

Communicating Uncertainty

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IOM Workshop on Characterizing and Communicating Uncertainty in
the Assessment of Benefits and Risks of Pharmaceutical Products

May 12, 2014

Informed Decisions Require

Understanding facts

What positive and negative outcomes might follow each possible choice?

Understanding values

What tradeoffs are best among those outcomes?

Both Involve Uncertainty

Uncertainty about Facts

Variability in individual outcomes due to unknown sources

Incomplete internal validity, from inevitable imperfections in evidence

Incomplete external validity, from inevitable differences between evidence and actual experience

Inevitable possibility of surprises in underlying science

Uncertainty about Values

Lack of experience with unfamiliar outcomes

Limited ability to predict experienced utility

Incommensurability of outcomes differing on multiple, diverse attributes

Unclear guidance from past decisions

Poorly Communicated Uncertainty Can Mean

Needless hesitation

Unwarranted confidence

Inappropriate choices

Personal regret

Interpersonal resentment

The Science of Communicating Uncertainty

Steps in Communication Design

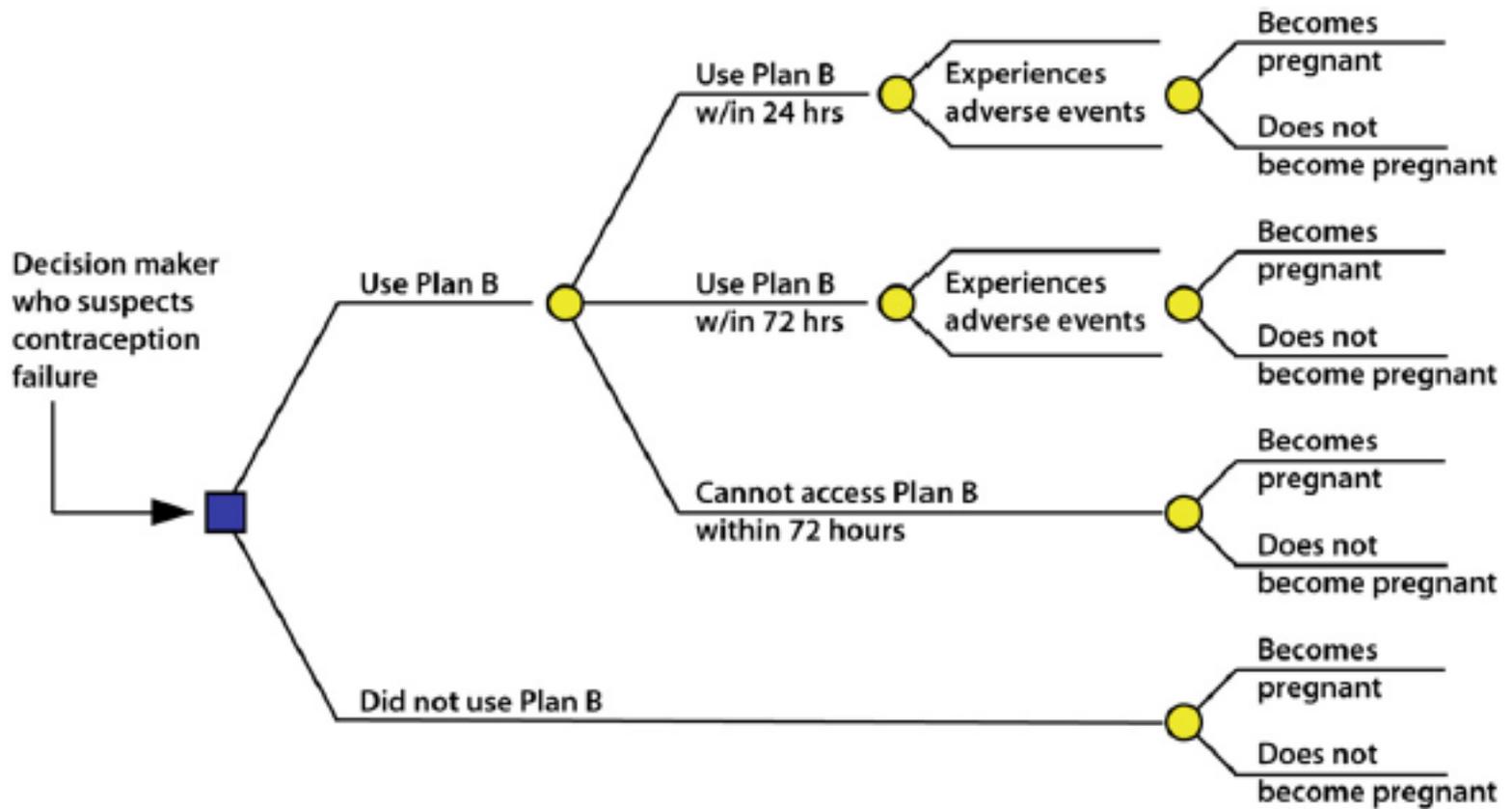
Characterize decisions

Describe existing beliefs

Draft messages to convey missing beliefs,
drawing on basic science of judgment

Evaluate adequacy of message

Repeat, as necessary



Decision tree for Plan B use after suspected contraceptive failure, with potential impact of availability.

Uncertainty about Facts

Representing Summary Uncertainty

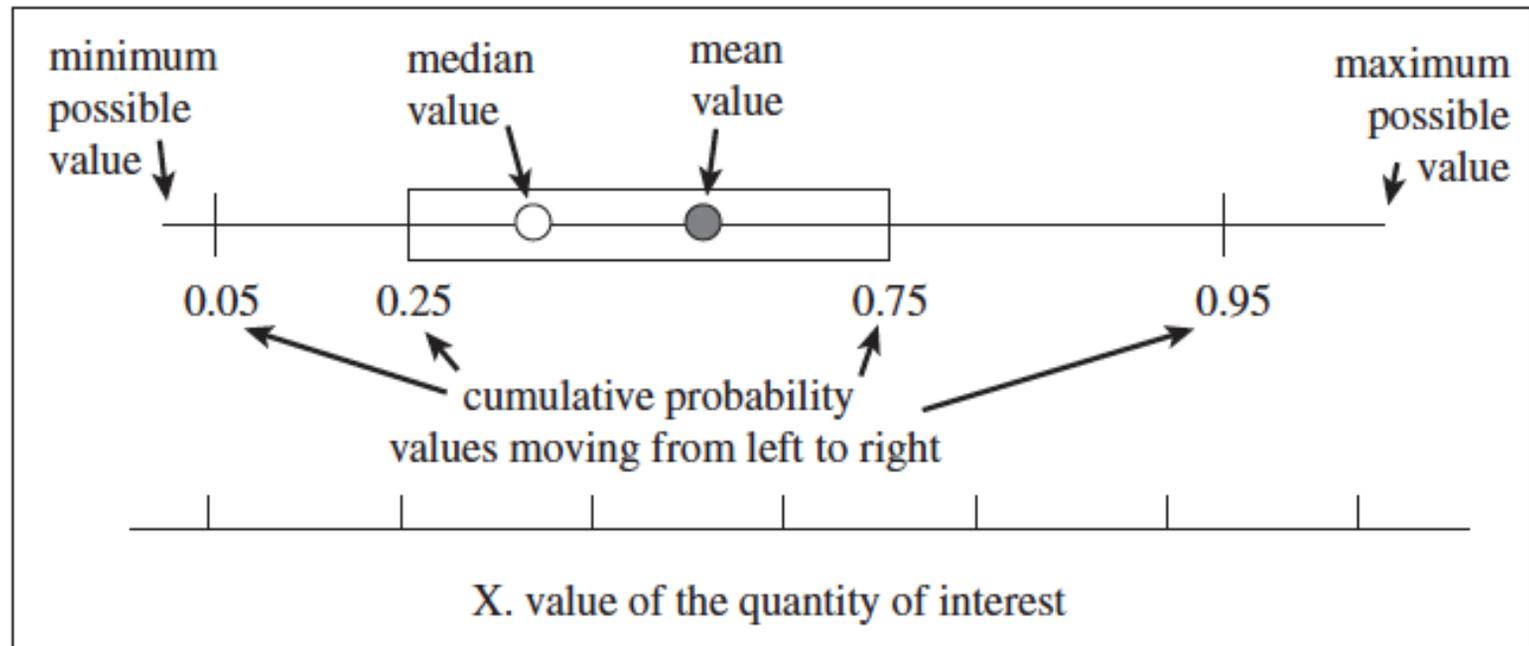


Figure 4. Recommended format for a box plot. When many uncertain results are to be reported, box plots can be stacked more compactly than probability distributions [18].

