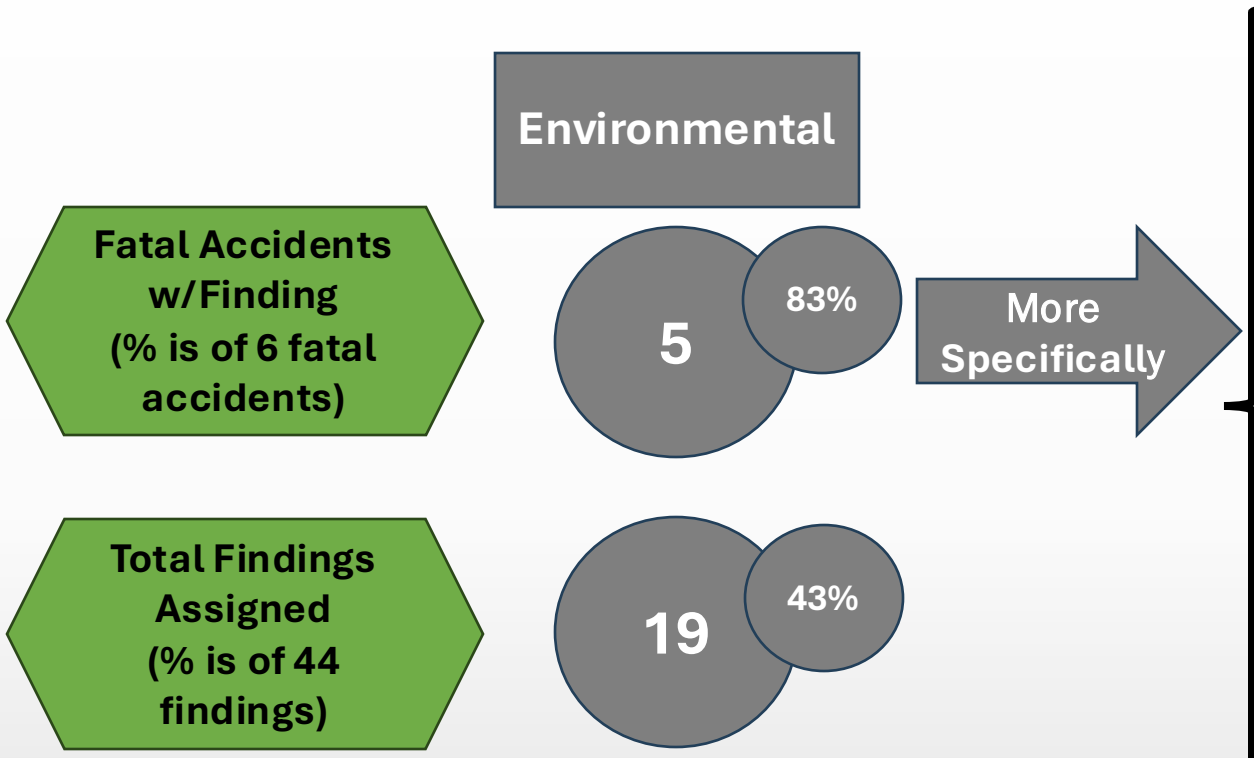
NTSB Findings: HAA Part 135 Fatal Accidents, 2016-2024



- As of Nov 2024, NTSB finding codes only available for 6 of 10 fatal accidents. Others are still under investigation.
- Each accident often has **MULTIPLE** categories of finding codes assigned.
- Each accident sometimes has **MULTIPLE** more specific findings assigned under a single finding category.

Federal Aviation Administration

NTSB Findings: HAA Part 135 Fatal Accidents, 2016-2024



More Specifically

Of the 5 fatal accidents w/Environmental findings:

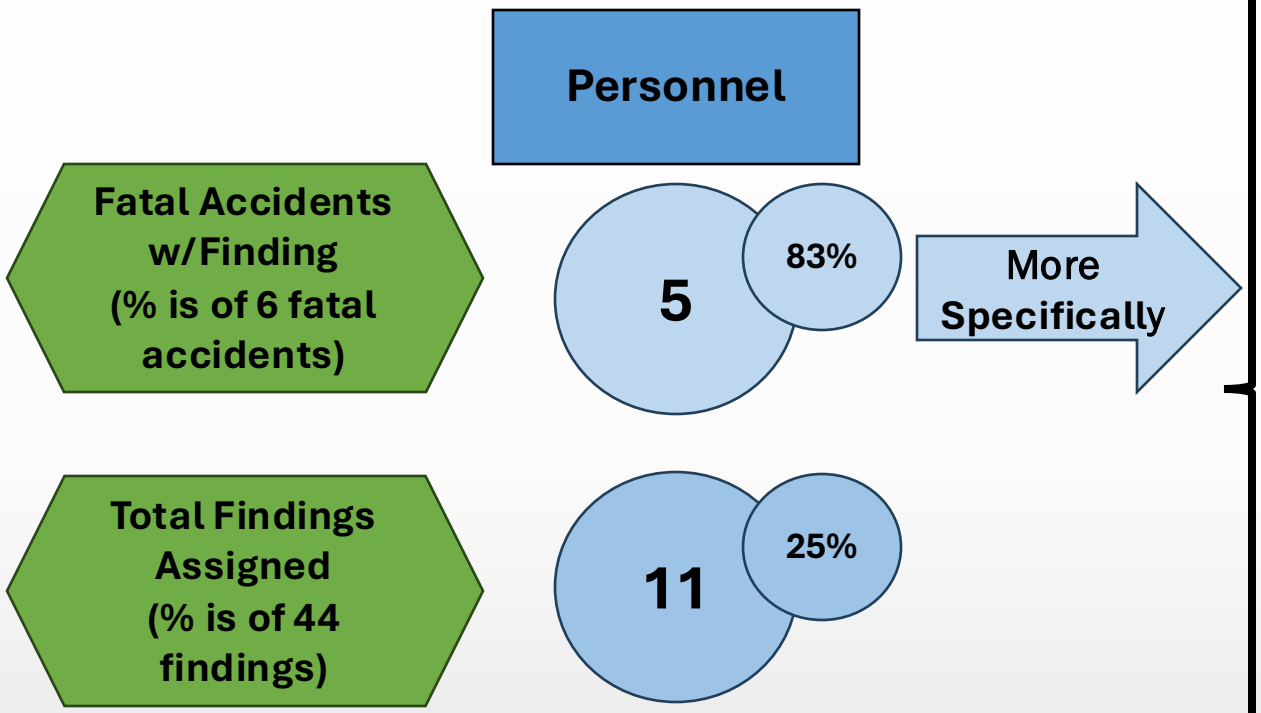
3 of 5 fatal accidents (60%) had:
- Ceiling/visibility/precip

2 of 5 fatal accidents (40%) had:
- Light condition

1 of 5 fatal accidents (20%) had 1 of the following:
- Meteorological services
- Object/animal/substance
- Physical workspace
- Terrain

- Of the 5 fatal accidents with an Environmental finding, 4 of the 5 had **MULTIPLE** Environmental findings cited.

NTSB Findings: HAA Part 135 Fatal Accidents, 2016-2024



More Specifically

Of the 5 fatal accidents w/Personnel findings:

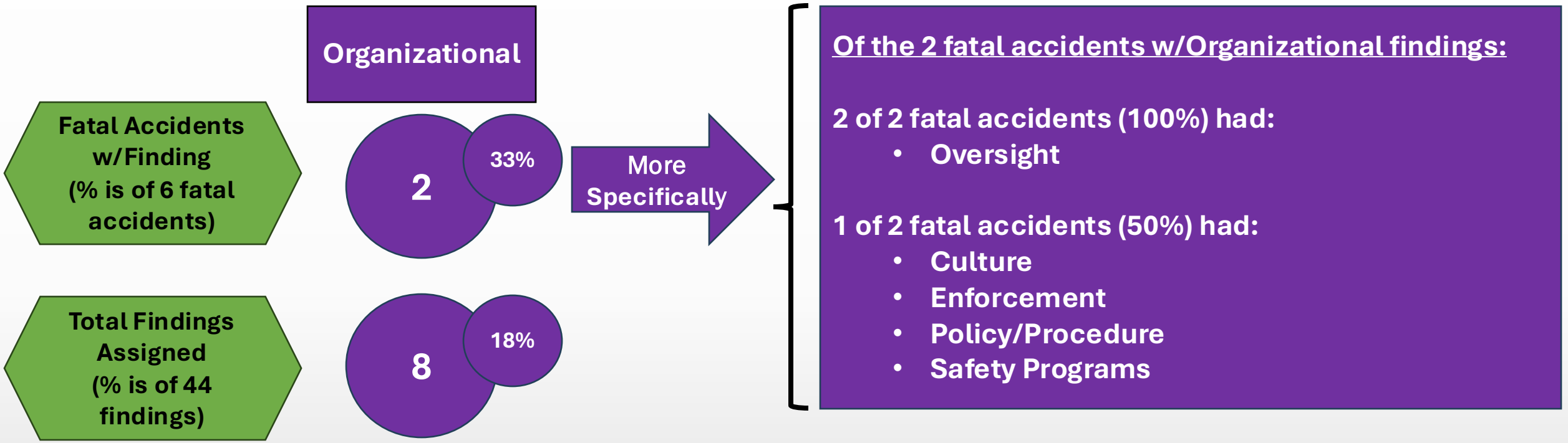
3 of 5 fatal accidents (60%) had:
- **Use of equip/info**

