Data, decisions and risk

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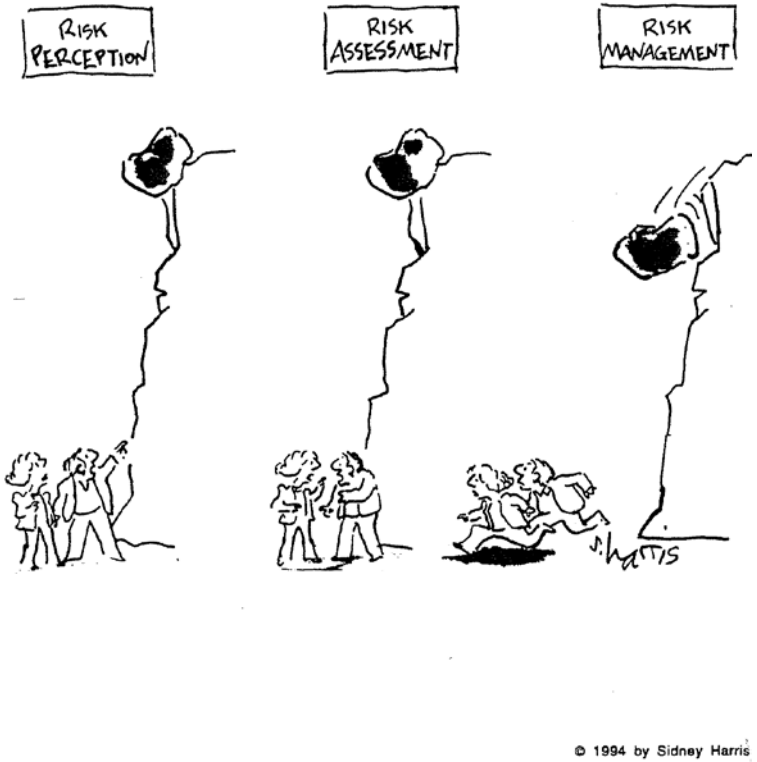
Sidney Harris perspective on risk …



A couple of questions to help calibrate the speaker ….

[Q1] Why are you attending this workshop?

[Q2] What legislative issue, if any, do you work on? For a committee?

Agriculture, Nutrition, and Forestry; Appropriations; Armed Services
Banking, Housing, & Urban Affairs; Budget; Commerce, Science, & Transportation
Energy and Natural Resources; Environment and Public Works; Finance
Foreign Relations; Health, Education, Labor, and Pensions
Homeland Security and Governmental Affairs; Judiciary Rules and Administration
Small Business and Entrepreneurship; Veterans' Affairs

Special, Select, and Other: Indian Affairs; Ethics; Intelligence; Aging

[Q3] What hazards and associated risks of adverse outcomes do you balance in your work? in your life?

[Q4] How do you manage these risks? What information do you need to manage these your exposure to these hazards?

[Q5] What would you like to take away from this session?

[Q6] Why is 1:30-3:00 one of the worst times to give a seminar or teach a class?

Outline

1. Stat for Staffer recap
2. Crowdsourcing – what ASA Risk Section members said
3. Recent encounters with risk, uncertainty and variability in the news
4. Concepts and context for discussing issues
5. Example: Avoiding future disease { Health, Education … }
6. Example: Environmental Management { Environment and Public Works }
7. Example: Highway Safety { Commerce, Science and Transportation }
8. Example: Institutional Fiscal Health { Banking, Housing … }
9. Example: Food Safety { Ag, Nutrition and Forestry }
10. Summary

Part of the ASA Statistics for Staffers

Designed to bringing Statistics to Congressional staff to help them do their jobs better

Held in conjunction with the Senate Office of Education and Training in a series they call "Critical Statistical Thinking.“

Thanks to Megan Daly, Senate Office of Education and Training & Steve Pierson, ASA Director of Science Policy.

