EXPLORING INDUSTRY MEDICAL RISK MANAGEMENT BEST PRACTICES FOR APPLICATION TO AEROSPACE MEDICINE

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7. Author(s) R. Lieberthal, I. Catovic, C. Mills, G. Chesterton		8. Performing Organization Report No. Product 4-5.B.1-4
9. Performing Organization Name and Address The MITRE Corporation 7515 Colshire Drive McLean, VA 22102		10. Work Unit No. (TRAIS) 11. Contract or Grant No. 693KA8-22-C-00001
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16. Abstract The Federal Aviation Administration (FAA) Office of Aerospace Medicine tasked MITRE's Center for Advanced Aviation System Development to investigate relevant industry best practices applicable to the forecasting and managing pilot medical risks. In particular, the research focused on the insurance industry for risk assessment expertise. MITRE gathered observations from sources including internal MITRE subject matter experts, insurance brokers, insurance companies, technology vendors, and trade associations. The research also applied TRIZ—the theory of inventive problem-solving. TRIZ proposes that narrow problems can be abstracted to broad problems for which broad solutions already exist. MITRE mapped key elements from the insurance industry process model to the elements of FAA's Safety Risk Management / Safety Assurance process of Order 8040.4B. This juxtaposition yielded a novel finding of the research: a unified process model with common elements. MITRE identified actions that can be adopted from the insurance domain best practices for each step of this unified process model.		
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EXECUTIVE SUMMARY

The Federal Aviation Administration's (FAA's) Office of Aerospace Medicine (AAM) tasked MITRE's Center for Advanced Aviation System Development to investigate relevant industry best practices applicable to the forecasting and managing pilot aeromedical risks. In particular, we looked towards the insurance industry, whose operations model rests on risk assessment expertise.

MITRE gathered observations from sources including internal MITRE subject matter experts, insurance brokers, insurance companies, technology vendors, and trade associations. The core research team analyzed and synthesized observations into conclusions about current practices.

MITRE also took inspiration from the theory of inventive problem solving (TRIZ). TRIZ proposes that narrow problems can be abstracted to broad problems for which broad solutions already exist. These broad solutions can be adapted and focused to yield narrow solutions to the problem at hand.

MITRE mapped key elements from the insurance industry process model to the elements of FAA's Safety Risk Management / Safety Assurance process of Order 8040.4B. This juxtaposition yielded a novel finding of the research: a unified process model with common elements. For each step of this unified process model, MITRE identified actions that can be adopted from insurance domain best practices for application in pilot medical certification:

