Risk Analysis

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National Nanotechnology Initiative Workshop on Stakeholder Perspectives on the Perception, Assessment, and Management of the Potential Risks of Nanotechnology

September 11, 2013

Overview

Process
Pitfalls
Proposals

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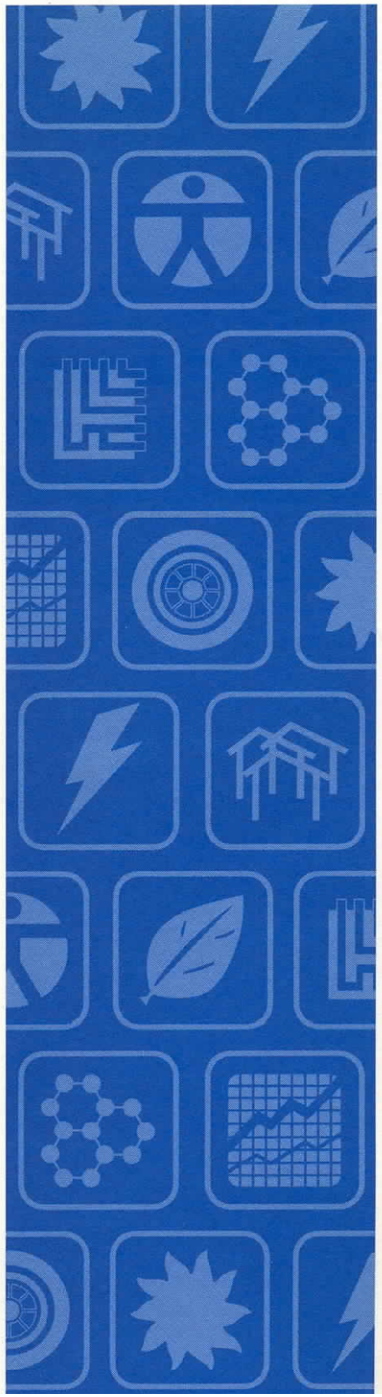
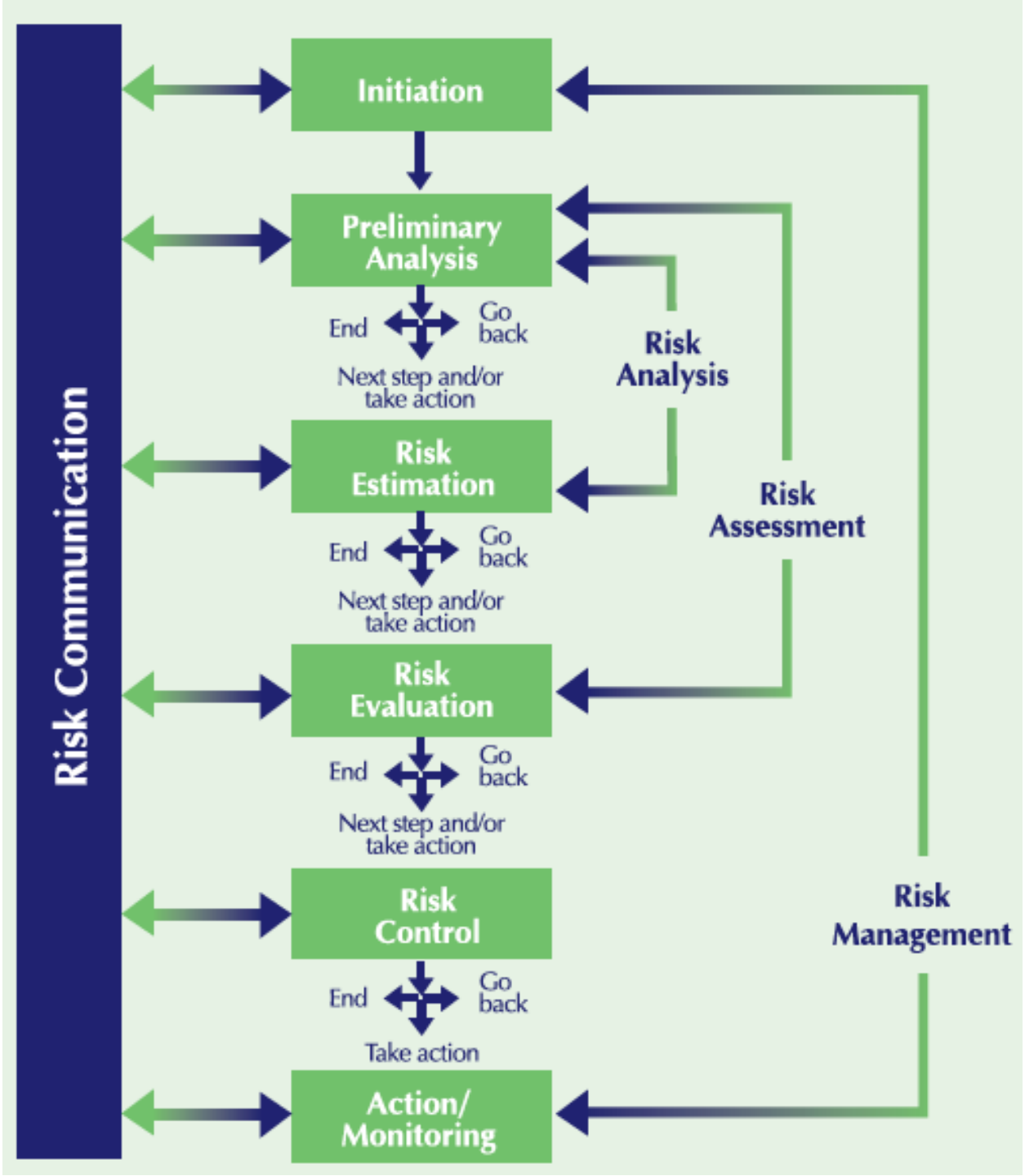
Pitfalls
Proposals