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Crowdsourcing - Emailed ASA Risk Section members

*"… what staffers should know about risk. I thought I might "crowd source" part of my talk. In particular, I would be interested in hearing what 2-3 ***risk*** ideas you would nominate as ***critical*** for staffers to learn/appreciate. Also include a sentence or two why you believe these ideas are important. Examples illustrating your concept are also welcome"*

Ideas:

"**absolute and relative risk** have been touched on, and so have issues of increases in risk expressed as multiples or absolute amounts"

"issues of **uncertainty and variability** as a whole need to be conveyed, that there are ways to deal with the lack of a "bright line"

“Uncertainty and variability are basic to the field. How can visualization of uncertainty be incorporated into business intelligence?”

“best is to display a **distribution**. Decisions shouldn't be based on single values, like just the overall average treatment effect … In health care, different patients respond differently to the same treatment … in environmental research, there is obvious geographic variation across the US. Again, one size (one, uniform policy) does not fit all ...at least in the sense that locally adaptive policies could be more economical and effective.”

“one basic idea I try to get forth to people in cancer screening is that you cannot demand zero cancer risk: you must be able to live with acceptable cancer risk”

“informatics/"big data" revolution is real. We have or soon will have WAY more data with which to address hard problems than we have properly-trained statistical analysts to handle it all”

“include elements of Decision Risk Analysis (Decision Analysis), focused on a decision tree”

“HRLP (High Risk, Low Probability) stuff is a good example … something like building a nuclear power plant (or not) might be an example” (founders of ASA Risk Section worked at the Nuclear Regulatory Commission)

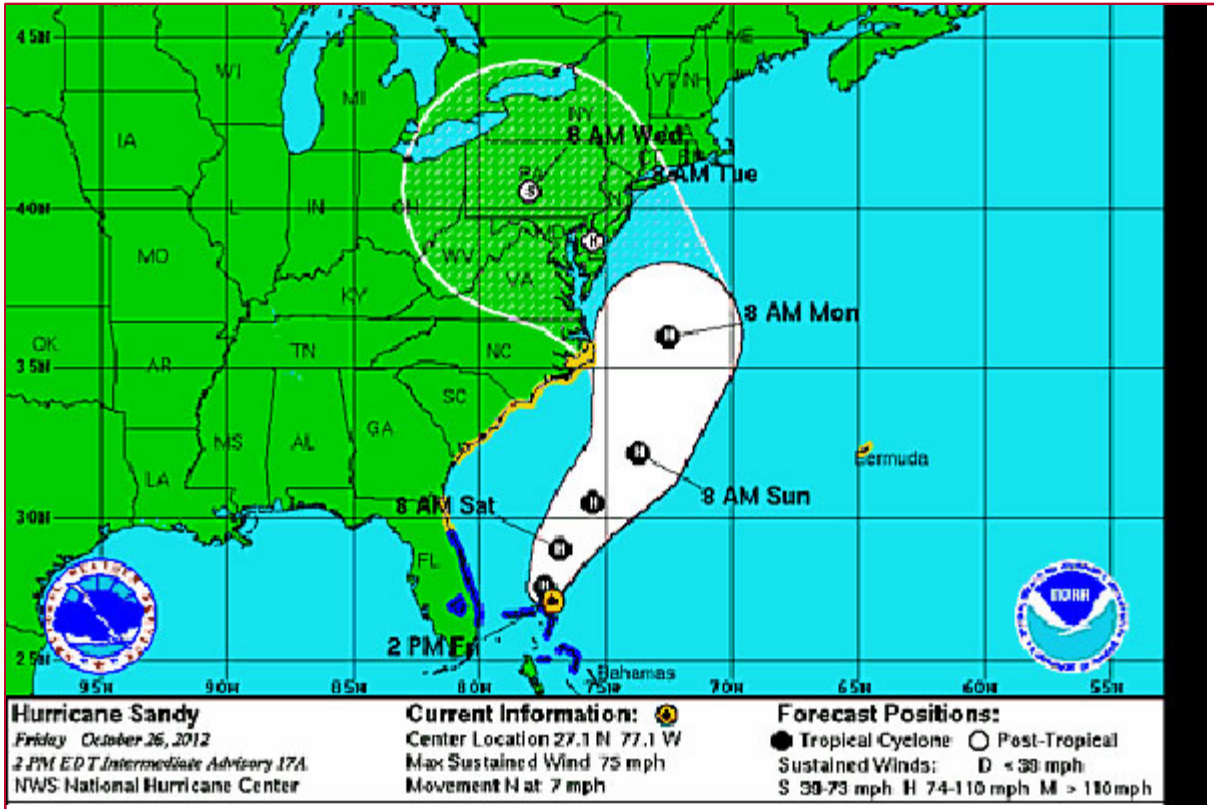
“might be interested in something on David Spiegelhalter's website - http://plus.maths.org/content/113-chance-death”

