The Moebus Aviation Report on "Scientific and Medical Evaluation of Flight Time Limitations": Invalid, Insufficient, and Risky

Alertness Solutions

January 2009

Introduction

Fatigue has been identified as a relevant and significant safety issue in a diverse range of operational environments, including all modes of transportation, healthcare, public safety, and manufacturing. Fatigue is a complex issue. An extensive scientific literature clearly demonstrates that fatigue related to sleep and circadian disruption reduces alertness and performance, and increases the risk and occurrence of errors, incidents, and accidents. As noted in the Moebus Aviation Report (MAR), the expert panel identifies a range of fatigue factors, including: extended time awake, reduced prior sleep, window of circadian low, cumulative issues, task, and other considerations.

While the extensive scientific literature on fatigue has definitively established its role in reducing alertness, performance, and safety, there remains a significant and critical gap in the scientific data available to address policy issues and provide specific solutions. There are few studies that have specifically tested an alertness strategy/fatigue countermeasure or compared an established regulatory policy to an alternative or quantified the benefits of implementing an Alertness Management Program (AMP)/Fatigue Risk Management System (FRMS).

Regulatory authorities continually confront this gap between the science establishing fatigue as a significant safety issue and having data to address policy issues or provide specific solutions in their efforts to address fatigue risks through policymaking. EASA's request for scientific and medical evaluation of 18 specific flight time limitation questions is one more example of such an effort. However, the resulting MAR addressing the 18 posed questions is invalid, insufficient, and risky. The following highlights some of the most significant and relevant issues in each of these areas.

I. Invalid

a. No data. In 13 of the 18 questions posed there is direct acknowledgement that no data is available to address the question or the data that are cited do not specifically address the question posed. Therefore, 73% of the questions do not have any data or relevant, appropriate data to provide an evaluation of the issue identified (e.g., #1, 6, 10, 13).

b. Recommendations without data. Though acknowledging no data or no relevant data are available, specific recommendations are still made to address the questions posed. The primary task identified was to provide a scientific and medical evaluation of the questions posed, however, the MAR goes beyond this tasking to provide specific recommendations intended for policy making. These recommendations were not data-driven and relied on generalizing from other information to fill the "data gap". However, the recommendations are presented in a manner to suggest that they could be used for data based policies.

c. Subjective data sources. A significant number of the scientific citations used to substantiate specific points were studies that utilized only subjective, self-reporting measures. Subjective, self-report measures can be discrepant from objective measures of alertness and performance, biased, and influenced by varied sources. It is critical that scientific data used as a basis for policy making be based on objective, measurable

outcomes related to performance, relevant operational variables, behavioral actions, errors, incidents, accidents and appropriate safety measures. Subjective measures can complement these other varied objective outcomes but are highly questionable as the exclusive source for an evaluation or recommendation. For example, the MAR cites previous NASA research related to a subjective survey on sleep quantity and quality in onboard crew rest/bunk facilities (1). Yet the MAR does not include a complementary NASA study that included objective physiological measures of sleep quantity and quality in onboard rest facilities during actual operations involving two different flight patterns and three different aircraft (2).

d. Ignores operational experience and safety history. While a scientific and medical evaluation of the 18 questions posed is relevant, equally relevant is the operational experience and safety history of the activities being addressed. Policy making to address established safety issues could consider safety data, operational experience, relevant scientific findings, and where appropriate, economic factors. When the MAR goes beyond scientific and medical evaluation to make "practical" recommendations, it enters a realm where these other relevant factors (safety data, operational experience, economics, etc.) become significant considerations.

e. No quantification of risk/benefit. In policy-making efforts, it is critical to go beyond documentation of an effect to quantifying specifics of the risk. Regarding fatigue, this translates into both quantifying the risk and identifying the specific areas where these risks are expressed. First, this allows decisions about what specific fatigue-related risks to address and their priorities. Second, it provides a basis for determining expected, quantifiable benefits and outcomes that could be measured by implementing policies and activities. The MAR expert panel made an effort to use this approach in a couple of its responses (e.g., #2, 12). However, the quantification of risks and subsequent, quantifiable benefits of implementing policies and recommendations should be the lead issue in addressing all of the questions posed.

