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16. Abstract
The Federal Aviation Administration's (FAA) Office of Aerospace Medicine is implementing Safety Management Systems (SMS) policies and requirements as described in FAA Orders 8040.4 and VS 8000.367. The safety risk management process may lead FAA to propose pilot medical certification policy requirements resulting in additional costs on pilots and other stakeholders. When making such policy decisions, the FAA should understand the cost implications relative to their presumed safety benefits. MITRE Corporation's Center for Advanced Aviation System Development (MITRE CAASD) proposed a decision framework and methods that FAA can use to evaluate the costs of such requirements relative to their presumed benefits. Specifically, MITRE researchers:

- Proposed a decision model that links policy decisions to various cost-bearing outcomes and the factors that introduce uncertainty into the decision-outcome chain;
- Described methods and sources through which the FAA could obtain data needed to use the decision model;
- Proposed methods through which the FAA could evaluate the value of additional information; and
- Proposed information sources and methods that could inform variables within the decision model.

This work advances the body of knowledge whereby FAA can evaluate changes to pilot medical certification requirements using a structured approach that addresses both safety and economic factors. MITRE recommends that FAA:

- Continue to refine a decision model, including cost-bearing outcomes and uncertainty factors, that supports cost analyses of safety risk management policymaking;
- Adopt a standardized process for using decision models as part of safety risk management;
- Train relevant personnel involved in policy making in the methods outlined in this presentation to ensure consistent and informed analyses;
- Conduct calibration sessions to ensure that experts can produce, in the absence of observed data, estimates that reflect their uncertainty;
- Apply the methods to a pilot study to test their feasibility in the Office of Aerospace Medicine's operational environment.

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Cost Analysis for State Safety Program Medical Certification Standards Decisions

January 2024

Regulators must understand the costs of required safety risk mitigations.

"There are cases where hazards with significant associated safety risk may exist, but because of the constraints within which the FAA must operate, the FAA may not be able to establish controls sufficient to mitigate the safety risk to a level that would be acceptable to the decision maker. Such limitations include the regulator's legal authority (which is established by statute and executive order), technological limitations, ***cost-benefit requirements for regulations****, the lack of cost-effective solutions, and rulemaking resource and time constraints."*

FAA Order 8040.4C

- FAA Order 8040.4C, Safety Risk Management Policy, describes the conditions for which safety mitigations must be applied.
- Safety mitigations, in the aeromedical certification context, include measures to assess pilot fitness to fly.
- Decisions regarding the acceptability of such mitigations require an understanding of their cost burdens relative to their safety benefit (reduced risk).

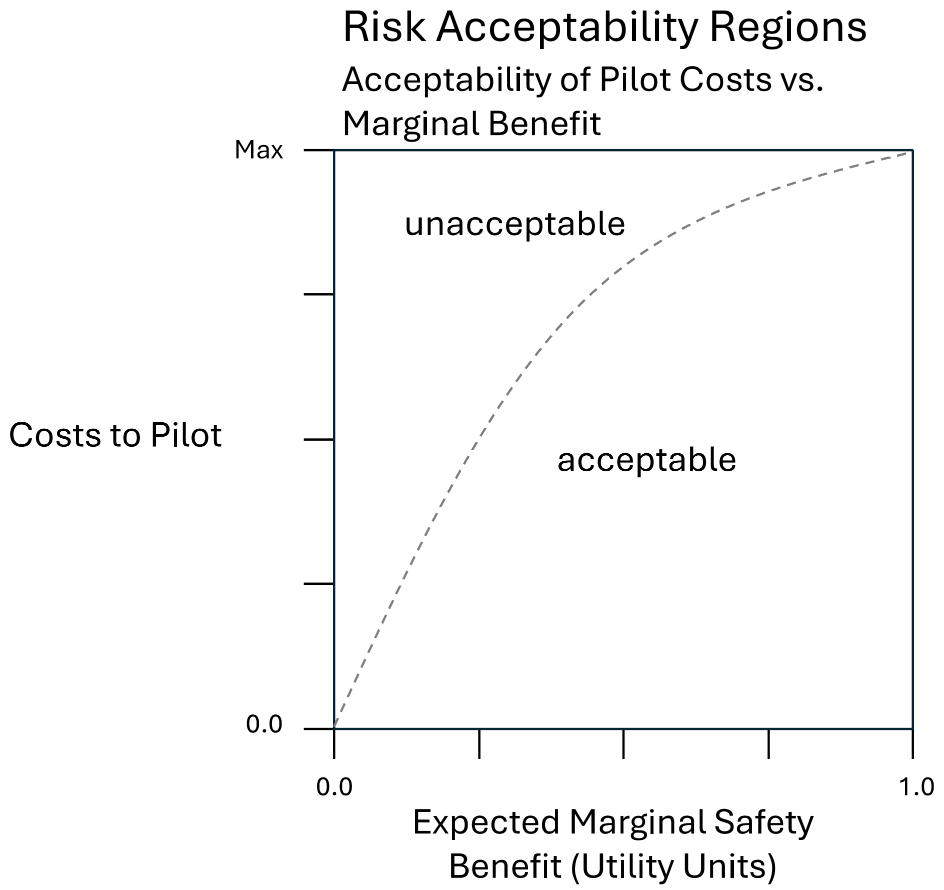


Figure 1. Identifying the Cost-Safety Risk Acceptability Boundary

Bow Tie models provide a visual depiction of safety threats, barriers, degradation factors, and consequences.