2 of 5 fatal accidents (40%) had:
- **Info processing/decision**
- **Perception/orientation/illusion**

1 of 5 fatal accidents (20%) had 1 of the following:
- **Action**
- **Impairment/incapacitation**
- **Personality/attitude**
- **Planning/preparation**

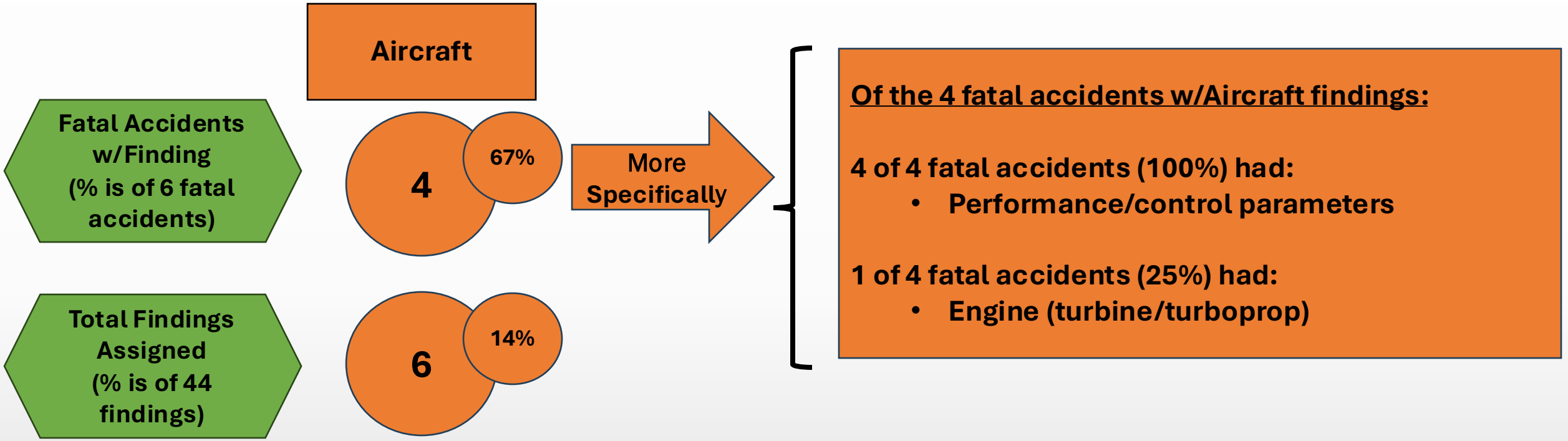
- Of the 5 fatal accidents with a Personnel finding, 4 of the 5 had <u>MULTIPLE</u> Personnel findings cited.

NTSB Findings: HAA Part 135 Fatal Accidents, 2016-2024



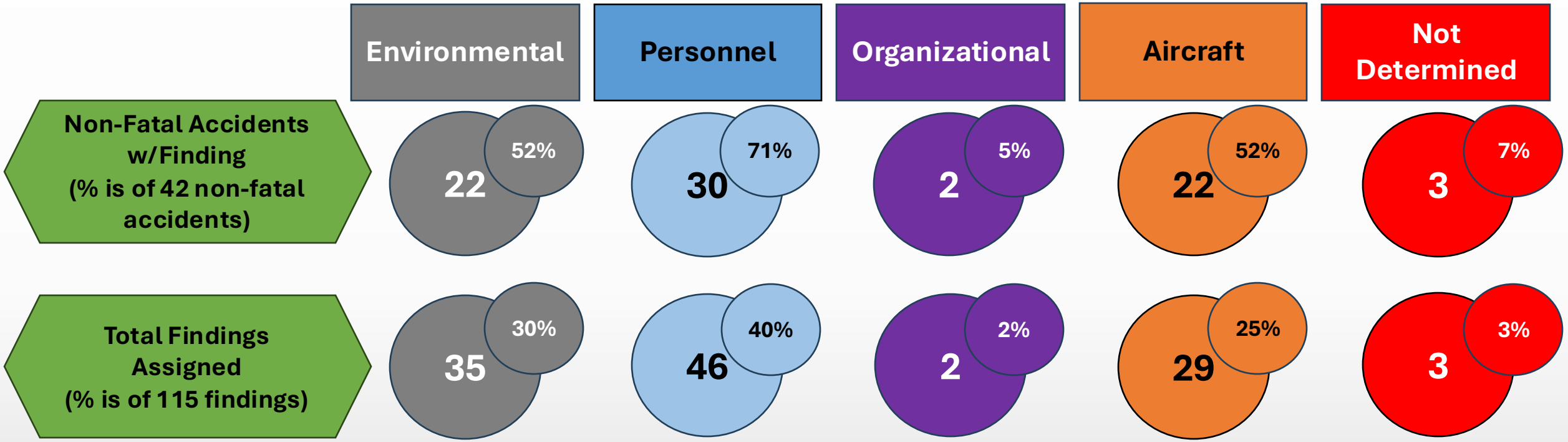
- Of the 2 fatal accidents with an Organizational finding, 1 of the 2 had **MULTIPLE** Organizational findings cited.

NTSB Findings: HAA Part 135 Fatal Accidents, 2016-2024



- Of the 4 fatal accidents with an Aircraft finding, 1 of the 4 had MULTIPLE Aircraft findings cited.

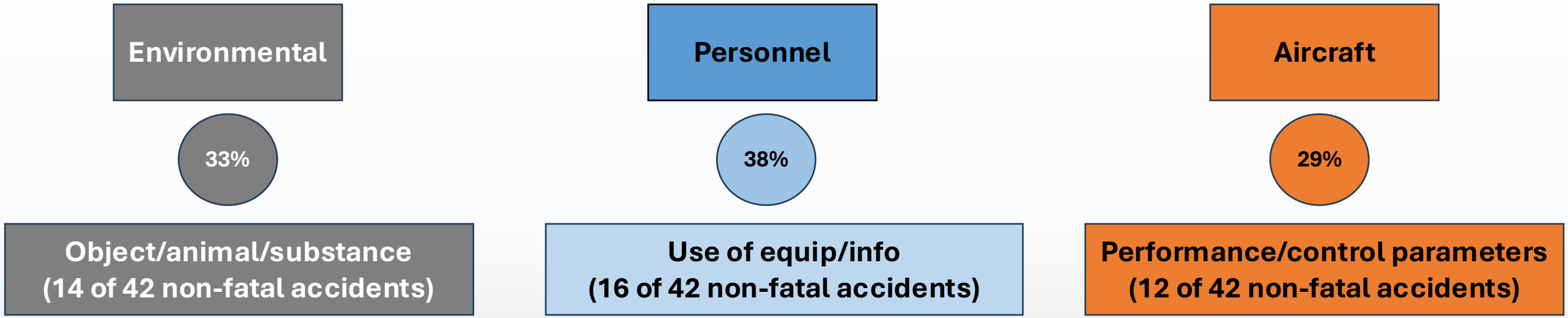
NTSB Findings: HAA Part 135 Non-Fatal Accidents, 2016-2024



- As of Nov 2024, NTSB finding codes only available for 42 of 48 HAA Part 135 non-fatal accidents. Others are still under investigation.
- Each accident often has **MULTIPLE** categories of finding codes assigned.
- Each accident sometimes has **MULTIPLE** more specific findings assigned under a single finding category.