CAN/CSA-Q850-97

Risk Management: Guideline for Decision-Makers

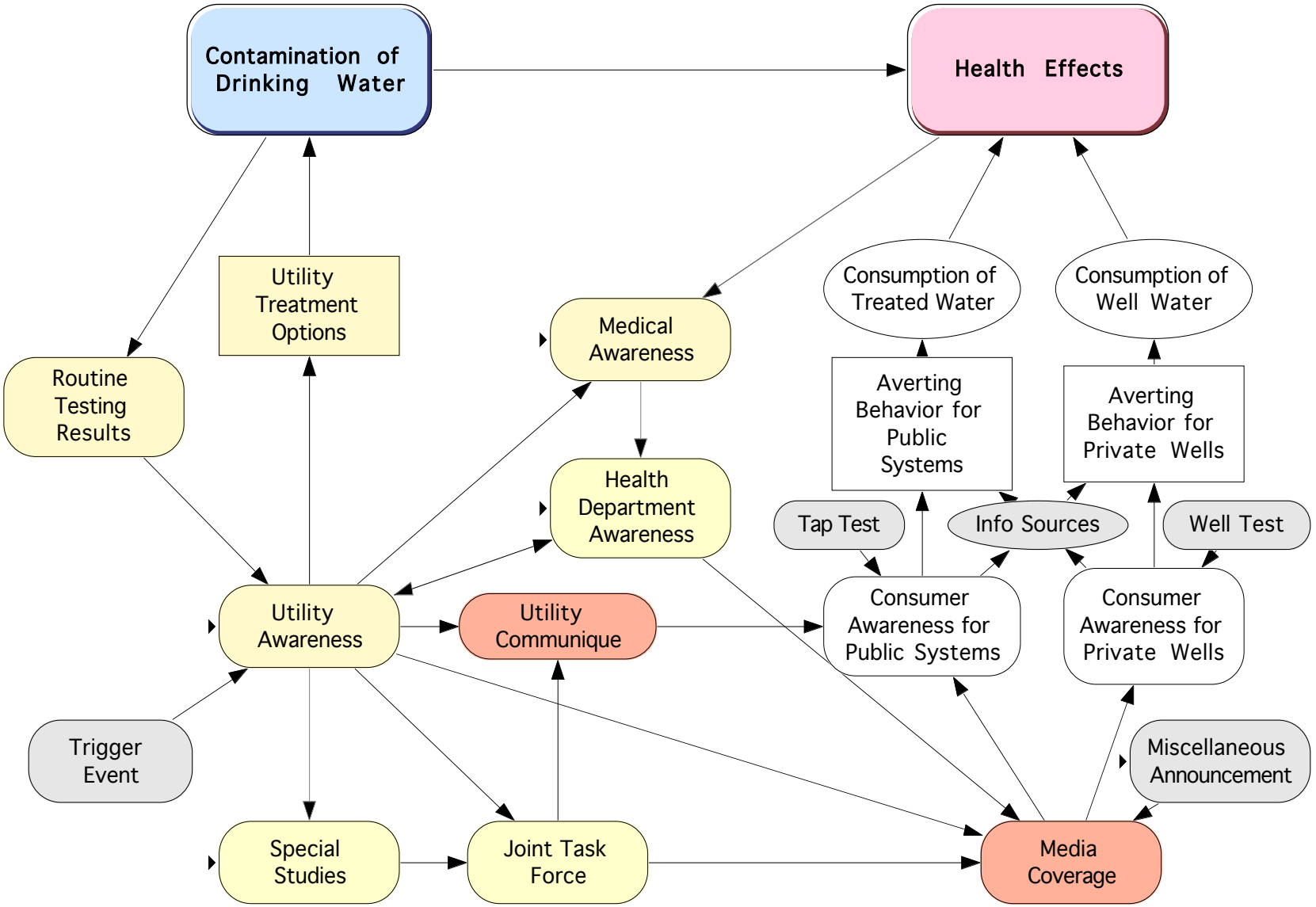
A National Standard of Canada


Risk Communication
Initiation
Preliminary Analysis
End
Go back
Next step and/or take action
Risk Analysis
Risk Estimation
End
Go back
Next step and/or take action
Risk Assessment
Risk Evaluation
End
Go back
Next step and/or take action
Risk Control
End
Go back
Take action
Risk Management
Action/ Monitoring

Waterborne Disease

cryptosporidium intrusions into domestic water supplies

Casman, E., Fischhoff, B., Palmgren, C., Small, M., & Wu, F. (2000). Integrated risk model of a drinking waterborne Cryptosporidiosis outbreak. *Risk Analysis, 20*, 493-509


Contamination of Drinking Water
Health Effects
Utility Treatment Options
Routine Testing Results
Medical Awareness
Consumption of Treated Water
Consumption of Well Water
Averting Behavior for Public Systems
Averting Behavior for Private Wells
Health Department Awareness
Tap Test
Info Sources
Well Test
Utility Awareness
Utility Communique
Consumer Awareness for Public Systems
Consumer Awareness for Private Wells
Trigger Event
Miscellaneous Announcement
Special Studies
Joint Task Force
Media Coverage

Decision | Averting_behavior | **Units:**

Title: Averting Behavior for Public Systems

Description: Do consumers do something to avoid any possible risk of cryptosporidial infection?

Correct averting behavior includes boiling drinking water and switching to safe water sources. Washing dishes, tooth brushing, and rinsing vegetables are not presently considered high risk behaviors for immunocompetent people in developed countries. Showering is not risky. Only filters with an absolute (not nominal) pore size ≤ 1 micron can effectively remove oocysts. (MMWR, 1995) Use of other types of filters do not constitute correct averting behavior.

reference:
MMWR 1995. Assessing the public health threat associated with waterborne cryptosporidiosis: report of a workshop. Rep. 44(RR-6):1-19.

0 = no action or inappropriate action (eg charcoal filter)
1 = avoid most tap water
2 = boil drinking water or use clean bottled water

expr

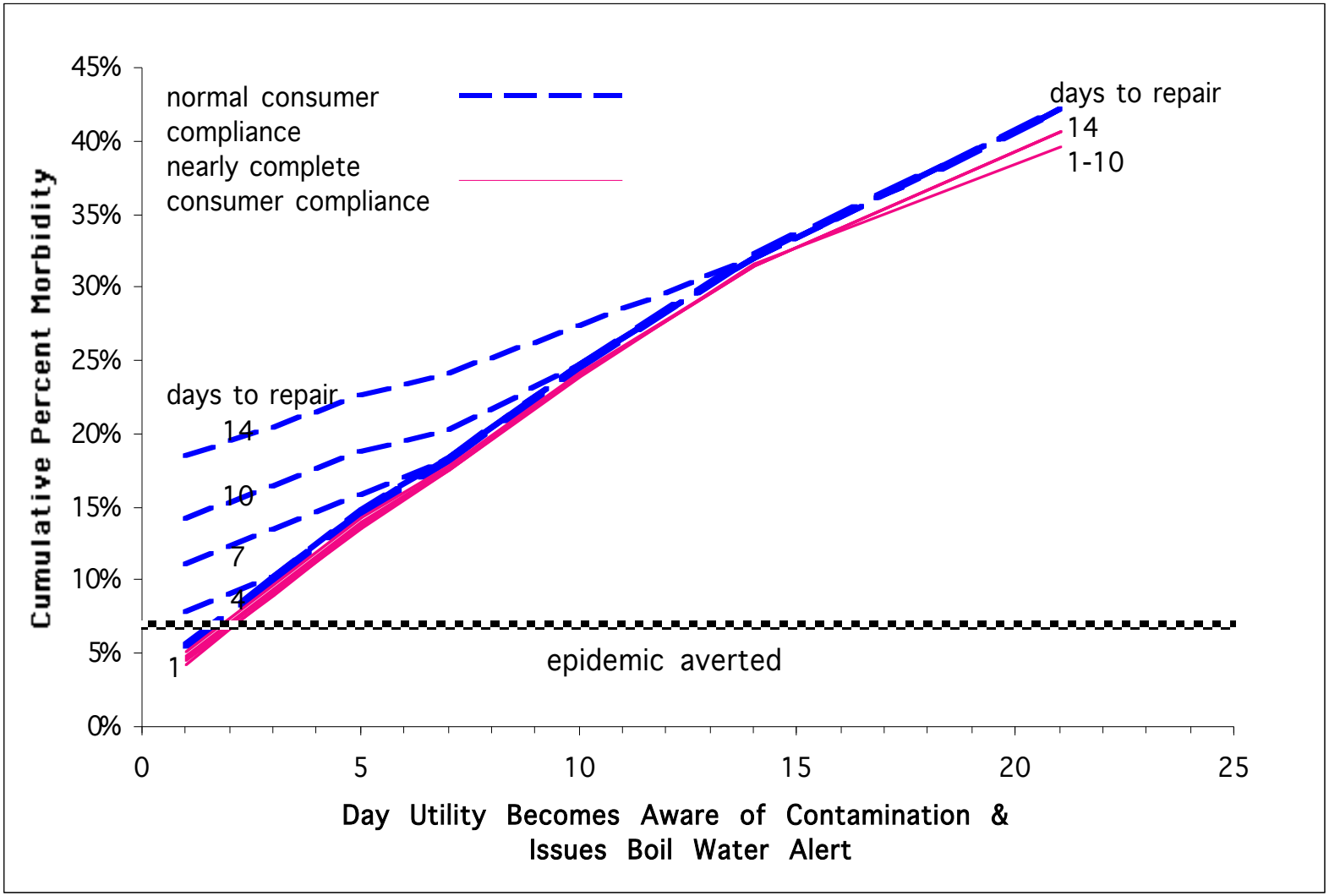
Definition:
```
if consumer_awareness =0 then 0
else
if consumer_awareness =1 then 1
else if   info_sources > 0 then 2
else 2
```

Inputs:

Consumer_a...	Consumer Awareness for Public Systems
Info_sources	Info Sources

Outputs:

Consumptio...	Consumption of Treated Water


45%
40%
35%
30%
25%
20%
15%
10%
5%
0%
Cumulative Percent Morbidity
normal consumer compliance
nearly complete consumer compliance
days to repair
14
1-10
days to repair
14
10
7
4
1
epidemic averted
0
5
10
15
20
25
Day Utility Becomes Aware of Contamination & Issues Boil Water Alert

Adequate Risk Models

Create clear, shared definitions of variables and relationships

Identify critical expertise

Organize existing evidence

Organize emerging evidence

Estimate risk and uncertainty

Adequate Communications

Contain the information that people need in accessible places and comprehensible form.