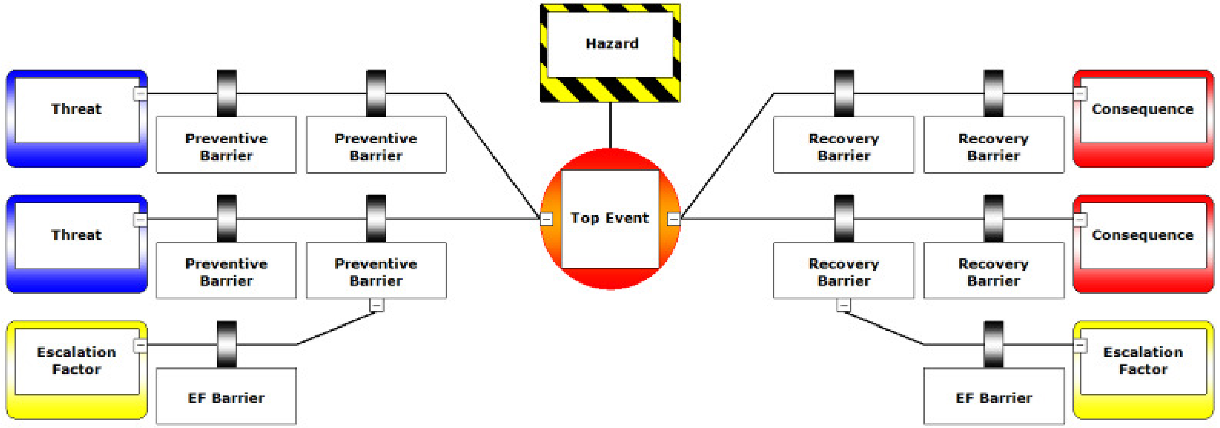


Figure 2. Bow Tie Risk Model

Barrier Types
- Passive hardware
- Active hardware
- Active hardware + human (sociotechnical)
- Active human (procedural)
- Continuous hardware

Source: *Bow Ties in Risk Management*, CCPS, Wiley, 2018.

Barrier Properties
- Active barriers must contain detect-decide-act elements.
- Valid barriers are:
  - effective: capable of blocking threat progression to a top event or to a consequence;
  - independent: independent of the threat and other barriers (no common failure modes); and
  - auditable: capable of being monitored and tracked.
- Escalation factors degrade the effectiveness of barriers.

The pilot medical fitness reference model provides a framework to address risks across service boundaries.

