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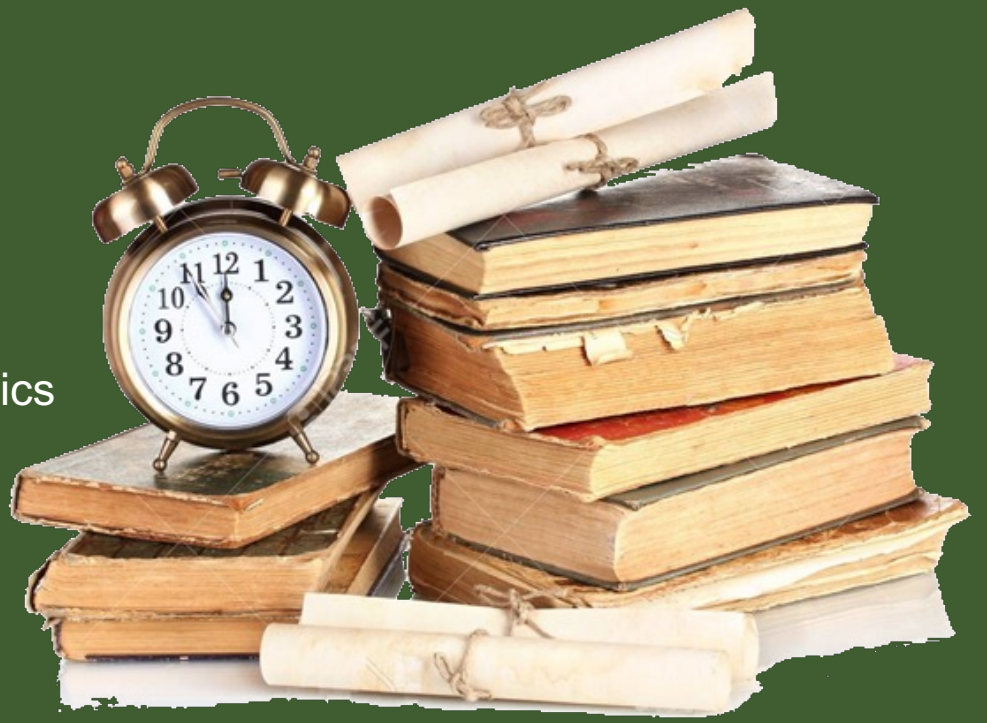
A Universal, Structured Framework for

Assessing Medical Benefit-Risk

Author Background

- A ‘Systems Engineering’ thought process
  - Formal Education:
    - Mechanical, Electrical, Software Engr. & Mathematics
  - Product Experience
    - Class I, II and III
    - Pure device products, Combination device/drug, device/biologic, device/drug/biologic
  - 30 years of Professional Experience
    - 15 years in product development
    - 15 years in product remediation
  - Risk Mgmt. transitioned from a necessary development task to consulting focus
  - Developed / patented the presentation’s content. (Pat. No. US 18/643,355 and PCT/US24/25797)



How did we get here?

Current State

Assessing Benefit-Risk is Foundational

- "First, do no harm" dates back to the Code of Hammurabi, around 2000 BCE
  - Often mis-attributed to the Hippocratic Oath, around 400 BCE.
- "First, do no harm" instructs medical practitioners to:
  - Not just think of how a treatment can be helpful.
  - To also think of how a treatment might cause harm.
  - And ensure, before performing medicine, that the balance favors the patient.