Inform the risk management process early enough to affect the design.

Overview

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Pitfall #1

Assuming that risk can be defined objectively.

Defining “Risk of Death”

probability of premature death

Defining “Risk of Death”

probability of premature death
vs.
expected life-years lost

Defining “Risk of Death”

probability of premature death
vs.
expected life-years lost

The choice of metric depends on whether a death is a death or one values deaths of young people more.

Other Possible Bases for Distinguishing among Deaths

Are the risks

- distributed equitably
- assumed voluntarily
- catastrophic
- well understood
- controllable
- dread
- borne by future generations

. . .

Fischhoff, B., Lichtenstein, S., Slovic, P., Derby, S. L. & Keeney, R. L. (1981). *Acceptable risk*. New York: Cambridge University Press.

Other Possible Risk Outcomes

injuries
illnesses
pre-term births
child abuse and neglect
unrealized potential
…

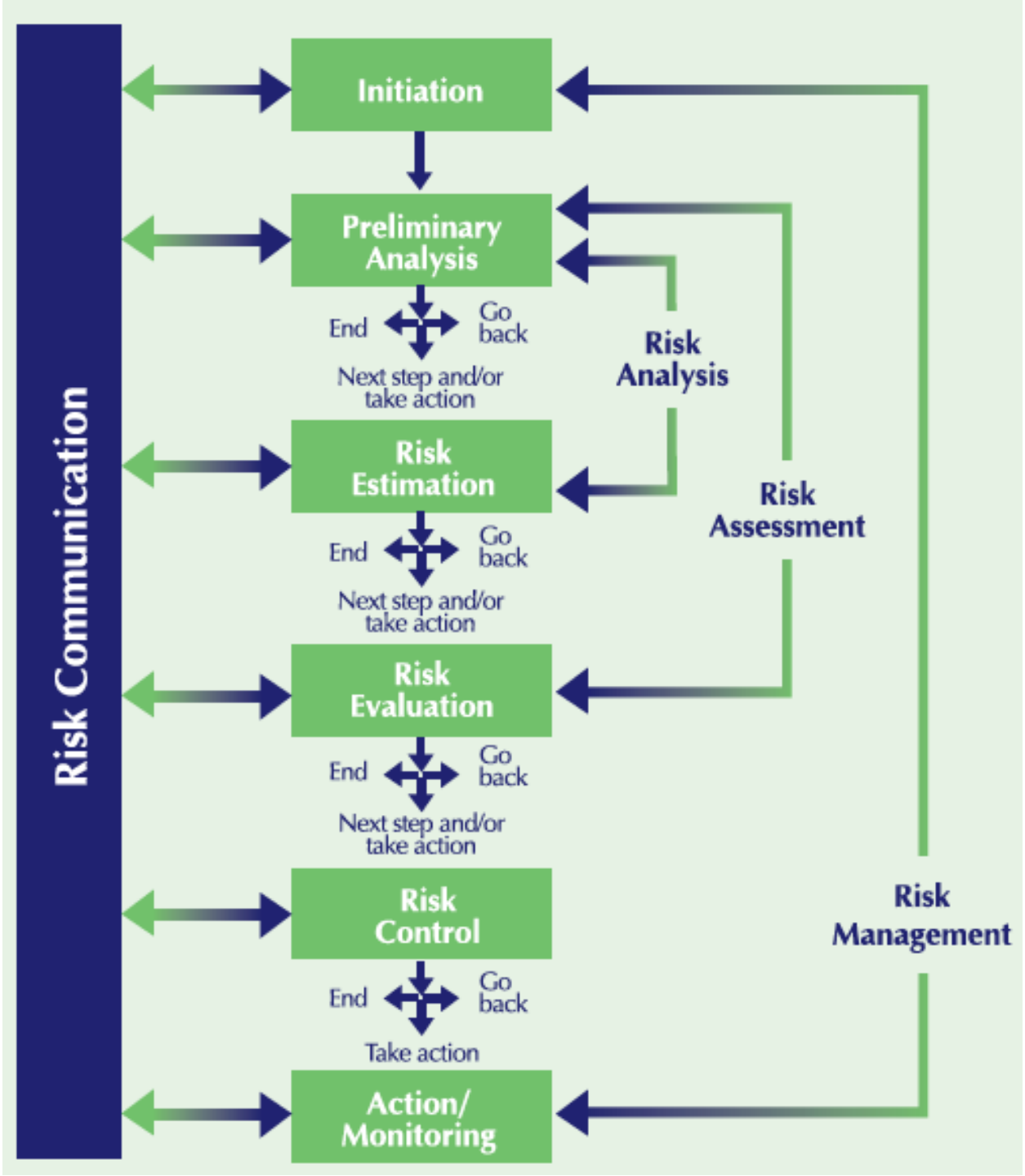
Fischhoff, B., Lichtenstein, S., Slovic, P., Derby, S. L. & Keeney, R. L. (1981). *Acceptable risk*. New York: Cambridge University Press.

Definitions

The terms of any analysis embody values that favor some interests.

When transparent, those assumptions are controversial.

As a result, common metrics obscure value issues, unless adopted by a credible public process.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"Discounting" Future Outcomes