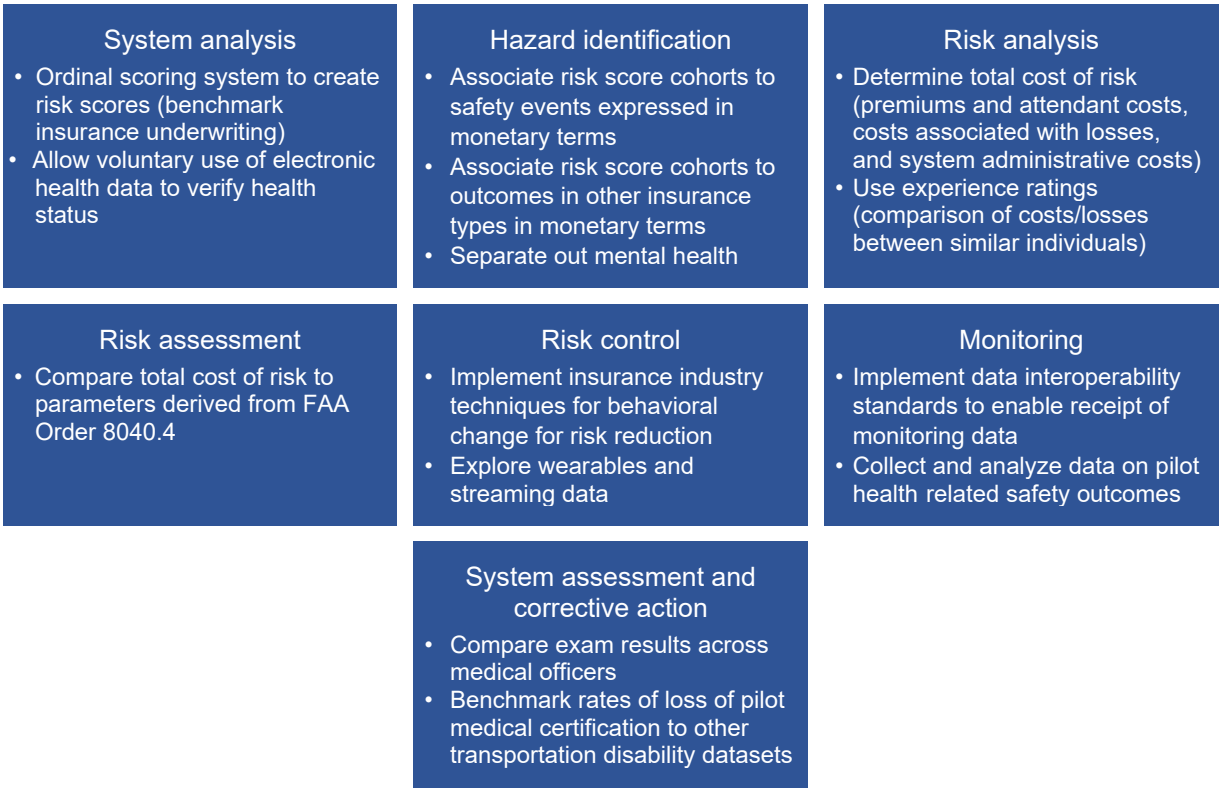

Figure 1. *Application of Industry Risk Management Best Practices to Office of Aerospace Medicine Safety Risk Management and Safety Assurance*

INTRODUCTION

Background

The Office of Aerospace Medicine (AAM) conducts risk management of pilot health-related risks, primarily through regulatory and compliance activities. As one of the oversight organizations within the Federal Aviation Administration's (FAA's) Aviation Safety (AVS) line of business, AAM is implementing its Safety Management System (SMS) responsibilities as prescribed in Order VS 8000.367 [1].

MITRE is conducting a set of tasks to support AAM's implementation of Safety Risk Management, which includes system analysis, hazard identification, and risk analysis and assessment. An important research thread is to explore the feasibility of forecasting undesirable outcomes using available data. Since other industries face similar challenges, AAM tasked MITRE to investigate solutions to such challenges that could apply to the pilot medical certification domain. In particular, we looked towards the insurance industry, whose business model rests on risk assessment expertise.

TRIZ Framework

The theory of inventive problem solving (TRIZ) is based on the premise that problems and solutions are repeated across industries and sciences. Systematic Inventive Thinking (SIT) is derived from TRIZ and is universally applied. In simple terms, TRIZ and SIT propose that narrow problems can be generalized to broad problems for which broad solutions already exist. These broad solutions can be adapted and focused to yield narrow solutions to the problem at hand. Although this route may seem more circuitous, problem-solvers can discover solutions that are elusive when attempting to proceed directly with a traditional approach (Figure 2).