Assessing Benefit-Risk is Foundational

Product Development

- US Congress started regulating Medical Devices in 1976
  - As the final product development task: Show the benefit over risk ratio is greater than one
- The EU started regulating Medical Devices in 1993
  - Annex I, Chapter 1, Sect. 1: Show the risks are acceptable when compared with the benefits
- Clinical Trials
  - The trial
  - The subjects

Quality System Compliance*

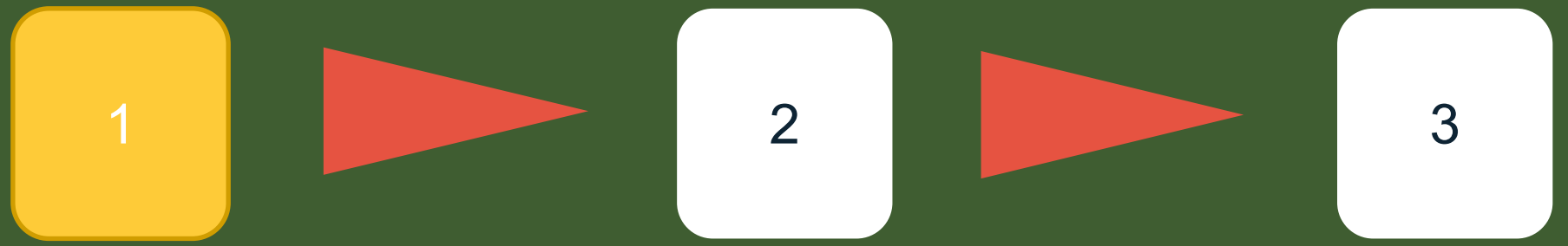
- Used to assess the impact of compliance gaps on patient risk.
- These assessments can lead to:
  - Taking no action
  - Product redesign
  - Legal actions against company
    - Field replacements
    - Product recalls
    - Shipment stoppage orders
    - Product Liability Lawsuits
  - Legal actions against company officers
    - Prison Time
    - Prohibition from managing a medical company

** Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions*, FDA, issued on December 27, 2016

From here, to where?

Future State

The Path Forward



Define one metric for benefit & risk

Populate the equation B > R

Simplify B > R to an obvious answer

Define one metric to measure benefit & risk

- FDA Guidance*
  - Example 1 of this guidance discusses an “an aesthetic device”.
    - The benefit for this device is simply stated as “moderate,” with “some patients . . . [seeing] long-term aesthetic improvement” and
    - The risks were stated as “adverse events of varying severity.”
  - These benefit and risk statements can not be compared objectively and directly

*_Factors to Consider Regarding Benefit-Risk in Medical Device Product Availability, Compliance, and Enforcement Decisions_, FDA, issued on December 27, 2016

Define one metric to measure benefit & risk

- Measuring Risk:
  - Many standards measure risk
    - ISO 60812:2018 - Failure Mode Analysis
    - IEC 1025, 1st Edition - Fault Tree Analysis
    - Risk Prediction for Surgery
  - ISO 14971 has become the **de facto** risk management standard for medical devices

Define one metric to measure benefit & risk

- 'Risk' is defined as a combination of 'Severity' and 'Probability', per ISO/IEC Guide 63:2019
  - TR 24971 provides the following tables as examples of objective metrics that can be defined for measuring Severity and Probability

Common Terms	Possible Description
Catastrophic / Fatal	Results in death
Critical	Results in permanent impairment or irreversible injury
Serious / Major	Results in injury or impairment requiring medical or surgical intervention
Minor	Results in temporary injury or impairment not requiring medical or surgical intervention
Negligible	Results in inconvenience or temporary discomfort

Common Terms	Examples of Probability Range
Frequent	$\geq 10^{-3}$
Probable	$< 10^{-3}$ and $\geq 10^{-4}$
Occasional	$< 10^{-4}$ and $\geq 10^{-5}$
Remote	$< 10^{-5}$ and $\geq 10^{-6}$
Improbable	$< 10^{-6}$

  - We will use an ordered pair of Severity and Probability to represent Risk; i.e., for the *i*th Risk,

$$R_i = (P_i, S_i)$$

Define one metric to measure benefit & risk

- Measuring Benefit:
  - Current State
    - Measuring Benefit lags badly relative to measuring Risk
    - Regulations require companies to monitor product Risk
      - No Regulations require companies to monitor benefit
    - Standards exist for measuring Risk
      - No standards exist for measuring benefit

Define one metric to measure benefit & risk

- Looking Closer
  - FDA definition of ‘patient’:
    - Any individual with, or at risk of, a specific health condition, whether or not he or she currently receives any therapy to prevent or treat that condition. Patients are the individuals who directly experience the benefits and harms associated with medical products.
  - The benefit from a medical treatment is the same as

    the reduction in the patient’s health condition from a medical treatment

Define one metric to measure benefit & risk

- A second Look
  - If we define ‘HC’ as the likely amount of harm from a specific health condition.
  - And ‘Risk’ is a ‘combination of the probability of occurrence and severity of a specific harm’
  - Then ‘HC’ is the Risk to someone’s health from their specific health condition.