Federal Aviation Administration

Highest Frequency NTSB Findings in HAA Part 135 Non-Fatal Accidents 2016-2024



USHST Completed Initiatives (2018-2022)

Air Ambulance Community: Contributed to development, implementation, and promotion

Completed Helicopter Safety Enhancements

1. Utilities and Construction Practice Guide
2. Safety Culture and Professionalism
3. Detection and Management of Risk Level Changes During Flight
4. The Final Walk Around
5. Development of Airman Certification Series for Rotorcraft
6. Stability Augmentation System/Autopilot
7. Simulators and Outside-the Envelope Flight Conditions
8. Helicopter Flight Data Monitoring
9. UAS in High-Risk Environments
10. Enhanced Helicopter Vision Systems
11. Make & Model Transition Training
12. Simulations for Safe Decision Making
13. Understanding of Basic Helicopter Aerodynamics
14. Pre-Flight Risk Assessment for Student Pilots
15. Recognition & Recovery of Spatial Disorientation
16. Hazards of Over-the-Counter Medication

Special Project for UIMC Prevention
"56 Seconds to Live"

Federal Aviation Administration

USHST In-Progress Initiatives (2023 forward)

Air Ambulance Community: Contributing to development

Questions?

AAQPS
Air Ambulance Quality and Patient Safety

Air Ambulance Safety Practices

Ben Clayton, Life Flight Network, CEO

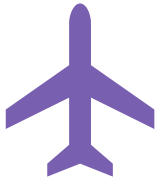
Air Ambulance Safety Practices

AAQPS
Air Ambulance Quality and Patient Safety

Safety Management Systems (SMS)

Technology and Training

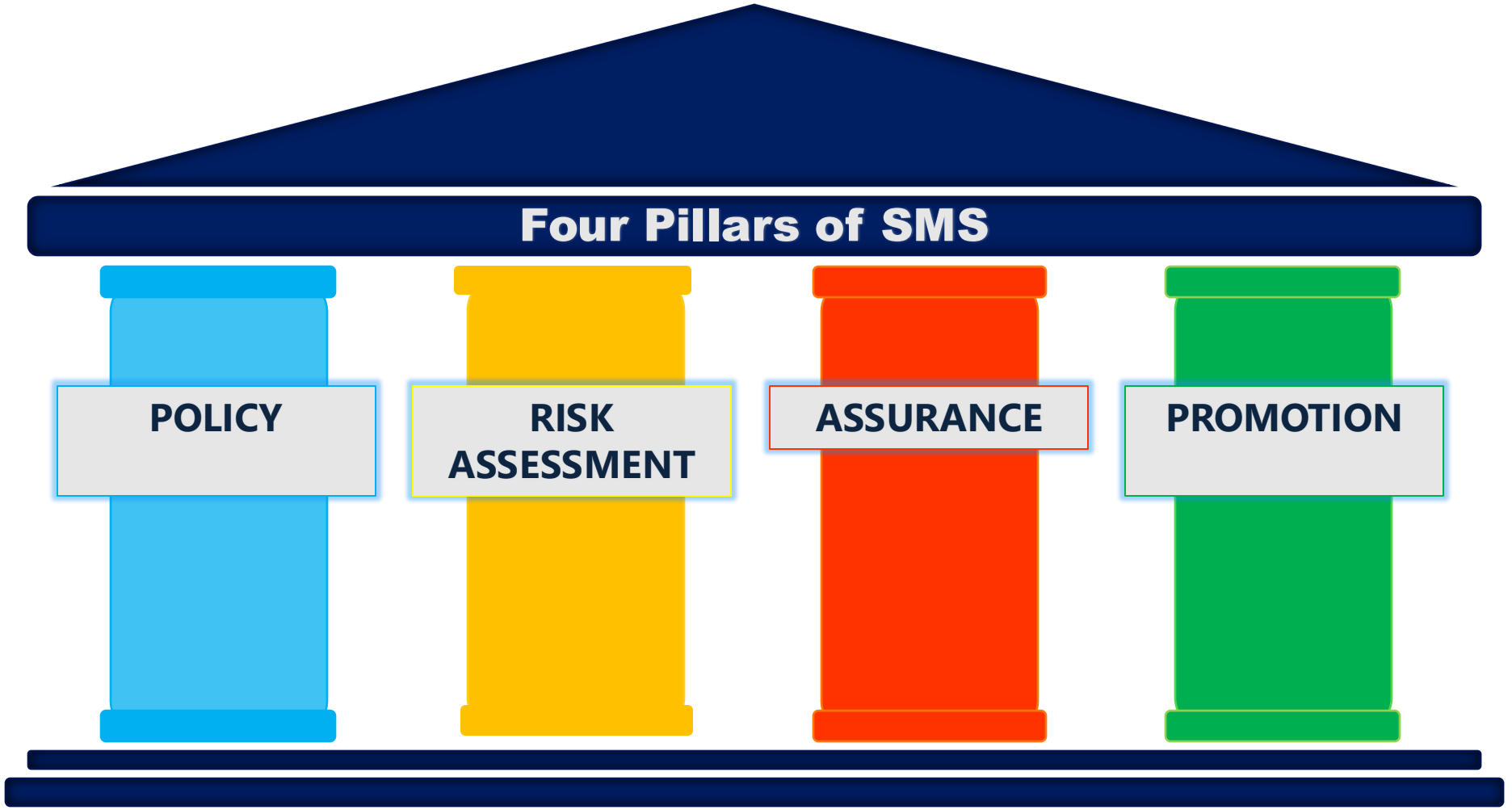
Flight Data Monitoring
Terrain Awareness
Autopilots/Stability Augmentation Systems
Night Vision Goggles



FAA Oversight

Safety Management System

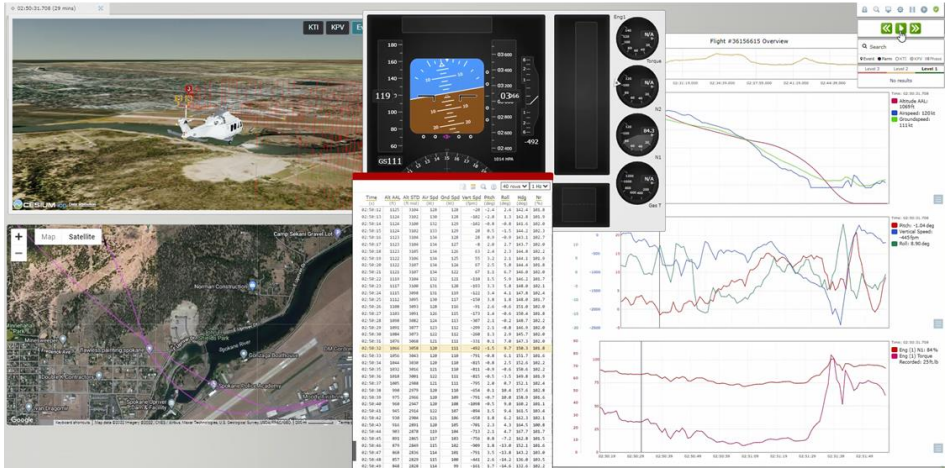
AAQPS
Air Ambulance Quality and Patient Safety



Technology and Training

Night Vision Goggles

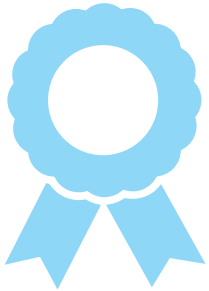
Terrain Awareness



Flight Data Monitoring

FAA Oversight

AAQPS
Air Ambulance Quality and Patient Safety



Part 135 Certificate Holders

Certificate Management Teams

Principal Operations Inspectors

FAA Safety Programs

Safety Management Systems (SMS)

Aviation Safety Action Program (ASAP

Line Operations Safety Audit (LOSA)

Flight Operational Quality Assurance (FOQA)

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A note about industry safety collaboration

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Questions?

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Committee Discussion

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Clinical Quality Environment

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Voluntary Certification and Standards

Eileen Frazer, RN, CMTE, Commission on Accreditation of Medical Transport Systems, Executive Director

camts
Commission on Accreditation of Medical Transport Systems

AAQPS
Air Ambulance Quality and Patient Safety

- **Mission:** CAMTS is a peer review organization dedicated to improving patient care safety by providing a dynamic accreditation process through the development of standards, education, and services that support our vision
- **Vision:** All patient receive appropriate and safe out-of-hospital care by qualified professionals
- **Values**
  - Fair
  - Ethical
  - Consistent
  - Accountable
  - Patient and Safety Focused

Types of Services Eligible for Accreditation

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Why CAMTS?