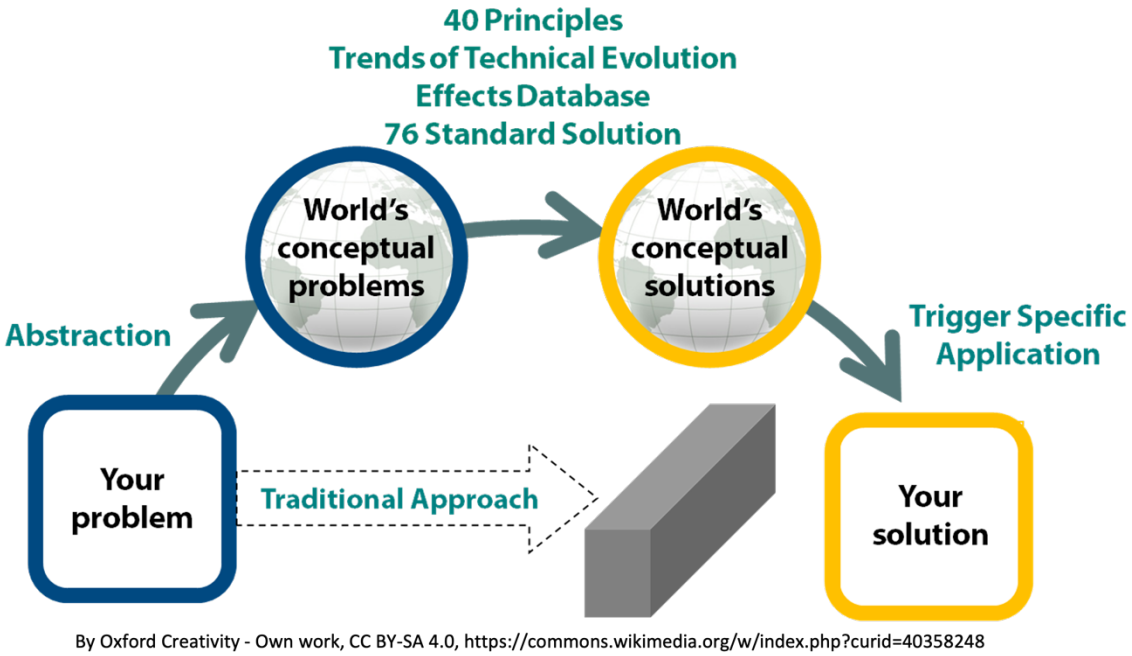

Figure 2. *TRIZ Conceptual Process*

In the TRIZ approach to problem-solving, broad problems can be reframed through pairs of contradictions—tensions between parameters wherein an improvement in one parameter leads to a worsening of the other. We then consider principles[1] effective at resolving these contradictions. These principles can be tailored to the problem domain—in this case, risk management—as summarized in Table 1.

Table 1. *Broad Problem Contradictions and Solution Principles from TRIZ/SIT*

Problem Contradictions	Broad Solution Principles
Accuracy vs. Efficiency: Insurers need to maximize accuracy while preserving efficiency. Increasing accuracy may require more data and analysis, potentially slowing down the process, while prioritizing efficiency may lead to potential oversights.	**Separation**: Separate the risk assessment process into stages or components to optimize accuracy and efficiency at different stages. **Universality**: Identify and implement risk management solutions that can be universally applied to different risk scenarios and policyholders. Develop a standardized risk assessment framework that can be applied across various lines of business and industries. Identify risk control measures that are universally effective in mitigating various types of risks. Develop adaptive coverage options tailored to individual policyholders while utilizing common core components. Explore risk management practices from other industries and adapt relevant concepts. Implement standardized risk reporting metrics that provide consistent and comparable risk data across the insurance portfolio. **Segmentation**: Divide complex risks or losses into manageable segments or categories. By breaking down the complexity into smaller components, insurers can focus on measuring and assessing each segment individually, leveraging specific expertise or specialized models for different risk categories.
Adaptability vs. Stability: Insurers must adapt to changing risk landscapes while preserving stability and consistency in risk assessments.	**Parameter changes**: Explore new ways to collect and analyze data, improve communication and reporting processes, or implement innovative control measures. **Feedback**: Establish feedback loops to continuously learn and adapt from risk assessment outcomes, enabling flexibility in response to new risks while ensuring stability in the overall process. Detect any deviations from expected performance, changes in risk exposure, or emerging risks.
Measurability vs. Security: Insurers rely on data for risk assessment, but there is a need to balance privacy concerns and ethical use of personal information with the benefits of sharing data.	**Preliminary action**: Offer safety training programs and risk reduction advice to policyholders. Develop early warning systems that identify potential risks and trigger timely risk management actions. Implement loss control programs. Conduct scenario planning and stress testing to anticipate the impact of various risk scenarios on the insurance portfolio. Introduce preventive policy measures, including policy endorsements that incentivize risk reduction efforts. Use data analytics and predictive modeling to identify early signals of potential risks. **Local quality**: Improve risk management in localized areas without adversely affecting the portfolio. Implement targeted risk management strategies designed to address identified risk exposures. These strategies may involve customized coverage options, risk reduction advice, or specialized underwriting guidelines for specific risks.