So, did I get any guidance from this voluntary response, non-probability sample of stat folks involved in the ASA Risk Section?

1)Reinforce ideas about risk

2)Consider meaning of uncertainty and variability

Let’s continue with a few recent stories where the risk of adverse outcome were front page news …



http://www.csmonitor.com/Science/Discoveries/2012/1026/Hurricane-Sandy-liveblog-Which-way-is-Sandy-headed-The-latest-Frankenstorm-track-video [Friday, Oct. 26 3:35 p.m. – CS Monitor)

What decisions did local governments need to make?

What decision did you make?

What did uncertainty mean here?

Did your behavior change as a function of this information?

Scientists convicted of manslaughter for failing to warn of earthquake http://www.guardian.co.uk/science/2012/oct/22/scientists-convicted-manslaughter-earthquake

"On 6 April 2009, an earthquake struck the Italian town of L'Aquila, a medieval settlement built on an ancient lake nestled in the Apennines. More than 300 people died, and 20,000 buildings were destroyed"

"A court in L'Aquila, Italy, has sentenced defendants to six years in prison despite lack of any reliable way to predict quakes"

"Scientists worldwide had decried the trial as ridiculous, contending that science has no reliable way to predict earthquakes"

Photograph: AP The accusation they make is not that experts failed to predict the L'Aquila earthquake, but that they failed to properly assess and communicate the risks.'
http://www.guardian.co.uk/commentisfree/2012/oct/23/italian-scientists-charged-laquila-earthquake?intcmp=239

What action steps do you think the scientists consider?

Is it possible to be certain when predicting events such as earthquakes? (Note that the report suggests that criticism is associated with the communication of risk more than the assessment here.)

Is the prediction of an earthquake that doesn't happen (false alarm) as bad as not predicting an earthquake that does occur (false negative)?

Does statistical thinking help with framing this?

So what do we mean by ideas such as “risk” “uncertainty” and “variability”?

RISK:
Economic: In financing a project, the risk that the project's output will not generate sufficient revenues to cover operating costs and to repay debt obligations.(http://www.investorwords.com/1646/economic_risk.html)

Environmental: EPA considers risk to be the chance of harmful effects to human health or to ecological systems resulting from exposure to an environmental stressor (http://epa.gov/riskassessment/basicinformation.htm#risk)

Financial: *investors' chance of loss* -the possibility of financial loss in an investment or speculation (http://www.qfinance.com/dictionary/financial-risk)

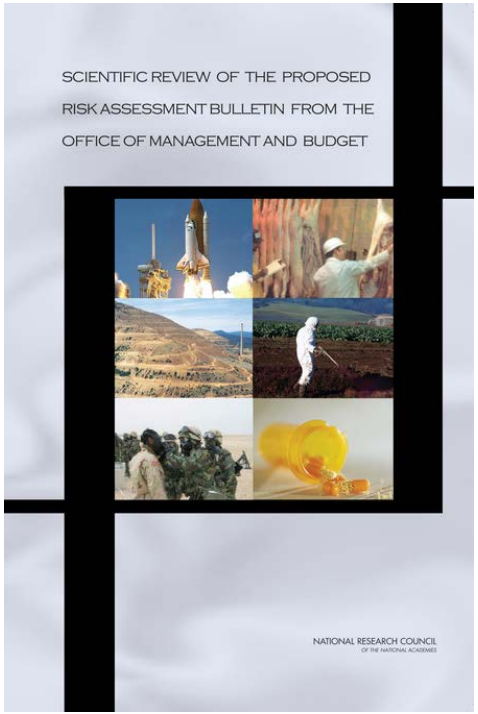
Hazard = agent associated with some adverse outcome