Define one metric to measure benefit & risk

- If R_B is the patient risk from the patient's health condition Before the medical treatment
- And R_A is the patient risk from the patient's health condition After the medical treatment

- Then the benefit of a medical treatment, B, is $R_B - R_A$; i.e., the reduction in the patient's health condition from a medical treatment

Define one metric to measure benefit & risk

- $B = R_B - R_A$ means *we* are measuring '*Benefit*', or *B*, using metrics for '*Risk*', or *R.*
- Therefore, we can use the metrics for measuring 'Risk' to measure 'Benefit'.
  - The same severities and probabilities used to describe the *patient risk from a device* used in medical treatment can now be used to describe the *patient risk from their health condition*.

The Path Forward

Define one metric for benefit & risk

Populate the equation B > R

Simplify B > R to an obvious answer

Populate the equation ‘ B > R ’

- We’ve already shown we can represent the overall Risk Level from a medical treatment as:

$$R = \{(P_1, S_1), (P_2, S_2), (P_3, S_3), \dots, (P_n, S_n)\}$$

- Now, we can represent the overall Benefit Level from a medical treatment similarly:

$$R^B = \{(P_1^B, S_1^B), (P_2^B, S_2^B), (P_3^B, S_3^B), \dots, (P_m^B, S_m^B)\}$$

$$R^A = \{(P_1^A, S_1^A), (P_2^A, S_2^A), (P_3^A, S_3^A), \dots, (P_m^A, S_m^A)\}$$

$$B = R_B \triangleq R_A$$

  - Where ‘ $\triangleq$ ‘ means the difference between the overall risk level to the left and the overall risk level to the right

Populate the equation ‘ B > R ’

- If we continue using the ‘curly bracket’ cap to designate a ‘set operation’ involving the overall risk of the set on the left and right, then

We want to show whether $B \overset{\frown}{>} R$ is true.

Since $B = R_B \overset{\frown}{=} R_A$ and $B \overset{\frown}{>} R$

then

$$R_B \overset{\frown}{=} R_A \overset{\frown}{>} R$$

or

$$R_B \overset{\frown}{>} R \cup R_A$$

. “The health risk before a procedure” must be greater than “the procedure’s risk and the health risk after the procedure”

Populate the equation ‘ B > R ’

- Suppose an aBR, has the following risks:

$$R^B = \{(P_5, S_5), (P_6, S_6), (P_7, S_7), (P_8, S_8), (P_{11}, S_{11}), (P_{12}, S_{12}), (P_{15}, S_{15}), (P_{16}, S_{16})\}$$

$$R^A = \{(P_9, S_9), (P_{10}, S_{10}), (P_{13}, S_{13}), (P_{14}, S_{14}), (P_{17}, S_{17})\}$$

$$R = \{(P_1, S_1), (P_2, S_2), (P_3, S_3), (P_4, S_4)\}$$

- If we substitute these three sets of risks into the equation $R_B \gtrsim R \cup R_A$, then
  - The union will combine two of the sets, so the equation will be populated by two sets of risks:
    - One of the sets of risks is on the lefthand side of the inequality.
    - The other set of risks on the righthand side of the inequality.