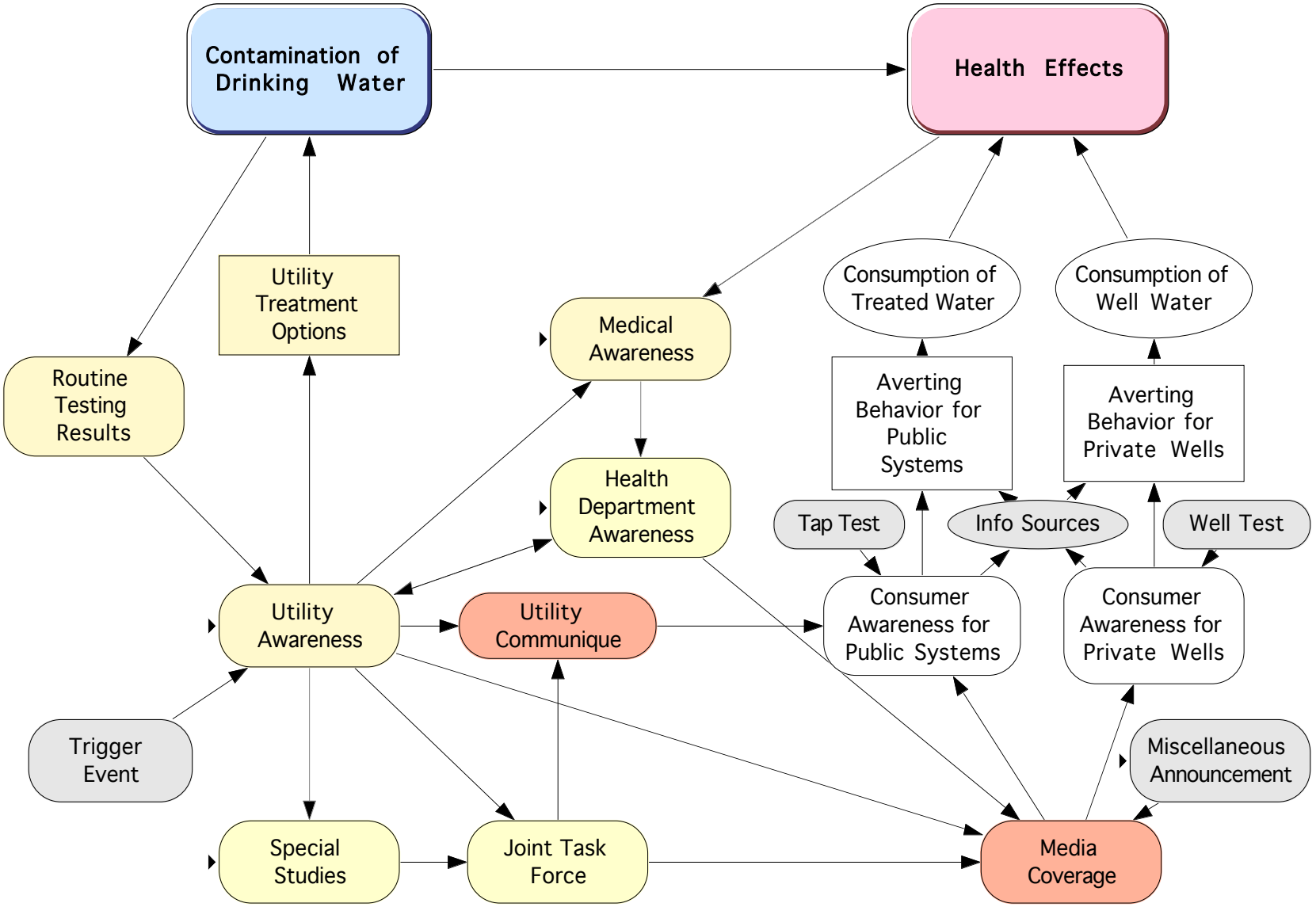
Reasons to value future outcomes less

-- valuing them less
  deliberately
  unthinkingly (hyperbolic discounting)
-- opportunity costs
-- not expecting to have them provided
-- not expecting to be there to get them
-- dreading the wait
-- wanting to live with the experience

Frederick S, et al. [2002]. Time discounting and temporal preference. *Journal of Economic Literature 4*0: 331-401

Pitfall #2

Limiting analyses to readily available experts and evidence.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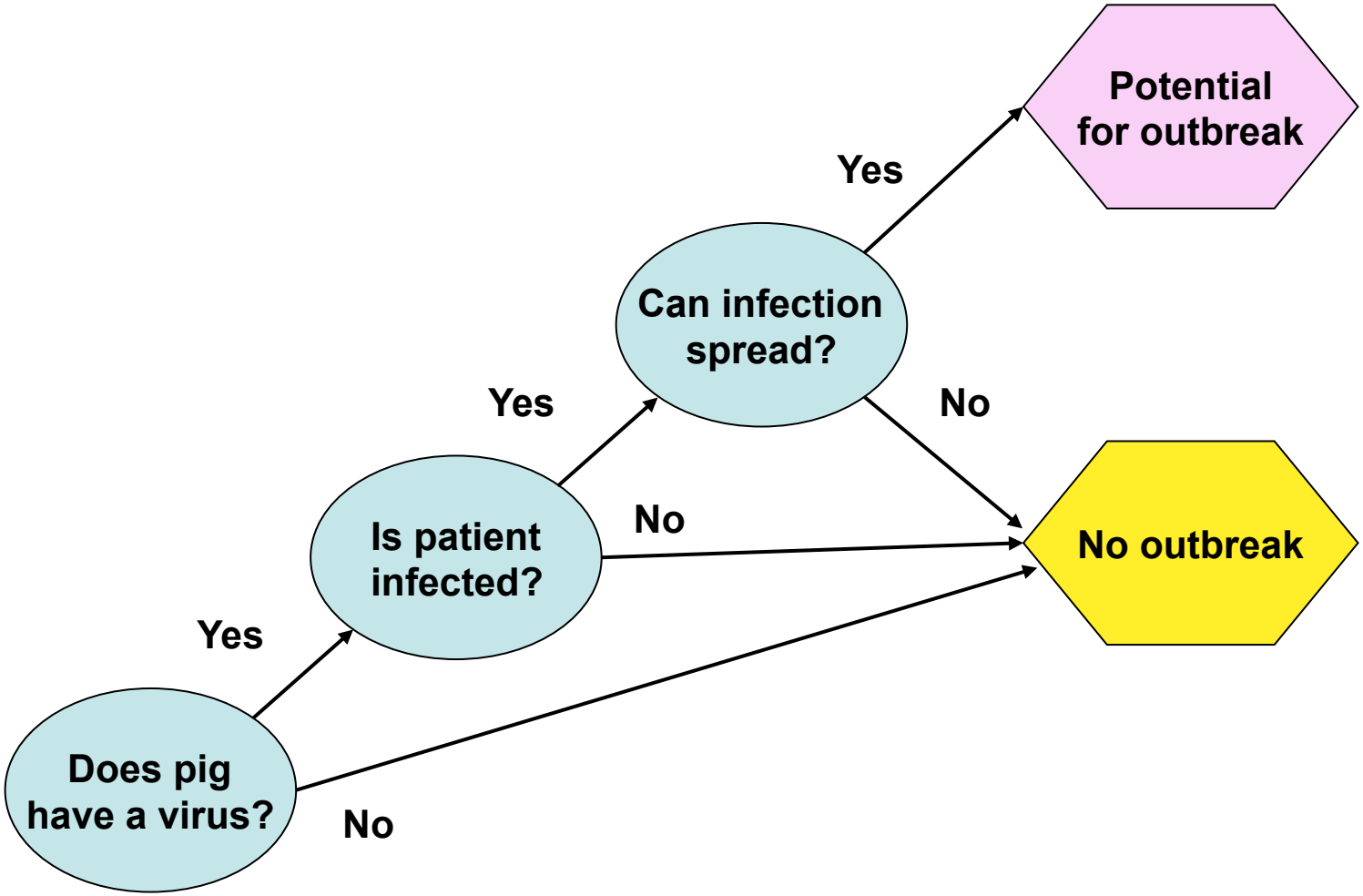
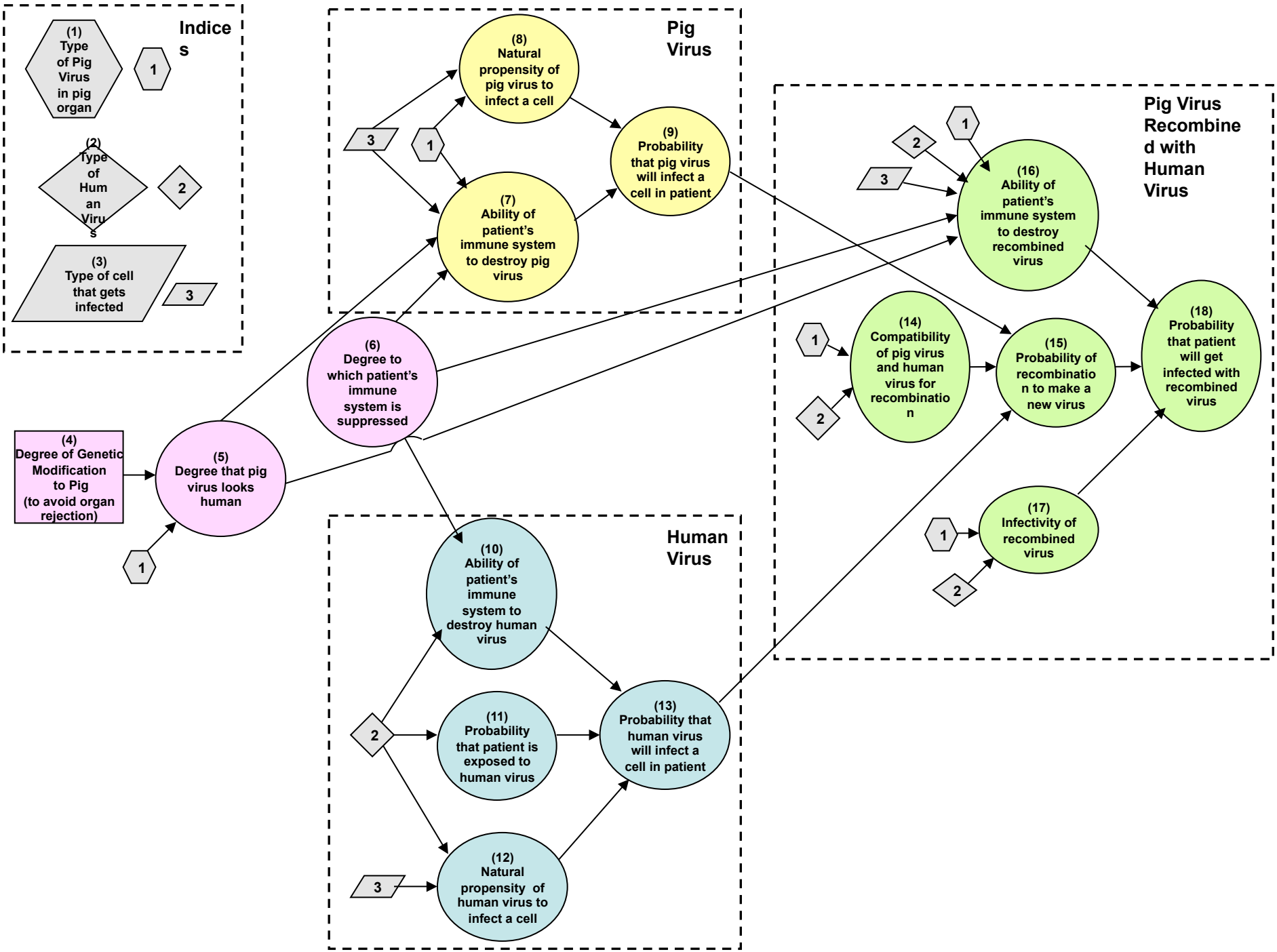
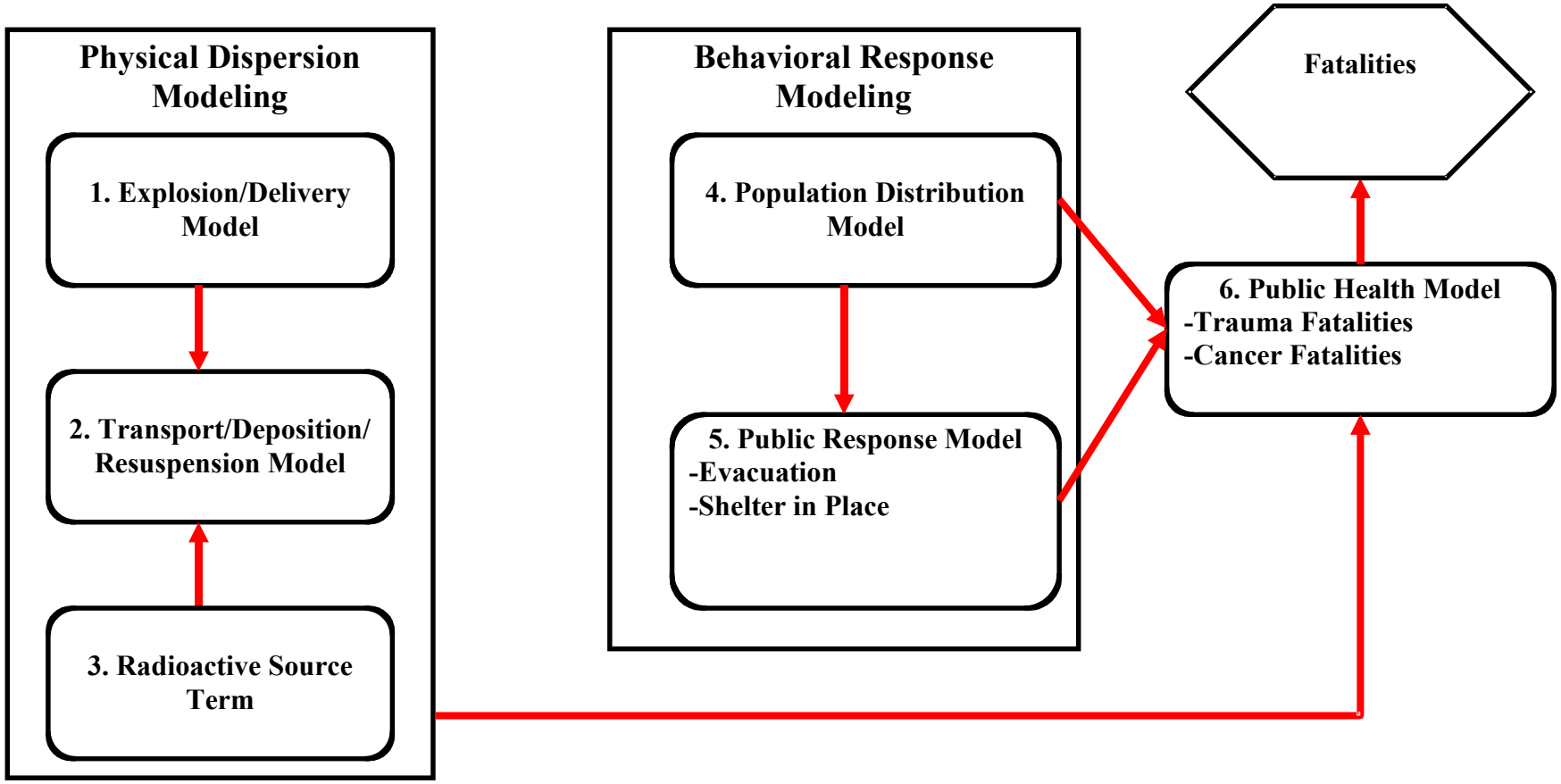
Xenotransplantation



