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Scenario-Based Framework: Risk Analysis of Biotechnology

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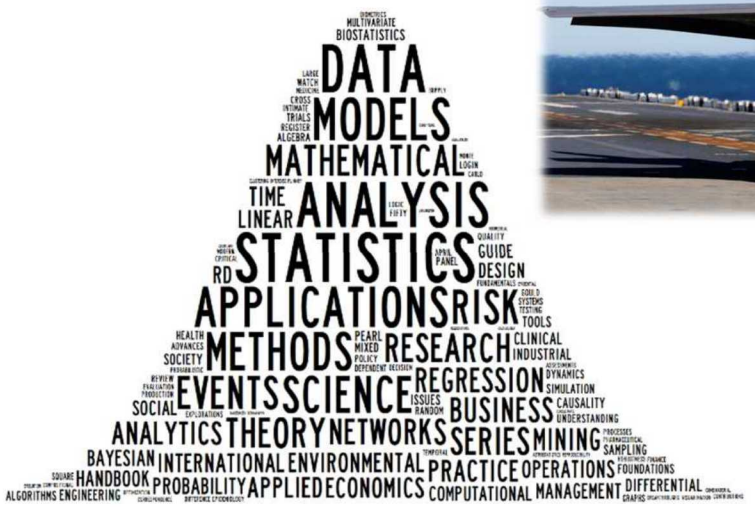

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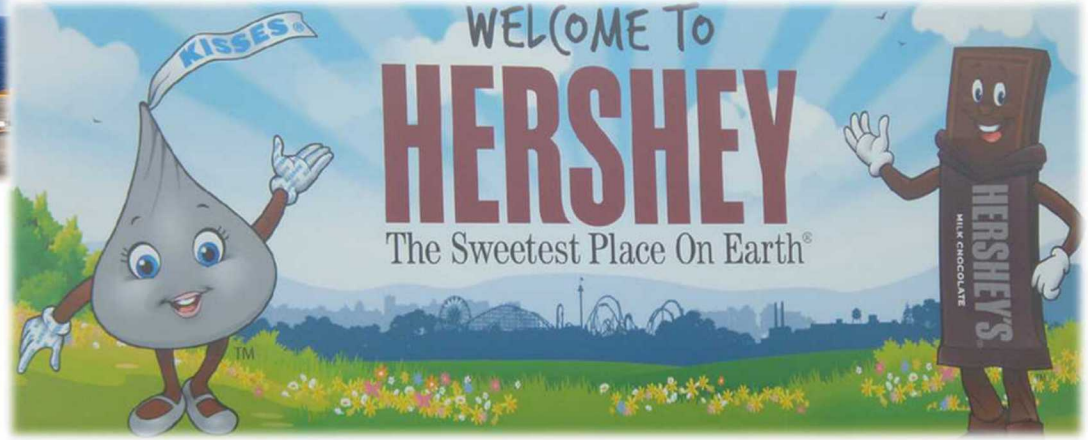


Risk Assessment of Biotechnology

Goal

- Using scenario-based risk analysis, propose a potential framework for analyzing the risk of emerging biotechnologies

Objectives

- Develop a relevant and useful scenario for our framework
- Provide a transparent and understandable explanation of the construction of the framework
- Construct a versatile framework that can be referenced and adapted for the risk analysis of other scenarios in emerging biotechnologies

This project is intended to construct an understandable, model framework for risk analysis of specific biotechnologies using a scenario-based approach

Biotechnology Background and Motivation

Emerging Technologies

- Genetic sequencing
- Gene synthesis
- Synthetic biology
- CRISPR/CAS9
- 23 & Me

CRISPR/CAS9

- Old technology, new ease of use
- Affordable and time-efficient

Areas of Uncertainty

- Monitoring and regulation
- Lone-wolf or state-sponsored?
- Unintended consequences?