[1] Refer to the SIT version of the contradiction matrix, available at www.systematic-innovation.com [5]

Problem Contradictions	Broad Solution Principles
Robustness vs. Precision: Analysts must ensure that risk estimates are valid (robust) against a range of conditions and not overly conditioned on a narrow set of circumstances while preserving necessary precision for assessment.	**Other Way Around:** Encourage reverse thinking by exploring scenarios where policyholders intentionally take on higher deductibles or self-insured retentions to align their interests with the insurer and incentivize risk management efforts. Consider a reverse underwriting approach where "policyholders" present risk management plans or safety initiatives to insurers for potential premium discounts or coverage enhancements. Identify highly desirable outcomes and work backward to determine the necessary risk management steps to achieve those outcomes. **Merging:** Merge data from various sources, such as policyholder information, claims history, external risk databases, and predictive analytics, to create a unified risk profile for each policyholder. Merge expertise from different departments, such as underwriting, claims, actuarial, and risk management, to form cross-functional risk teams. Merge various risk assessment technologies, including artificial intelligence, machine learning, and big data analytics. Merge data from devices and telematics technology to monitor and assess risks in real-time, which can lead to usage-based insurance policies for auto insurance, rewarding safe driving behaviors. Merge data-driven insights with expert judgment to make well-informed risk management decisions.
Security vs. Connectability: Insurers must increase the interconnectedness of data and information while preserving security requirements.	**Dynamization:** Incorporate dynamic and adaptive measures to respond to changing risk landscapes and ensure the continuous improvement of risk management practices. Use real-time data collection, dynamic risk models, and adaptive underwriting guidelines. **Another dimension:** Incorporate data from external sources to enhance risk assessment and gain a broader understanding of potential risks. Introduce economic indicators to assess how economic changes impact policyholder risks and claims frequency. Introduce collaborative risk management strategies involving partnerships with policyholders, industry associations, or risk management experts. Use holistic risk mapping to visualize interconnected risks.

FAA AAM PROBLEM DEFINITION

Narrow Problem

AAM's narrow problem is managing the risks to the National Airspace System associated with pilots suffering incapacitation due to a medical condition. The FAA manages risks within an SMS framework. [2] Several aspects of the FAA's SMS complicate the application of risk management to the aeromedical domain:

- Medical data collected specifically from the pilot population comprise a relatively small dataset from which to identify hazards and assess risk;
- Pilot performance degradation rarely manifests as an observed, recorded outcome;
- The pilot-aircraft system is complex, and the link between medical condition degradation and costly outcomes is not well understood;
- Pilot medical certification is currently coupled to types of operations (airline transport, commercial, private), so risks tend to be assessed and managed across the entire pilot population.

Broad Problem

We can view the FAA AAM narrow problem more broadly as identifying and managing risks—the uncertain probabilities of occurrence of future outcomes with undesired consequential outcomes. During the project definition phase, we recognized that the insurance industry would be a likely area to find risk management expertise. To reveal commonality with the insurance domain, we expressed elements of the insurance process as a process flowchart and juxtaposed it to the Safety Risk Management (SRM) and Safety Assurance (SA) processes from FAA Order 8040.4B, as shown in Figure 3.