Populate the equation ‘ B > R ’

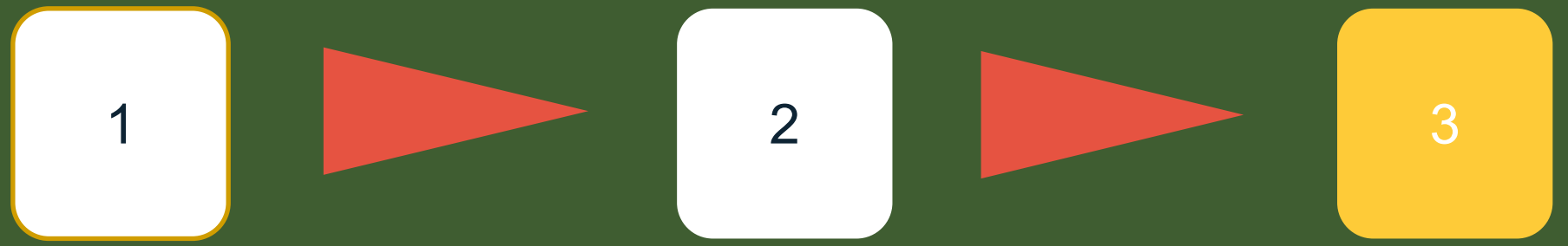
- We will find it helpful to use the table format to organize our two sets of risks.

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected				R_7	
Often	R_{11}				
Frequent			R_{15}, R_{16}		
Probable					R_8
Occasional		R_{12}			
Remote			R_5		
Improbable				R_6	

>

$R_A \cup R$	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often		R_{10}			R_{17}
Frequent	R_9	R_1	R_{14}		
Probable				R_4	
Occasional		R_2			
Remote					
Improbable		R_{13}	11 X R_3		

The Path Forward



Define one metric for benefit & risk

Populate the equation B > R

Simplify B > R to an obvious answer

Simplify ‘ B > R ’ to an obvious answer

- We need to simplify this equation until it is intuitively clear whether B > R

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
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Simplify ‘ B > R ’ to an obvious answer

- Consider simplifying algebraic equations:

Equation	Simplification Step
$3x^2 + 7 = 55$	Original Equation

Simplify ‘ B > R ’ to an obvious answer

- Consider simplifying algebraic equations:

Equation	Simplification Step
$3x^2 + 7 = 55$	Original Equation
$3x^2 + 7 - 7 = 55 - 7$	Subtract a number from both sides
$3x^2 + 0 = 48$	Simplify the Addition on both sides
$\frac{3x^2}{3} = \frac{48}{3}$	Divide by a number on both sides
$\frac{3}{3}x^2 = 16$	Simplify the Division on both sides
$\sqrt{x^2} = \sqrt{16}$	Take the square root of both sides
$x = \mathbf{4}$	The final answer

Simplify ‘ B > R ’ to an obvious answer

- We need to simplify this equation until it is intuitively clear whether B > R

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected				R_7	
Often	R_{11}				
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$\supset$

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Simplify ‘ B > R ’ to an obvious answer

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Frequent	R_9	R_1	R_{14}		
Probable				R_4	
Occasional		R_2			
Remote					
Improbable		R_{13}	11 X R_3		

- There are four ways to simplify this equation.
- What is one, *simple* thing we can we do to <u>both sides</u> to simplify this equation? Keep it obvious.

Simplify ‘ B > R ’ to an obvious answer

- What is special about the two circled risks?

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected				R_7	
Often	R_{11}				
Frequent			R_{15}, R_{16}		
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vs

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Probable				R_4	
Occasional		R_2			
Remote					
Improbable		R_{13}	11 X R_3		

- These two cells each contain a single risk with the same combination of Severity and Probability.

Simplify ‘ B > R ’ to an obvious answer

- What is special about the two circled risks?

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected				R_7	
Often	R_{11}				
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Frequent	R_9	R_1	R_{14}		
Probable				R_4	
Occasional		R_2			
Remote					
Improbable		R_{13}	11 X R_3		

- We can remove a risk with the same combination of Severity and Probability from both sides of the equation without changing whether the equation is true.