AAQPS
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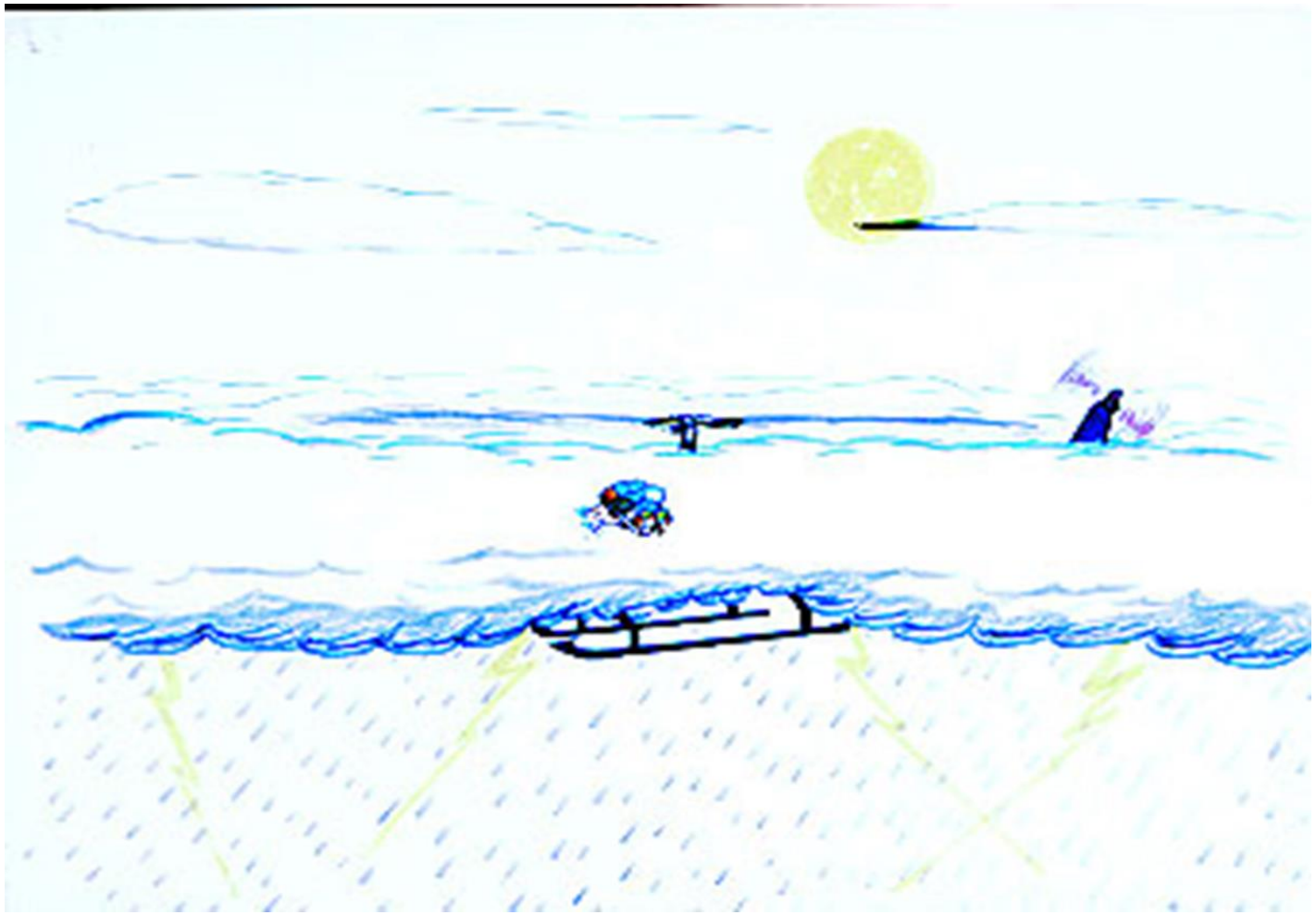
- In the early 1980s there were no published standards specific to Air Medical Transport in the civilian sector
  - ASHBEAMS had its first meeting in 1980 and started to create “Recommended Quality Standards for Hospital-based Emergency Air Medical Services” in 1986
  - NFNA (now ASTNA) formed in 1981 and published “Practice Standards for Flight Nursing” in 1986
  - NTSB did a study in 1988 with recommendations
  - CAMTS incorporated in 1990 referencing the ASHBEAMS, NFNA, HAI Safety Guidelines and NTSB recommendations into the 1st Edition Accreditation Standards published in 1991



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BY 1988, Weather was the highest probable cause for 23 accidents by the NTSB and 21 of the 23 occurred at night.

BETA Tested Guidelines at Several Hospital Helicopter Programs 1988 - 1989

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- Along with Safety Issues we found:
  - Medical crews not aware of emergency egress procedures, survival, or of critical phases of flight.
  - Medical Configuration and common practices (oxygen tank between patient's legs)
  - Medical protocols inconsistent with types of care provided
  - Medical Directors' involvement was minimal

Current Member Organizations of CAMTS

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- AsMA
- AMOA
- AMPA
- ASTNA
- AAP
- AACN
- AARC
- ACEP
- ACS
- AAMS

- ACCT
- ENA
- IAMTCS (NAACS)
- ICAPP (IAFCCP)
- NATA
- NAEMSP
- NANN
- NASEMSO
- CAMTS Global
- US TransCOM –liaison
- Ad hoc members

It is this wide diversity of experience that provides its strength and integrity

Factors that Affect Creation of Standard

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- Must be specific enough to be measurable and meaningful, but also adaptable to the variables:
  - Regulations (local, state, national, international)
  - Medical team differences
  - Available resources

Continuous Review of Accidents and Incidents

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Hospital Helipad Issues

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- **Communications policies** will include:
  - Staging if more than one aircraft is expected
    - Air to air communications
    - Hosting common frequencies
    - Sharing satellite tracking information between comm centers
- **Crew Coordination**
  - Strict enforcement of sterile cockpit
  - One medical crewmember taking active part in watching for obstructions during the critical stages of flight
- **Training for Security** to assist crews in loading and unloading around the helicopter on hospital helipads

Responding to Fatal Accidents in 2008

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- NTSB held Hearings in Feb 2009 that resulted in the following recommendations:
  - Operational Control/Business Models (Competition/Helicopter Shopping)
  - Flight Ops (risk tools, SMS)
  - Equipment (NVGs, HTAWS)
  - Training (Simulator, AMRM)
  - FAA Oversight (135 or separate regulations)

Standards are Dynamic – Not Static

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- There were developing technologies not widely used in the first decade compared to the second decade:

	1994-2003	2004-2018
NVGs	No	Yes
Satellite tracking	No	Yes
GPS mapping software	No	Yes
HTAWS	No	Yes
CRM/AMRM	No	Yes
SMS	No	Yes
Operational control	No	Yes
Flight simulators	No	Yes
Improved wx reporting	No	Yes

Safety and Quality in Medical Transport Systems

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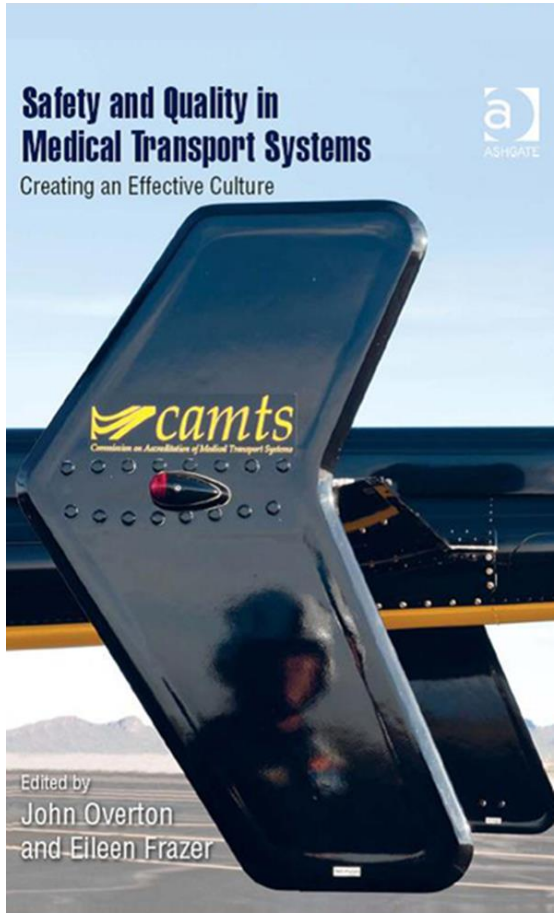
Assembled noted experts in human factors, safety, and risk management, Just Culture and Threat and Error Management to create this reference book – the first of its kind – to address an effective safety and quality culture for EMS, fire and rescue, public and private services around the world