Bruine de Bruin, W., Güvenç, Ü. Et al. (2009). Communicating about xenotransplanation: Models and scenarios. *Risk Analysis, 29*, 1105-1115


Indices
(1) Type of Pig Virus in pig organ
1
(2) Type of Human Virus
2
(3) Type of cell that gets infected
3
Pig Virus
(8) Natural propensity of pig virus to infect a cell
(9) Probability that pig virus will infect a cell in patient
(7) Ability of patient's immune system to destroy pig virus
3
1
(6) Degree to which patient's immune system is suppressed
(4) Degree of Genetic Modification to Pig (to avoid organ rejection)
(5) Degree that pig virus looks human
1
Human Virus
(10) Ability of patient's immune system to destroy human virus
(11) Probability that patient is exposed to human virus
(12) Natural propensity of human virus to infect a cell
2
3
(13) Probability that human virus will infect a cell in patient
Pig Virus Recombined with Human Virus
(16) Ability of patient's immune system to destroy recombined virus
1
2
3
(14) Compatibility of pig virus and human virus for recombination
1
2
(15) Probability of recombination to make a new virus
(18) Probability that patient will get infected with recombined virus
(17) Infectivity of recombined virus
1
2

Evacuation Strategies



Dombroski, M., Fischhoff, B., & Fischbeck, P. (2006). Predicting emergency evacuation and sheltering behavior: A structured analytical approach. *Risk Analysis, 26*, 1675-1688

