A Comparison of Risk Evaluation in Emergency Medical Services Helicopter Operation Regulations

Joseph P. McLaine

Terry L. von Thaden

A COMPARISON OF RISK EVALUATION IN EMERGENCY MEDICAL SERVICES HELICOPTER OPERATION REGULATIONS

Joseph P. McLaine
Human Factors Division, Institute of Aviation
University of Illinois at Urbana-Champaign
Savoy, IL

Terry L. von Thaden, PhD
Human Factors Division, Institute of Aviation
University of Illinois at Urbana-Champaign
Savoy, IL

This study represents a comparison of Helicopter Emergency Medical Services (HEMS) operations, between US Federal Aviation Regulations (FARs), and European Joint Aviation Regulations Operations Specifications. Presently, US regulations allow HEMS operators to conduct work under FAR Part 135, Commercial Aviation Operations, or under FAR Part 91, General Aviation Operations. This allows HEMS operators to accept a greater level of risk by substituting lower minimum procedural standards under FAR Part 91 than under FAR Part 135, and may be partly culpable for a higher rate of fatal crashes in HEMS operations conducted under FAR Part 91. In stark contrast, explicit criteria and minimum operating considerations are stated in the European regulations. The Federal Aviation Administration (FAA) has been slow to take a similar clear and firm regulatory stance as that of its European counterpart regarding the human factors involved in the risk assessment of HEMS operations. Providing clearly defined steps to analyze and mitigate unnecessary threats, developing optimum performance guidelines, as well as minimum acceptable operational standards would benefit not only the US HEMS industry but also the patients and public it serves by reducing exposure to preventable dangers.

Introduction

The importance of rotary-wing and vertical flight air transport in critical life-support missions (e.g. helicopter transport) has been well documented (Baker et. al, 2006; Gisvold, 2002; Brathwaite et. al, 1998). Additionally, major natural disasters such as hurricanes, wildfires or floods, have forced Emergency Management authorities to employ helicopters in the rescue of citizens from otherwise unnavigable terrain. The ability of rotary-wing aircraft to provide platforms while hovering, or to land in tight spots where fixed-wing aircraft would otherwise be unable to operate, prove their worth in saving lives. In recent years there have been numerous products designed specifically to assist with the operational safety of this vital service, including radar altimeters, weather radar and wire-strike prevention kits. However, over the past ten years, even as airframes and the technology used by aircrews have improved, the rate of fatal crashes in emergency medical services helicopters (HEMS) in the United States has risen significantly (Baker et. al, 2006).

The vast majority of fatal HEMS crashes are categorized as result of Controlled Flight Into Terrain (CFIT) accidents, such as continuance of flight into rapidly deteriorating weather and/or unaided flight

during low visibility conditions (e.g., night). A recent National Transportation Safety Board (NTSB) Aviation Special Investigation Report on Emergency Medical Services Operations identified several issues regarding training, decision-making, and policy in HEMS operations (NTSB, 2006). Top among these issues were the safety recommendations that all HEMS operations comply with commercial operation specifications when medical personnel are onboard, risk evaluation programs, and formalized dispatch and flight following procedures.

Within the 2006 NTSB special report, Board members stated that even though the HEMS industry is booming, there is no data regarding the exact number, type or mission summaries of HEMS operators in the United States (NTSB, 2006a). The HEMS industry has undergone a burgeoning expansion in this country since the early 1990s, akin to airline deregulation in the late 1970s. The number of accidents has nearly doubled during this rapid period of growth (Baker, 2006; NTSB 2006a). While there are approximately 650 EMS helicopters operating in the US, there appears to be sparse data on the number of outfits providing HEMS services to the nation's hospitals. According to a recent study by McKenna and Nelms (2005), the EMS marketplace can best be described as "unsettled." A large number of independent or stand-alone programs have commenced operations unaffiliated with any hospital or medical establishment. It has been primarily these operators who have fueled the industry's explosion in recent years. The study further asserts that the HEMS sector serves as a "pressure cooker," and the stress is a result of competition between operators. The tremendous increase in the number of HEMS operators has over-saturated the available need for emergency helicopter transport. Several studies have addressed aspects such as operational control, risk assessment procedures, and expert collaboration on whether immediate vertical evacuation requires (or justifies) the added expense and risk of HEMS operations (Baker, et al, 2006; Brathwaite et. al, 1998).

