
Webinar starting soon...
WHEN RISKS COMPETE:
MAKING INFECTION PREVENTION DECISIONS MORE TRANSPARENT AND DEFENSIBLE

THANK YOU FOR JOINING

WEBINAR HOUSEKEEPING

- Continuing education credits are attained upon completion of the survey at the end of the presentation
- Send us questions through Q&A and we'll try to get to them at the end.
- PDF of the deck will be available after the presentation.





PRESENTER:

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Speaker Disclosure:
Diane Cullen

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- The views expressed are my own.
- This presentation is for educational purposes only.
- Multi-Criteria Decision Analysis (MCDA) is presented as one potential framework for supporting structured decision-making and risk assessment.
- No products, services, or manufacturers are being endorsed through the use of the decision-making framework presented.
- This presentation does not advocate replacing manufacturer instructions, regulatory requirements, accreditation standards, or organizational governance processes.



WHEN RISKS COMPETE:

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July 16, 2026

OBJECTIVES

1. Describe common challenges associated with problematic MIFUs, including situations where multiple acceptable approaches exist.
2. Summarize key elements of APIC's risk assessment framework, including the role of evidence collection and multidisciplinary review
3. Recognize limitations of the evidence phase in supporting consistent decision-making across teams
4. Describe a structured approach to comparing evidence using defined criteria such as patient safety, infection prevention effectiveness, workflow feasibility, and compatibility
5. Explain the positive impact of making decisions through structured comparison and documentation practice

How This Presentation Started for Me...

A reflection from both sides of the table.

PAST: STANDARDS PERSPECTIVE

A common response to IFU questions:



"YOU CAN'T RISK ASSESS OUT OF IFUS."

- Protecting patients
- Ensuring consistency
- Interpreting standards

YEARS LATER...

TODAY: INFECTION PREVENTION PERSPECTIVE

The real question we face: As IPs, every day.



- BALANCED EVALUATION
- DOCUMENTED DECISIONS
- TRANSPARENT & DEFENSIBLE OUTCOMES

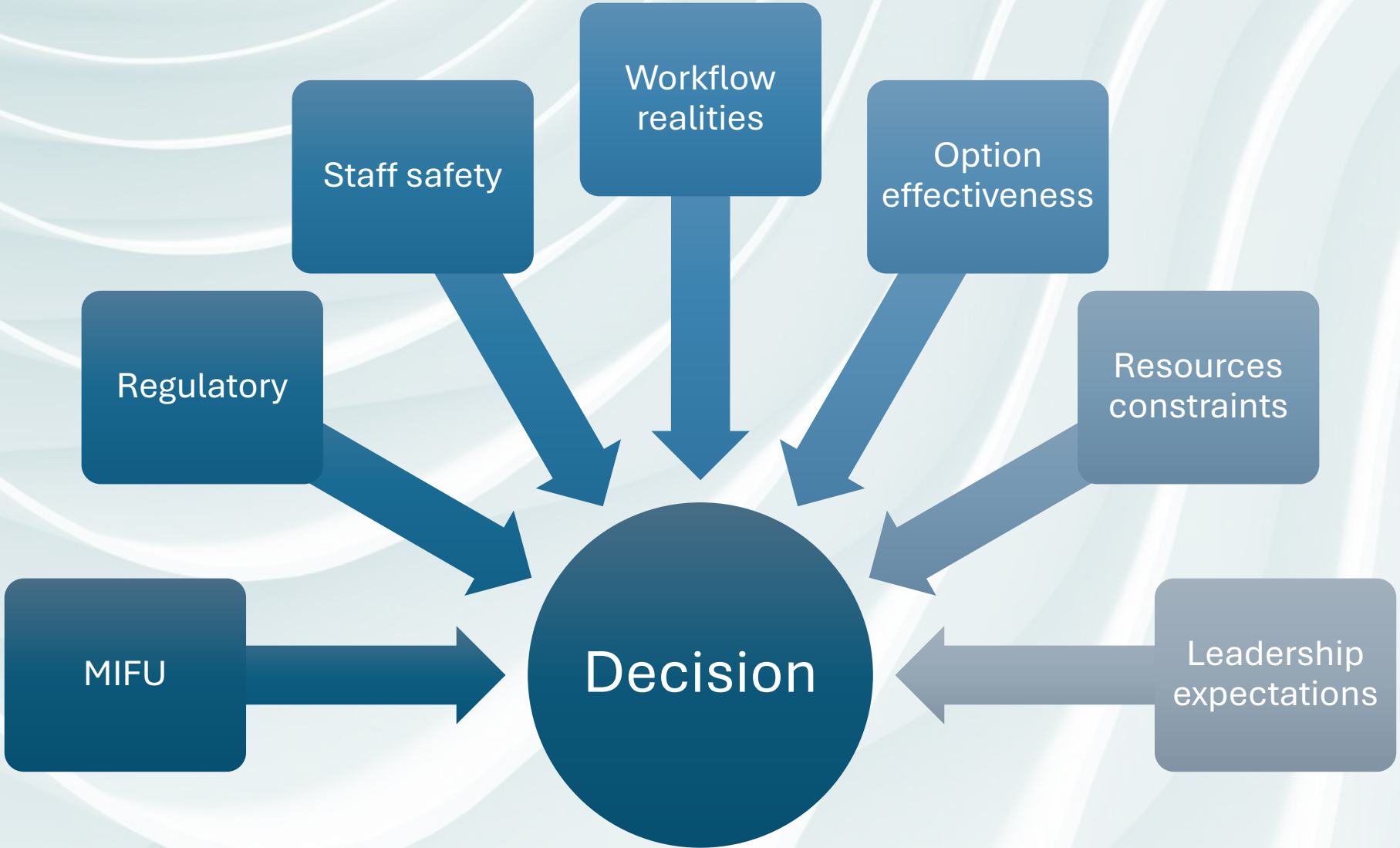
The challenge isn't whether IFUs matter.

The challenge is evaluating IFUs alongside everything else.