Classes of hazards (Lowrance 1980):

1. Infectious and degenerative disease (e.g. Influenza)
2. ‘natural’ catastrophes (e.g. Earthquakes, Hurricanes)
3. Failure of large technological systems (e.g. failure of dams, power plants, planes, say from structural malfunction)
4. Discrete small-scale accidents (e.g. highway, workplace)
5. Low-level delayed effect hazards (e.g. radiation, stress, chemicals such as pesticides)
6. Sociopolitical disruption (e.g. terrorism)

[lots of other classifications exist such as health hazards and physical hazards]

Recent NAS/NRC reports (4423 reports when searching “risk” in titles”) …



- Medical Care Economic Risk: Measuring Financial Vulnerability from Spending on Medical Care (2012)
- Analysis of Cancer Risks in Populations Near Nuclear Facilities: Phase I (2012)
- A Risk-Characterization Framework for Decision-Making at the Food and Drug Administration (2011)
- Health Risks from Dioxin and Related Compounds: Evaluation of the EPA Reassessment (2006)
- Risk Analysis and Uncertainty in Flood Damage Reduction Studies (2000)
- Diet and Health: Implications for Reducing Chronic Disease Risk (1989)

Data needed for many formal assessments of risk associated with hazards …

1. Exposure assessment
   - Who is exposed?
   - How often?
   - To how much?

2. Relationship between some hazard exposure and some adverse response (aka dose-response relationship)

UNCERTAINTY: "**lack or incompleteness of information** … depends on

- quality, quantity and relevance of data
- reliability and relevance of models and assumptions"

For example, true relationship between elevated cholesterol levels and cardiovascular disease?

Why characterize uncertainty? (from Box 4-2, NRC 2009)

- informs the affected public about the range of possible risks from an exposure that they may be experiencing.
- informs the decision-maker about the range of potential risks that result from the decision
- helps in evaluating any decision alternative on the basis of the possible risks, including the most likely and the worst ones

VARIABILITY: "true differences in attributes due to **heterogeneity or diversity**

- usually not reducible by further measurement or study
- can be better characterized" [NRC 2009]

For example, if two people are on identical statin dosage, will they both experience same cholesterol reduction?

Why assess variability?

- enables the development of risk-management options that focus on the people at greatest risk rather than on population averages.

For example, the risk from exposures to particular vehicle emissions varies in a population and can be much higher in those close to roadways than the population average. That has implications for zoning and school-siting decisions.

TAKE HOME MESSAGE …

VARIABILITY – property of the system – can be better characterized

UNCERTAINTY – property of the decision maker and researcher – can be reduced

Always ask about sources of variability and uncertainty that lie behind estimates that are reported!

EXAMPLE: Avoiding future disease

Decision to be made:

Option to manage high cholesterol and risk of coronary heart disease (CHD)

(photo: www.visualphotos.com)

(follows ideas presented in Risk Assessment chapter in *Medical Uses of Statistics*)

We balance on decisions among options against likelihood of adverse outcomes

Suppose you (say a 45 year old, male, non-smoker) show up for your annual physical and your blood work results show the following:
+ cholesterol of 311 mg/dL
+ high-density lipoprotein (HDL) of 32 mg/dL
+ systolic blood pressure (SBP) of 110 mmHg

What do you think a physician might say? Based on what?

Physician: You have a 9% risk of coronary heart disease in the next 10 years
Patient: What does 9% mean? Absolute risk? Relative Risk? Odds Ratio?

