Risk Characterization

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Outline

- What is Risk Characterization
- Sources of Uncertainty & Variability
- Principles of Good Practice for Monte Carlo
- Recent issues of concern

Objective & Formal Definition

- "What do other assessors, decision-makers, and the public need to know about the primary conclusions and assumptions, and about the balance between confidence and uncertainty.
  - In the risk characterization, conclusions about hazard and dose response are integrated with those from the exposure assessment. In addition, confidence about these conclusions, including information about the uncertainties associated with the final risk summary, is highlighted."

- FH Habicht II (Deputy Admin, EPA) "Guidance on Risk Characterization for Risk Managers and Risk Assessors", memorandum to Asst Admin & Regional Admin (1992). http://www.epa.gov/oswer/riskassessment/habicht.htm

How Much is Enough

- "The level of detail considered in a risk assessment and included in the risk characterization should be commensurate with the problem's importance, expected health or environmental impact, expected economic or social impact, urgency, and level of controversy, as well as with the expected impact and cost of protective measures."

Presidential-Congressional Commission on Risk

Sources of Uncertainty & Variability (EPA Guidance)

- Guidance for Risk Characterization, EPA, Feb 1995
  - http://www.epa.gov/osa/spc/pdfs/rcguide.pdf

U&V: Dose Response

- Appropriateness of model(s) used
- Appropriateness of data set(s) used
- Selection of interspecies factors
- Correspondence between route of exposure in studies and route of concern to the manager
- Correspondence between duration
- Differential susceptibilities

U&V: Exposure Assessment

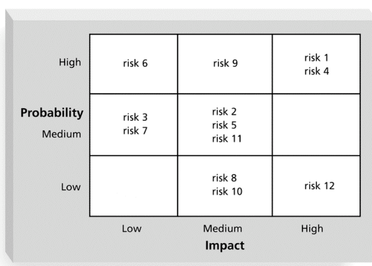
- Input parameters and choices of models (if any)
- Analytical techniques
- Behavioral and intake factors

Nonquantifiables

- The inability to quantify U/V does not mean it does not exist, and this should be a part of risk characterization

Digress on Alternatives to Monte Carlo

- Qualitative risk assessment
  - Subjective
  - Use for comparative purpose not quantitative decisions



- Imprecise probability arithmetic

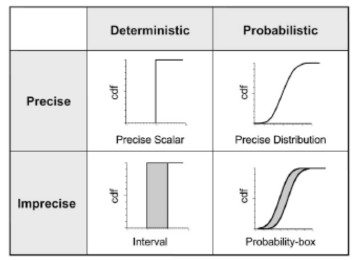


Fig. 2 Dimensions of uncertainty

JM Aughenbaugh et al., J. Mechanical Design, July 2006

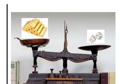
Principles of Good Practice

Principles of Good Practice for the Use of Monte Carlo Techniques in Human Health and Ecological Risk Assessments

David E. Burmaster[1] and Paul D. Anderson[2]

Risk Analysis, Vol. 14, No. 4, 1994

1. Show all formulae
2. Present point estimates
3. Present (classical) sensitivity analyses to reduce number of variables used for MC
4. Limit probabilistic analysis to issues of regulatory and practical importance
5. Provide details on how input distributions were selected
6. Separate **to the extent possible** variability & uncertainty
7. Use measured data to inform inputs **whenever possible**



8. Report goodness of fit for input distribution parametric fits
9. Discuss presence or absence of correlations amongst the inputs (|r|>.6)
10. Provide detailed information and graphs (including down to regulatory risk of concern); taable of descriptive statistics
11. Provide probabilistic sensititivity analysis differentiating variability from uncertainty and report graphically

12. Investigate stability of central moments and tails to # of trials and tails (functional forms) of input distributions
13. Present name and quality of random number generator
14. Discuss limitations of methods and of the interpretation of results

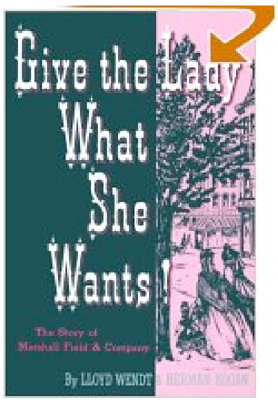
Presentation of Results

Univariate

Graphical Communication of Uncertain Quantities to Nontechnical People

Harald Ibrekk[1] and M. Granger Morgan[2]

Risk Analysis 7:519 (1983)



Graphical Communication 521

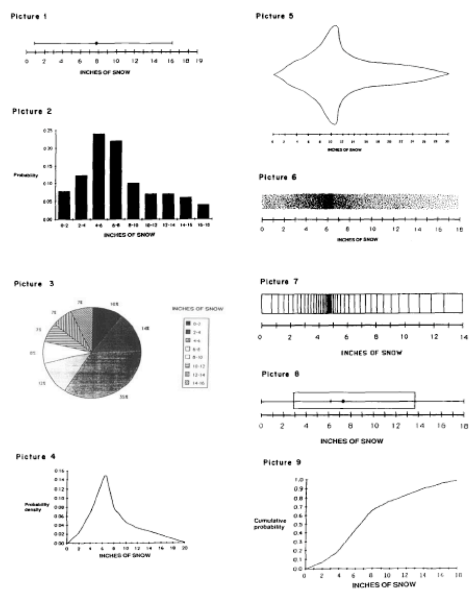
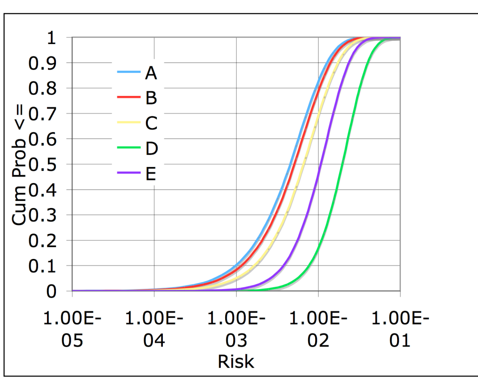


Fig. 1. Illustrations of the nine displays for communicating uncertain estimates for the value of a single variable used in the experiments.

2nd Order Monte Carlo

- Attempting to separate variability and uncertainty and convey the information in 2 dimensions



Second-order Monte Carlo simulation[(23)] is then performed as follows:

1. A set of parameters considered as uncertain is randomly selected from the respective distributions.
2. The risk assessment is performed, considering these parameters as fixed. This risk assessment takes into account the variability of other parameters and leads to an empirical density function reflecting variability of the risk in the population, given the uncertain parameters. Various statistics (i.e., the mean and the 25th, 50th, 75th, 95th, and 99th percentiles) of this empirical density are evaluated and stored.
3. 1,001 repetitions of the Steps (1) and (2) are performed, leading to 1,001 empirical density functions of the risk, and 1,001 sets of statistics.
4. The 50th percentile (median) of each statistic is then used to establish an estimate of this statistic; the 2.5th and 97.5th percentiles of each statistic are then considered as the CI 95 bounds of this statistic.

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Pouillot et al., Risk Analysis 24:1:1 (2004) 16

Most recent concerns

- Susceptible subpopulations
- Environmental justice and equitable distribution
- Affordability of mitigation measures