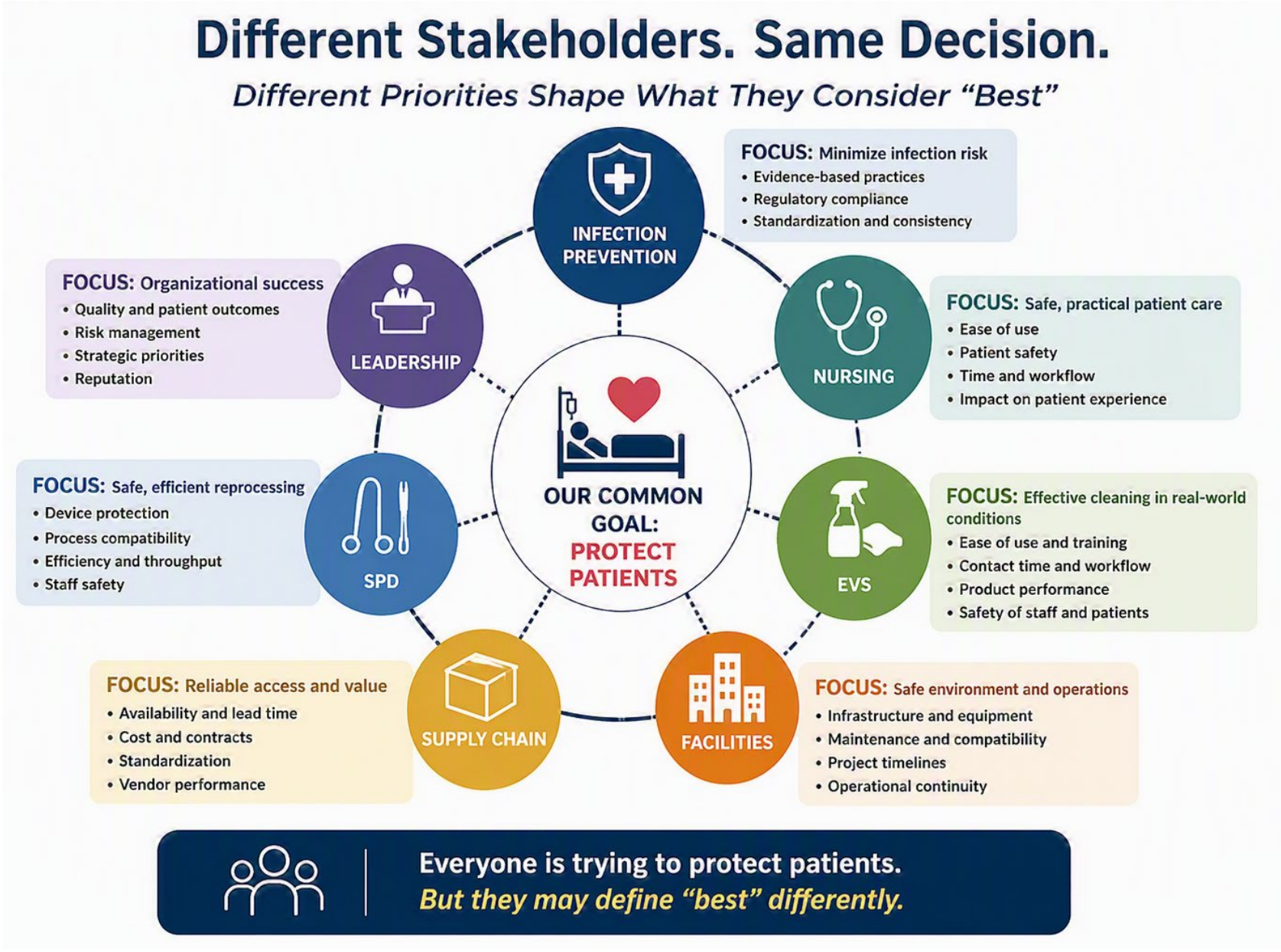


UNDERSTANDING THE DECISION CHALLENGE

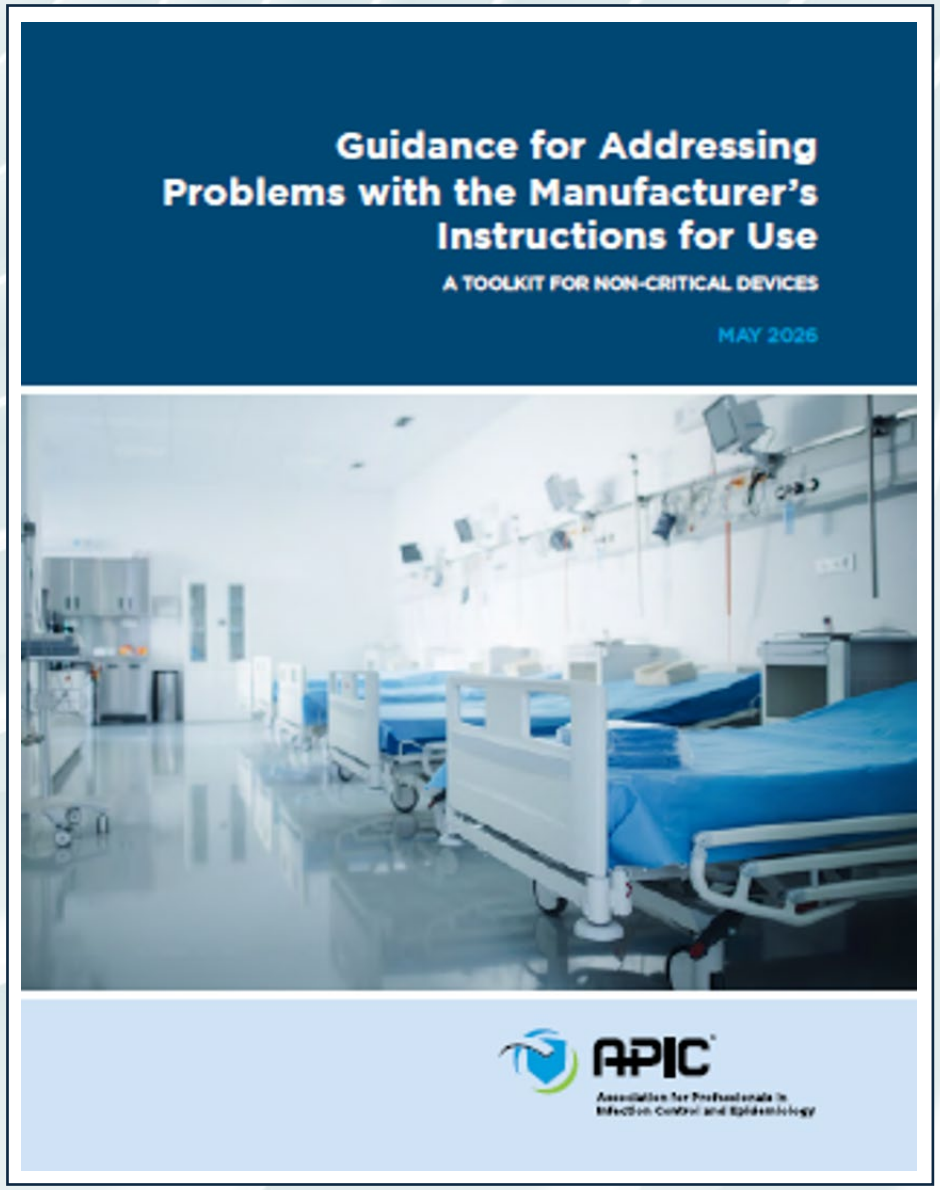
Why Infection Prevention Decisions Become Difficult



Why Smart People Disagree



What APIC Gives Us…



[[[Thank-you)-APIC]]]:

Estela K, Wagner T, Townsend S, Aslam A. *Guidance for Addressing Problems with the Manufacturer's Instructions for Use. A Toolkit for Non-Critical Devices*. 2026.