Representing Uncertain Knowledge

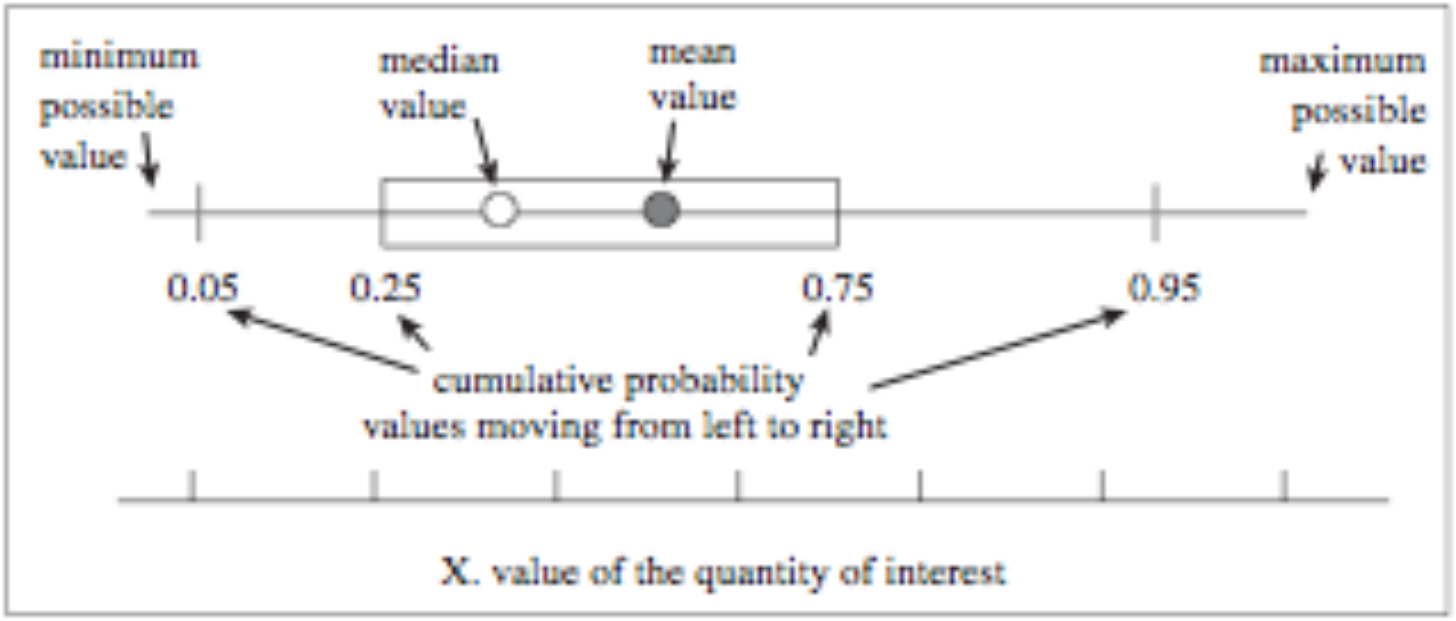
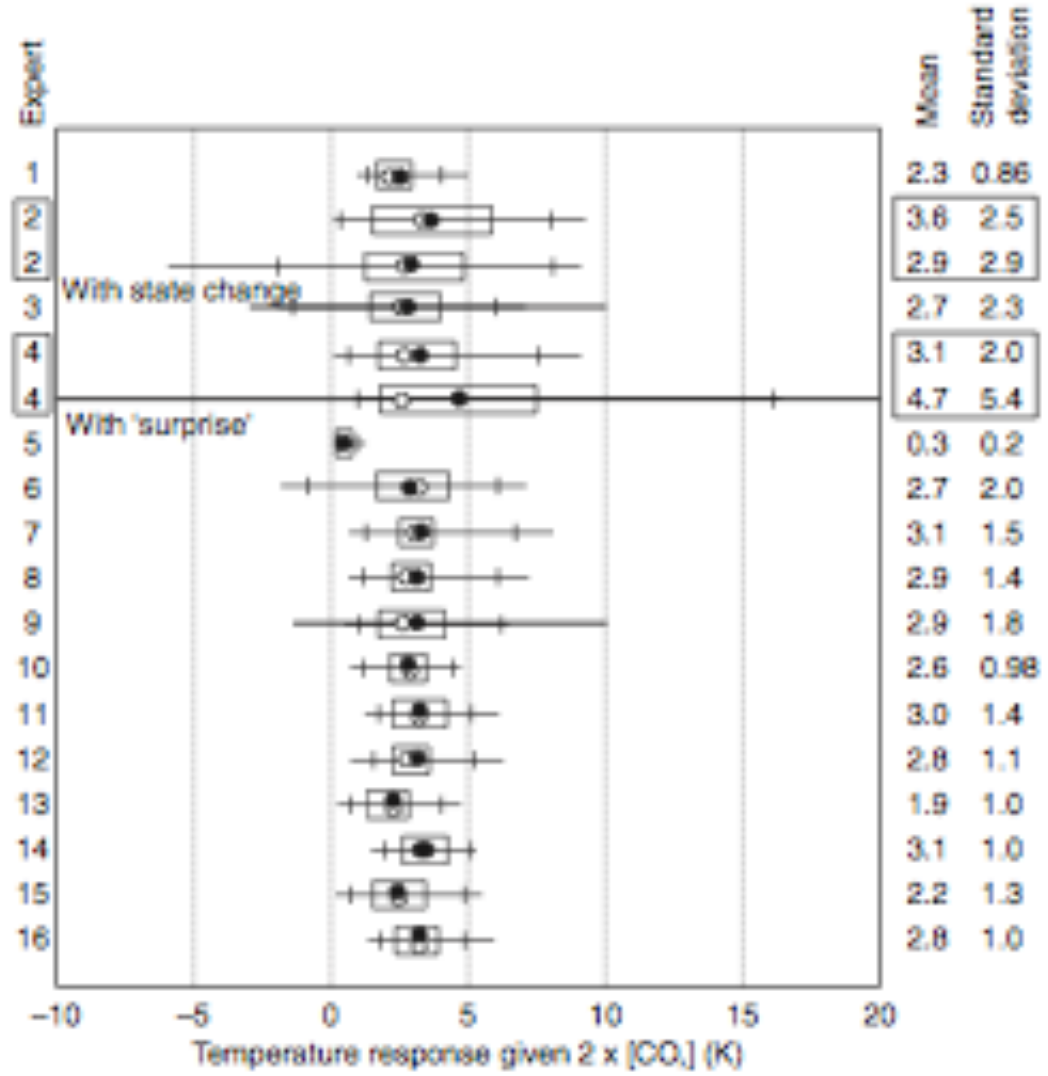


Figure 4. Recommended format for a box plot. When many uncertain results are to be reported, box plots can be stacked more compactly than probability distributions [18].

Campbell, P. (2011). Understanding the receivers and the receptions of science's uncertain messages. *Philosophical Transactions of the Royal Society, 369*, 4891-4912.



10. Climate experts' judgements of the probabilities of changes in globally averaged surface temperature, if atmospheric CO_2 doubles

Morgan, M.G. & Keith, D. (1995). *Environmental Science and Technology, 2*9, 468-476.

Pitfall #3

Choosing to fly blind when communicating.

Adequate Communications

Contain the information that people need in accessible places and comprehensible form.

Inform the risk management process early enough to affect the design.

Adequate Communications Require Research

Because our intuitions are often faulty.

Common Knowledge Effect

Exaggerating how much other people share our knowledge.

As a result, failing to provide critical information.

Adequate Communications Require Research

Because our intuitions are often faulty.

Because behavior is always complex.

Some Principles of Judgment

People are good at tracking what they see, but not at detecting sample bias.

People have difficulty projecting non-linear trends.

People have limited ability to evaluate the extent of their own knowledge.

People have difficulty imagining themselves in other visceral states.

People can be affected by transient emotions.

Some Principles of Choice

People can be prisoners to sunk costs, hating to recognize losses.

People dislike uncertainty.

People consider the return on their investment in making decisions.

People are insensitive to opportunity costs.

People may not know what they want, especially with novel questions.

Overview

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Risk Management Requires

Domain specialists
Risk and decision analysts
Behavioral scientists
Systems specialists

Proposal #1

Creating an independent resource center available to those who don’t know where to go when looking for risk management help.

Resource Center Goals

publication-quality scientific support for
-- quality assurance
-- economies of scope
-- pool lessons learned
-- anticipate problems
-- involve academic researchers

Proposal #2

Standardize procedures for making and communicating about decisions.

Figure 1: FDA Benefit-Risk Framework

Decision Factor	Evidence and Uncertainties	Conclusions and Reasons
Analysis of Condition		
Current Treatment Options		
Benefit		
Risk		
Risk Management		
Benefit-Risk Summary Assessment		

FDA. (2013). *Structured approach to benefit-risk assessment for drug regulatory decision making*. Draft PDUFA V implementation plan (2/13). FY2013-2017.

Prescription Drug Facts: Lunesta (Eszopiclone)

What is this drug for?	To make it easier to fall or to stay asleep
Who might consider taking it?	Adults age 18 and older with insomnia for at least 1 month
Who should NOT take it?	People under age 18
Recommended testing	No blood tests, watch out for abnormal behavior
Other things to consider doing	Reducing caffeine (especially at night), exercise, regular bedtime, avoid daytime naps

LUNESTA Study Findings

788 healthy adults with insomnia for at least 1 month -- sleeping less than 6.5 hours per night and/or taking more than 30 minutes to fall asleep-- were given LUNESTA or a sugar pill nightly for 6 months. Here's what happened:

What difference did LUNESTA make?	People given a sugar pill	People given LUNESTA (3 mg each night)
Did LUNESTA help?		
LUNESTA users fell asleep faster (15 minutes faster)	45 minutes to fall asleep	30 minutes to fall asleep
LUNESTA users slept longer (37 minutes longer)	5 hours 45 minutes	6 hours 22 minutes
Did LUNESTA have side effects?		
Life threatening side effects		
No difference between LUNESTA and a sugar pill	None observed	
Symptom side effects		
More had unpleasant taste in their mouth (additional 20% due to drug)	6% 6 in 100	26% 26 in 100
More had dizziness (additional 7% due to drug)	3% 3 in 100	10% 10 in 100
More had drowsiness (additional 6% due to drug)	3% 3 in 100	9% 9 in 100
More had dry mouth (additional 5% due to drug)	2% 2 in 100	7% 7 in 100
More had nausea (additional 5% due to drug)	6% 6 in 100	11% 11 in 100

How long has the drug been in use?