Simplify ‘ B > R ’ to an obvious answer

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected				R_7	
Often	R_{11}				
Frequent			R_{15}, R_{16}		
Probable					R_8
Occasional					
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Improbable				R_6	

>

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Often		R_{10}			R_{17}
Frequent	R_9	R_1	R_{14}		
Probable				R_4	
Occasional					
Remote					
Improbable		R_{13}	11 X R_3		

- Simplifying the equation by removing one risk from the same cell on each side of the equation is called ‘Removing Identical Risks’.

Simplify ‘ B > R ’ to an obvious answer

- Another way to simplify the equation is to change how a risk is represented.

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected				R_7	
Often	R_{11}				
Frequent			R_{15}		
Probable					R_8
Occasional					
Remote			R_5		
Improbable				R_6	

$\supset$

$R_A \cup R$	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
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Often		R_{10}			R_{17}
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Improbable		R_{13}	11 X R_3		

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R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected				R_7	
Often	R_{11}				
Frequent			R_{15}		
Probable					R_8
Occasional					
Remote			~~R_5~~		
Improbable			10 X R_5	R_6	

$\geq$

$R_A \cup R$	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often		R_{10}			R_{17}
Frequent	R_9	R_1			
Probable				R_4	
Occasional					
Remote					
Improbable		R_{13}	11 X R_3		

  - Since each probability gets 10X smaller with each lower row, we can trade the probability of a risk for the number of times a risk appears.

Simplify ‘ B > R ’ to an obvious answer

- Another way to simplify the equation is to change how a risk is represented.

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected				R_7	
Often	R_{11}				
Frequent			R_{15}		
Probable					R_8
Occasional					
Remote					
Improbable			10 X R_5	R_6	

$R_A \cup R$	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often		R_{10}			R_{17}
Frequent	R_9	R_1			
Probable				R_4	
Occasional					
Remote					
Improbable		R_{13}	11 X R_3		

  - This is called ‘Moving Redundant Risks’.
  - Why would we do this?

Simplify ‘ B > R ’ to an obvious answer

- Another way to simplify the equation is to change how a risk is represented.

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected				R_7	
Often	R_{11}				
Frequent			R_{15}		
Probable					R_8
Occasional					
Remote					
Improbable			10 X R_5	R_6	

>

$R_A \cup R$	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often		R_{10}			R_{17}
Frequent	R_9	R_1			
Probable				R_4	
Occasional					
Remote					
Improbable		R_{13}	10 X R_3 R_3		

  - We change how risks are represented if it enables us to ‘Remove Identical Risks’.

Simplify ‘ B > R ’ to an obvious answer

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected				R_7	
Often	R_{11}				
Frequent			R_{15}		
Probable					R_8
Occasional					
Remote					
Improbable				R_6	

$\supset$

$R_A \cup R$	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often		R_{10}			R_{17}
Frequent	R_9	R_1			
Probable				R_4	
Occasional					
Remote					
Improbable		R_{13}	R_3		

- So far, we’ve identified two algebraic rules for simplifying the equation:
  - Remove Identical Risks
  - Moving Repeated Risks

Simplify ‘ B > R ’ to an obvious answer

- The next algebraic rule also changes how risks are represented by using bands of cells with similar risks.
  - Each company needs to confirm this with their own clinical review, but adjacent cells with the same number and color have approximately the same amount of risk.

Semi-quantitative **probability** levels	Qualitative **severity** levels				
	Negligible	Minor	Serious / Major	Critical	Catastrophic / Fatal
Expected	7	8	9	10	13
Often	6	7	8	9	12
Frequent	5	6	7	8	11
Probable	4	5	6	7	10
Occasional	3	4	5	6	9
Remote	2	3	4	5	8
Improbable	1	2	3	4	7

Simplify ‘ B > R ’ to an obvious answer

- Moving risks along these bands is called Moving Similar Risks.