APIC Provides the Foundation

APIC Guidance Gets Us to the Decision Point



MIFU CONCERN

A potential issue is identified with the manufacturer's instructions for use.

MANUFACTURER CLARIFICATION

Seek clarification from the manufacturer as needed.

EVIDENCE REVIEW

Review available evidence and relevant information.

MULTIDISCIPLINARY RISK ASSESSMENT

Bring together relevant stakeholders to assess risks and balance competing considerations.

DECISION POINT

Reach a decision based on a structured risk assessment.

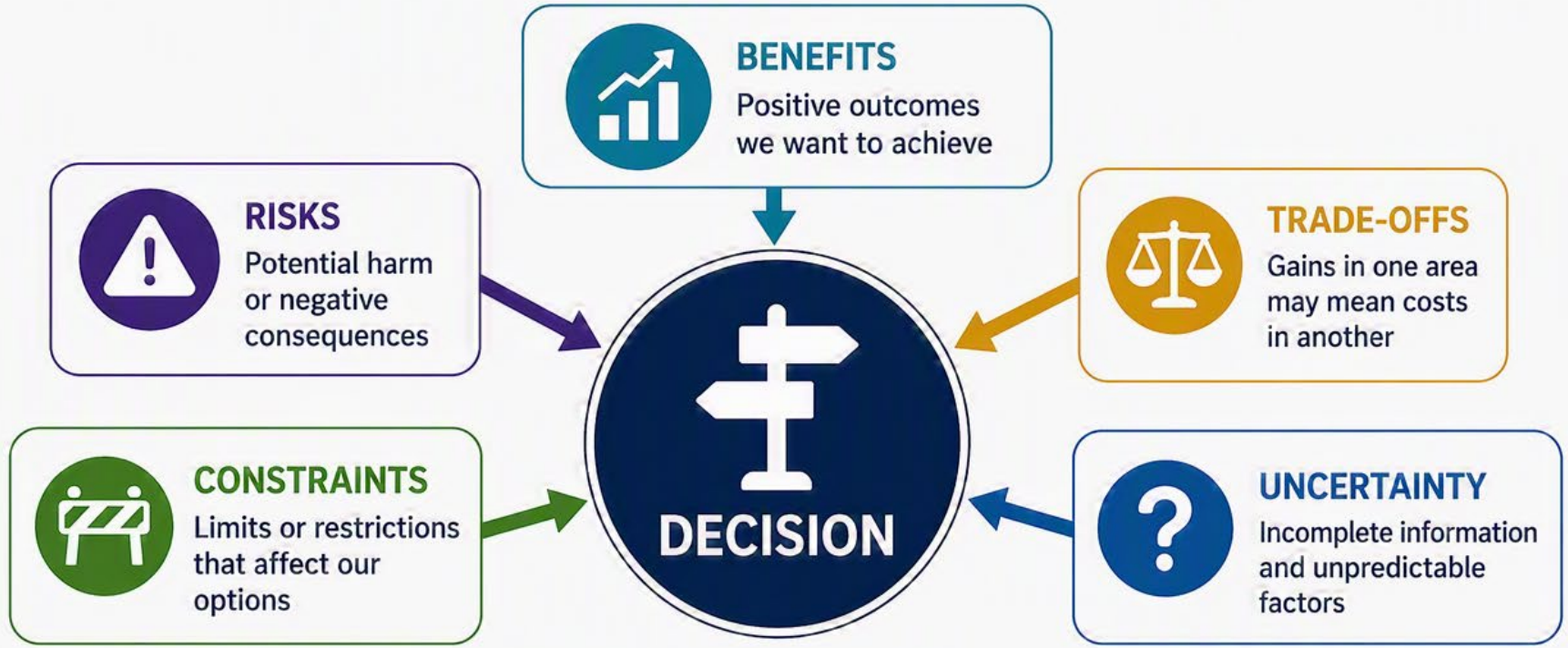
APIC TOOLKIT FOUNDATION

APIC guidance provides the essential foundation.
It gets us to the decision point.

Estela K, Wagner T, Townsend S, Aslam A. *Guidance for Addressing Problems with the Manufacturer's Instructions for Use. A Toolkit for Non-Critical Devices*. 2026.

What Is a Risk Assessment?

A structured evaluation of competing factors to support a decision when no option is perfect.