While hospitals may appreciate the ever-present ability to choose one or several HEMS operators when emergency air transport may be required, several questions remain concerning whether patients could be transported just as quickly, and possibly safer, via ground ambulance. Even though the HEMS industry provides a crucial benefit to many citizens, especially those in rural areas and far from available medical care, the service is dramatically over utilized. Fueling this argument are studies analyzing air ambulance transport as it affects the ultimate survival of trauma patients (Chappell, et al., 2002; Brathwaite, et al., 1998). The authors concluded that HEMS transport did not affect the estimated overall odds of survival and proposed a reappraisal of the cost-effectiveness and transport criteria when ground assets are also available.

Understandably, the desire of both hospitals and HEMS companies has been to improve the financial outcome of operations, but unfortunately the desire to cut costs has led to aggressive HEMS practices among some operators in the industry. As an illustration, a successful HEMS mission flown in a $4 million Instrument Flight Rules (IFR)-equipped helicopter with all of the niceties and safety features the company could install on the airframe earns the exact same amount per mission as a $1 million basic Visual Flight Rules (VFR)-equipped helicopter. Additionally, helicopter pilots may be inadequately paid, especially those flying for independent outfits. Instead of salaried positions, available with a select few HEMS operators, the majority of HEMS pilots are paid by the number of missions completed.

Not only are helicopters inherently unstable airframes and more dangerous platforms than their fixed-wing counterparts, their rescue missions involve much more dangerous hazards (Durnford, et al., 1995; Braithwaite, 1997). HEMS missions are often flown at night, into unfamiliar locations, oftentimes in poor/deteriorating weather, and close to the ground, 0-500' Above Ground Level (AGL) (Murdock, 1997). Wires, antennae and other dangerous terrain features at such low altitudes increase the danger for helicopter pilots.

The Federal Aviation Administration (FAA) has acknowledged concerns about the HEMS industry, and has taken steps to improve the training and awareness of pilots, dispatchers, EMS flight crews, nurses, doctors and other attending personnel beginning with a special task force in 2004 (FAA, 2006a). In a fact sheet released January 2006, the FAA proposed a partnership to improve the safety culture at EMS operators and recommended short- and long-term strategies for accident reduction (FAA, 2006a). However, the FAA has delayed issuing rule changes to the FARs, choosing instead to work within the existing regulations. The FAA's stated immediate focus includes risk management training for all HEMS flight crews, and provision of "airline-type FAA oversight" through identifying regional HEMS operational hubs (FAA, 2006a). Important safety issues such as clearly defined HEMS weather minimums, equipment/crew requirements for HEMS operators, and guidelines for determining the necessity of air evacuation have yet to be addressed.

In fact, it appears there may be resistance and even industry pressure on the FAA to avoid enhancing regulatory oversight of the HEMS industry. In a publicly released whitepaper the Helicopter Association International (HAI), addresses the issues of increased regulation and states their vehement opposition to such requirements with statement such as:

> "Wide sweeping and arbitrary mandates of equipage or aircraft capabilities of questionable efficacy, or similar broad-brush interventions are not appropriate and do not recognize the varied environment, needs and requirements of individual operators in various regions or operating conditions" (HAI, 2005:3).