Lunesta was approved by FDA in 2005. As with all new drugs we simply don't know how its safety record will hold up over time. In general, if there are unforeseen, serious drug side effects, they emerge after the drug is on the market (when a large enough number of people have used the drug).

http://www.vaoutcomes.org/

Proposal #3

Create shared understanding by common knowledge of essential scientific approaches.

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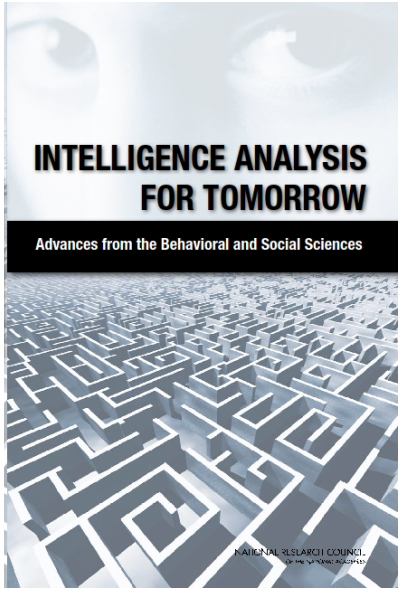
Create shared understanding by common knowledge of essential scientific approaches.
Seek fluency, not technical mastery.

NAS Report for DNI

Consensus Report



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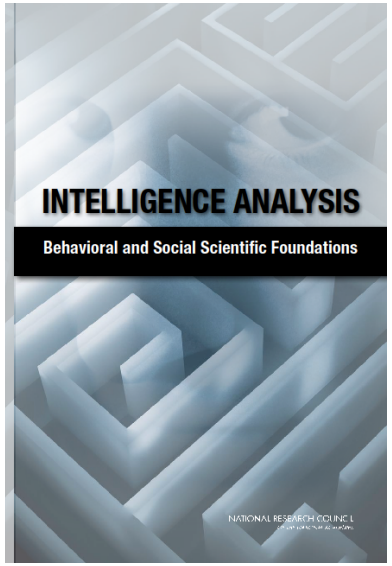
Edited Readings



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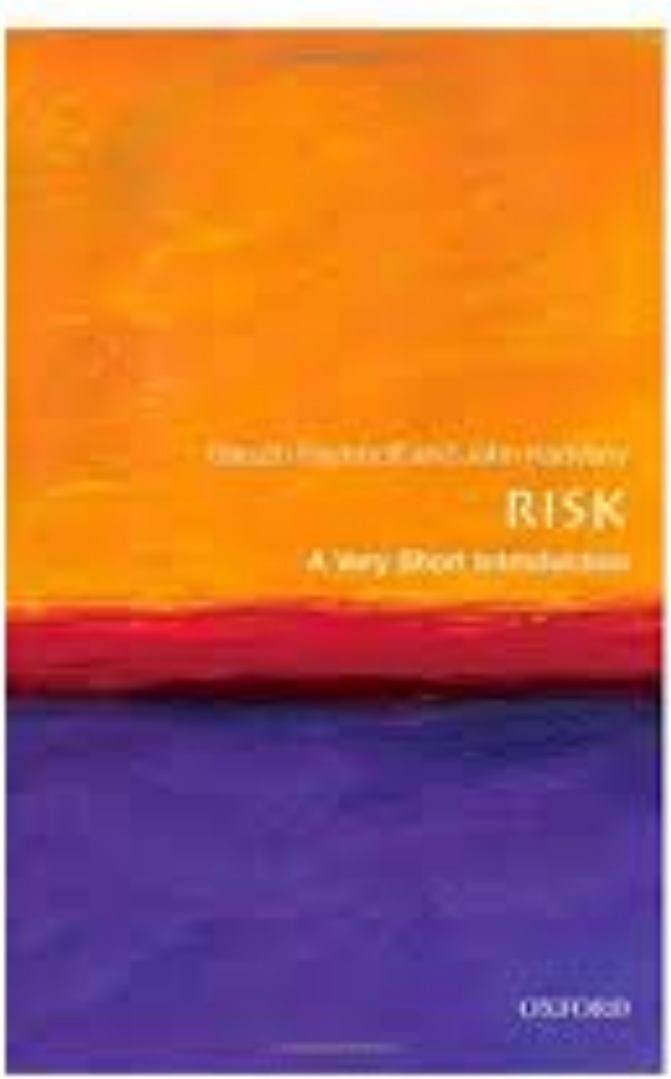
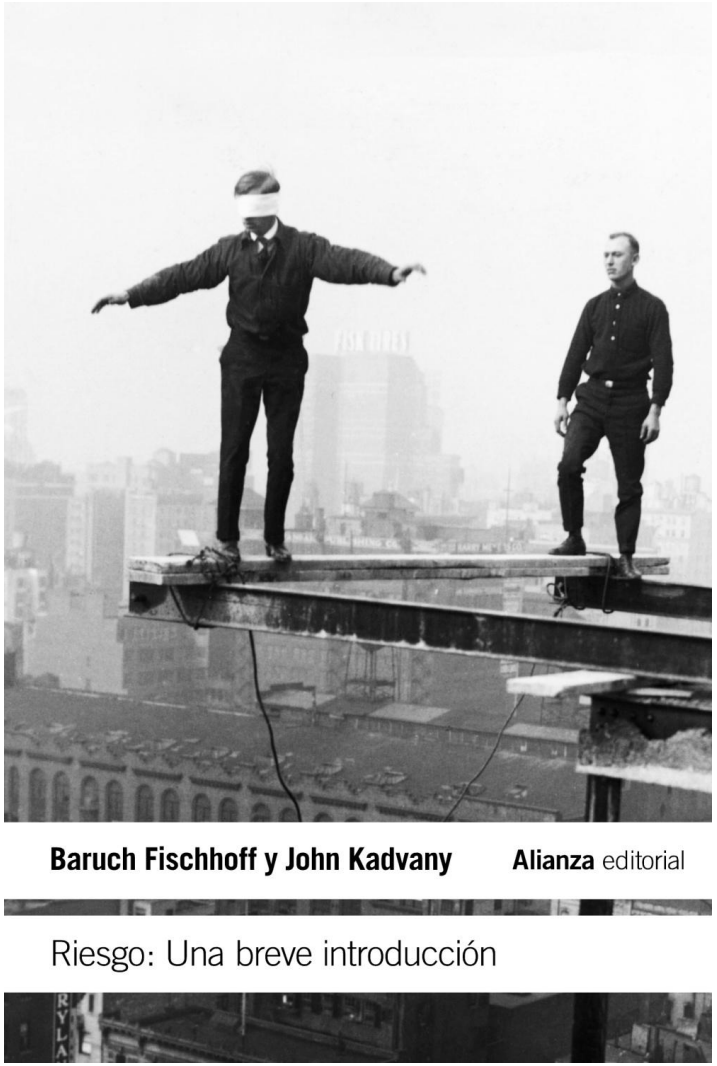
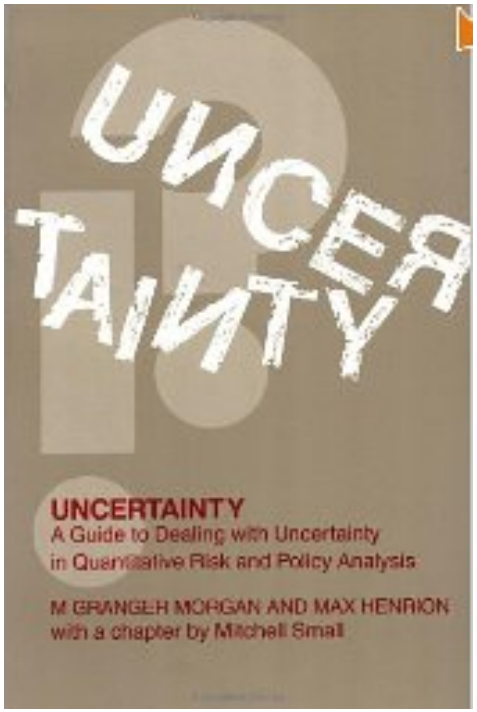
Essential Analytical Methods