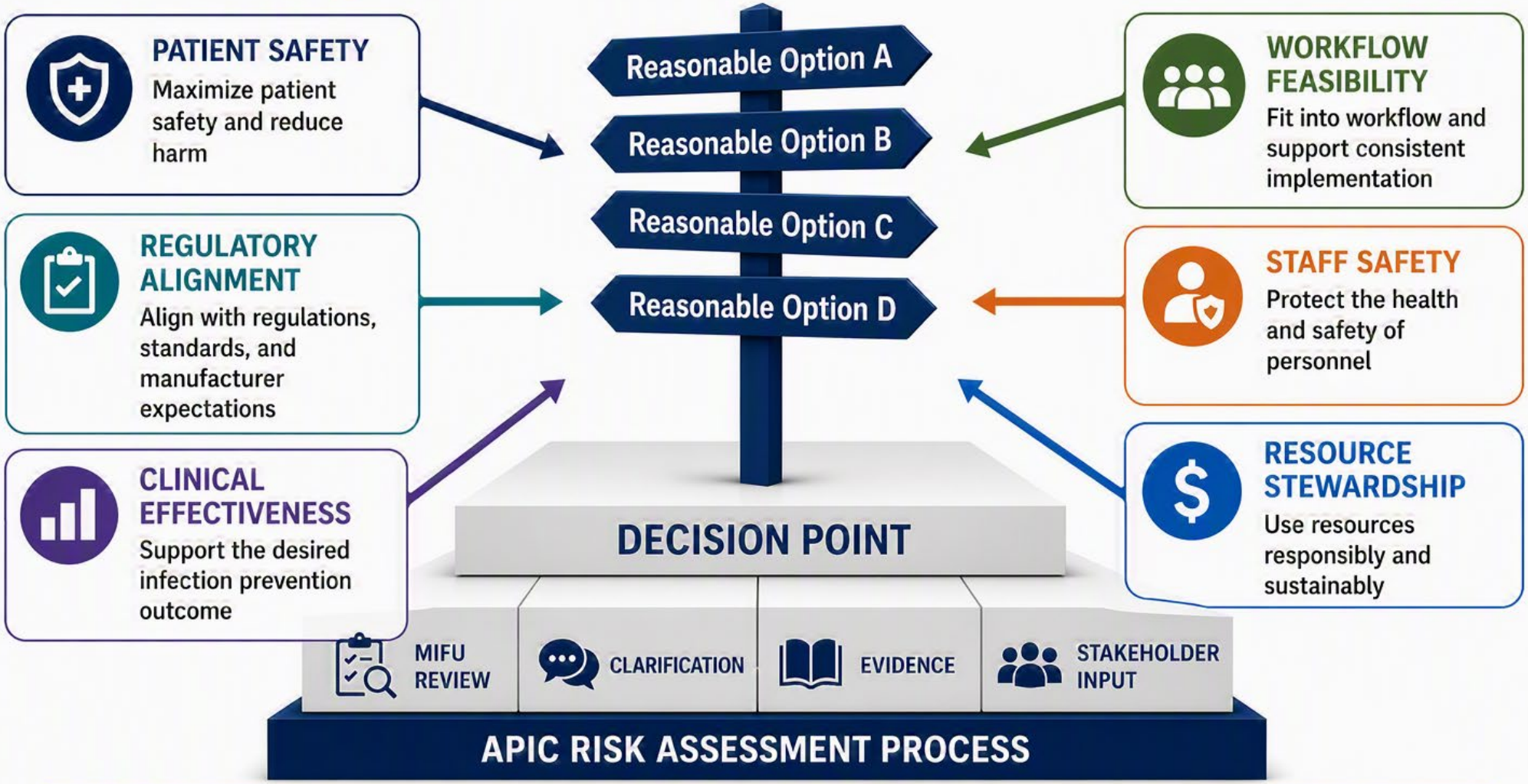
A risk assessment doesn't eliminate uncertainty.
It helps us make decisions despite uncertainty.

The challenge isn't recognizing that risk exists.

The challenge is determining which risks matter most when multiple considerations compete.

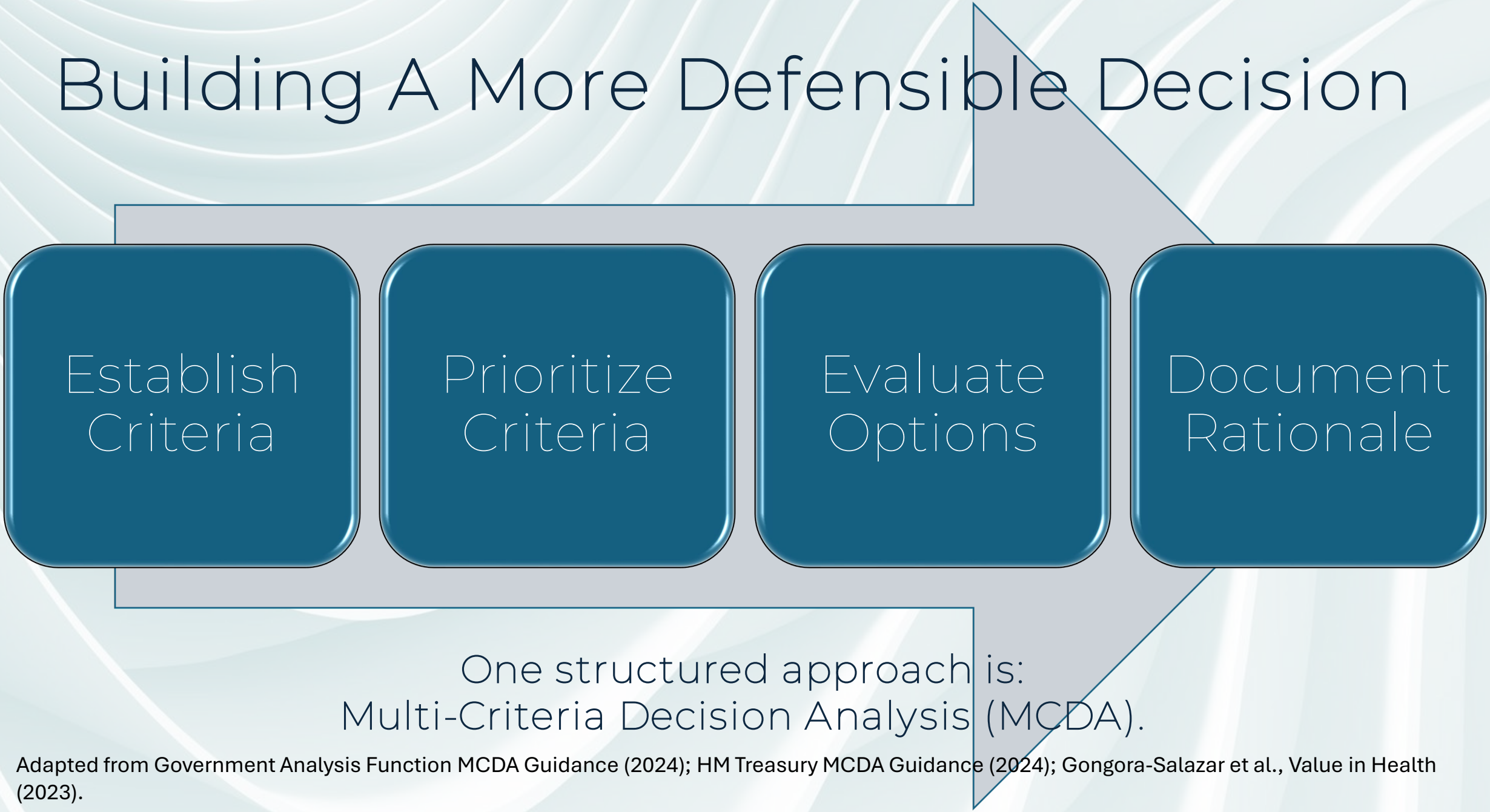
When Multiple Reasonable Options Remain

How should those options be evaluated?