Areas of Concern

- Gain of function
- Embryonic modification
- Enhancements
- DIY potential

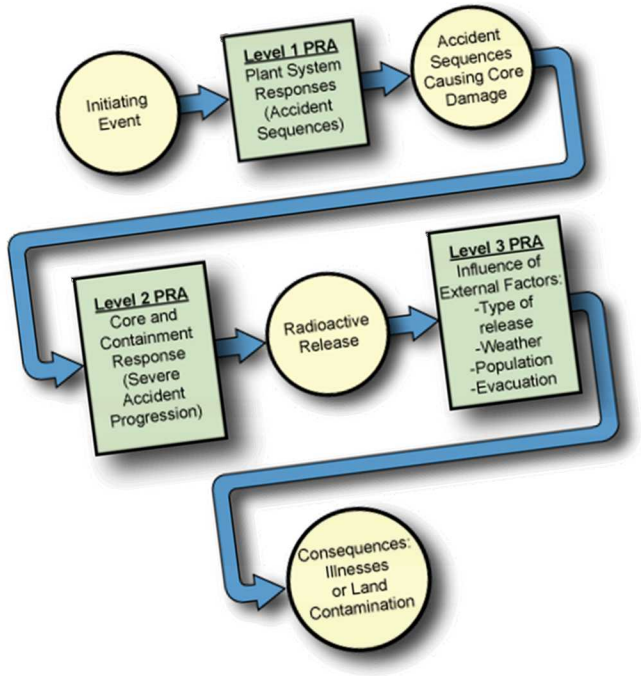
Potential Benefits

- Medical cures
- Food supply
- Improved surveillance and detection for law enforcement

Risk Background and Motivation

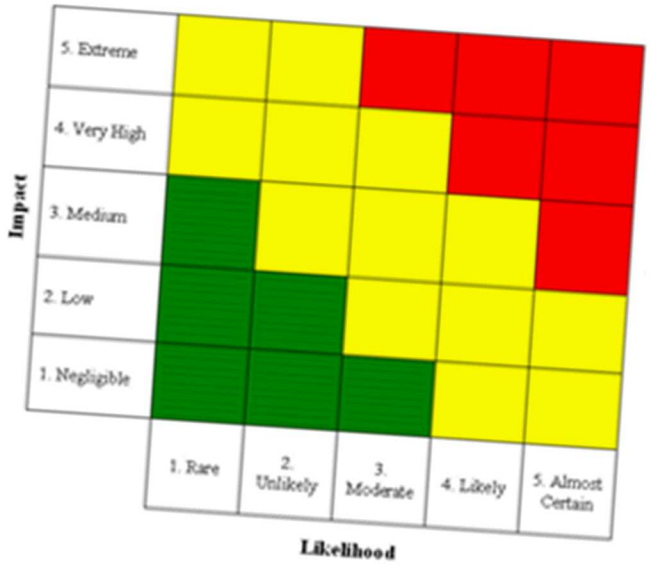
Definitions of Risk

- Likelihood vs. Consequence
- Threat, Vulnerability, Consequence
- A major problem area…



Assessing Risk

- Quantitative vs. qualitative
- Relative vs. absolute
- Difficulty vs. probability
- Scenario-based
- Another major problem area…



Problem Areas

- Risk education
- Excessive benefits and "risk-blindness"
- Inherently unquantifiable
- Relative vs. absolute
- Difficulty vs. probability
- Scoring and ranking systems
- Another major problem area…

Golden Rules

- Scope the problem
- Use **transparent** frameworks
- Utilize scenarios
- Rigorously identify variables and assumptions

Risk Questions: A Breakdown

What is the risk of *biotechnology* to the national security of the United States?

The Main Question

What is the risk of *dual-use* biotechnology to the national security of the United States?

What is the risk of a *malicious use* of biotechnology to the national security of the United States?

What is the risk of a malicious use of *CRISPR/CAS 9* to the national security of the United States?