Ambiguous Regulations. HEMS operations are covered under Title 49 of the Code of Federal Regulations, FAR Part 135: Commuter and On Demand Operations (FAA, 2006b). Specifically, HEMS regulations are addressed in a single section, 135.271, which covers only duty-day and flight hour restrictions for aircrews. Other sections within FAR Part 135 address strict weather minimums and define several equipment requirements for certificated operators. However, as currently written, HEMS operations are required be conducted under FAR Part 135 *only* when a patient is actually transported; otherwise HEMS operations may be conducted under FAR Part 91: General Operating & Flight Rules, which is significantly less restrictive in terms of weather and defined equipment minimums, especially in uncontrolled airspace (see Table 1 for a comparison of FAR Parts 135 and 91). This gap in regulatory oversight effectively allows HEMS pilots, owners and dispatchers to select which regulatory minimums they wish to comply with during almost any segment of the mission. For example, a HEMS operator could legally take off from their home station with marginal Visual Meteorological Conditions (VMC), and remain under VFR as defined by FAR Part 91 while enroute to an accident scene. Only after collecting the patient(s) would they be required to apply the more stringent operational minimums for weather and crew duty considerations required under FAR Part 135. In actuality, even the Government Accountability Office (GAO) recognizes that a HEMS flight could consist of three distinct, separate legs, each with their attendant regulations and safety considerations: 1) positioning from base to patient pickup (Part 91); 2) patient transport (Part 135); and 3) repositioning back to base (GAO, 2007). Following this logic, there could easily be twice as many flights conducted under the less stringent regulations of Part 91 than under Part 135.

Table 1. Comparison of FAR Parts 91 and 135

	Part 91	**Part 135**
Weather and Visibility Minimums	"Clear of Clouds" (≤ 1200'AGL in Uncontrolled Airspace)	½ mile vis (DAY) 1 mile vis (NIGHT) when flying ≤ 1200' AGL
Equipment Req'd	Basic VFR / IFR Requirements	Specified for each certificate holder
Duty Period	**N/A**	No more than 8 hrs of flight time in 24 consecutive hrs
Crew Rest	**N/A**	10 consecutive hrs preceding / 8 consecutive hrs during any 24
Other	PIC must have "adequate opportunity to see any air traffic or obstruction in time to avoid a collision."	Mandates visual reference to the ground (DAY), and visual reference to surface lights (NIGHT)

The FAA has also published a series of Operational Specifications (OpSpecs) for certificated commercial HEMS operators Under FAR Part 119 (FAA, 2006b), yet these OpSpecs mainly encompass requirements for management and technical personnel. This ambiguity presents an opportunity for both pilots and HEMS owner/operators alike to circumvent the FAA's objective to ensure safe practice and adequate decision-making when it comes to air transport in emergency operations. This ambiguity allows operators to avoid providing HEMS aircrews the proper psychological framing needed when making a decision to accept a mission or not.

Much of the previous research has focused on accident records, fatality reports, and other quantifiable outcomes of HEMS mishaps (Baker, et al., 2006). However, there are no available records regarding the frequency of pilots or operators launching their aircraft in unsafe conditions, only to subsequently abort, returning to base without serious incident. While not historically tracked, data on these aborted missions may allow researchers and safety professionals the opportunity to determine risk patterns and identify poor decision-making in the operational field.

In actual modern practice, HEMS pilots and owner/operators are presented with a wealth of information about weather, mission type, route planning, and operational requirements for the anticipated flight. With each additional piece of information comes an increased level of bias, which is ranked by importance of the role, expertise, and cue correlation from Long Term Memory (LTM). Situational, or suggestive, training as well as procedural and/or design remediation can be proposed to improve the institutional process of decision making (Wickens, et al, 2000). The HEMS industry is a complex web of operators, doctors, medical crews, ground support personnel, and financial backers. Each of these players has a representative sample of these biases and heuristics present when making a decision whether to launch a mission. One aspect of bias not covered in detail within the research literature involves flight crew knowledge of the specific details of the mission; does the pilot know the condition of the patient and their need for evacuation? Informing pilots of the nature of the emergency or condition of the patient certainly offers motivation to undertake a more risky course of action. By improving the type and amount of training, providing realistic situations where HEMS operators can apply new decision making schema, and by improving the decision process within the organizations themselves, the HEMS industry could see significant reductions in the fatal crash rate.

Who is the Launch Authority? The Federal Aviation Regulations are rather un-ambiguous when defining the responsibility and authority inherent in the role of aircraft Pilot in Command: "The Pilot in Command of an aircraft is directly responsible for, and is the final authority as to, the operation of that aircraft" (FAR 91.3(a)). While the pilot exerts ultimate responsibility over the flight, there is a chain of biases and influences that may emerge in his decision-making process thus clouding his judgment. However, the FAA does not explicitly address the complex and often time-critical decisions about whether or not to launch a HEMS mission. A HEMS accident discussed in the NTSB report cited a CFIT crash in Pyote, TX and listed several contributing factors including the dark night conditions, inadequate preflight planning and preparation, and pressure to complete the mission induced by the pilot because of the nature of the EMS rescue flight itself.