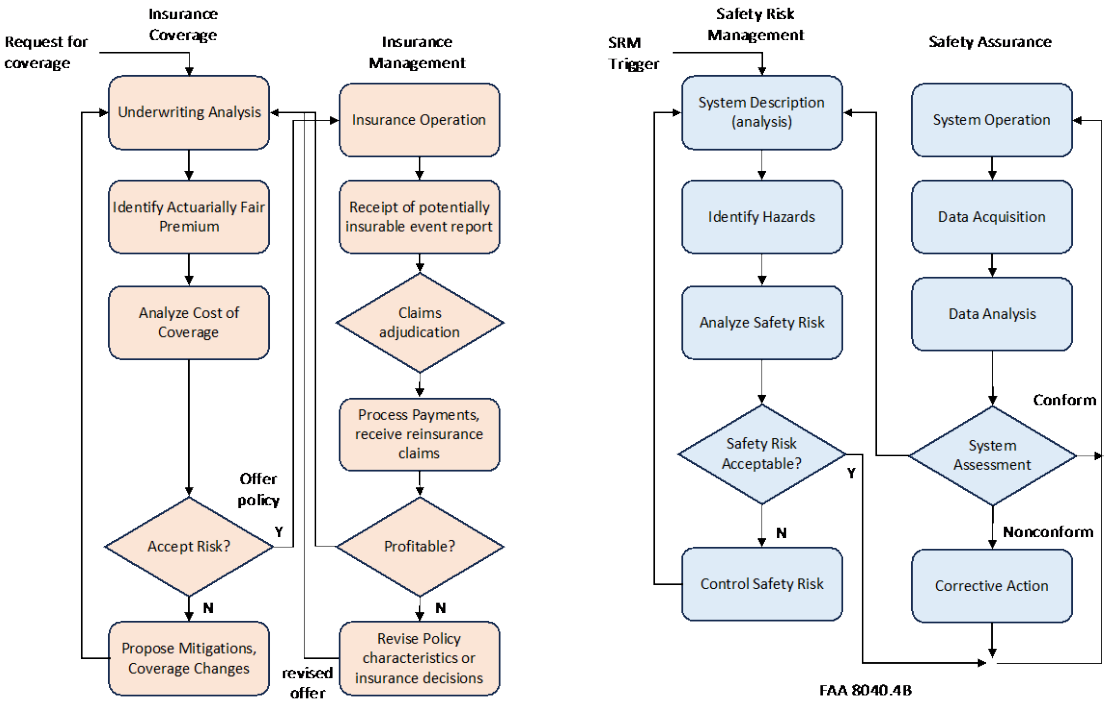

Figure 3. *Juxtaposition of Insurance Industry and FAA Safety Risk Management / Safety Assurance Processes*

The similarity of the process models can be expressed through descriptions of each step applicable to aviation safety and insurance, as shown in Table 2.

Table 2. *Linking Terminology of the Insurance Industry and FAA Risk Management Models*

Insurance Step	SRM / SA Step	Common Model Process Description
Underwriting analysis	System analysis	System analysis: Define system scope/boundaries; gather information regarding system changes; develop risk acceptance plan; describe and model system context and operational environment.
Identify actuarially fair premium	Identify hazards	Hazard identification: Identify conditions that can potentially cause a negative outcome. Hazard sources include operational environment, equipment, policies, and procedures
Analyze cost of coverage	Analyze risks	Risk analysis: Determine the likelihood of occurrence of events of specified outcome severity. The aviation safety consequence is pilot incapacitation, and the insurers' consequence may be a large payout.
Accept risk?	Accept risk?	Risk assessment: Assess each risk against the risk acceptance criteria identified in the safety risk acceptance plan.
Propose mitigations and coverage changes	Control safety risk	Risk control: For unacceptable risks, propose mitigations or changes in risk exposure.
Insurance operation	System operation	System operation: The entire system in operation.
Receipt of potentially insurable event report	Data acquisition	Monitoring: Collect, manage, and monitor operational data using reporting systems, investigation, monitoring, and audits.
Claims adjudication / Process payments, receive reinsurance claims.	Not applicable	Not applicable
Determine profitability	System assessment	System assessment: Identify potential new hazards or ineffective safety risk controls and determine conformance with requirements.
Revise policy characteristics or insurance decisions.	Corrective action	Corrective action: Prioritize and implement corrective actions to mitigate or eliminate safety issues identified during system assessments. Periodically review/monitor completed corrective actions to evaluate the effectiveness and completeness of the original corrective actions.