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

Representing Pedigree of Science

Outcome	Measure	Proxy (How well does the measure get at the key outcome?)	Empirical Basis (How strong are the best data on these measures?)	Methodological Rigor (How strong are the best methods available to the science?)	Validity (How well have results been confirmed from different sources?)
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Funtowicz, SO, & Ravetz, J. (1990). *Uncertainty and Quality in Science for Policy*. London: Kluwer

Uncertain Economic Knowledge

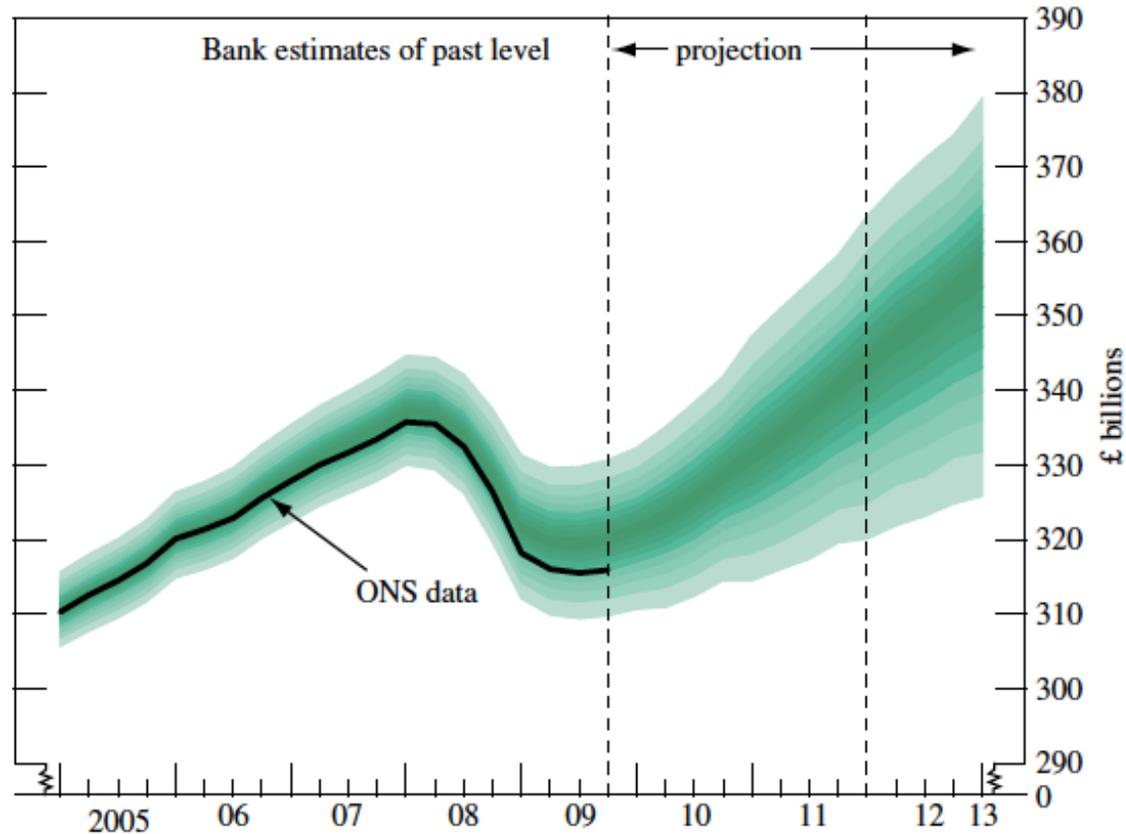


Figure 7. GDP level fan chart. February 2010 *Inflation Report*.

Aikman, D., Barrett, P., et al. (2011). Uncertainty in macroeconomic policy-making: art or science. *Philosophical Transactions of the Royal Society*, 369, 4798-4817.