Yet does the decision rest solely with the pilot? Companies maintaining operational control (ownership) over various HEMS operations have not been adequately addressed in the regulations. For instance, a flight crew hired and paid by the number of actual evacuations performed would be far more likely to depart in marginal conditions with less than adequate equipment, or accept a riskier destination than a similar HEMS crew with a salaried position. There is tremendous pressure to fly HEMS missions, including corporate, competitive, situational and even pressure from other pilots in the industry. The NTSB special report quotes a pilot in Arizona as saying, "If I don't fly at least 25 missions per month, I don't get paid!" (NTSB, 2006a).

The pressure to fly is often exacerbated by the practice of hospitals simply calling whatever HEMS company is next on the list until they find one that will accept the mission. Several accident reports have noted cases where previous flight crews had refused missions because weather was not conducive to flight (NTSB, 2006). HAI maintains that:

> "…adherence to current regulations is far more effective than generating new regulations. Within the bounds of prudent standardization the individual operators should maintain the flexibility to amend their shortcomings without inheriting restrictive regulations that might be the proper solution for someone else's problem" (HAI, 2005:4).

HAI goes on to state that, "Ultimately, it is the responsibility to some extent of the FAA, but primarily of industry to take the steps necessary to enhance safety in HEMS operations" (HAI, 2005: 8). Since the HEMS industry does not adhere to a standard practice, it appears it is time for the FAA to step in and apply more stringent regulations on an industry entrusted with public welfare.

Comparing the Regulatory Stance on HEMS. In stark comparison to the US, other countries engage in a vastly different approach and stated philosophy towards HEMS operations. While each country has individual needs and regulatory bodies governing aviation in their individual airspace, most states participate in the International Civil Aviation Organization (ICAO) standards for safety, security, efficiency and regulation of civilian air transport. As the sole United Nations body charged with developing international standards for aviation safety, ICAO has very few Standards and Recommended Practices (SARPs) addressing concerns directly related to HEMS (ICAO, 2007), instead leaving the stringent governance of HEMS operations to the discretion of the owner states.

Interestingly, within the European continent, there has been a concerted effort to manage aviation safety standards and procedures through the Joint Aviation Authorities (JAA; note transition to the European Aviation Safety Agency (EASA) forthcoming). As a body of the European Civil Aviation Conference (ECAC), which is itself a collection of aviation regulatory authorities from a number of member European countries, the JAA/ECAC endeavors to harmonize their statutes closely with those from the US. The JARs make numerous specific references to HEMS operations, yet appear to be more conservative and specific in their definitions and release authority guidelines than the FAA. There are explicit definitions and lengthy descriptions of the differences between the terms "HEMS," "Air Ambulance," and "Search and Rescue-SAR" as well as a very comprehensive section on risk mitigation (JAA, 2006).

By separately defining "HEMS" and "Air Ambulance" operations, the JAR-OPS 3 regulations draw an analogy between these operations and a ground-based ambulance [emphasis added]:

> "If called to an **emergency**, an ambulance would proceed at great speed, sounding its siren and proceeding against traffic lights – thus **matching the risk of operation** to the risk of a potential death = <u>HEMS operations</u>," and "For a transfer of a patient (or equipment) where life and death...**is not an issue**; the journey would be conducted without sirens and...**matching the risk to the task** = <u>air ambulance operations</u>."(JAR OPS 3, Subpart B: 2-B-2).

The JAR-OPS make clear distinctions between HEMS/Air Ambulance, and SAR (i.e., SAR is usually conducted by police and/or military units). However, they also state that the SAR label shall not be used to circumvent the intent of the JAR-OPS 3, or to permit HEMS operations to a "lesser standard" (JAR OPS 3, Subpart B: 2-B-2.). The JAA acknowledges that HEMS operations are "performed in the public interest," and as such, merit a thorough level of control and regulation to minimize the public risk.