APIC provides the foundation. | *The next challenge is evaluating competing considerations.*

Building A More Defensible Decision



One structured approach is:
Multi-Criteria Decision Analysis (MCDA).

Adapted from Government Analysis Function MCDA Guidance (2024); HM Treasury MCDA Guidance (2024); Gongora-Salazar et al., Value in Health (2023).

Decisions Already Have Criteria

The difference is whether those criteria are visible.

TYPICAL COMMITTEE DISCUSSION

- "We've always done it this way."
- "Surveyors prefer this."
- "Nursing likes this."
- "It's cheaper."
- "It's easier."



Characteristics

- ✕ Implicit
- ✕ Inconsistent
- ✕ Difficult to defend

VS.

STRUCTURED EVALUATION

Explicit Criteria
Clearly defined factors that matter.

Explicit Priorities
Relative importance is discussed and documented.

Explicit Rationale
The reason for the decision is visible and defensible.



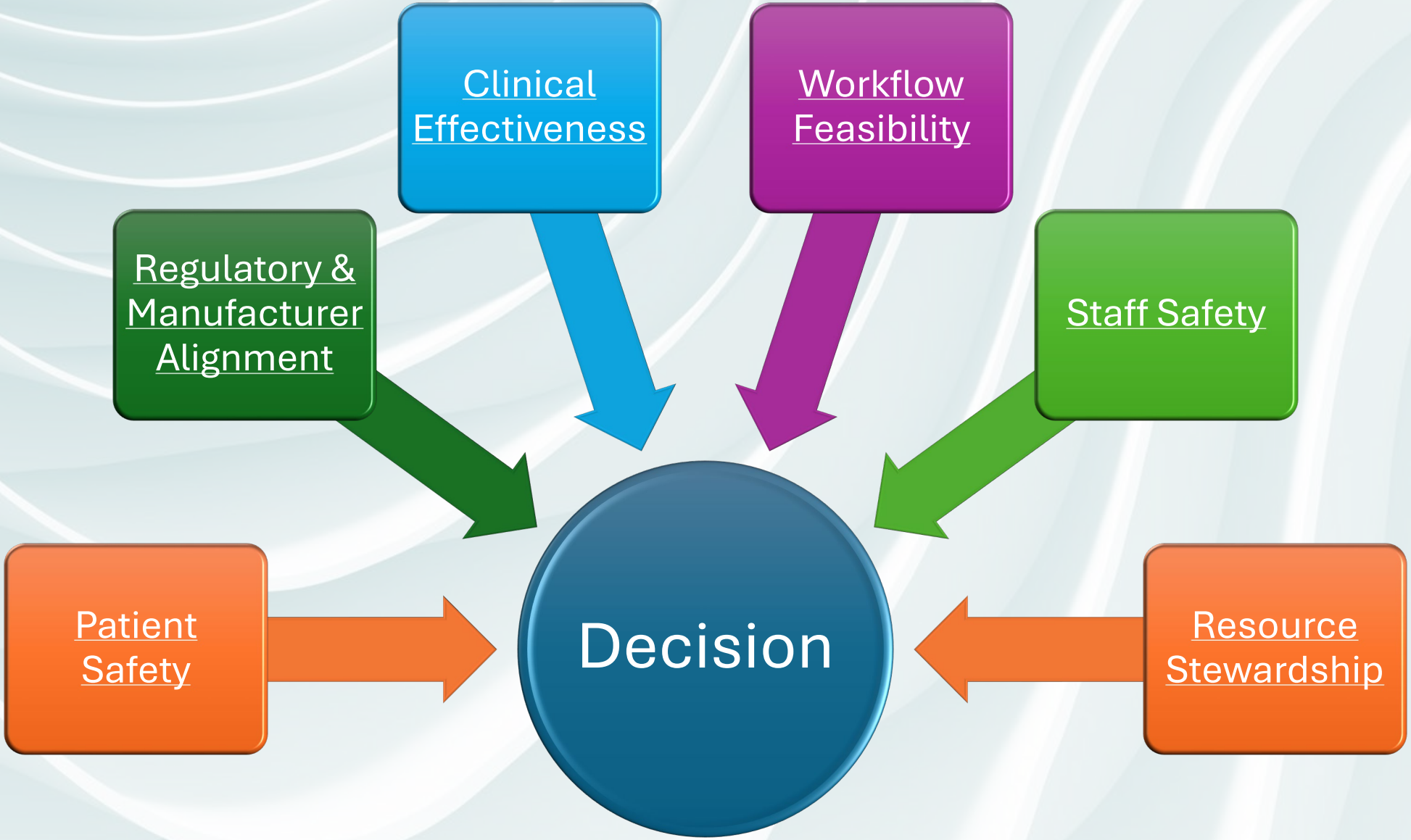
Characteristics

- ✓ Transparent
- ✓ Consistent
- ✓ Easier to defend

Criteria are already influencing decisions.

Most organizations simply have not made them visible.

Common Domains In Structured Risk Assessments



Patient Safety

Primary Question:

- Which option best protects patient from harm?

Consider:

- Likelihood of patient harm
- Potential for infection transmission
- Severity of adverse outcomes
- Impact on vulnerable populations

Bottom line:

- Patient outcomes remain the ultimate priority.

Regulatory & Manufacturer Alignment

Primary Question:

- How well does the option align with applicable requirements and guidance?

Consider:

- Manufacturer instructions for use
- Regulatory expectations
- Accreditation standards
- Professional guidance documents

Bottom line:

- Regulatory and manufacturer expectations should be considered and addressed as part of a defensible decision-making process.

Clinical Effectiveness

Primary Question:

- Will the option achieve the intended infection prevention outcome?

Consider:

- Available evidence
- Expected effectiveness
- Reliability of results
- Consistency of performance

Bottom line:

- An acceptable option must be capable of achieving the intended infection prevention goal.

Workflow Feasibility

Primary Question:

- Can staff realistically and consistently implement the approach?

Consider:

- Ease of implementation
- Training burden
- Workflow disruption
- Compliance likelihood

Bottom line:

- A perfect solution that cannot be followed is not a practical solution.

Staff Safety

Primary Question:

- What impact does the option have on workforce safety?

Consider:

- Exposure risk
- PPE burden
- Training and competency requirements
- Ergonomic considerations
- Operational safety concerns

Bottom line:

- Protecting patients should not require creating unnecessary risk for healthcare personnel.

Resource Stewardship

Primary Question:

- Can the organization sustain the decision responsibly?