Background:

- risk calculator based on the Framingham Heart Study - http://hin.nhlbi.nih.gov/atpiii/riskcalc.htm
- Third Report of the Expert Panel on Detection, Evaluation, and Treatment of High Blood Cholesterol in Adults (Adult Treatment Panel or ATP III)

Here are your options:

1. Do nothing
2. Change diet and/or exercise more
3. Take a statin drug

What information will help you decide?

Exploring background leading to the 9% risk estimate …

Risk Ratio = probability of disease in an "exposed" individual relative to an unexposed individual

Odds ratio = odds of disease in an exposed individual relative to the odds in an unexposed individual

Odds = Pr(adverse outcome) / Pr(NO adverse outcome)

Absolute risk = Pr(adverse outcome in exposed) – Pr(adverse outcome in unexposed)

Unexposed = normal, healthy levels of cholesterol (<200 mg/dL)

How are risks predicted? Separate models for women and men … other variables that are important predictors of CHD?

Pr(CHD) = function(age, smoking status, hypertension status, cholesterol level,…)

+ distribution?: individual has CHD with probability "Pr(CHD)" and
doesn't have CHD with probability "1-Pr(CHD)"
(underlying distribution: binomial)

+ model uncertainty?: what type of model should be fit? E.g. Logistic regression
what variables should be in the model?

+ parameter uncertainty?: how do we estimate the regression coefficients?

Is the model any good for predicting disease?

Sensitivity = Pr(model predicts CHD GIVEN CHD occurs)

False Positive Prob. = Pr(model predicts CHD GIVEN no CHD)

Specificity = Pr(model predicts no CHD GIVEN no CHD) = 1-False Positive Prob.

ROC curve (ROC = Receiver Operating Characteristic)

- Plot of sensitivity (y-axis) vs. false positive probability (x-axis)
- Wilson et al. (1998) Prediction of coronary heart disease using risk factor categories. Circulation 97: 1837-1847, doi:10.1161/01.CIR.97.18.1837 (http://circ.ahajournals.org/citmgr?gca=circulationaha;97/18/1837)
  Figure 1 from this article is reproduced on the next page