Uncertain Economic Knowledge

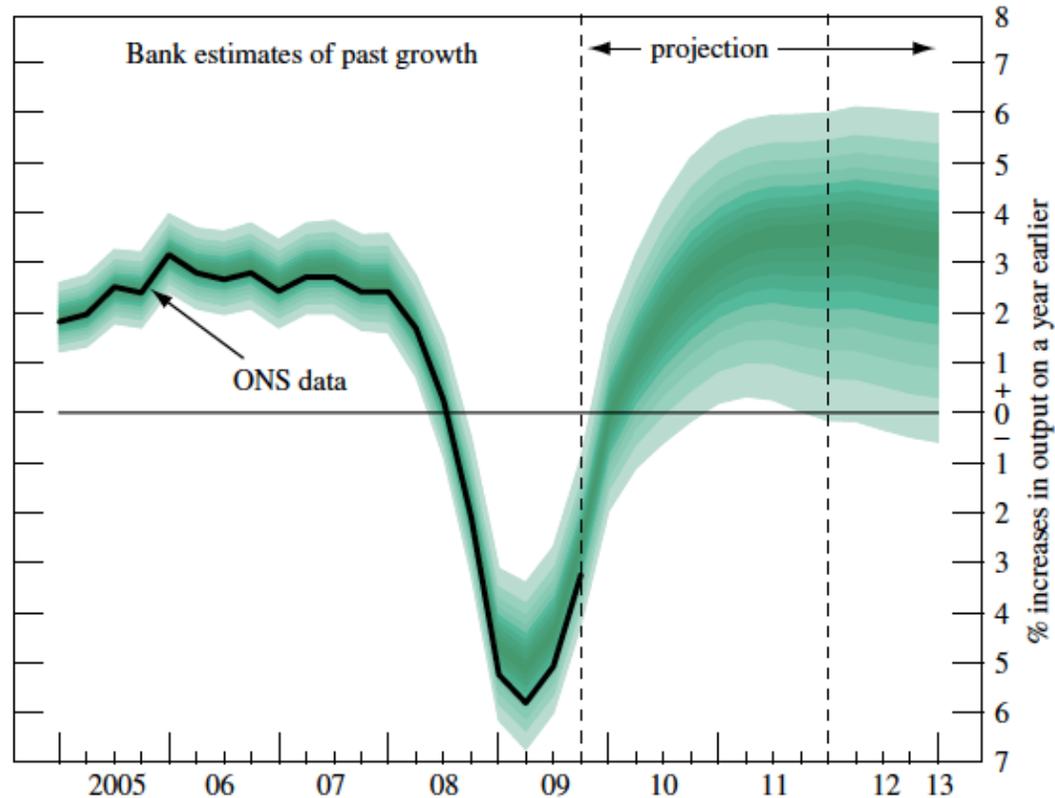


Figure 6. GDP growth fan chart. February 2010 *Inflation Report*.

Aikman, D., Barrett, P., et al. (2011). Uncertainty in macroeconomic policy-making: art or science. *Philosophical Transactions of the Royal Society*, 369, 4798-4817.