Published by ASHGATE – December 2012



CAMTS Anonymous Survey Tool

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Air Ambulance Quality and Patient Safety

- When we addressed the basics of a safety culture such as accountability, authority, professionalism and organizational dynamics, we needed a way to measure these attributes

- Scoring and comments are submitted electronically by each employee

Summary of Safety Culture Survey

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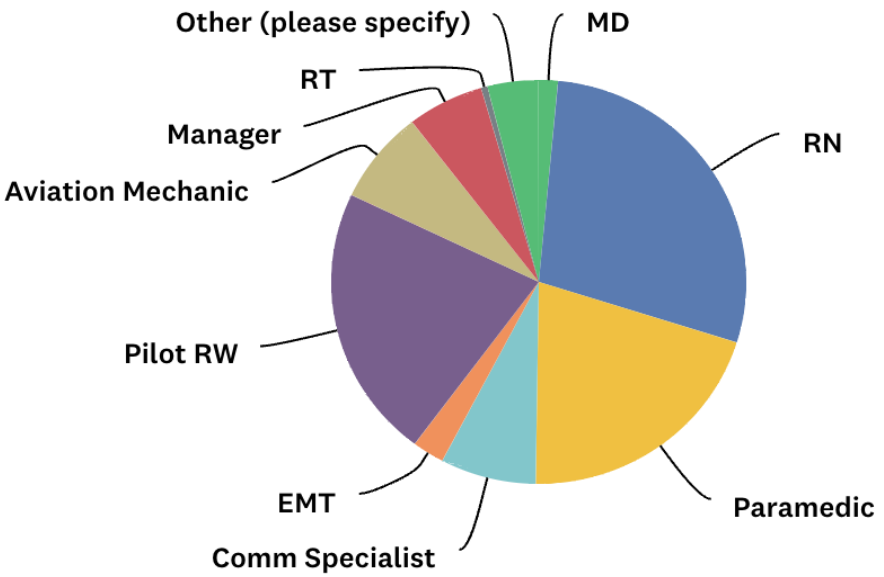
Air Ambulance Quality and Patient Safety

- 56% returned (202 out of 358 sent)



Summary of Safety Culture Survey

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Patient Care – Scope of Care

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Air Ambulance Quality and Patient Safety

- Mission Types: Staffing must be commensurate with the mission statement and scope of care of the medical transport service
- All Equipment, medications and interventions listed below are pertinent to the program's mission and scope of service (which includes scope of care)
- Equipment, Medications, Interventions and Quality listings in each type of care build on each other starting with BLS to ALS to Critical Care and Specialty Care.
  - 03.01.01 Basic Life Support
  - 03.01.02 Advanced Life Support
  - 03.01.03 Critical Care
  - 03.01.04 Specialty Care

Patient Care

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- Quality management and utilization review
- Standardized education with required competencies
- Human patient simulators for skills maintenance and clinical competency
- AMRM
- Medical Direction

Training

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Safety Education for Medical Teams

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Specific to the In-Flight and Surface Transport Environment

- Medical patient transport considerations (assessment/treatment/preparation handling/equipment)
- Altitude physiology
- Day-and night-flying protocols
- EMS communications (radios) and familiarization with EMS system
- Extrication devices and rescue operations (ranging from familiarity to explicit training depending on the service's mission statement) (RW)
- General aircraft safety
  - Strongly recommended to have the aircraft physically present when providing this training
  - Training addresses: (RW/FW)
  - Training related to situations dealing with an incapacitate pilot is encouraged
- Haz Mat
- Highway scene safety management

Medical Direction – Relevant with Current Protocols

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Equipment Added for Neonatal Transports

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04.00.00 Communications and Communications Specialists that may include OCC

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Includes Staffing, Training, Safety, QM and staff meeting involvement with the entire crew

05.04.03 Pilot Qualifications

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- The pilot must possess at least a commercial rotorcraft rating. An instrument helicopter rating is required for pilots completing flights under instrument flight rules (IFR) and is encouraged for all others
- The pilot in command must possess 2000 total flight hours or total flight hours of at least 1500 hours and recent experience that exceeds the operator's pre-hire qualifications such as current air medical and/or search and rescue experience or ATP rated, prior to an assignment with a medical service with the following stipulations:
  - A minimum of 1200 helicopter flight hours
  - At least 1000 of those hours must be PIC in rotorcraft (500 hr may be in tiltrotor)
  - 100 hours unaided (if pilot is not assigned to an NVG base/aircraft)
  - 50 hours unaided if the pilot has 100 hours aided (if assigned to an NVG base/aircraft)
  - A minimum of 500 hours of turbine time—1000 hours of turbine time strongly encouraged
- ATP certificate and instrument currency strongly encouraged

05.04.03 Pilot Qualifications

AAQPS
Air Ambulance Quality and Patient Safety

- As an alternative to the flight hours in 05.04.03 2. a program may develop and submit a Pilot in Command (PIC) Experience Evaluation Tool
- The tool should evaluate a pilot's education, training, and experience to determine if that pilot has the necessary background and experience to be a safe and effective PIC, taking into consideration the program's operation needs, scope of serve, service area, airframe type, operational environment, etc.
- To be considered as an alternative to meeting the Standard, the program must submit a CAMTS Class Two Report of Change along with the Evaluation Tool
- Once accepted, the effectiveness of the tool must be evaluated as part of the program's quality management process
- The tool will be specific to the program, however an example that can be used as a starting point can be found in Addenda C

Prepare for Unexpected Challenges

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Medicine and transport are two professions that rely on standardized processes and procedures. Striving to meet compliance with standards through a process such as accreditation propels a medical transport service into a dynamic flow of performance improvement and benchmarking with a committed purpose and a focus on the future.

camts
Commission on Accreditation of Medical Transport Systems

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GLOBAL camts
Commission on Accreditation of Medical Transport Systems

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Switzerland

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Air Ambulance Quality and Patient Safety

NEMSIS Overview and Report-out on Current Data and Gaps in Data

Eric Chaney, EMS Specialist NTHSA, OEMS

Clay Mann, Principal Investigator, NEMSIS TAC

The National EMS Information System

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Air Ambulance Quality and Patient Safety

- The National EMS Information System (NEMSIS) provides standardized EMS documentation and data collection practices to facilitate the sharing of EMS data with local, state, and national organizations