Consider:

- Cost
- Resource availability
- Standardization opportunities
- Operational impact
- Long-term sustainability

Bottom line:

- Resources matter because sustainability matters.

Every decision shifts risk somewhere else



Improve one area
→ impact another

There is
no perfect option

There are trade-offs
that must be evaluated



Sources: Government Analysis Function, An Introductory Guide to MCDA (2024); HM Treasury, Use of MCDA in Options Appraisal of Economic Cases (2024).

Making Priorities Visible

Not all criteria carry equal influence.

We measure influence to reflect what matters most in this decision.



We use a simple way to measure influence so we can compare options fairly.

The exact numbers matter much less than the conversation that led to them.

Sources: Government Analysis Function, An Introductory Guide to MCDA (2024); HM Treasury, Use of MCDA in Options Appraisal of Economic Cases (2024)

Scores Reflect Performance

Every option is evaluated against the same criteria using the same approach.

Comparison of Options:
Evaluate each option against criteria

Criteria	Current Process	Alternative Process 1	Alternative Process 2
Patient Safety	5	5	5
Regulatory Alignment	4	1	5
Clinical Effectiveness	5	4	3
Workflow Feasibility	2	5	4
Staff Safety	4	4	1
Resource Stewardship	1	5	3

Scoring Rubric

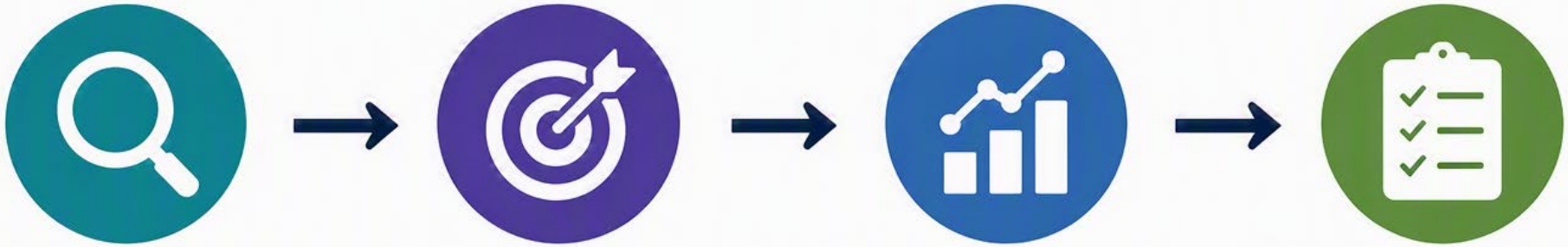
5 – Strongly aligns with criterion

3 – Mixed impact/ trade-offs

1 – Significant concerns

Scoring describes performance

THIS IS SIMPLER THAN IT LOOKS



WHAT MATTERS?

Identify the factors that influence the decision.

WHAT MATTERS MOST?

Determine the relative importance of each factor.

HOW DO THE OPTIONS COMPARE?

Evaluate how each option performs against the factors.

WHY DID WE CHOOSE IT?

Document the rationale behind the decision.

A structured conversation about difficult decisions.

Which Option Is Better?

Every option has strengths. Every option has trade-offs.

Criteria	Current Process	Alternative Process 1	Alternative Process 2
Patient Safety	5	5	5
Regulatory Alignment	4	1	5
Clinical Effectiveness	5	4	3
Workflow Feasibility	2	5	4
Staff Safety	4	4	1
Resource Stewardship	1	5	3

Scoring Scale (1–5): 1 Very Poor | 2 Poor | 3 Moderate | 4 Good | 5 Excellent

YOUR TURN

Based on the scores, which option do you believe is best?

Consider:

- ✓ Strengths
- ✓ Weaknesses
- ✓ Trade-offs
- ✓ What matters most in this situation

Remember: The answer may depend on what matters most to your organization.

Which Option Is Better?

Every option has strengths. Every option has trade-offs.

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YOUR TURN

Based on the scores, which option do you believe is best?

Consider:

- ✓ Strengths
- ✓ Weaknesses
- ✓ Trade-offs
- ✓ What matters most in this situation

Remember: The answer may depend on what matters most to your organization.

There is no perfect option. Each option has benefits, risks, and trade-offs.

→

The best option is the one that best aligns with what matters most.



APPLYING THE FRAMEWORK

Different Priorities, Different Choices

There is no perfect option—only the best fit for where you are in life.

A — EARLY CAREER / STARTING OUT

Build, grow, and create flexibility



Big House in the Suburbs

- ✓ More space
- ✓ Great for family and guests
- ✓ Large yard
- ✗ Longer commute, higher cost

B — MID-LIFE / BUSY SEASON

Convenience and access matter most



Loft-Style Home in the City

- ✓ Walk to work, restaurants, events
- ✓ Modern amenities
- ✓ Less maintenance
- ✗ Less space, more noise, parking challenges

C — LATER LIFE / SIMPLIFYING

Comfort, ease, and peace of mind



Ground-Level Townhouse

- ✓ Quiet community
- ✓ Easy access, no stairs
- ✓ Less to maintain
- ✗ Less space, smaller yard

Which criteria matter most in this decision?

Space & Layout | Location | Affordability | Maintenance | Convenience | Lifestyle Fit

These factors influence every choice.
Their importance changes based on your situation.

Your priorities shape your decision.

What matters most to you today?

Different priorities lead to different choices.

Right home for today | Right home for this season | Right home for the future

No home is perfect.
The best choice depends on which criteria matter most.

Making priorities explicit helps you compare trade-offs and choose the option that best fits your needs.

Let's Apply This to Infection Prevention Decisions!



Organization A: Resource-driven Alternative 1 Becomes Preferred

Criteria	Weight
Patient Safety	20%
Regulatory Alignment	20%
Clinical Effectiveness	15%
Workflow Feasibility	10%
Staff Safety	5%
Resource Stewardship	30%



Criteria	Current Process	Alternative Process 1	Alternative Process 2
Patient Safety	5	5	5
Regulatory Alignment	4	1	5
Clinical Effectiveness	5	4	3
Workflow Feasibility	2	5	4
Staff Safety	4	4	1
Resource Stewardship	1	5	3

The Weighted Score Results Are….