The insurance industry also applies processes related to, but distinct from, SMS, including Quality Management and relevant to the Safety Promotion processes of the FAA Aviation Safety SMS. "A robust and focused Quality Management System operates internally in AVS to assure operational safety and SMS requirements are met effectively and efficiently" [1]. Quality Management in the insurance industry is provided through industry benchmarking and the use of multiple insurance companies to cover a given risk, which also could be considered an example of risk management (dispersing risk) vs. quality management. "Safety Promotion is a combination of training and communication of safety information to support the implementation and operation of an SMS in an organization" (14 CFR 5.5). Safety Promotion is provided in the insurance industry through continuing education and industry meetings (conferences).

SOLUTION CONVERGENCE

Broad Solution Features

We viewed three features or dimensions of the broad solutions from the industry to reveal practices that could apply to the more narrow problem facing FAA AAM:

1. Model elements: Insurance industry models for *Insurance Coverage* and *Insurance Management* (see Figure 3) that could be directly applied to SRM and SA or to these and other parts of the SMS with modifications. Modifications primarily relate to the different outcomes of the insurance industry (financial) and aviation (safety) and differences in data types, data quantity, and accessibility.
2. Insurance industry implementation: Insurance industry benchmarked practices for steps within the generic/unitary model. These are specific methods, technologies, and stakeholders in the insurance industry who can transfer the identified model elements and techniques to the SMS.
3. Aeromedical analogy (Broad solutions translated to narrow solutions): Translation of benchmarked practices into potential alternative problem solutions within the context of managing pilot medical risk in the SMS framework.

An insight that emerged from the research was the relative emphasis, or weight, placed on the "pre-operation" and "in-operation" (or left-hand and right-hand) parts of each process model depicted in Figure 3. In insurance, substantially more effort is dedicated to insurance coverage (left-hand side) than insurance management (right-hand side) when compared to the FAA's effort allocation between SRM (left-hand side) and SA (right-hand side). Once an insurance company has written a contract, its ability to adjust based on environmental changes or incentivize risk avoidance by an insured individual is relatively low. Contrast that with the ability of the FAA to respond to new information by imposing changes or mandating additional safety behaviors as part of the SA process. As a result, many of the aspects of the *Insurance Coverage* portion of the model translate to SA, as discussed below.

From Broad Solution to Narrow Solution

Table 3 shows the broad solutions from industry best practices that could be adapted to a narrow solution to the FAA AAM problem for each respective step of the general model.

Table 3. *Broad and Narrow Solutions Associated with Common Model Process Steps*

Common Model Process	Broad Problem Solution	Narrow Problem Solution
System analysis	Identify opportunities to create standardized processes, frameworks, and guidelines that can be universally applied to risk management and insurance operations. Identify actuarial models for underwriting. TRIZ principles: standardization, segmentation, universality	Develop an ordinal scoring system assigning pilots to risk cohorts based on the likelihood of future changes in health state. This system can benchmark approaches used in insurance underwriting under conditions of data scarcity. A pilot's score would be developed from current health status data captured on the FAA Form 8500-8. Pilots could be allowed to share their Electronic Health Record and medical claims data with the FAA to expedite and enhance the verifiability of their current health status.