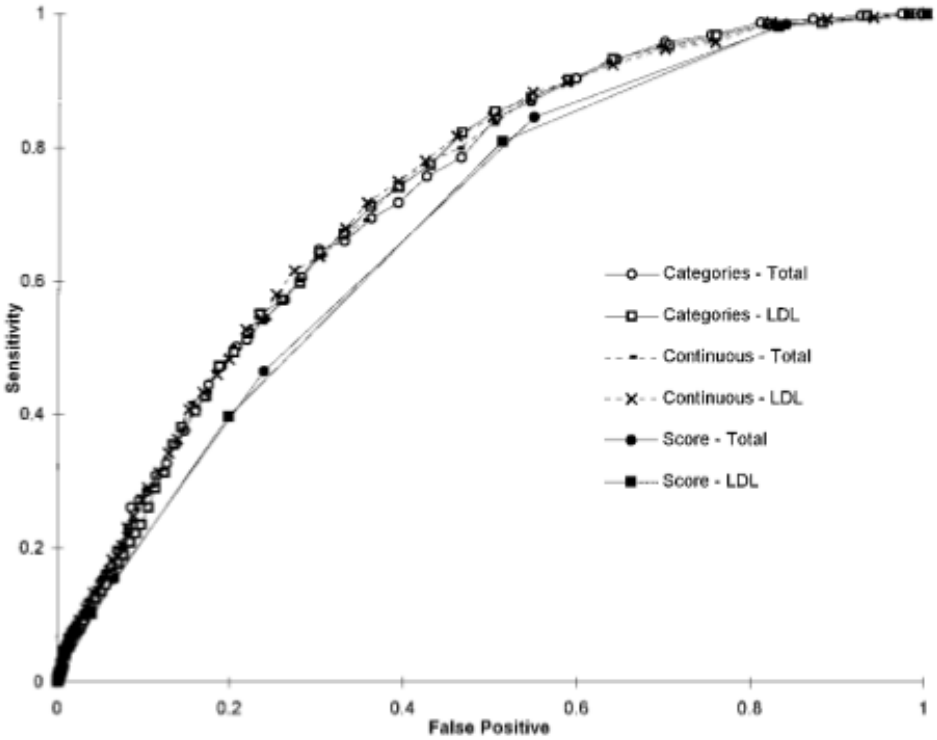


Figure 1. Receiver operating characteristic curves for prediction of CHD in Framingham men over a period of 12 years. Separate plots were used for continuous, categorical, and risk factor sum models, according to whether TC or calculated LDL-C was used.

Trade-offs in prediction? Each point on the previous curve reflects test performance for a particular cutpoint

Pick different cut points for deciding if a person would be predicted to have CHD – for example,
+ if a predicted probability ≥ 0.55, then predict CHD

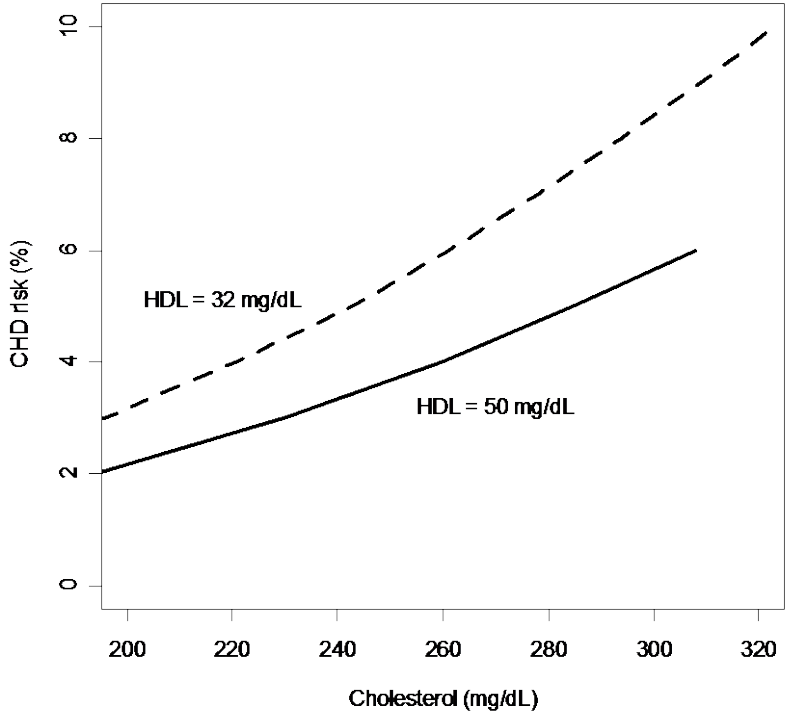
+ if a predicted probability < 0.55, then predict no CHD

Some people with no CHD with have a predicted probability ≥ 0.55 (False +)

Some people with CHD will have a predicted probability < 0.55 (False -)

Ten-year Risk (%) of CHD as a Function of Cholesterol (mg/dL) at Two Levels of HDL (mg/dL) for a 45-Year-Old Male Nonsmoker with Normal SBP.

Q: So what is the benefit of moving from Cholesterol levels of 311 mg/dL to 200 mg/dL?



Options (revisited):

1. Do nothing
2. Change diet and/or exercise more
3. Take a statin drug

Risk prediction model is not perfect but may be willing to accept false positive error if intervention is not noxious – so 9% risk may lead to rejection of option 1

Now, how much can a change in diet/exercise impact cholesterol level?

Need: studies available? Controlled trials where individuals randomized to diet/exercise conditions and followed for a significant time?

How about the impact of statin drugs on cholesterol?

Studies (clinical trials investigating statin impact on cholesterol)?