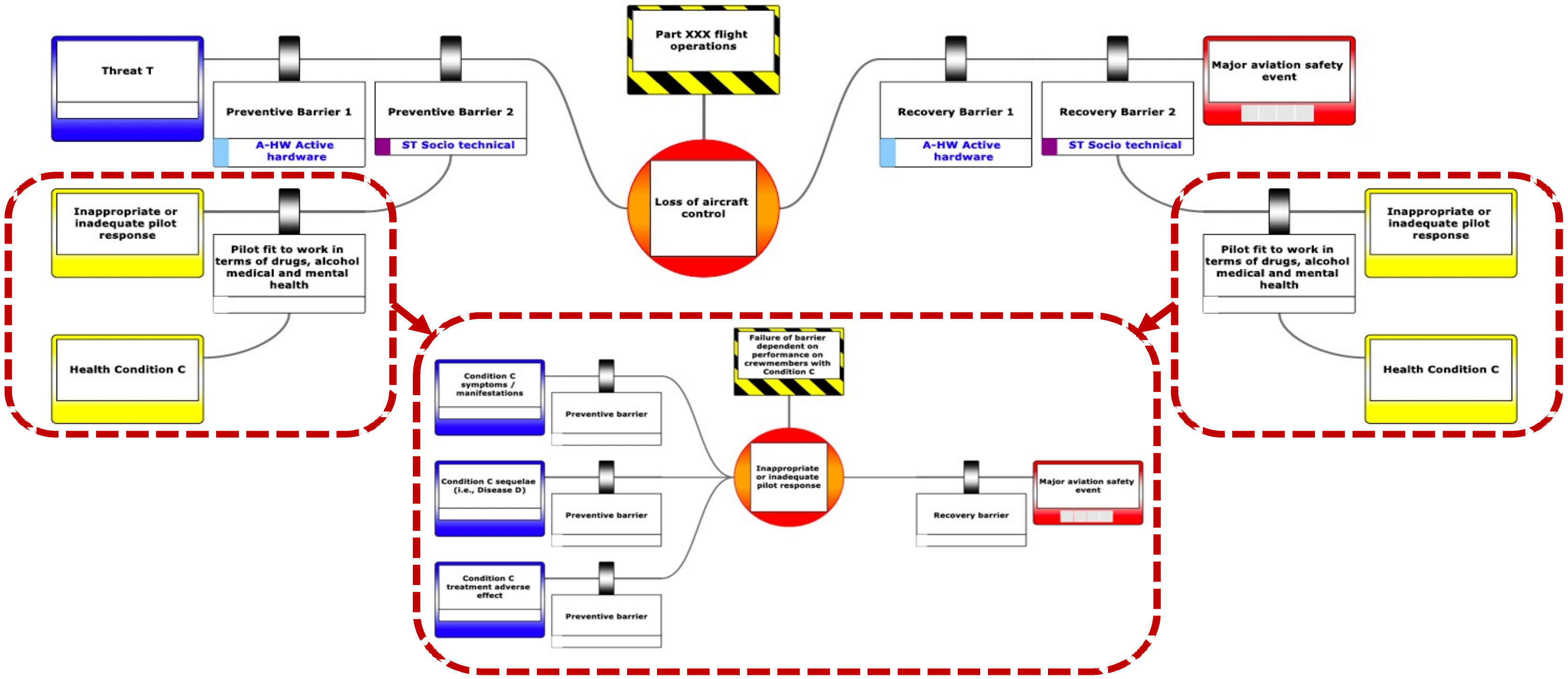


Figure 1. Linked Bowtie Risk Models, from *Concept for a State Safety Program Pilot Medical Fitness Reference Model*.

- Barriers have less than perfect probability of effectiveness.
- The decision to regulate a medical condition and to maintain barriers comes with costs and uncertain benefits.
- **The model does not support decision making with uncertainty where benefits must be weighed against costs.**

A risk-based framework supports connected processes for decisions involving uncertainty and loss potential.

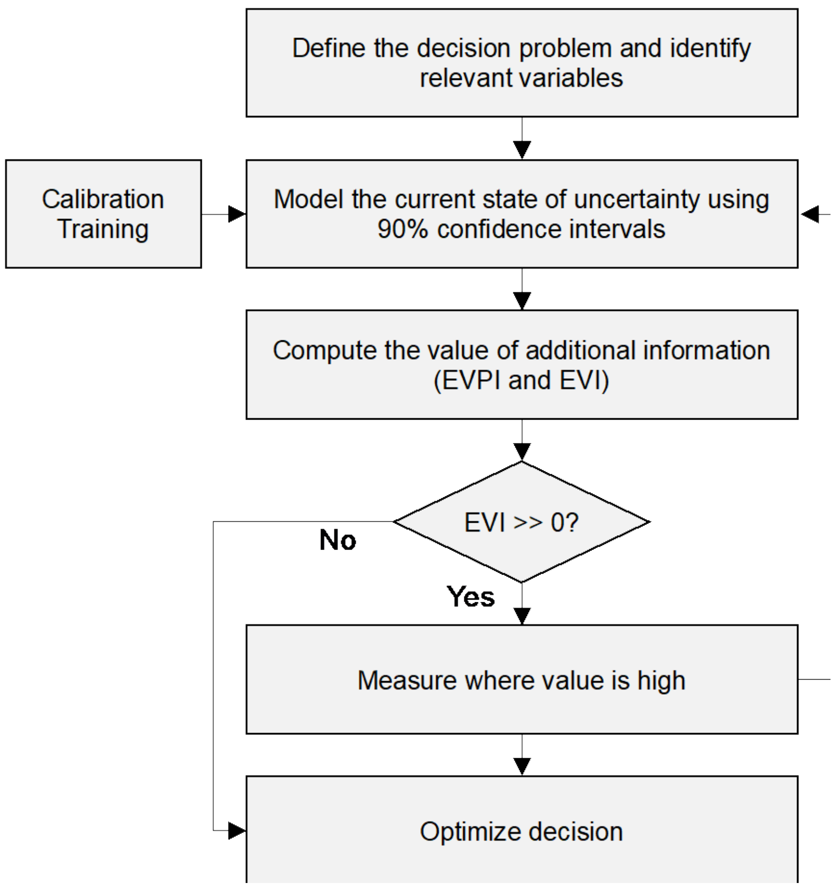


Figure 3. Value of Information Analysis Framework

Uncertainty is the source of the risk of loss and therefore of the risk associated with decision-making. Whether this uncertainty is acceptable depends on the costs associated with the potential for making the wrong decision.