Uncertainty about Values

Multi-attribute characterization
Constructive preferences

Common Risk Dimensions

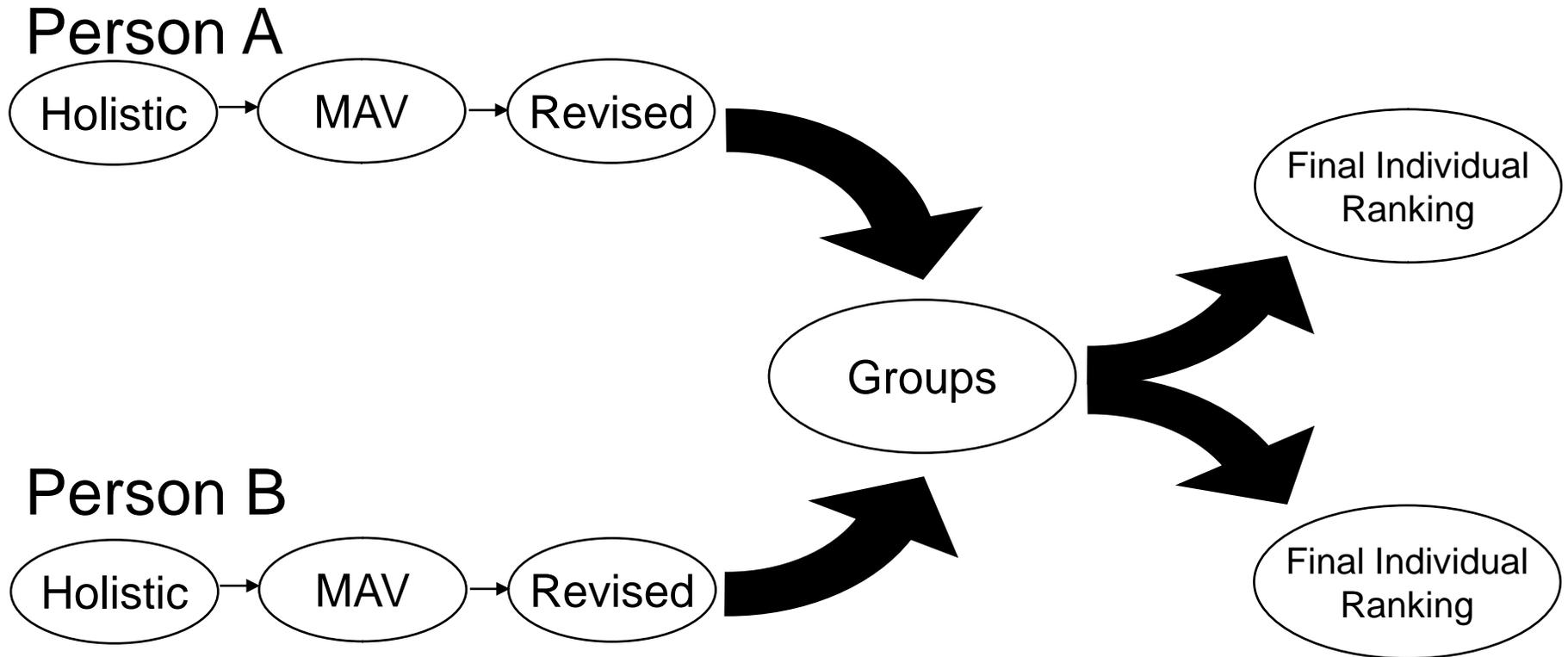
Factor 1: Dread Risk

Involuntary
Inequitable
Catastrophic
Dread
Uncontrollable
Increasing
Affects future generations

Factor 2: Unknown Risk

Unknown to science
Unknown to exposed
Unobservable
Delayed effects
New

A Process for Preference Construction



(MAV = multi-attribute value assessment)

Morgan, K.M., DeKay, M.L., Fischbeck, P.S., Morgan, M.G., Fischhoff, B., & Florig, H.K. (2001). A deliberative method for ranking risks (2): Evaluation of validity and agreement among risk managers. *Risk Analysis*, 21, 923-938

Reactive Measurement

People construct their preferences from seemingly relevant basic values.

Process should deepen understanding, but might induce bias.

Barriers to Using the Science

Experts' Reluctance to Express Uncertainty

See it as misplaced imprecision

Expect to be misunderstood

Fear being punished for candor

Uncomfortable with the elicitation method

Barriers to Constructive Preference Elicitation

Fear of reactive measurement, shifting burden of responsibility to respondent

Preference for standardization, lacking approach to respondent heterogeneity

Prefer greater sample size to more precise measurement, as route to greater statistical power

Two Proposals for Regulatory Decision Makers

Proposal #1

Create standard procedures for making and communicating 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? <i>Life threatening side effects</i> No difference between LUNESTA and a sugar pill	None observed	
<i>Symptom side effects</i>		
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).

Schwartz, L., & Woloshin, S. (2013). The Drug Facts Box: Improving the communication of prescription drug information. *PNAS*, 110, 14069-14074.