Common Model Process	Broad Problem Solution	Narrow Problem Solution
Hazard identification	Proactively gather and analyze data on emerging risks, loss, trends, and industry developments; collaborate with domain experts. Create an actuarial premium model. TRIZ principles: segmentation, dynamization, other dimension	Actuarial pricing involves assessing the potential risk of insuring clients and finding the price ranges that can accept this risk. Actuarial pricing can be applied to pilot medical certification by relating ordinal risk scores to safety events expressed in monetary terms (e.g., diverted flights, aircraft damage or loss, etc.). Alternatively, current actuarial pricing models for disability, worker's compensation, and loss of license insurance can be leveraged to develop a composite (total) cost, which will be in monetary terms. Data acquisition would come from existing agency safety data, health data acquired under other research, and health insurance claims data shared by carriers and their health insurance companies (see "Price Transparency and Pilot Data Ownership (PDO)" in the "Transition Opportunities section below for more detail). Mental health conditions should be addressed separately, analogous to the mental health "carve-outs" used in managed care.
Risk analysis	Conduct risk modeling to estimate the likelihood of events of varying severity. Since historical data exhibit a wide range of outcomes, use simulation modeling to address the uncertainty associated with estimates of modeling parameters and their distribution functions. TRIZ principles: merging, another dimension	Determine a "total cost of risk," including premiums and attendant costs, costs associated with losses (occurrence of aviation safety events), and system administrative costs. Use experience ratings to analyze risk. An experience rating is based on an insured party's recorded historical losses. Blend pilot "experience rated" data with data from the general population, meaning losses experienced by similar populations not covered by an insurance company using actuarial "credibility" analysis [3] [4] to increase forecast confidence and generate distributions for sensitivity analysis.
Risk assessment	Assess the tolerability of risk against established risk acceptance values as prescribed in the risk acceptance plan. Weigh loss exceedance probabilities against opportunities. TRIZ principles: standardization, segmentation	Compare the total cost of risk to established parameters for likelihood and uncertainty of aviation safety events derived from FAA Order 8040.4. Use the output to decide whether to accept the risk or require additional risk controls.
Risk control	Mitigate risks by establishing protocols and incentivizing behaviors that avoid or reduce exposure. Establish controls that reduce the likelihood of event occurrence or the magnitude of its damage/outcome. TRIZ principles: preliminary action, local quality, other way around	Implement existing and emerging insurance industry techniques to determine behavioral changes needed to reduce risk to an acceptable level. Insurance tools include streaming/periodic data, limitations on the time and scope of coverage, and behavior monitoring during the coverage period. Explore applications for wearable technology in healthcare.

Common Model Process	Broad Problem Solution	Narrow Problem Solution
Monitoring	Establish key risk indicators that can be measured and tracked. Use current technology and real-time data to detect sudden changes in risk exposure. TRIZ principles: feedback, dynamization	Develop a set of Fast Healthcare Interoperability Resources-based interoperable common data elements for pilot medical certification, streaming data, and medical claims data to allow ongoing monitoring of pilot health status for select special issuances. Collect and analyze safety data to verify that risk controls achieve the desired effect regarding the observed rate of pilot health-related incapacitation events.
System assessment and corrective action	Adapt risk management and safety controls in response to changing conditions. TRIZ principles: standardization, segmentation, parameter changes	Compare agency medical certification results across medical officers and benchmark rates of loss of medical certification by condition, decision (acceptance or denial), and other factors to transportation disability datasets to reduce variation in risk management. While dispositions by condition will differ across transportation modes, expected relative rates can be established.

Quality Management System Requirements

Finally, the use of insurance industry and aviation practices beyond those shown in Figure 3 can be incorporated through our recommendations that incorporate quality management and safety promotion as part of broader AVS and Quality Management System requirements:

- Benchmarking results in terms of pilot health (i.e., certified or denied certification) across examiners and compared to other professions with high requirements for health to ensure safety. These benchmarks are used to identify outliers regarding examiners and individual pilots.
- Promotion of the work, findings, and best practices through industry conferences. The research team implemented this finding through a presentation and in-person panel meeting at the Casualty Actuarial Society 2023 Spring Meeting. A future presentation is planned for the American Public Health Association 2023 Annual Meeting to continue disseminating and refining these results.