II. Insufficient

a. Practical recommendations. The MAR goes beyond scientific and medical evaluation to provide specific policy recommendations. The expressed intention was to provide "practical" recommendations. The MAR panel expertise was clearly defined by its ability to address the scientific and medical evaluation requested by EASA. Individuals with expertise in "practical" issues related to aviation operations, policymaking, and regulations should address these specific arenas.

b. Managing circadian disruption. One of the complex issues to address in effectively managing fatigue involves circadian disruption. There are a variety of ways that circadian rhythms are disrupted in flight operations: night flights, crossing time zones, changing duty times (start and end), cumulative effects, stabilization/adjustment considerations; as well as influenced by light/dark cues, sleep schedules, and other factors. While acknowledging "acclimatization" as an issue, there is insufficient evaluation or guidance on how to address this complex issue. Though it is likely that insufficient information is

available to provide specific, comprehensive recommendations, those in the MAR (e.g., reduced night time flight duty periods) are not substantiated by the scientific literature.

c. FRMS recommendations. For decades, policy makers have attempted to control or eliminate fatigue in operational settings through the use of "Hours of Service" (HOS) regulations. It has become clear that these policies are "necessary but not sufficient" to effectively manage the complex nature of fatigue in real-world operational settings. Using a programmatic, comprehensive approach to managing fatigue has been proposed with implementation guidance since the mid-1990s (3, 4). Objective measures have demonstrated the effectiveness of an Alertness Management Program to enhance sleep and performance during actual aviation operations (5). The most recent iteration of a programmatic approach to address fatigue involves an FRMS. However, current recommendations to implement an FRMS are often accompanied by suggestions that it should provide for "regulatory relief" that allows greater flexibility within established HOS regulations. A critical element that remains to be defined is how to translate the implementation of an AMP or FRMS into specific "flexibility" of the established HOS. What specific "flexibility" is allowed if an organization effectively implements an FRMS? Is an organization with an established AMP or FRMS allowed to fly more sectors, extend flight duty periods, reduce rest, use earlier start times or allowed some other "flexibility"? Again, there is a gap between data showing the effectiveness of an AMP/FRMS and the specific flexibility benefits that would be allowed.

d. Data for policies and solutions. The number of scientific studies designed to address specific policy issues or alertness strategies/fatigue countermeasures is minimal. Actual operational scenarios and issues drive the policy and strategy questions raised. The EASA request is one more example of an effort to apply scientific data to these operational and policy questions and needs. However, the MAR response further demonstrates the gap between data establishing fatigue as an operational safety issue and data from scientific studies designed to address specific policy and operational requirements.

e. Discrete approach. Managing fatigue is a complex issue that crosses systems, organizational, and individual levels. Addressing discrete policy and operational issues is necessary but will not be sufficient to effectively manage fatigue in complex operational settings. Collecting discrete policy issues and recommendations into "one answer/system" cannot be expected to result in an overall, effective, and integrated policy and operational structure. Discrete issues and recommendations do not provide an integrated perspective but can result in policies out of context from the complex, interactive nature represented by the fatigue issues they are intended to address.