Proposal #2

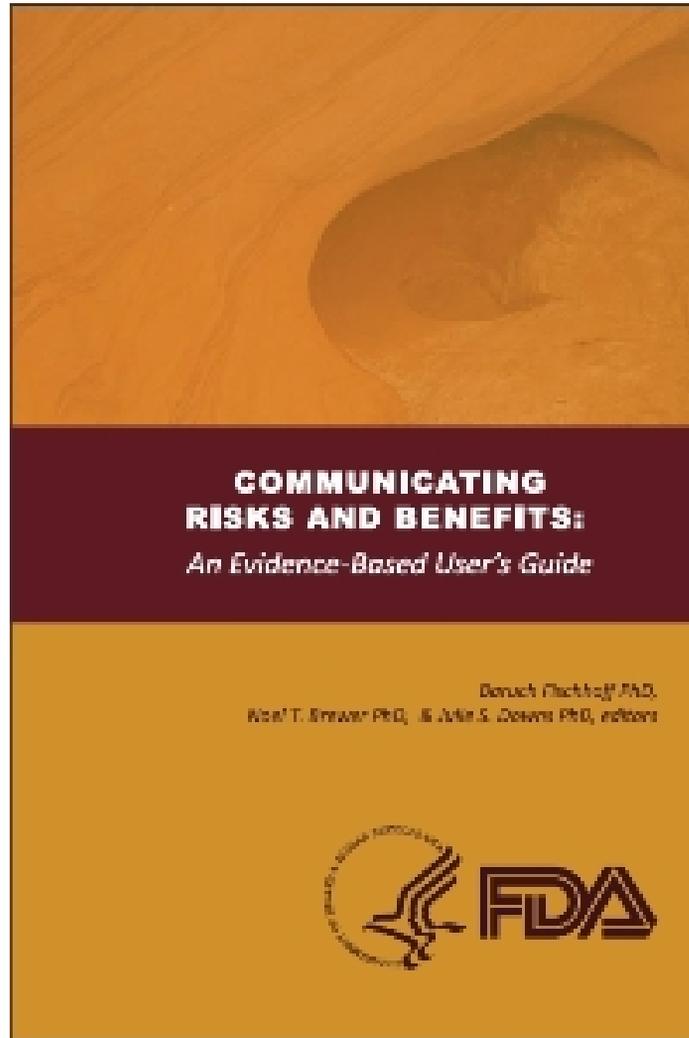
Create a resource center to provide experts with publication-quality support in eliciting and communicating uncertainty.

Proposal #2

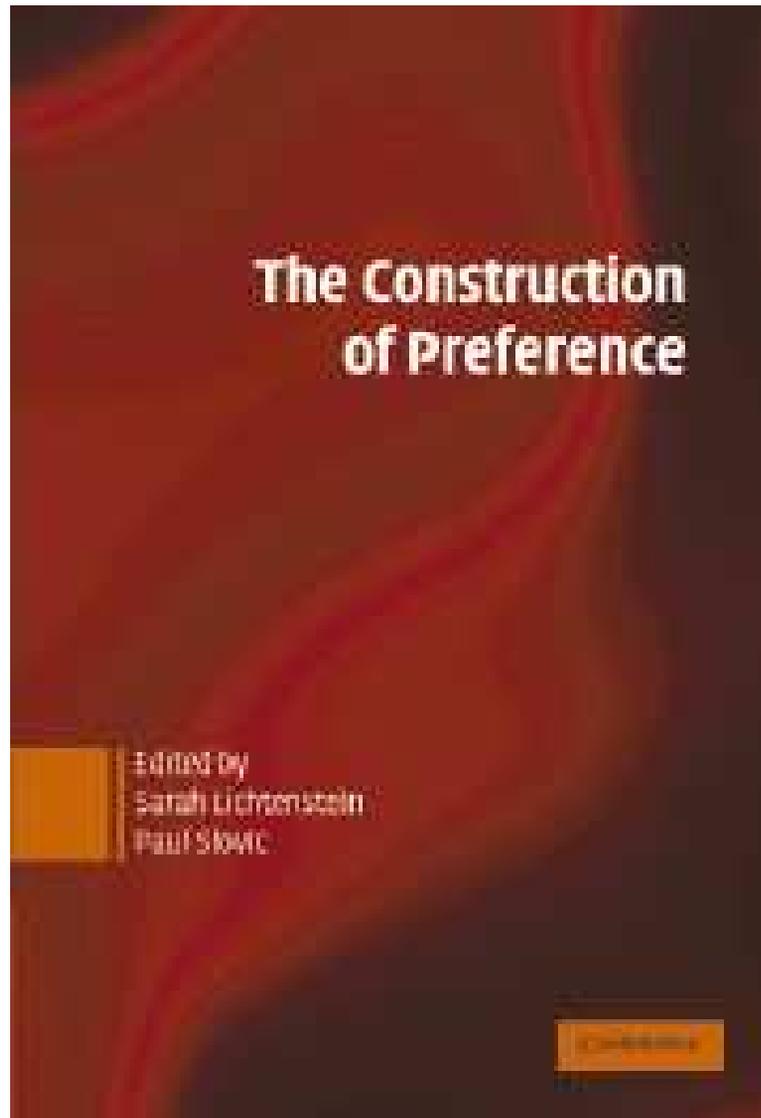
Create a resource center to provide experts with publication-quality support in eliciting and communicating uncertainty.