TRANSITION AND FUTURE WORK OPPORTUNITIES

To support the needs of the FAA as a risk-based regulator, the MITRE team also assessed opportunities to implement the proposed narrow solutions through future work. This assessment resulted in four specific future engagements with external partners that can implement the solutions identified in the research. Those opportunities were:

- Disability data assessment and integration into actionable strategies for pilots: this relates to the solution that would involve acquiring data on disability rates that would provide a benchmark for comparison.
- Adding insurance approaches and health promotion to SMS and Safety Promotion: these approaches are industry standards and can be implemented through a combination of outside vendors and MITRE subject matter experts.
- Price transparency and Pilot Data Ownership (PDO): recent regulations have enabled the type of data sharing proposed as a solution and would require legal and technical implementation, as discussed below.
- Separating the mental health component of medical assessment: specific subcontractors and vendors provide mental healthcare and mental health assessment.

Disability Data Assessment and Integration into Actionable Strategies for Pilots

- Conducting joint research projects using disability insurance benchmark data
- Comparing aviation with other industries, obtaining leading indicators of disability
- Identifying outlier results for airlines, aviation medical examiners, or types of transportation
- Generalizing pilots by demographics to anticipate underreported conditions

Table 4: *Disability Data Assessment*

MITRE Collaborators and Equipment	Subcontractors	Method
Health Innovation Center Transportation Innovation Center MiDAS	Integrated Benefits Institute (IBI) Casualty Actuarial Society	Predictive analytics

Adding Insurance Approaches and Health Promotion to SMS and Safety Promotion

- Adding identified components into the SMS workflow
- Developing communication strategies for pilots (e.g., pamphlets)
- Underwriting “scoring” system; populating the “bow-tie” with safety data
- Performing analysis of alternatives and cost analysis

Table 5: *Adding Insurance Approaches*

MITRE Collaborators and Equipment	Subcontractors	Method
Transportation Innovation Center Health Innovation Center HIPE Lab	Actuarial consultant	Actuarial science Health communications

Price Transparency and Pilot Data Ownership (PDO)

- Using price transparency rules to share back individual or aviation carrier-level claims data (with permission)
- Implementing models developed to expedite or streamline the aeromedical exam process

Table 6: *Price Transparency and PDO*

MITRE Collaborators and Equipment	Subcontractors	Method
Modeling and Analysis Innovation Center Health FFRDC Synthea™	GoInvo Harvey Watt AMS Analytics	Prototype approach

Separating Mental Health Component of Medical Assessment

- Identifying organizations that provide mental health "carve-out" benefits
- Analyzing publicly available data on high-incidence conditions and drugs
- Prototyping approach to outsource assessment of mental health conditions
- Obtaining price quotes for subcontractors to purchase insurance against errors in diagnosis or assessment of pilots

Table 7: *Separating Mental Health Component*

MITRE Collaborators and Equipment	Subcontractors	Method
Health Innovation Center	Magellan Health Beacon Health Options Teledoc	Stakeholder engagement

BIBLIOGRAPHY

[1] D. H. Boulter, "AVS Safety Management System (AVSSMS) with Quality Management System (QMS)Requirements (Order VS8000.367D)," U.S. Department of Transportation, Federal Aviation Administration, Washington, D.C., 2023.

[2] Federal Aviation Administration, "SMS Explained - Safety Management System," 2023. [Online]. Available: https://www.faa.gov/about/initiatives/sms/explained/components. [Accessed 31 5 2023].

[3] G. W. Fellingham, H. D. Tolley and T. N. Herzog, "Comparing Credibility Estimates of Health Insurance Claims Costs," *North American Actuarial Journal,* vol. 9, no. 1, pp. 1-12, 2005.

[4] R. Norberg, "A credibility theory for automobile bonus systems," *Scandinavian Actuarial Journal,* no. 2, pp. 92-107, 1976.

[5] Oxford Creativity, "TRIZ Innovation Materials," TRIZ Innovation Centre, 2022. [Online]. Available: https://www.triz.co.uk/learning-centre-innovation-materials. [Accessed 17 7 2023].