National EMS Data Standard

NEMSIS v3 Web Services Guide

NEMSIS V3 Schematron Guide

Legend

Dataset Level: N National S State D Deprecated

Usage: M = Mandatory , R = Required , E = Recommended, or O = Optional

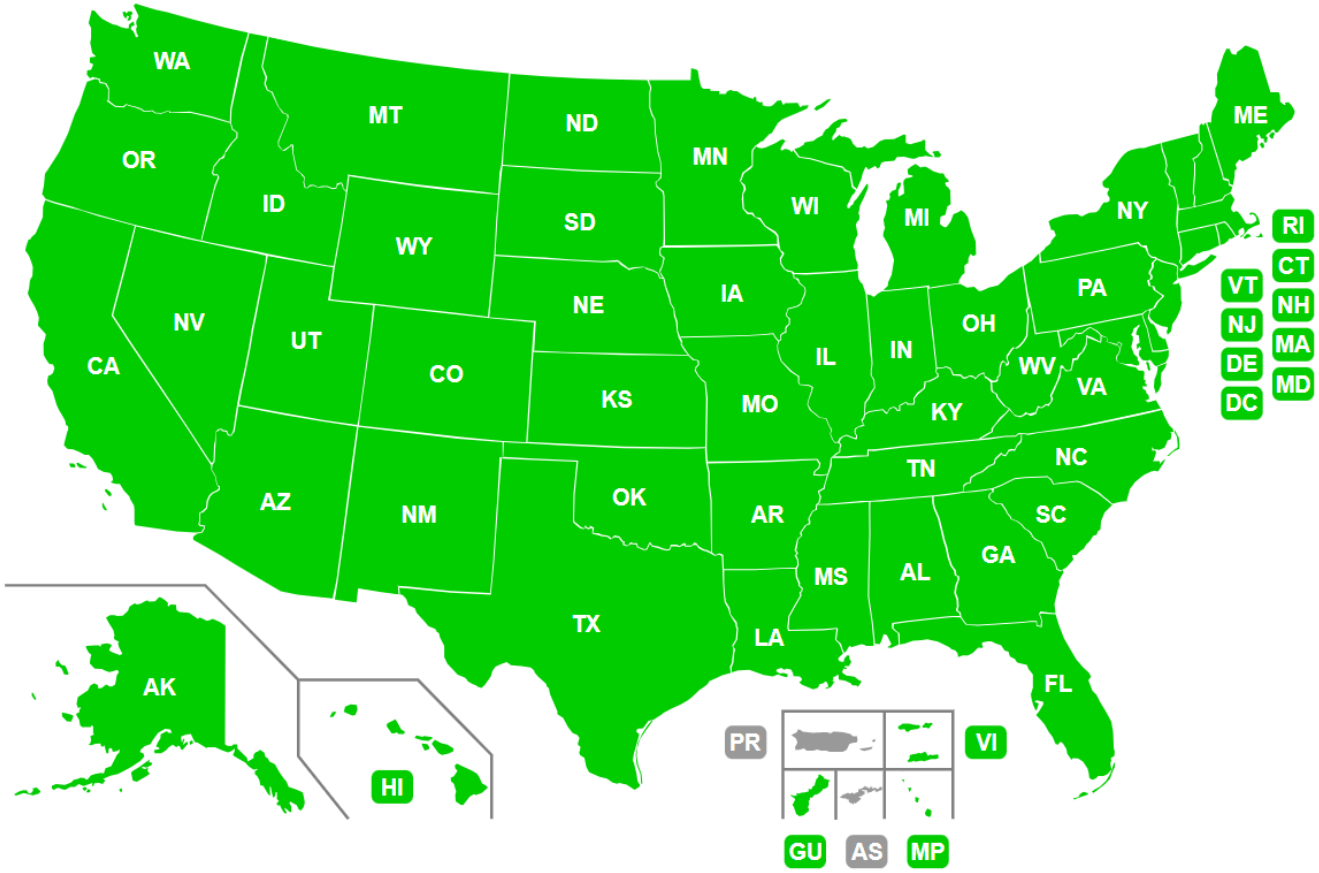
Attributes: N = Not Values, P = Pertinent Negatives , L = Nillable, and/or C = Correlation ID

eVitals

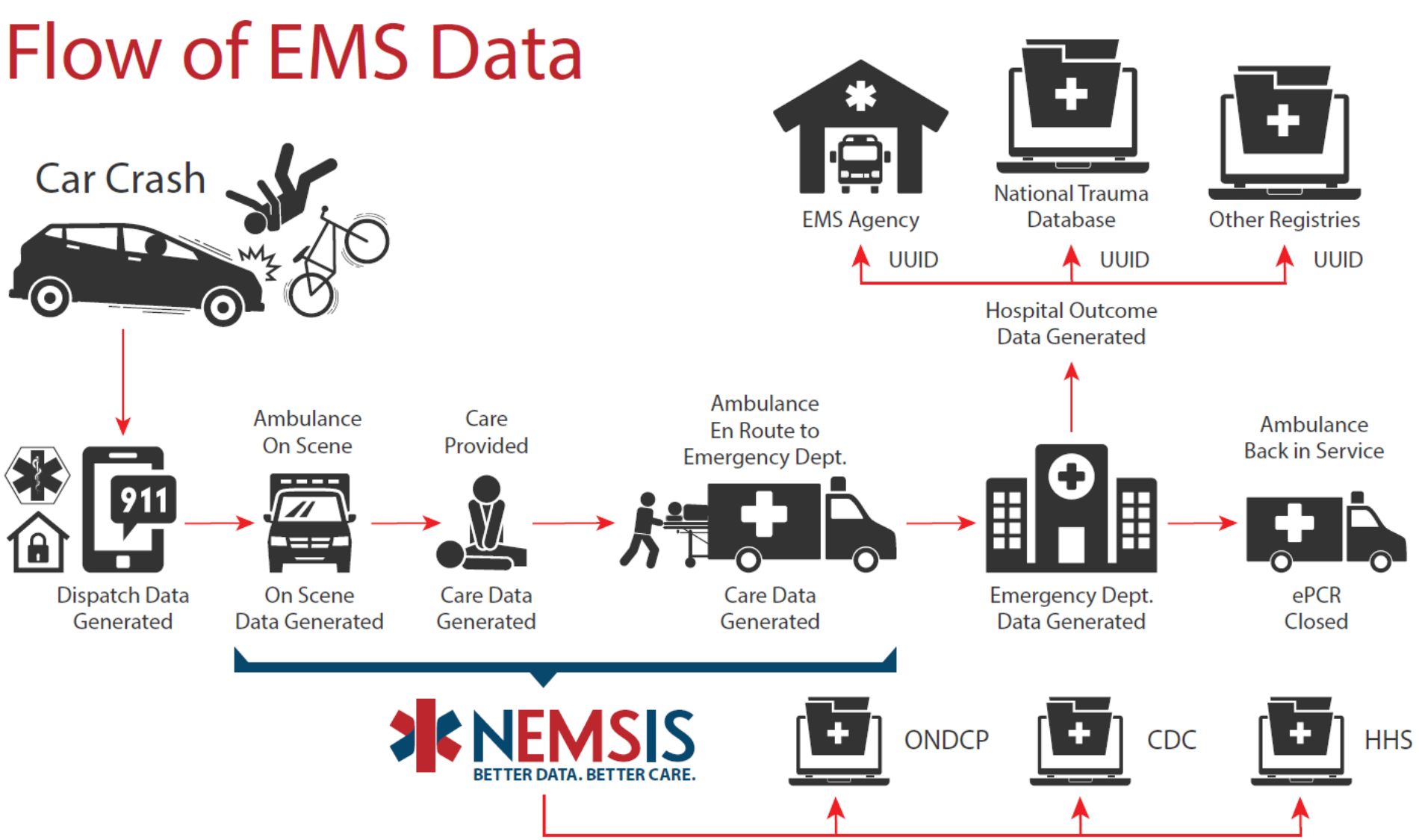
1 : M	eVitals.VitalGroup								C
1 : 1	eVitals.01 - Date/Time Vital Signs Taken	N	S	R				N, L	
1 : 1	eVitals.02 - Obtained Prior to this Unit's EMS Care	N	S	R				N, L	
1 : 1	eVitals.CardiacRhythmGroup								C
1 : M	eVitals.03 - Cardiac Rhythm / Electrocardiography (ECG)	N	S	R				N, L, P	C
1 : 1	eVitals.04 - ECG Type	N	S	R				N, L	
1 : M	eVitals.05 - Method of ECG Interpretation	N	S	R				N, L	C
1 : 1	eVitals.BloodPressureGroup								
1 : 1	eVitals.06 - SBP (Systolic Blood Pressure)	N	S	R				N, L, P	
0 : 1	eVitals.07 - DBP (Diastolic Blood Pressure)	S	E					N, L, P	
1 : 1	eVitals.08 - Method of Blood Pressure Measurement	N	S	R				N, L	
0 : 1	eVitals.09 - Mean Arterial Pressure	O							
1 : 1	eVitals.HeartRateGroup								
1 : 1	eVitals.10 - Heart Rate	N	S	R				N, L, P	
0 : 1	eVitals.11 - Method of Heart Rate Measurement	O							
1 : 1	eVitals.12 - Pulse Oximetry	N	S	R				N, L, P	
0 : 1	eVitals.13 - Pulse Rhythm	O							
1 : 1	eVitals.14 - Respiratory Rate	N	S	R				N, L, P	
0 : 1	eVitals.15 - Respiratory Effort	O							
1 : 1	eVitals.16 - End Tidal Carbon Dioxide (ETCO2)	N	S	R				N, L, P	
0 : 1	eVitals.17 - Carbon Monoxide (CO)	S	E					N, L, P	
1 : 1	eVitals.18 - Blood Glucose Level	N	S	R				N, L, P	
1 : 1	eVitals.GlasgowScoreGroup								
1 : 1	eVitals.19 - Glasgow Coma Score-Eye	N	S	R				N, L, P	
1 : 1	eVitals.20 - Glasgow Coma Score-Verbal	N	S	R				N, L, P	
1 : 1	eVitals.21 - Glasgow Coma Score-Motor	N	S	R				N, L, P	
1 : M	eVitals.22 - Glasgow Coma Score-Qualifier	N	S	R				N, L	C
0 : 1	eVitals.23 - Total Glasgow Coma Score	S	E					N, L, P	