- quality assurance
- economies of scope
- anticipate common problems
- trusted personal relationships
- stimulate basic applied research

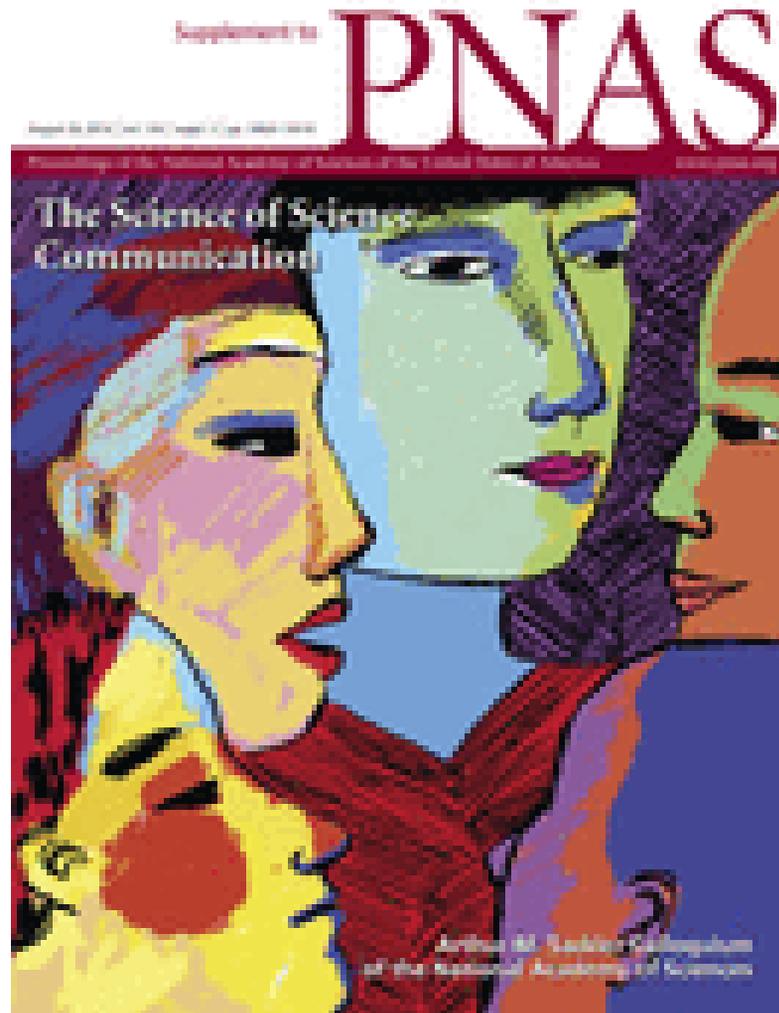
Some Research Resources



<http://www.fda.gov/AboutFDA/ReportsManualsForms/Reports/ucm268078.htm>



Lichtenstein, S., & Slovic, P. (eds.) (2006). *The construction of preferences*. New York: Cambridge University Press



<http://onlinedigeditions.com/publication/?i=174803>

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

The background of the slide is a stylized illustration of a city. The buildings are rendered in shades of orange, yellow, and brown, with dark brown windows. Overlaid on the city are several bright blue lines that connect different points, suggesting a network or communication paths. The lines are thicker and more prominent in the foreground, fading slightly as they connect to buildings in the background.

The Science of Science Communication II

September 23–25, 2013

at the National Academy of Sciences building
2101 Constitution Avenue, NW
Washington, DC

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

Orderly Treatment of Uncertainty May Produce

More useful science

by addressing decision makers' needs.

Better science

by encouraging disciplined reflection.

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
- Fischhoff, B., & Kadvany, J. (2011). *Risk: A very short introduction*. Oxford: Oxford University Press.
- Fischhoff, B., Lichtenstein, S., Slovic, P., Derby, S. L. & Keeney, R. L. (1981). *Acceptable risk*. New York: Cambridge University Press. (NUREG/CR-1614).
- Kahneman, D. (2011). *Thinking, fast and slow*. New York: Farrar Giroux & Strauss.
- Morgan, M.G., Henrion, M. (1990). *Uncertainty*. New York: Cambridge University Press.
- Slovic, P. (ed.) (2000). *Perception of risk*. London: Earthscan.

Research Articles

- Bruine de Bruin, W., Parker, A., & Fischhoff, B. (2007) Individual differences in adult decision-making competence (A-DMC). *Journal of Personality and Social Psychology*. 92, 938-956.
- 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/>