III. Risky

a. Unintended consequences. Without quantified risk/benefit analyses to project expected outcomes, implementing individual or collective recommendations from the MAR creates a significant risk for unintended consequences. One example of an existing unintended consequence involves flight time limitations. In the United States, the 8 hr flight time limitation creates transcontinental schedules that involve one day flight, followed by a

day sleep period, then a return night flight and subsequent day schedules that continue the sleep and circadian disruption. An innovative flight schedule was evaluated that maintained duty limits but allowed a flight time greater than 8 hrs. This provided the opportunity to complete two transcontinental flights in one duty period, allowing no sleep or circadian disruption. This innovative schedule was associated with significantly increased sleep and in-flight performance, quantified by objective measures during actual operations (5). Though the 8 hr flight time limitation is intended to reduce fatigue, the unintended consequence in this circumstance was to create sleep and circadian disruption. Increasing the flight time while maintaining the duty limit resulted in more sleep and better performance.

b. Integrated policy system. Given the complexity of addressing fatigue issues in operational settings, it is critical that policies intended to manage fatigue involve an integrated system of regulations. Individual policies or a collection of discrete regulations will only add to the potential for negative unintended consequences to occur. An integrated policy system provides the opportunity to comprehensively address the diverse industry, organizational, and individual issues that exist related to fatigue management.

c. Policies based on no data, unrelated data or subjective data. Globally, regulatory authorities continue to confront the challenges of creating effective policies that manage fatigue in aviation and other operational settings. Regulatory authorities, to their credit, have acknowledged a role for using scientifically based data in the development of regulatory policies. However, when no data is available to address an issue or data that does not directly address an issue is used or if only subjective data (with its acknowledged limitations) is relied upon, then the objective of developing scientifically based regulations cannot be met.

d. No quantification of risk/benefits. The MAR is just one example of regulatory considerations that have not quantified specific fatigue risks or the expected outcomes/benefits of implementing recommendations in the form of regulatory policy. Again, scientific data clearly demonstrate that fatigue degrades alertness and performance and increases risk for errors, incidents, and accidents. However, greater specificity of quantified fatigue risks are needed to justify a specific change or policy and will be critical to evaluate whether the intended outcome/benefit is attained.

e. Policy based on diverse data sources. Given the complexity of fatigue issues, it is critical that diverse data sources are used as the basis for policy development. Flight time limitations regulations are fundamentally safety policies and therefore, relevant safety data should be a critical source that informs regulatory efforts. Operational experience is another important source that deserves significant weight in policy-making. Where appropriate, economic factors based on quantitative risk/benefit analyses can provide another relevant input to policy activities. Scientific data that is relevant and objective provides another perspective and useful guide for creating regulations. Together, these diverse data sources provide the most robust foundation upon which to base flight time limitations regulatory policies.

f. Application without precedent/testing. Besides the need for implementation of an integrated policy system (addressed in *b* above), there could be significant risks implementing discrete policies or multiple ones without some testing. If there is no precedent for a particular policy or system, then the potential for unintended consequences increases. Safety and operational evaluations that include some pilot testing of potential implementation scenarios would create important data to evaluate outcomes (safety, operational, fatigue, economic, etc.).

g. Ongoing evaluation. Many flight time limitations regulations have been in use for decades without significant revisions. Though discussed, reviewed and changes proposed, few significant revisions have emerged. Therefore, a significant enhancement to the implementation of regulatory policies related to flight time limitations would be the development and implementation of an ongoing evaluation system. With quantified safety risks and benefits identified, regulators and the aviation industry should determine whether the intended outcomes are being realized after policies are implemented. This evaluation should be conducted over a short-term with a clear mechanism to change any policies that are not providing the intended benefits and outcomes.

Further Considerations, Limitations, and Opportunities

a. Few effective examples. HOS issues are complex and create significant challenges to managing fatigue in diverse operational settings. Safety must remain the fundamental issue that is the focus of policy efforts and regulations should be informed by safety data, operational experience, relevant scientific findings, and where appropriate, economic factors. The use of anecdote, conjecture and generalization from unrelated data sources can distract effective efforts and create negative unintended consequences.