In stark contrast to the FAA, the JAR-OPS 3 section on HEMS states decisively that [emphasis theirs], "<u>The underlying principle is that the aviation risk should be proportional to the task</u>" (JAR OPS 3, Subpart B: 2-B-2.). The JAA even footnotes James Reason when addressing the issue of Safety Management (JAA, 2006). The European regulations expressly define concepts such as comparative risk, risk management, and the concept of a wide-ranging safety culture. The JAR-OPS 3 regulate the HEMS crew composition, duty and rest periods, reference Crew Resource Management (CRM) principles, as well as explicitly cover risk management. Additionally, the JARs describe how it is the responsibility of the medical professional (doctor) to determine between HEMS/Air Ambulance mission designation, and not the pilot's responsibility. HEMS mission designation is separate from launch authority discussed above in the FARs, but the JAR-OPS 3 also state that the "commander (PIC) makes an operational judgment over the conduct of the flight." Table 2 shows the difference between the JAR OPS regulations and the FARs.

Table 2. Comparison of HEMS Regulations

	JAR-OPS 3	**FAR Part 91 / Part 135**
Risk Management	The <u>aviation risk</u> must be **proportional to the task**	**N/A**
Crew Required	<u>At least</u> a Pilot and a HEMS Crewmember occupying the two front seats at all times	**N/A**
Definition of HEMS & Air Ambulance	Comparative/potential risk must only be to a level appropriate to the task	**N/A**
Equipment Requirements	HEMS aircraft must <u>all</u> meet stringent IFR equipment requirements	**N/A**
Launch Authority	HEMS designation from a medical professional, and conduct of flight remains with commander (PIC)	Ultimately PIC, but fails to address other operational considerations within industry

It is interesting to note the actual differences in the regulations between the FAA and the JAA in regard to HEMS operations. The safety of "third party" non-flying citizens on the ground, patients, as well as aircrews is of utmost concern to the JAA. While the Europeans have thoroughly addressed HEMS safety and risk considerations, as well as maintained a very conservative threshold towards its application, it appears as almost an afterthought in the US regulations.

Rather than focusing on proactive efforts to improve safety in the US HEMS community, there appears to be regulatory stagnation and irresponsibility. The Air Medical Resource Management (AMRM) program, a version of CRM that integrates pilots, medical crew, and ground communications specialists, in the HEMS decision making cycle has been proposed to the FAA (McKenna, 2005). While this AMRM guidance was created for the FAA, they have not yet publicly endorsed the practice. However, numerous proactive HEMS operators have adopted the AMRM concept on their own. Additionally, the FAA's proposals and guidance for increased training and inspection of HEMS procedures have failed to address the most significant problems facing the industry: fostering a culture of safety and a deterministic decision-based community of pilots, aircrews, owners, and medical crews on the ground.

Recommendations

An enhanced regulatory posture for HEMS operations by the US government is strongly suggested. Regulations addressing the specific risk considerations to HEMS operations, as well as requirements for certification, including training, equipment, operational oversight, and launch authority would clarify what is now ambiguous in the regulations in use today. In addition, the regulations need to clearly address stringent weather minimums for HEMS operations, including provisions for forecast weather, especially when planning flights in uncontrolled airspace. Regardless of how many FAA Notices are published; the regulation is the bottom line. HES operations should be conducted under FAR Part 135 and HEMS aircraft should be crewed by at least two qualified members in the front seats to assist with obstacle detection and avoidance, communication and navigation, as is mandatory in the JAR OPS specifications. Minimum equipment specifications and aircrew training is also recommended in accordance with JAR OPS specifications.

Risk assessment and evaluation programs, including all employees associated with the HEMS mission, from dispatcher to doctor, should also be adopted. These decision making tools would allow critical analysis, undertaken by the all of the players involved in the decision, of conditions that pose a hazard to the successful completion of flights. In addition, decision support should be provided regarding predetermined levels of risk commensurate with the potential payoff gained in patient safety and hospital care for launching an aircraft in support of a mission. The goal would be to utilize HEMS in only the most serious of conditions.