Participating States and Territories

AAQPS
Air Ambulance Quality and Patient Safety



Flow of EMS Data



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Near Real-Time Data Exchange

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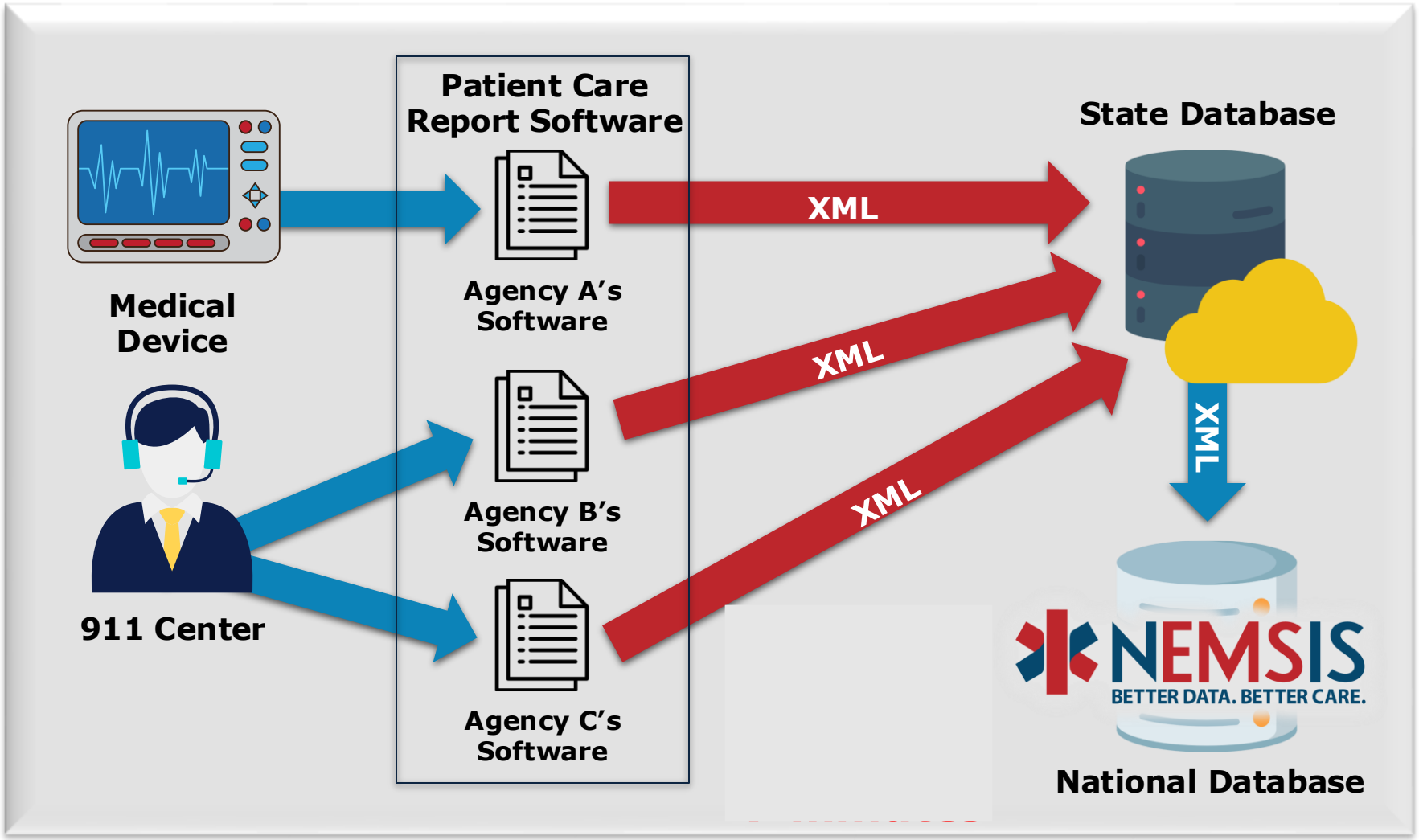

Submission Lag 25% (hours)	18.8
Submission Lag 50% (hours)	30.4
Submission Lag 75% (hours)	67.1

NEMSIS 2023 Air-Medical Frequencies

AAQPS
Air Ambulance Quality and Patient Safety

Primary Role of the Unit	
	Frequency
Air Transport-Helicopter	272,790
Air Transport-Fixed Wing	48,991

eResponse.07 - Primary Role of the Unit

Definition

The primary role of the EMS unit which responded to this specific EMS event

National Element	Yes	Pertinent Negatives (PN)	No
State Element	Yes	NOT Values	No
Version 2 Element	E02_05	Is Nillable	No
Usage	Mandatory	Recurrence	1 : 1

Associated Performance Measure Initiatives

Airway Cardiac Arrest Pediatric Response STEMI Stroke Trauma

Code List

Code	Description
2207003	Ground Transport
2207005	Non-Transport Administrative (e.g., Supervisor)
2207007	Non-Transport Assistance
2207009	Non-Transport Rescue
2207011	Air Transport-Helicopter
2207013	Air Transport-Fixed Wing

"Type of Service Requested" by "Primary Role of the Unit"			
Type of Service Requested	Primary Role of the Unit		
	Air Transport-Helicopter	Air Transport-Fixed Wing	Total
Emergency Response (Primary Response Area)	92,538	6,117	98,655
Emergency Response (Intercept)	2,855	594	3,449
Hospital-to-Hospital Transfer	171,186	37,573	208,759
Other Routine Medical Transport	4401	4,049	8,450
Emergency Response (Mutual Aid)	462	26	488
Public Assistance	1266	604	1,870
Standby	82	28	110
Total	272,790	48,991	321,781

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eResponse.05 - Type of Service Requested

Definition

The type of service or category of service requested of the EMS Agency responding for this specific EMS event.

National Element	Yes	Pertinent Negatives (PN)	No
State Element	Yes	NOT Values	No
Version 2 Element	E02_04	Is Nillable	No
Usage	Mandatory	Recurrence	1 : 1

Associated Performance Measure Initiatives

Airway Cardiac Arrest Pediatric Response STEMI Stroke Trauma

Code List

Code	Description
2205001	911 Response (Scene)
2205003	Intercept
2205005	Interfacility Transport
2205007	Medical Transport
2205009	Mutual Aid
2205011	Public Assistance/Other Not Listed
2205013	Standby

eScene.09 - Incident Location Type

Definition

The kind of location where the incident happened.

National Element	Yes	Pertinent Negatives (PN)	No
State Element	Yes	NOT Values	Yes
Version 2 Element	E08_07	Is Nillable	Yes
Usage	Required	Recurrence	1 : 1

Associated Performance Measure Initiatives

Airway Cardiac Arrest Pediatric Response STEMI Stroke Trauma

Attributes

NOT Values (NV)
7701001 - Not Applicable 7701003 - Not Recorded

Constraints

Pattern
Y92\.[0-9]{1,3}

"Incident Location Type" by "Primary Role of the Unit"			
Incident Location	**Primary Role of the Unit**		
	Air Transport-Helicopter	**Air Transport-Fixed Wing**	**Total**
Private Residence	608	107	715
(PR type)	750	68	818
(PR type)	615	3	618
(PR type)	838	49	887
(PR type)	7,471	583	8054
Hospital	182,720	42,315	225,035
(H type)	1,220	12	1,232
Public Building	628	1	629
(PB type)	2,539	31	2,570
Athletic Field	786	7	793
Street/Highway	942	19	961
(SH type)	8,593	196	8,789
(SH type)	1,840	11	1,851
(SH type)	1,512	2	1,514
(SH type)	4,403	2,254	6,657
Doctor Office	903	681	1,584
Farm	627	8	635
Transport vehicle	24,548	218	24,766
(TV type)	773	10	783
(TV type)	934	3	937
Campsite	1,363	8	1,371
Railroad Track	1,012	14	1,026
Wilderness	3,454	45	3,499