b. The AMP/FRMS solution. The use of an AMP or the recent FRMS approach, offers a complement to the traditional HOS policy scheme. Data and consideration of AMP and FRMS activities are a promising evolution of efforts to effectively manage fatigue. Two critical issues remain to be addressed. First, clearly demonstrating the benefits and outcomes of an AMP/FRMS, especially as they are implemented in diverse settings and potentially in different forms. Second, what are the specific operational and HOS changes and flexibility that will be allowed/provided to organizations that implement an AMP or FRMS?

c. External review. The enthusiasm expressed in the MAR introduction in the form of self-congratulatory comments is best reserved and determined by appropriate external, peer review, and other commentaries that evaluate the report.

d. Relevant expertise. It is important to acknowledge that members of the expert panel have made numerous contributions to the scientific literature related to fatigue; some are well established and distinguished scientists in the field. Their integrity is evident when the panel directly acknowledges that no data are available to address a question or when acknowledging that generalizations are attempted in an effort to provide an answer. However, given the current state of the scientific literature, it may not be possible to meet

the actual request posed by EASA. A scientific and medical evaluation of flight time limitations can be conducted based on available and appropriate literature. However, moving from scientific and medical evaluation to policy recommendations once again confronts the gap in available data to address specific regulatory issues. Offering "practical" recommendations would involve safety, operational, and policymaking expertise that is beyond the scope of the stated "scientific and medical evaluation of flight time limitations" task.

e. The Opportunities. The following offers one potential path to move regulatory policies regarding flight time limitations forward: 1) better quantification of fatigue risks as they relate to specific flight time limitations issues (use as baseline for change); 2) better quantification of expected benefits and outcomes; 3) use of objective data (performance, ops and safety measures) to quantify risks and benefits; 4) method to test proposed changes and then ongoing efforts to track actual implemented changes in regards to unintended consequences and to quantify whether expected outcomes are achieved; 5) mechanism to revise policies based on whether benefits are achieved and unintended consequences that are discovered; 6) define specific organizational changes and flexibility allowed in flight time limitations if an effective AMP or FRMS is implemented.

Conclusion

The MAR acknowledges that no data are available or uses unrelated data or relies on subjective findings to provide a scientific and medical evaluation of flight time limitations. Then goes beyond this tasking to suggest "practical" recommendations without using safety, operational or policymaking expertise or data. Examples are provided that demonstrate how the resulting MAR is invalid, insufficient, and risky. A path that provides an opportunity to pursue policy development related to flight time limitations is outlined.

Mark R. Rosekind, Ph.D
Kevin B. Gregory

Alertness Solutions
1601 S. De Anza Boulevard
Suite 200
Cupertino, California 95014
United States
408-253-1019
bealert@alertsol.com

References

1. Rosekind, M.R., Gregory, K.B., Miller, D.L., Co, E.L. (2000). Crew factors in flight operations XII: A survey of sleep quantity and quality in on-board crew rest facilities. (Technical Memorandum 2000-20961). Moffett Field, CA: NASA.

2. Rosekind, M. R., Gregory, K. B., Miller, D. L., Oyung, R. L., Neri, D. F., & Dinges, D. F. Sleep quantity and quality of augmented long-haul flight crews in on-board crew rest facilities. *Sleep Research*, 1997, 26:41.

3. Rosekind, M.R., Gander, P.H., Gregory, K.B., Smith, R.M., Miller, D.L., Oyung, R.L., Webbon, L.L., and Johnson, J.M. Managing Fatigue in Operational Settings 2: An Integrated Approach. *Journal of Behavioral Medicine*, 1996, 21:166-170.

4. Rosekind, M.R., Managing work schedules: An alertness and safety perspective.
In Kryger, M.A., Roth, T., and Dement, W.C. (Eds.), *Principles and Practice of Sleep Medicine,* 4th ed., Philadelphia: Elsevier Science, 2005.

5. Rosekind, M.R., Gregory, K.B., Mallis, M.M. Alertness management in aviation operations: Enhancing performance and sleep. *Aviation, Space, and Environmental Medicine*, 2006, 77(12): 1256-65.