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected				R_7	
Often	R_{11}				
Frequent			R_{15}		
Probable					R_8
Occasional					
Remote					
Improbable				R_6	

$R_A \cup R$	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often		R_{10}			R_{17}
Frequent	R_9	R_1			
Probable				R_4	
Occasional					
Remote					
Improbable		R_{13}	R_3		

- As with Moving Redundant Risks,
  we use Moving Similar Risks to set-up removing risks, which simplifies to:

Simplify ‘ B > R ’ to an obvious answer

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often	R_{11}				
Frequent				R_8	
Probable					
Occasional					
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$R_A \cup R$	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often					
Frequent	R_9	R_1			
Probable				R_4	
Occasional					
Remote					
Improbable		R_{13}	R_3		

- So far, we’ve identified three algebraic rules for simplifying the equation:
  - Remove Identical Risks
  - Moving Repeated Risks
  - Moving Similar Risks

Simplify ‘ B > R ’ to an obvious answer

- And the final algebraic rule is the most powerful: Remove Unequal Risks

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often	R_{11}				
Frequent				R_8	
Probable					
Occasional					
Remote					
Improbable				R_6	

$\overset{\sim}{>}$

$R_A \cup R$	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often					
Frequent	R_9	R_1			
Probable				R_4	
Occasional					
Remote					
Improbable		R_{13}	R_3		

- For Remove Unequal Risks, we want to pick ‘b’ and ‘d’ so:
  - ‘b’ and ‘d’ are as close to the same size as possible, and
  - $b \overset{\sim}{>} d$

Simplify ‘ B > R ’ to an obvious answer

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often	R_{11}				
Frequent			4 X R_8		
Probable				5 X R_8	
Occasional					
Remote					
Improbable				R_6	

$R_A \cup R$	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often					
Frequent	R_9	R_1	**4 X R_8**		
Probable					
Occasional					
Remote					
Improbable		R_{13}	R_3		

- In ‘Remove Unequal Risks’, it is easier to visualize which risk is greater if we superimpose a ‘ghost’ risk from the left-hand side to compare the size of risks.

Simplify ‘ B > R ’ to an obvious answer

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often	R_{11}				
Frequent			4 X R_8		
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$\tilde{\geq}$

$R_A \cup R$	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often					
Frequent	R_9	R_1	**4 X R_8**		
Probable					
Occasional					
Remote					
Improbable		R_{13}	R_3		

- Suppose ‘b’ is 2 X R_8 and ‘d’ is R_9 and R_1.
  Then $b \tilde{\geq} d$, ‘b’ and ‘d’ can be removed without changing whether $B \tilde{\geq} R$.

Simplify ‘ B > R ’ to an obvious answer

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often	R_{11}				
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Remote					
Improbable				R_6	

$\tilde{>}$

$R_A \cup R$	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often					
Frequent	~~R_9~~	~~R_1~~	2 X R_8		
Probable					
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- Suppose ‘b’ is 2 X R_8 and ‘d’ is R_9 and R_1.
  Then $b \tilde{>} d$, ‘b’ and ‘d’ can be removed without changing whether $B \tilde{>} R$.

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Frequent	~~R_9~~	~~R_1~~	2 X R_8		
Probable					
Occasional					
Remote					
Improbable		R_{13}	R_3		

- Similarly, suppose ‘b’ is 2 X R_8 and ‘d’ is R_{13} and R_3.
  Then $b \tilde{\geq} d$, ‘b’ and ‘d’ can be removed without changing whether $B \tilde{\geq} R$.

Simplify ‘ B > R ’ to an obvious answer

R_B	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often	R_{11}				
Frequent					
Probable				5 X R_8	
Occasional					
Remote					
Improbable				R_6	

$\tilde{\geq}$

$R_A \cup R$	Negligible	Minor	Serious /Major	Critical	Catastrophic / Fatal
Expected					
Often					
Frequent					
Probable					
Occasional					
Remote					
Improbable		~~R_{13}~~	~~R_3~~		

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- Risks remain on the ‘B’ side of the equation.
- No risks remain on the ‘R’ side of the equation.

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Often					
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Probable					
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Remote					
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TRUE

- Risks remain on the ‘B’ side of the equation.
- No risks remain on the ‘R’ side of the equation.

} Benefit exceeds Risk

Questions?

Now? Raise a hand!

Later? Send an e-mail!
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