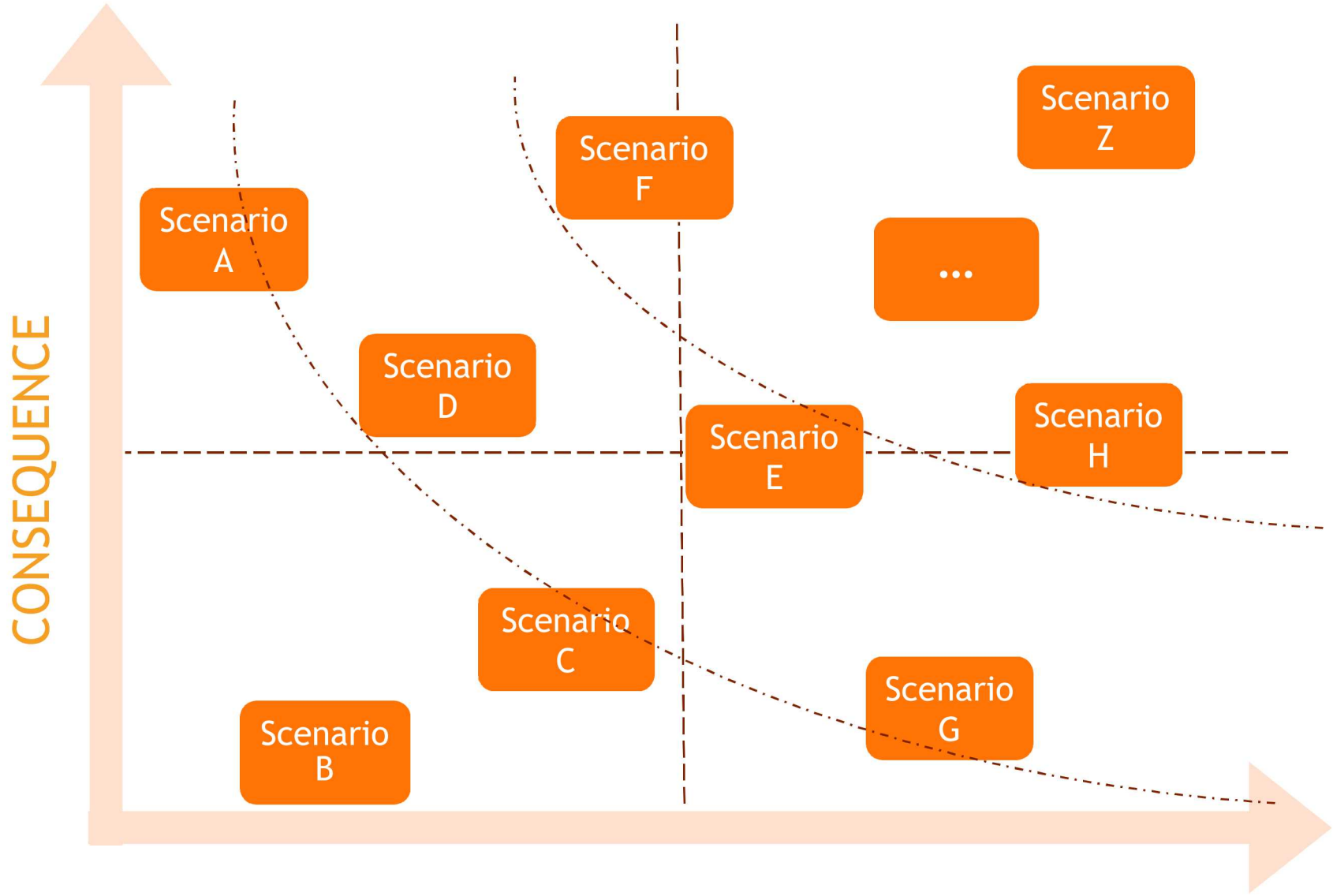
Our question

What is the risk of a *failure to detect* the malicious use of CRISPR/CAS9 to the national security of the United States?