Submitting State	Primary Role of the Unit		
	Air Transport-Helicopter	Air Transport-Fixed Wing	Total
AK	569	3,686	4,255
AL	6,548	33	6,581
AR	7,143	362	7,505
AZ	8,511	2,664	11,175
CA	13,186	1,916	15,102
CO	6,718	3,426	10,144
CT	1,207	29	1,236
DC	1,971	35	2,006
DE	1,981	0	1,981
FL	19,188	904	20,092
GA	12,361	238	12,599
HI	318	0	318
IA	5,329	14	5,343
ID	2,100	708	2,808
IL	9,233	122	9,355
IN	5,415	66	5,481
KS	4,645	2,750	7,395
KY	10,482	66	10,548
LA	4,798	32	4,830
MA	3,731	269	4,000
MD	2,208	80	2,288
ME	1,580	406	1,986
MI	2,238	609	2,847

Submitting State	Primary Role of the Unit		
	Air Transport-Helicopter	Air Transport-Fixed Wing	Total
NM	3,144	4,651	7,795
NV	3,059	834	3,893
NY	5,653	272	5,925
OH	2,595	323	2,918
OK	5,451	418	5,869
OR	5,484	2,525	8,009
PA	21,754	20	21,774
RI	18	76	94
SC	4,613	72	4,685
SD	1,838	4,739	6,577
TN	8,949	241	9,190
TX	7,332	2,068	9,400
UT	4,170	1,226	5,396
VA	10,100	33	10,133
VT	2	1	3
WA	7,441	4,080	11,521
WI	6,279	90	6,369
WV	2,025	7	2,032
WY	2,107	2,545	4,652
Total	272,790	48,991	321,781

Air Agency Count and 2024 Events (to date)

AAQPS
Air Ambulance Quality and Patient Safety

Submitting State	Air Agency Count	Event Count
AK	10	6,180
AL	40	6,694
AR	31	5,499
AZ	13	14,824
CA	39	53,769
CO	21	13,384
CT	3	36,735
DC	2	2,980
DE	3	2,218
FL	15	23,775
GA	6	10,332
IA	12	3,312
ID	4	5,196
IL	14	6,767
IN	12	10,937
KS	16	7,089
KY	3	5,888
LA	5	1,740
MA	3	6,004
MD	1	1,685
ME	2	2,582
MI	8	3,009
MN	10	9,134
MO	14	8,371
MS	11	1,211
MT	14	5,187
OR	4	4,578
PA	4	577
SC	11	3,554
SD	7	6,856
TN	7	609
TX	72	32,023
UT	12	4,397
VA	12	7,077
WA	3	12,865
WI	6	4,175
WV	5	4,779
WY	6	2,402

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Questions?

Connect with NEMSIS

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- Facebook: https://www.facebook.com/NemsisTac
- Twitter: http://www.twitter.com/NEMSISTAC
- LinkedIn: https://www.linkedin.com/company/nemsis
- YouTube: https://www.youtube.com/c/NEMSISTAC

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Committee Discussion

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Break

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Public Comments

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Flight Safety Discussion

10/12/2024

2024 Air Ambulance Quality Patient Safety Tasking

Federal Aviation Administration

Air Ambulance Quality and Patient Safety

- The Department of Transportation (DOT) in coordination with the Department of Health and Human Services (HHS) proposed a new AAQPS task to make recommendations in response to “The No Surprises Act” (Section 106(g)), as part of the Consolidated Appropriations Act, 2021, Public Law (Pub. L.), 116-260.

Air Ambulance Quality and Patient Safety

- Congress directed DOT and HHS to establish the AAQPS to provide recommendations to the Secretary of Health and Human Services and the Secretary of Transportation on options to establish quality, patient safety, and clinical capability standards for each clinical capability level of air ambulances.
- The Committee, in consultation with relevant experts and stakeholders, as appropriate, shall develop and make publicly available a report on any recommendations submitted to Congress. The report must be developed and made publicly available no later than 180 days after the date of the Committee's first meeting.

Air Ambulance Quality and Patient Safety

- **The Flight Safety Subcommittee is tasked with:**
  - Identifying any potential regulatory, guidance, and operational gaps that are applicable to air ambulance operations (e.g., Subpart L of Part 135, AC 135-14B, AC 135-15).
  - Providing recommendations addressing the following but not limited to:
    - Options for improving service reliability during poor weather, night conditions, or other adverse conditions. This should include but not limited to items such as weather reporting, landing zones (LZ), infrastructure, maintenance reliability, aircraft availability, operational control centers, Visual Flight Rules and Instrument Flight Rules minimums, and night operations (helipad vs. LZ).

Air Ambulance Quality and Patient Safety

- **Improving service reliability :**
  - Some areas of air ambulance operations that exist may need improvements or do not exist and may need to be added to increase service reliability.
  - Examples of areas for consideration:
    - Weather reporting
    - Landing Zones (from ground and flight crew perspectives)
    - Maintenance Reliability
    - Helicopter Availability
    - Flight Following potential impacts
    - VFR and IFR Minimums
    - Night operations (helipad vs. LZ)
  - What are greatest impact to fixed-wing air ambulance operations?

Air Ambulance Quality and Patient Safety

- **The subcommittee is also tasked with:**
  - Providing recommendations addressing the following but not limited to:
    - Differences between air ambulance vehicle types, services, and technologies, and other flight capability standards, and the impact of such differences on patient safety. When evaluating these differences, the recommendations should be categorized by type of aircraft conducting the air ambulance service (e.g., airplane, helicopter, powered-lift) with special emphasis placed on services provided (e.g., off-airport to helipad transportation versus airport-to-airport transportation).

Air Ambulance Quality and Patient Safety

- The subcommittee should pay particular attention to any technology or equipment an air ambulance utilizes. Specifically, describe how the safety benefits from the technology or equipment would justify the costs.
- The subcommittee should describe the mechanism (i.e., through policy, rulemaking, guidance material, operator specific training, or other mechanisms identified by the Subcommittee) that the FAA should consider for implementing the recommendations.

Air Ambulance Quality and Patient Safety (AAQPS)

- The Flight Safety Subcommittee should utilize interdependency and critical thinking to collaborate with the Clinical Standards Sub-Committee to enhance flight safety, patient safety, and service reliability.
- The subcommittee should describe the mechanism (i.e., through policy, rulemaking, guidance material, operator specific training, or other mechanisms identified by the Subcommittee) that the FAA should consider for implementing the recommendations.

Federal Aviation and Air Ambulance Regulations

Questions?

AAQPS
Air Ambulance Quality and Patient Safety

Committee Discussion

AAQPS
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Clinical Standards Discussion

Clinical Standards Subcommittee

AAQPS
Air Ambulance Quality and Patient Safety

- The Clinical Standards Subcommittee is tasked with:
  - Identifying any potential statutory, regulatory, guidance, and clinical standards gaps that are applicable to air ambulance clinical standards and quality
- Providing recommendations addressing the following:
  - Qualifications for different clinical capability levels and tiering of such levels
  - Patient safety and quality standards
  - Clinical triage criteria for air ambulances

Qualifications for Different Clinical Capability Levels and Tiering

AAQPS
Air Ambulance Quality and Patient Safety

- This may include considerations related to:
  - Specialty care versus critical care
  - Regional certification requirements and cross state regulatory rules
  - Specialty certification requirements
  - Scope of care and crew composition

Patient Safety and Quality Standards

AAQPS
Air Ambulance Quality and Patient Safety

- This may include considerations related to:
  - Infection prevention and control
  - Communication and coordination with receiving medical facilities
  - Standards of clinical care in the field
  - Outcomes of care and accountability
  - Readiness capabilities

Clinical Triage Criteria for Air Ambulances

AAQPS
Air Ambulance Quality and Patient Safety

- This may include considerations related to:
  - Triaging systems currently available and used
  - Overtriaging and undertriaging
  - Triage standardization

AAQPS
Air Ambulance Quality and Patient Safety

Committee Discussion

Final Reflections

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- Committee final reflections and recommendations for future discussion topics
- Future meeting dates
  - February 18, 2025, 10am-5pm ET (virtual)
  - May 8, 2025, 10am-5pm ET (virtual)
  - Agendas for future meetings will be made public
- Email AAQPS@cms.hhs.gov to provide additional comments

AAQPS
Air Ambulance Quality and Patient Safety

Thank you!