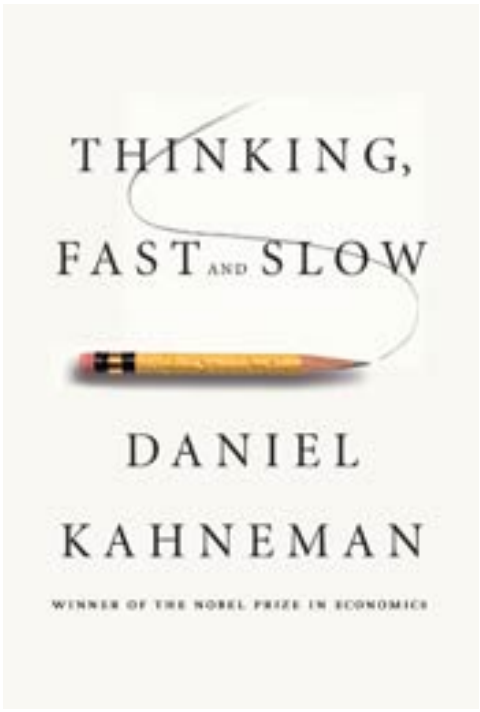
Risk analysis
Decision analysis
Signal detection theory
Game theory
Economics
Behavioral psychology
Communications
…

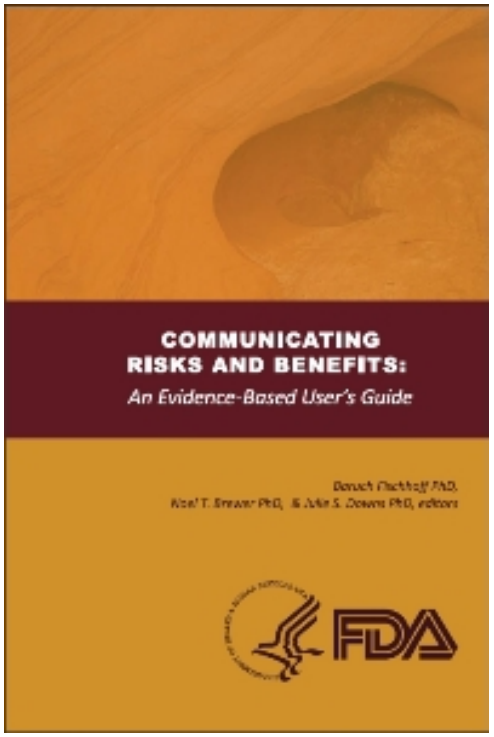




Fischhoff, B., & Kadvany, J. (2011). *Risk: A very short introduction*. Oxford: Oxford University Press.







Morgan, M.G., & Henrion, M. (1990). *Uncertainty*. New York: Cambridge.
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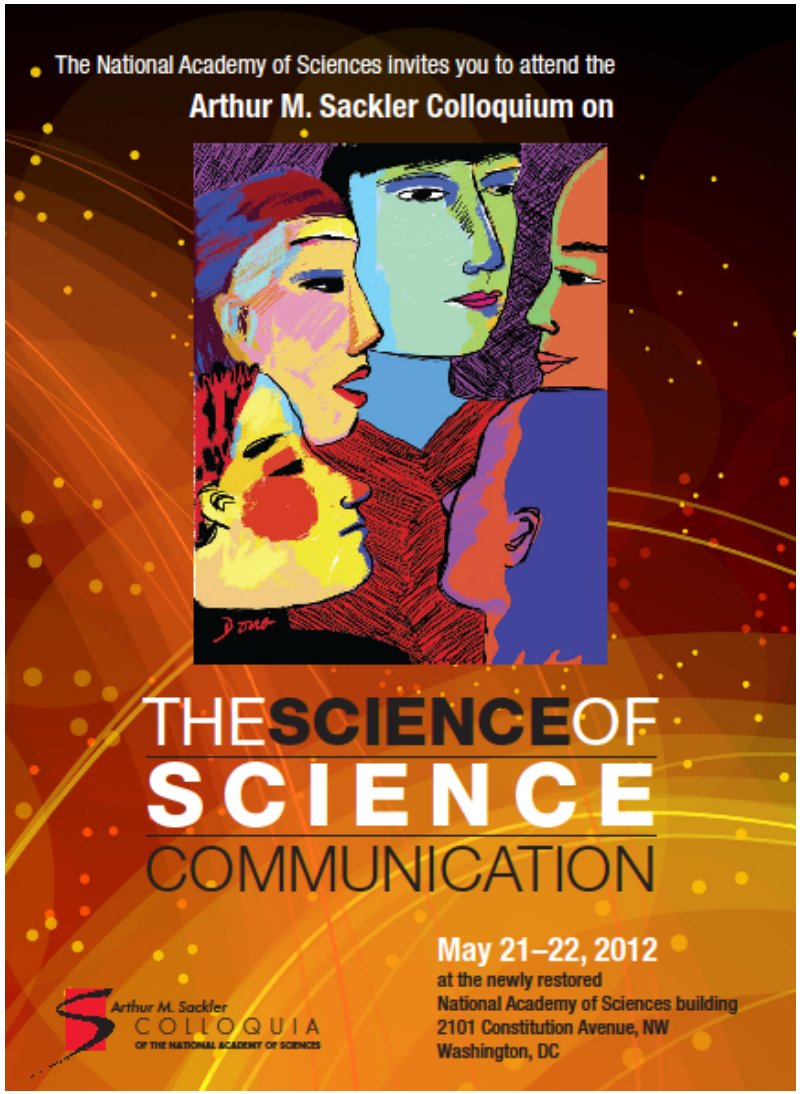

http://www.pnas.org/content/110/Supplement_3

http://www.nasonline.org/programs/sackler-colloquia/completed_colloquia/science-communication.html

http://www.nasonline.org/programs/sackler-colloquia/upcoming_colloquia/science-communication II.html

Books

Fischhoff, B., Brewer, N., & Downs, J.S. (eds.). (2011). *Communicating risks and benefits: An evidence-based user's guide*. Washington, DC: Food and Drug Administration. http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm268078.htm

Fischhoff, B., & Chauvin, C. (eds.). (2011). *Intelligence analysis: Behavioral and social science foundations*. Washington, DC: National Academy Press http://www.nap.edu/catalog.php?record_id=13062

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Slovic, P. (ed.) (2000). *Perception of risk*. London: Earthscan.

Research Articles

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Fischhoff, B. (1992). Giving advice: Decision theory perspectives on sexual assault. *American Psychologist*, 47, 577-588.

Fischhoff, B. (2011). Communicating the risks of terrorism (and anything else). *American Psychologist, 66*, 520-531.

Fischhoff, B. (2012, Summer). Communicating uncertainty: Fulfilling the duty to inform. *Issues in Science and Technology*, *29*, 63-70 ,

Fischhoff, B., Bruine de Bruin, W., Guvenc, U., Caruso, D., & Brilliant, L. (2006). Analyzing disaster risks and plans: An avian flu example. *Journal of Risk and Uncertainty*, 33, 133-151.

http://www.hss.cmu.edu/departments/sds/src/faculty/fischhoff.php

Carnegie Mellon Electricity Center: http://wpweb2.tepper.cmu.edu/ceic/

Center for Climate and Environmental Decision Making: http://cedm.epp.cmu.edu/index.php

Center for Risk Perception and Communication: http://sds.hss.cmu.edu/risk/

Center for Human Rights Science: http://www.cmu.edu/chrs/