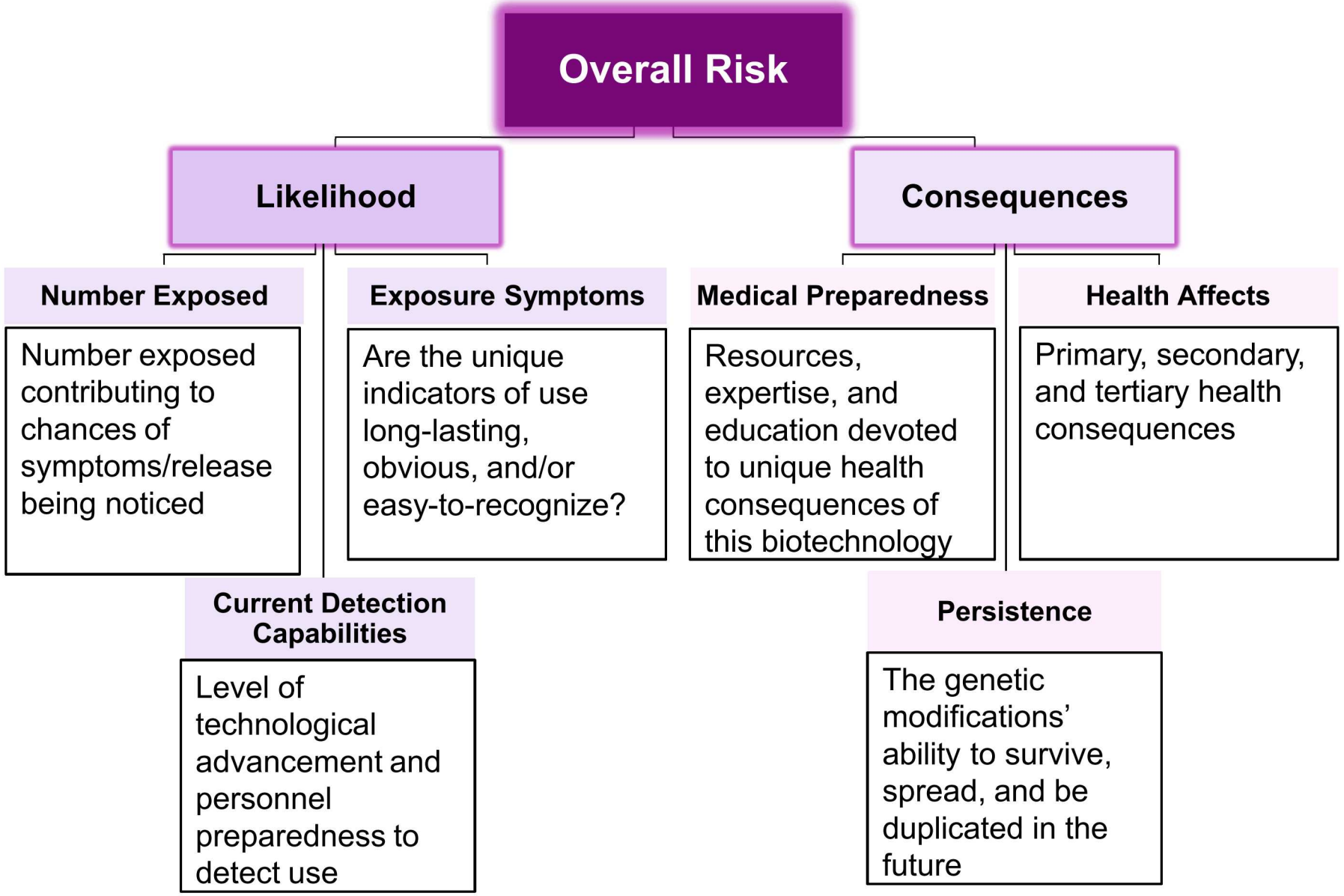
The Big Questions

What is the risk of a failure to detect the malicious use of CRISPR/CAS9?

Methodology: **Relative Assessments**



Proposed Framework – Risk of a Failure to Detect



Likelihood Assessment

Current Detection Capabilities

- Can the precursors of this attack be detected before release?
- Are current detection resources capable of detecting the signs of release post-attack?
- What is the efficacy of resources allocated to detection?

Number Exposed

- Does the ease of detecting the use of biotechnology depend on the number of victims with noticeable symptoms?

Exposure Symptoms

- Are there symptoms unique to the use of a CRISPR/Cas9 modified organism?
- Are the symptoms of this use apparent and observable?
- What is the length of time between release and first opportunities to detect the release?
- What level of clinical experience is needed to recognize the symptoms of these attacks?

Consequence Assessment

Medical Preparedness

- What treatments are currently available to treat the health effects of a CRISPR/Cas9 modified organism?
- Are the treatments readily available? What is their efficacy?
- Does any research or medical knowledge exist regarding a reversal or counter-acting of the genetic change to a CRISPR/Cas9 modified organism?