Helicopter air transport is a critical feature of our Nation's healthcare system, but the rise in accident rates in recent years demonstrates a need to take a very critical look at all aspects of the overall HEMS flight risk to the American public. Any critical analysis of the HEMS industry in this country must not separately consider the regulations, the aircraft, or the individuals making the launch decisions; a comprehensive review demands consideration of the comprehensive picture in order to gain an appreciation for the complexities and challenges facing HEMS operations.

References

Baker, S., Grabowski, J., Dodd, R., Shanahan, D., Lamb, M., and Li, G. (2006). EMS helicopter crashes: What influences fatal outcome? *Annals of Emergency Medicine,* 47(4), 351-356.

Brathwaite, C., Rosko, M., McDowell, R., Gallagher, J., Proenca, J. and Spott, M. (1998). A critical analysis of on-scene helicopter transport on survival in a statewide trauma system. *Journal of Trauma-Injury Infection and Critical Care*, 45(1), 140-146.

Braithwaite, M. (1997). A Review of U.S. Army Helicopter Accidents, 1987-1995. *USAARL Report 97-13*

Chappell, V.L. MD, Mileski, W.J. MD, Wolf, S.E. MD, Gore, D.C. MD. (2002). Impact of discontinuing a hospital-based air ambulance service on trauma patient outcomes. *Journal of Trauma-Injury Infection & Critical Care,* 52(3), 486-491.

Durnford, S.J., Crowley, J., Rosado, N., Harper, J., and DeRouche, S. (1995). Spatial Disorientation: A Survey of U.S. Army Helicopter Accidents. *USAARL Report 95-25.*

Federal Aviation Administration (2006a). Fact Sheet on EMS Helicopter Safety.

Federal Aviation Administration (2006b). *Title 49 Code of Federal Regulations, Federal Aviation Regulations*. Downloaded 11/06/2006 from: http://www.airweb.faa.gov/Regulatory_and_Guidance_Library/rgFAR.nsf/.

Gisvold, S.E. (2002). Helicopter emergency medical service with specially trained physicians – does it make a difference? *Acta Anaesthesiologica Scandinavica* 46, 757-758.

Helicopter Association International (HAI). (2005). Improving safety in helicopter emergency medical service (HEMS) operations. Helicopter Association International: Alexandria, August.

Joint Aviation Authority (JAA). (2006). *Joint Aviation Regulations – The JAA HEMS philosophy*. JAR-OPS 3 Subpart B.

McKenna, J. and Nelms, D.W. (2005). Staying safe and healthy. *Rotor and Wing,* 39(10), 26-32.

Murdock, M. and Braithwaite, M. (1997). Reining in a Hazard. *U.S. Army Safety Center FlightFax,* 25(7), 2-4.

National Transportation Safety Board (2006). *Special Investigation Report on Emergency Medical Services Operations.* Report No. SIR-06/01. Washington DC: Author.

National Transportation Safety Board (2006a). Emergency medical services helicopter accident near Pyote, Texas, March 21, 2004. NTSB ID # FTW04FA097.
http://www.ntsb.gov/ntsb/brief2.asp?ev_id=20040325X00375&ntsbno=FTW04FA097&akey=1

O'Hare, D. (2003). Aeronautical Decision Making: Metaphors, Models and Methods. *In P. Tsang & M. Vidulich (eds) Principles and Practice of Aviation Psychology,* pp201-238. NJ: Lawrence Erlbaum Associates.

Orasanu, J. and Martin, L. (1998). Errors in aviation decision making: a factor in accidents and incidents. *Proceedings of the Workshop on Human Error, Safety, and Systems Development,* pp. 100-107, April, Seattle, WA.

International Civil Aviation Organization (2007). http://www.icao.int/

U.S. Army Combat Readiness (Safety) Center Website. ASMIS-1 (Army Safety Management Information System) https://crc.army.mil/home/

U.S. Government Accountability Office (2007). *Improved Data Collection Needed for Effective Oversight of Air Ambulance Industry*. GAO-07-353. Washington DC: Author.

Wickens, C. and Hollands, J. (2000). *Engineering Psychology and Human Performance* (3rd Edition). NJ: Prentice Hall.