A Value of Information analysis informs decisions about reducing this uncertainty through research and data collection investments:

- Model the decision, identifying the decision nodes, chance nodes, and outcomes involved.
- Calibrate experts to produce interval estimates when faced with scarcity of observed data.
- Compute the expected value of perfect information (EVPI) and the expected value of information (EVI).
- Collect data for variables with high information value.
- Determine decision-maker’s risk tolerance boundary.

Influence diagrams show relationships between uncertain factors, decisions, and outcomes.

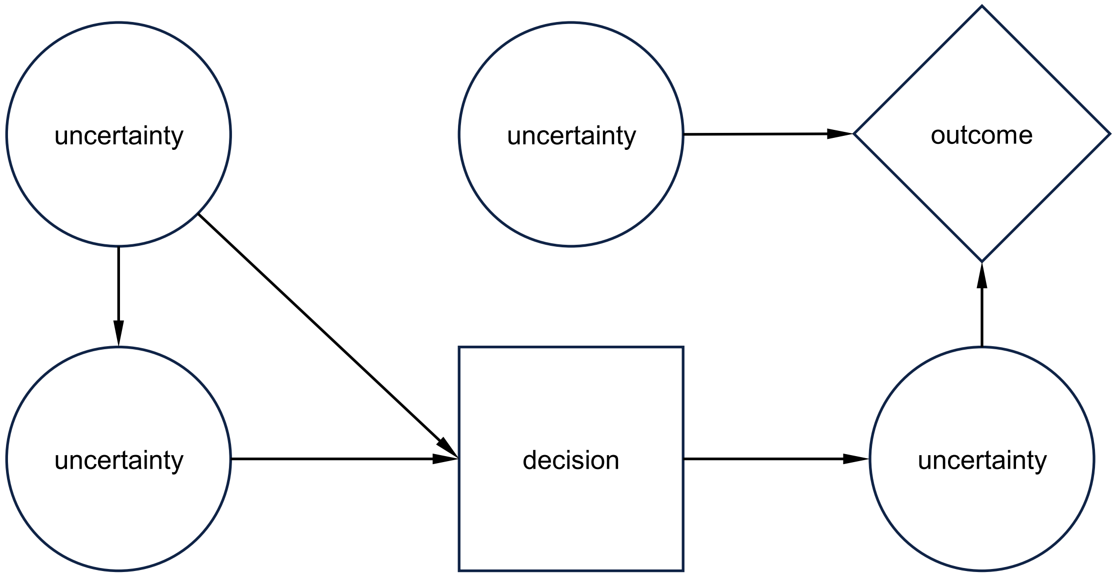
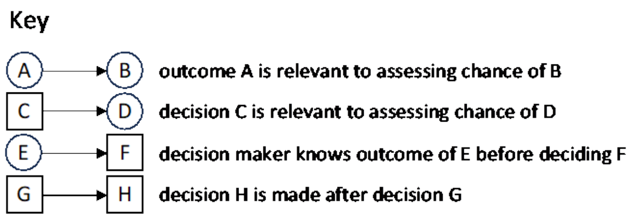


Figure 3. Generic Influence Diagram



- The **decision risk** is that the chosen alternative will not be optimal or will not return benefits that exceed cost.
- Decision analysis provides a framework in which to evaluate the uncertainties and decision risks.

The decision to regulate a medical condition comes with the risk that costs will exceed safety benefits.

1. Regulators may have prior knowledge about the safety risks posed by a specific condition and severity*.

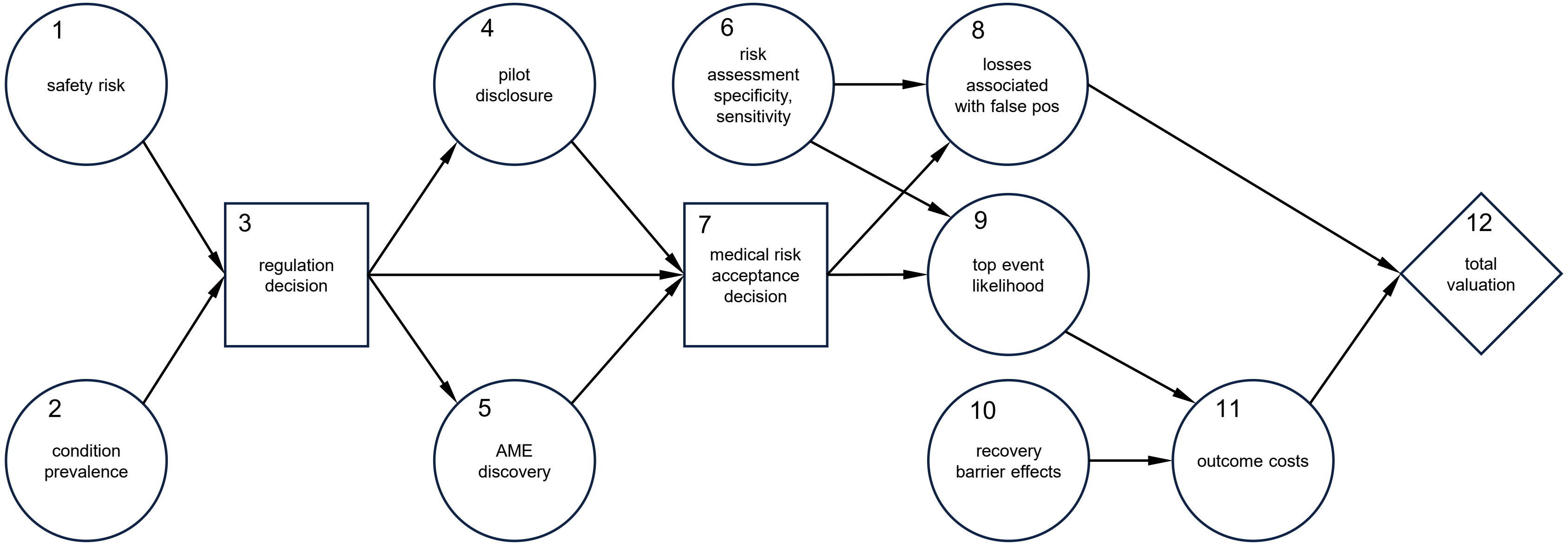
4. There is uncertainty about the likelihood that a pilot will disclose a condition.