Organization B: Alignment and Workflow-driven Alternative 2 Becomes Preferred

Criteria	Weight
Patient Safety	25%
Regulatory Alignment	35%
Clinical Effectiveness	10%
Workflow Feasibility	20%
Staff Safety	5%
Resource Stewardship	5%

Criteria	Current Process	Alternative Process 1	Alternative Process 2
Patient Safety	5	5	5
Regulatory Alignment	4	1	5
Clinical Effectiveness	5	4	3
Workflow Feasibility	2	5	4
Staff Safety	4	4	1
Resource Stewardship	1	5	3

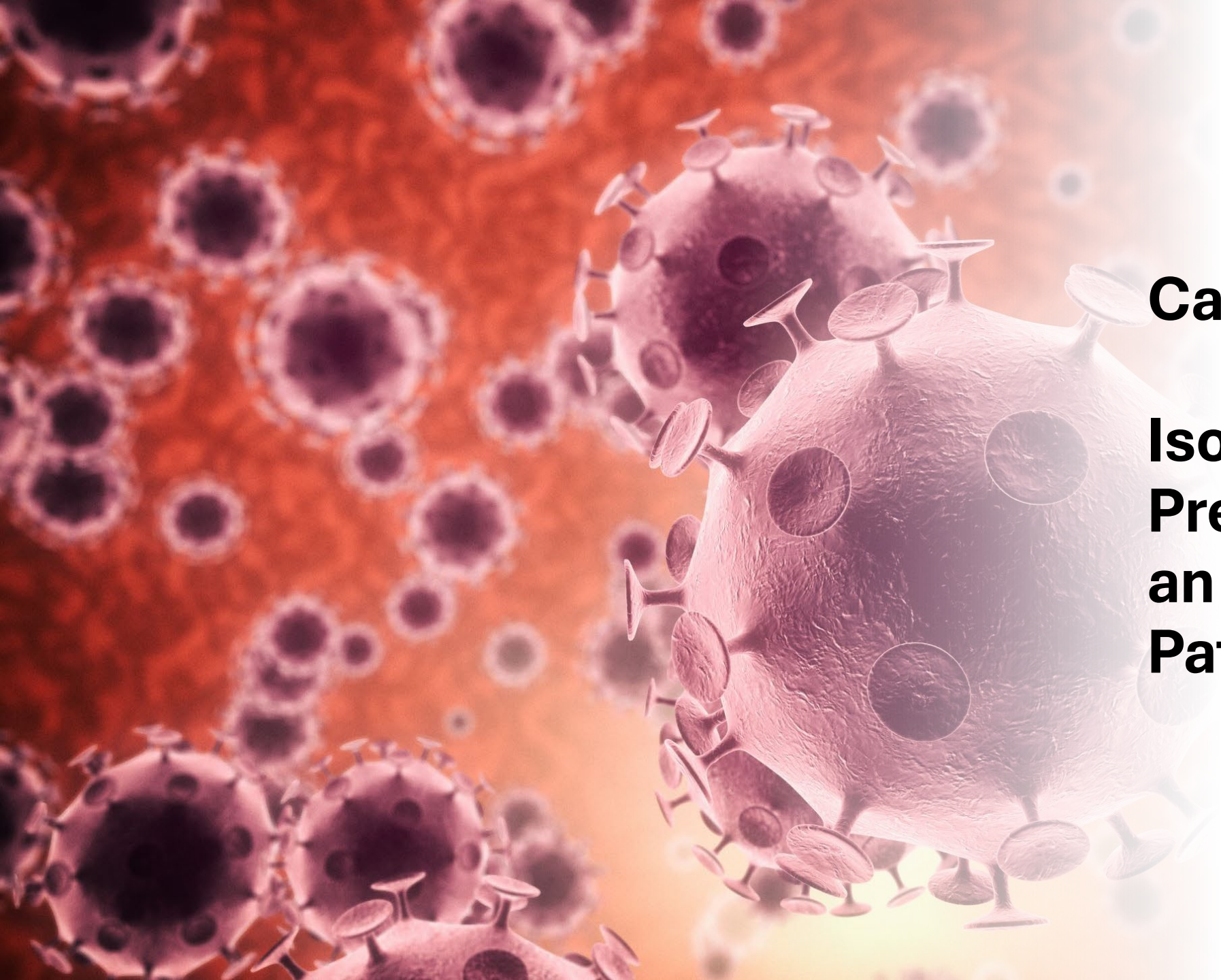
The Weighted Score Results Are….

Organization C: Equal-weighting Alternative 1 Becomes Preferred

Criteria	Weight
Patient Safety	16.67%
Regulatory Alignment	16.67%
Clinical Effectiveness	16.67%
Workflow Feasibility	16.67%
Staff Safety	16.67%
Resource Stewardship	16.67%

Criteria	Current Process	Alternative Process 1	Alternative Process 2
Patient Safety	5	5	5
Regulatory Alignment	4	1	5
Clinical Effectiveness	5	4	3
Workflow Feasibility	2	5	4
Staff Safety	4	4	1
Resource Stewardship	1	5	3

The Weighted Score Results Are….



Case Example:

Isolation Precautions for an Emerging Pathogen

Case Example: Isolation Precautions for an Emerging Pathogen

THE SCENARIO

- Limited evidence
- Evolving guidance
- Operational challenges

THE QUESTION

What precautions should be implemented?

POSSIBLE APPROACHES

OPTION A	OPTION B	OPTION C	OPTION D	OPTION E
Standard Precautions	Enhanced Precautions	Respiratory Precautions	Airborne Isolation	Hybrid Approach
Surgical mask for all care	N95 for select procedures	N95 for all patient care	Negative pressure room + N95	Combination based on risk and resources

Multiple reasonable options exist.
Each has benefits, risks, and trade-offs.

Same Framework. Different Problem.

The context changes, but the decision logic stays the same.

THE EXACT SAME SIX DOMAINS

- Patient Safety
- Regulatory & Manufacturer Alignment
- Clinical Effectiveness
- Workflow Feasibility
- Staff Safety
- Resource Stewardship

SAME DECISION LOGIC

Define Options → Score Each Option → Apply Weights → Compare Results → Make & Document Decision

THE "AHA" MOMENT

Different issue. Same framework. Same structured approach.
Better decision. Stronger rationale.

WHY THIS MATTERS

- Not a product-specific tool
- Works across any infection prevention decision
- Makes trade-offs visible
- Supports transparency and defensibility
- Builds consistency across the organization

Whether selecting isolation precautions, addressing construction risks, choosing equipment, or prioritizing IP initiatives—the same framework helps us evaluate competing risks and make the best defensible decision.

From Scores to a Defensible Decision

We apply our priorities (weights) to the scores to identify the option that best aligns with what matters most.