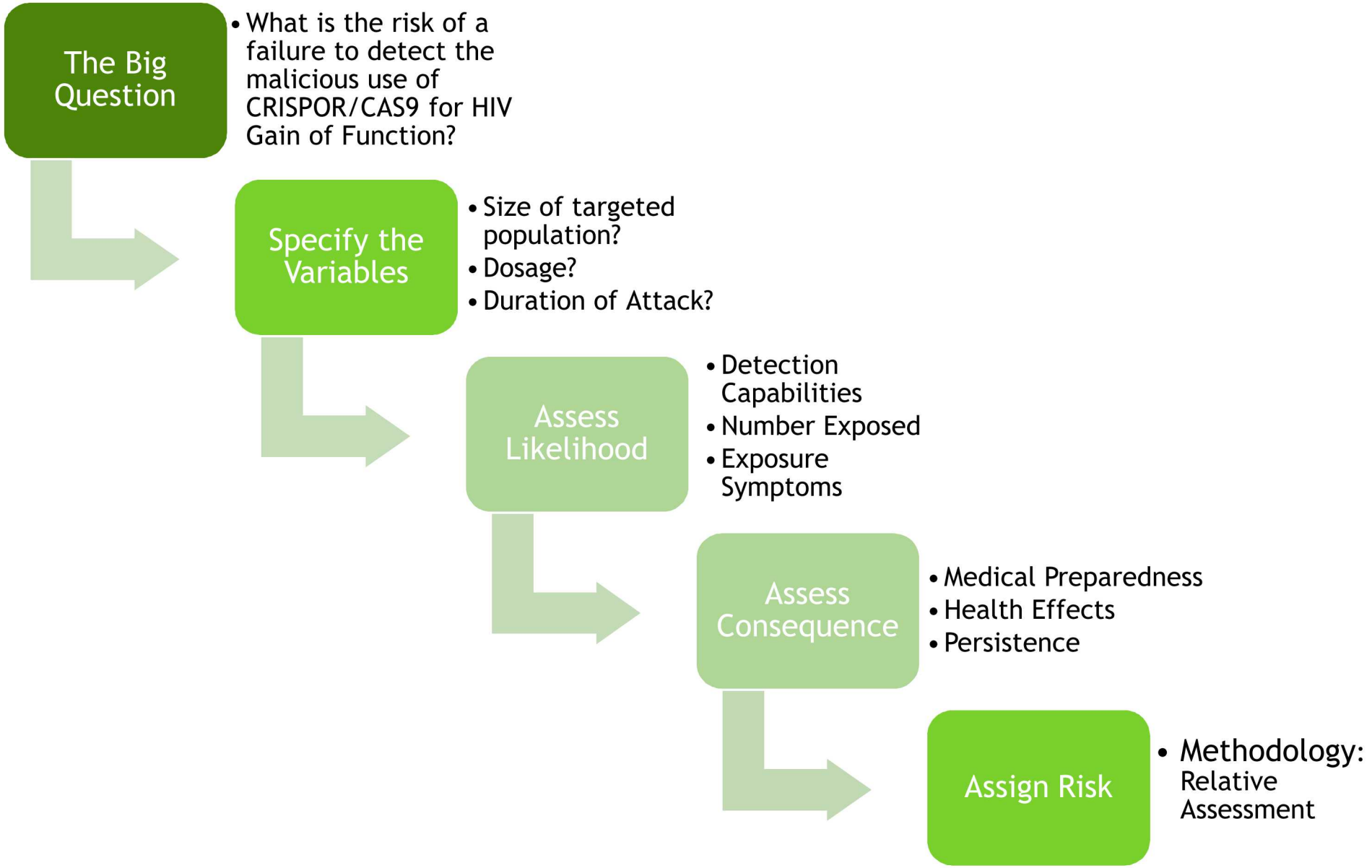
Health Effects

- What is the length of the negative health effects?
- Are the health effects a nuisance or debilitating? Will those exposed make others vulnerable?
- Magnitude of those successfully infected?