6. Risk assessment specificity/sensitivity refers to rates of false positives, false negatives, etc.

8. False positives lead to costs: healthy pilots having to spend resources to resolve their case.

9. There is some chance that a pilot determined to be an acceptable risk will contribute to a system top event due to medical cause.

12. Total valuation is a function of outcome costs, costs of false positives, etc.



2. There is some uncertainty about the prevalence of the condition and severity levels in the target population.

3. The decision to regulate a condition considers prior knowledge and the prevalence of the condition in the population.

5. There is uncertainty about the likelihood that an AME will detect a condition that isn't disclosed by the pilot.

7. The risk acceptance decision:
- allow
- allow with limitations
- disallow

10. There is uncertainty about the likelihood that recovery barriers will be effective at preventing loss.

11. There is uncertainty about the costs associated with undesired outcomes such as aircraft divert.

Figure 4. Office of Aerospace Medicine Decision Model as an Influence Diagram.

***:** Condition severity, such as those represented by CHA_2DS_2-VASc score or PHQ-9 score, may have different safety risks associated with them.

Approaches to inform uncertainty nodes.

Node	Node Description	Node Type	Data Type	Approach
1	Regulators' prior baseline knowledge about the risks posed by a specific condition	Uncertainty	Prob [0,1]	Gather expert insights or analyze historical pilot data (pilot population, age, health) to estimate probabilities using statistical methods.
2	The uncertainty about the prevalence of the condition in the general population	Uncertainty	Prob [0,1]	Use statistical analysis of epidemiological, population health data, and medical data (condition/severity) or surveys to estimate probabilities.
3	The decision to regulate a condition considering prior knowledge and the prevalence of the condition in the population	Decision	Categorical	Not applicable. (Discrete choice).
4	The uncertainty about the likelihood that a pilot will voluntarily disclose a medical condition.	Uncertainty	Prob [0,1]	Use surveys, pilot-focused psychological experiments, past rates of disclosure on similar conditions with implication on job security, or calibrated expert elicitation to assess likelihood of disclosure for a given policy.
5	The uncertainty about the likelihood that an AME will detect a condition that is not visible or revealed by the pilot	Uncertainty	Prob [0,1]	Analyze past diagnostic test and medical examination data to model rates of condition discovery or use simulations, and whether the incapacitation is acute or subtle. Reference analogous populations with concealment behavior.
6	Risk assessment specificity/sensitivity refer to rates of false positives, false negatives, etc.	Uncertainty	Prob [0,1]	Analyze audit data on past adjudication decisions, conduct meta-analysis of adjudication accuracy, or consult expert judgement to estimate rates of confusion matrix.

Approaches to inform uncertainty nodes.

Node	Node Description	Node Type	Data Type	Approach
7	Adjudication decision	Decision	Categorical	Not applicable. (Discrete choice).
8	False positives in the adjudication decision leading to costs: healthy pilots having to spend resources to resolve their case	Uncertainty	Distribution	Apply pilot survey data, qualitative data from past adjudication decisions, and pilot healthcare data to economic models (e.g., cost analysis) to analyze costs associated with false positives (e.g., Gamma distribution).
9	The probability that a pilot deemed a low risk will have a disease manifestation leading to the top event.	Uncertainty	Prob [0,1]	Apply historical data on aviation incidents reports (NTSB reports) and certified pilots' health data to economic models, simulations, or risk analysis.
10	The probability that recovery barriers will be effective at preventing top event from leading to cost-bearing incident or accident.	Uncertainty	Prob [0,1]	Apply aviation safety incident data and data on past barriers to economic models (e.g., statistical inference), or elicit expert judgement to estimate distribution of the effectiveness of barriers.
11	The uncertainty about the costs associated with off-nominal outcomes such as aircraft diverts.	Uncertainty	Distribution	Apply aviation incident data and economic cost data to economic models (e.g., statistical inference) or cost analysis to estimate the distribution of costs related to outcomes.
12	Total valuation is a function of outcome costs, costs of false positives, etc.	Outcome	Distribution	Leverage cost and event probability distributions from nodes 1-11 to conduct cost-benefit analysis with Monte Carlo simulation.