THE SIX DOMAINS (OUR PRIORITIES)	WEIGHT (%)	ISOLATION PRECAUTIONS OPTIONS (SCORES 1–5)				
		OPTION A Standard Precautions	OPTION B Enhanced Precautions	OPTION C Respiratory Precautions	OPTION D Airborne Isolation	OPTION E Hybrid Approach
Patient Safety Protects patients from harm	30%	2	4	5	5	4
Regulatory & Manufacturer Alignment Meets requirements	25%	3	4	4	5	4
Clinical Effectiveness Achieves intended outcome	20%	2	4	5	5	4
Workflow Feasibility Can be implemented consistently	10%	5	4	2	1	4
Staff Safety Protects healthcare personnel	10%	2	4	5	5	4
Resource Stewardship Sustainable use of resources	5%	5	3	2	1	4
TOTAL WEIGHTED SCORE (OUT OF 5.0)		2.70	3.95	4.30	4.40	4.00

SCORING SCALE (1–5): 1 Very Poor · 2 Poor · 3 Moderate · 4 Good · 5 Excellent

THE RESULT

Based on our priorities, the highest overall score is:

OPTION D
Airborne Isolation

Total Weighted Score: 4.40 / 5.0

WHY THIS OPTION?

- Provides the strongest protection for patients and staff
- Best aligns with regulatory expectations
- High clinical effectiveness
- Trade-offs in workflow and resources were considered and accepted given our priorities

DECISION DOCUMENTED

- Risks considered
- Evidence reviewed
- Stakeholders engaged
- Rationale explained

Scores show how each option performs. → Weights reflect what matters most. → Together, they lead to a transparent, defensible decision.

What Makes a Decision Defensible?

Defensibility Isn't Luck. It's a Process.



1 ISSUE RECOGNIZED
Identify and clearly define the problem.

2 RIGHT STAKEHOLDERS ENGAGED
Include the perspectives that matter.

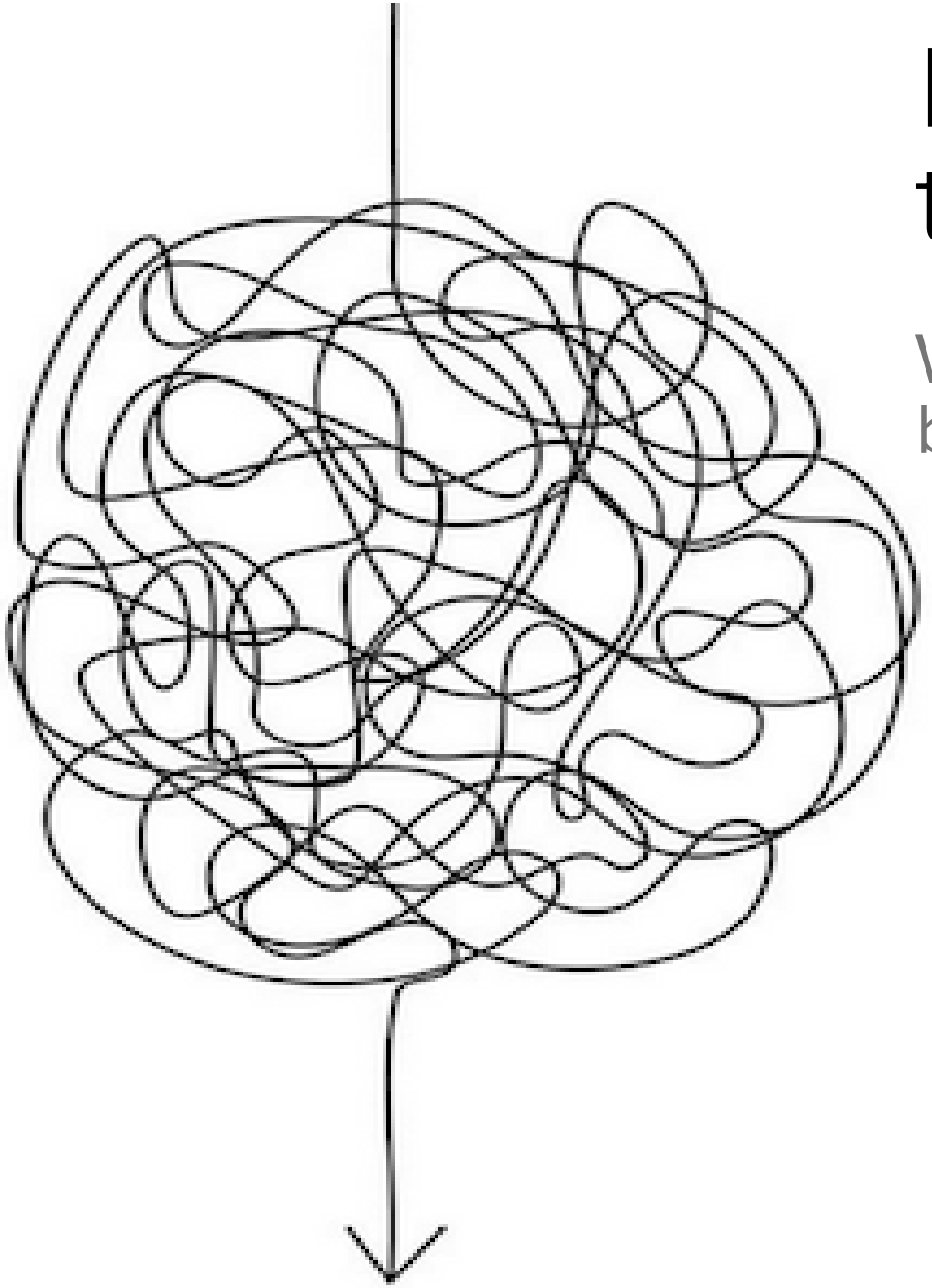
3 PRIORITIES MADE VISIBLE
Reflect what matters most in this situation.

4 OPTIONS EVALUATED SYSTEMATICALLY
Apply the same criteria consistently.

5 RATIONALE DOCUMENTED
The decision can be explained and defended.

A DEFENSIBLE DECISION ISN'T PERFECT.

It's transparent, structured, explainable, and documented.



From Complicated to Defensible

When infection prevention decisions become complicated:

- ✓Recognize the issue
- ✓Make priorities visible
- ✓Engage the right stakeholders
- ✓Ensure leadership understands and owns the decision
- ✓Document the rationale

Defensibility isn't about finding a perfect answer…
It's about being able to explain why a reasonable answer was chosen.

Thank You

Diane Cullen, JM, MBA, MSN, RN, CIC, CPHQ

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Metrex Survey

Please scan the code to access our survey. Survey is required to receive CE credit.

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