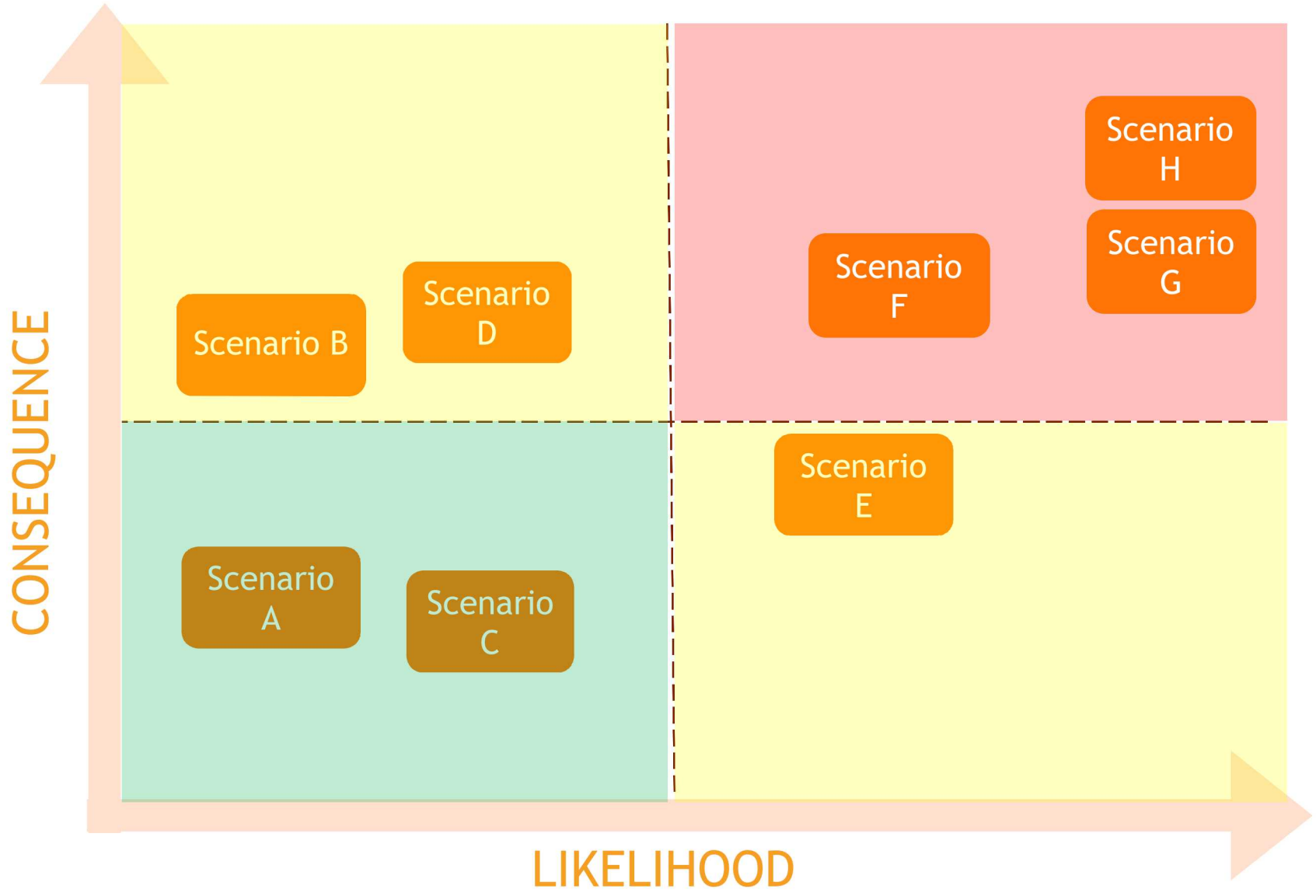
Persistence

- Can or will this attack be modeled by other potential adversaries?
- Is this transmissible?
- Is the vulnerability to humans somatic or germ-line? Will it affect generations to come or just those exposed?

Putting the Framework to Use



Assign Risk – Remember Methodology



Summary

What have we accomplished?

- Example of an approach to risk analysis using a scenario-based framework
- Specific and well-defined scenario to develop easily applicable situational analysis
- A repeatable and transparent process to analyze risk in multiple scenarios

How can we improve?

- Seek out more medical and viral expertise to increase applicability
- Challenge constants and research further to determine effects on risk
- Interchange variables and assumptions… study differences in each situation

Next steps

- Study additional scenarios involving biotechnologies with this framework
- Develop multiple scenarios, then compare and contrast
- Begin moving up the risk question ladder, slowly but surely

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