In cases of data scarcity, decision analysts rely on uncertainty distributions from calibrated experts.

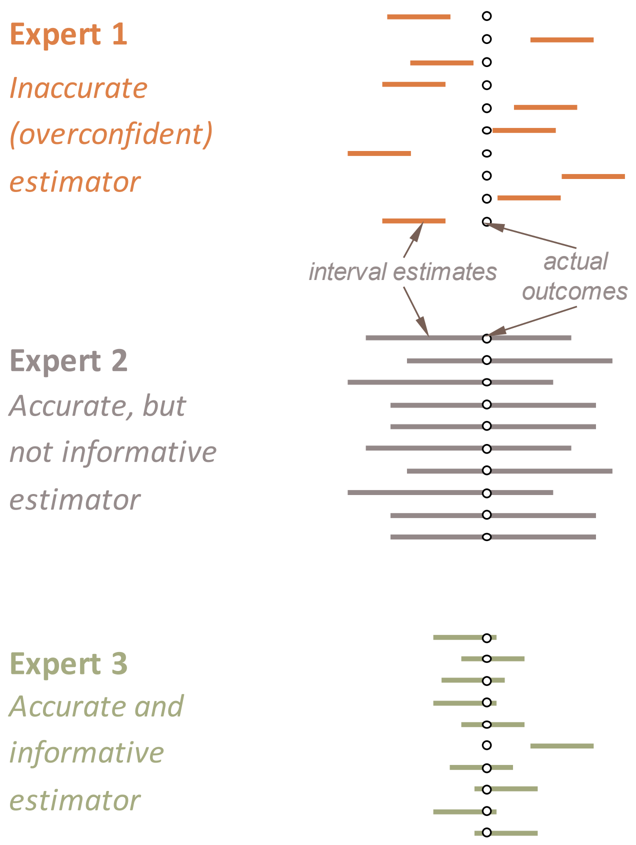


Figure 5. Non-Calibrated and Calibrated Experts' Interval Estimates

- When relying on human experts – rather than observed data – to produce estimates, we want 90% of their confidence intervals to contain the true value in the long run.
- Experts tend not to accurately express their own uncertainty.
- Experts can be be calibrated through controlled sessions.
- Interval estimates can have density functions (shapes) to convey dominant regions of belief/probability.

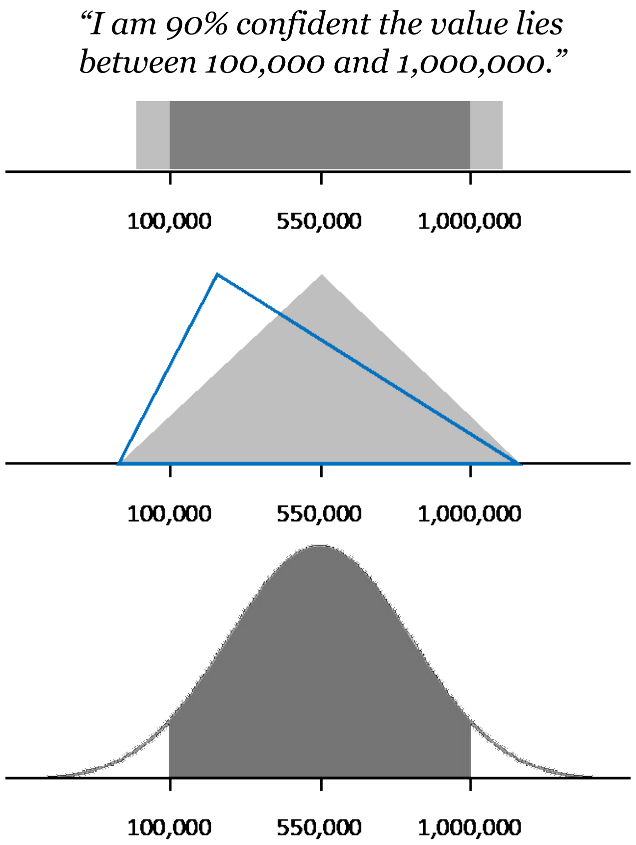


Figure 6. Interval Estimates as Distributions.

A Value of Information analysis tells us where we should allocate resources to reduce variables' uncertainties.

- Decision analysis questions:
    - Is there too much uncertainty to make the decision?
    - Where should we reduce our uncertainty through additional data collection?
    - What should we be willing to spend to reduce that uncertainty?
- Monte Carlo simulates virtual decisions to generate a distribution of outcomes:
    - We note what we would have done with the benefit of 'clairvoyance' and calculate expected opportunity loss (EOL).
    - Eliminating EOL would require perfect information (EVPI).

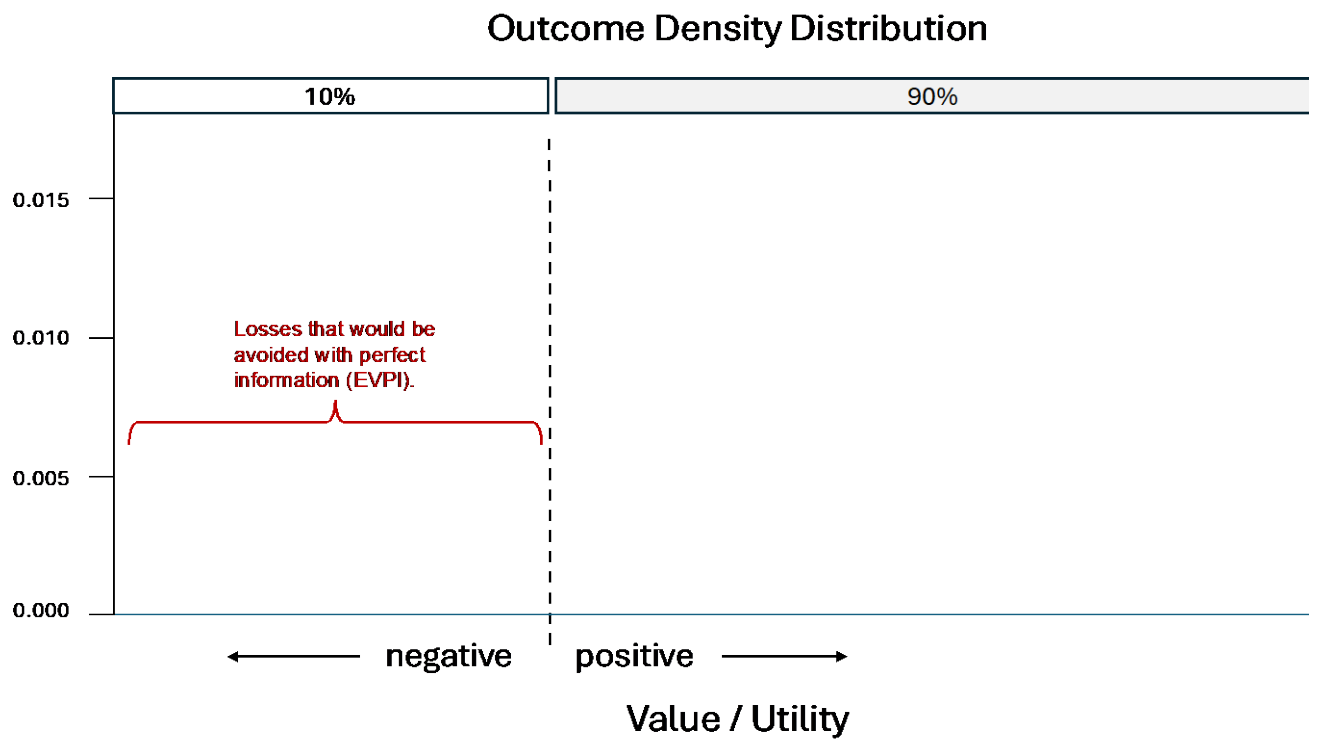


Figure 7. Example Density Distribution of Output Variable, in Units of Value or Utility.

The decision model can be referenced when events trigger the SRM process.

The SRM Process is initiated by the following "triggers":

- New or revised process or procedures
- New or revised operation or environment
- New or revised system, organization or resources
- New or revised product or service
- New hazards (identified in the SA functions)
- Ineffective risk controls (identified in the SA function)

SRM Trigger	Examples	Potential Changes to Diagram
New or revised operation or environment	• Increase in pilot age limit • Research study comes finding 2% higher rate of Condition C in the pilot population than in the general population	Change condition prevalence, adjudication decision, losses associated with false pos
Ineffective risk control	• Safety Assurance identifies higher risk posed by individuals with Condition C • Safety Assurance determines that barrier has higher false positive rate than previously known • Pilot non-disclosure of health conditions	Change safety risk, pilot disclosure, AME discovery, recovery barrier effects
External policy change with potential to impact risk control	• Increase in pilot age limit • FAA is no longer allowed to impose Barrier B1 for Condition C • FAA is now able to collect EHR data to estimate condition prevalence among pilots	Change to regulation decision, AME Discovery, pilot discovery, risk assessment specificity and sensititivty
New risk control, OR Updating a risk control, OR Novel or highly visible situation	• First time special issuance for a condition • New treatment for Condition C reduces risk of top event given Condition C with Severity S • Adverse effects in vaccine with emergency use authorization	Change to safety risk, pilot disclosure, AME discovery, risk assessment specificity and sensitivity, recovery barrier effects, and top event likelihood

Acronyms

Acronym	Definition
EVPI	Expected Value of Perfect Information
EVI	Expected Value of Information
EOL	Expected Opportunity Loss
SRM	Safety Risk Management
SMS	Safety Management System

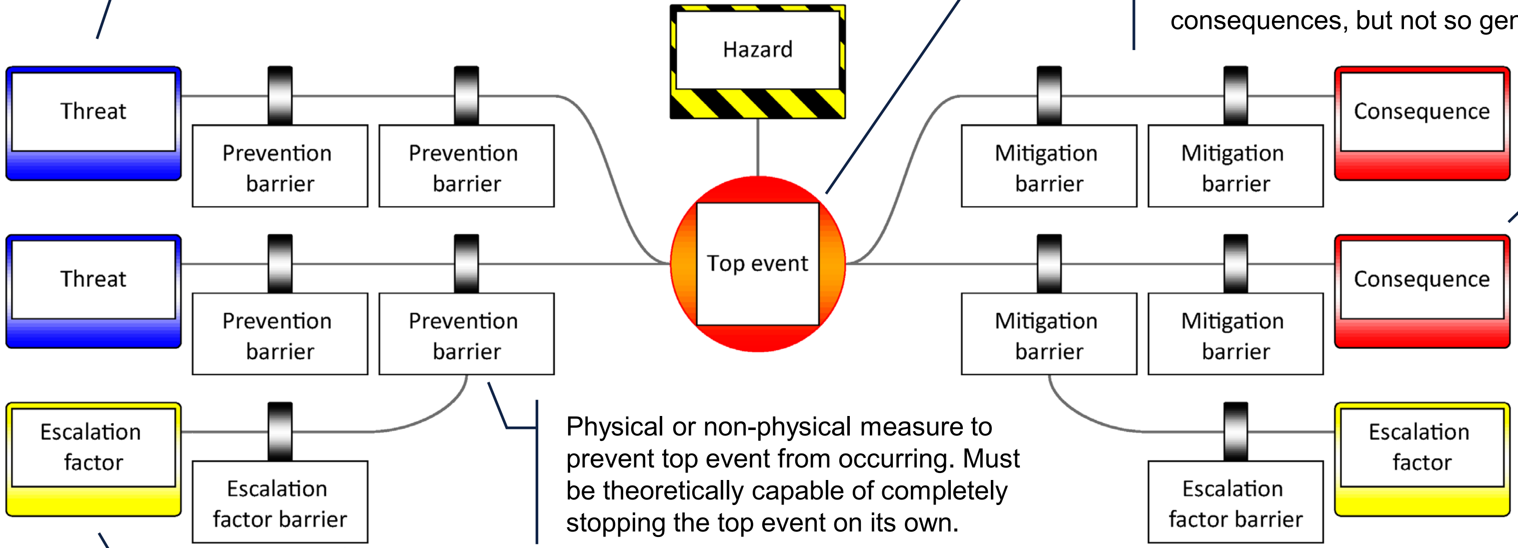
Appendix A.2

Bow Tie models provide a visual depiction of safety threats, barriers, degradation factors, and consequences.

Potential reasons for loss of control of the hazard leading to the top event. The threat should lead to the top event if not for the prevention barriers. Threats should have a direct causation and be specific. Threats should be sufficient – able to reach the top event without depending on another threat. Threats are not barrier failures.

Hazard: An operation or activity with potential to cause harm. Hazards are a normal part of business; often necessary to run an operation. Should be specific enough to focus the bowtie on a particular risk of interest. Should include situational context or an indication of scale.

Moment when control over the hazard is lost, releasing its harmful potential. Not a consequence (yet). Should describe how/what control is lost. Should be narrow enough to generate several threats and consequences, but not so general that it generates more than ten.



Consequence: Unwanted outcome that could result from the top event and lead to damage or harm.

Physical or non-physical measure to prevent top event from occurring. Must be theoretically capable of completely stopping the top event on its own.

A measure to prevent or mitigate the escalation or degradation factor from reducing the effectiveness of a prevention barrier. They can not by themselves prevent a top event.

Similar to a degradation factor. Condition that reduces the effectiveness of controls. An escalation factor cannot directly cause the top event or consequence rather it increases the likelihood that the scenario will progress because the associated control will be degraded or fail

Core barrier attributes

- Effective: can on its own prevent a threat from developing into the top event.
- Independent: should be independent of the threat and of other barriers on that pathway.
- Auditable: should be capable of being audited to check that it works. Should theoretically allow for performance standards of the functionality of a barrier.

Source: *Bow Ties in Risk Management*, CCPS, Wiley, 2018.

NOTICES

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