- Must be available as part of pharmaceutical approval process
- Demonstration of efficacy (cholesterol reduced with statin exposure) and safety (side effects with statin exposure?)

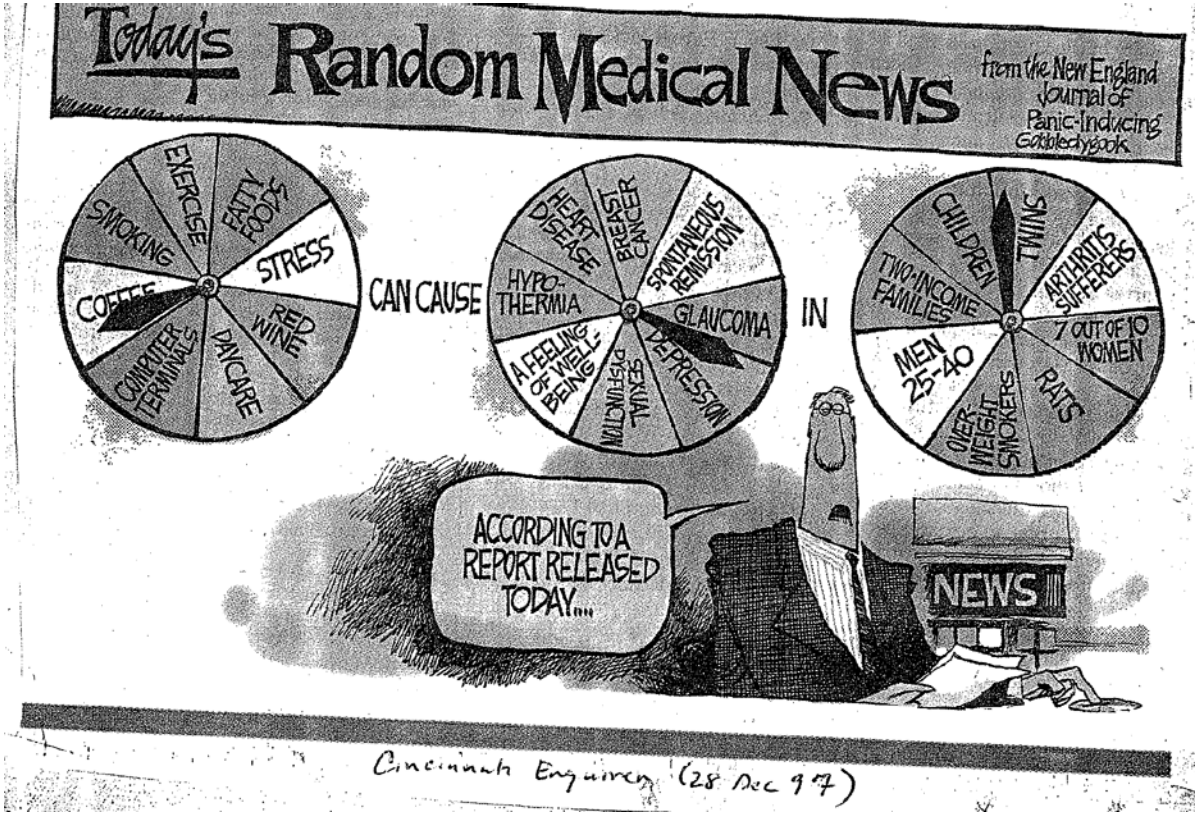
Issues:

- Same statin dose may not have the same impact on all treated (variability)

Questions:
So what do you think the patient should do? How many of you would take the statin? How many would try to modify exercise/diet? Do nothing?

Bottom line:

Health hazard risk evaluations involve more than the random spins (figure: Jim Borgman)



The last example focused on individual decision in the context of a hazard associated with potential health risks.

Can we think about how this might work on a larger institutional scale?

A series of vignettes follow to explore this …

EXAMPLE: Environmental Management

Decision to be made:

Set level of a stressor allowed to be discharged in receiving waters

(photo: peakwater.org)

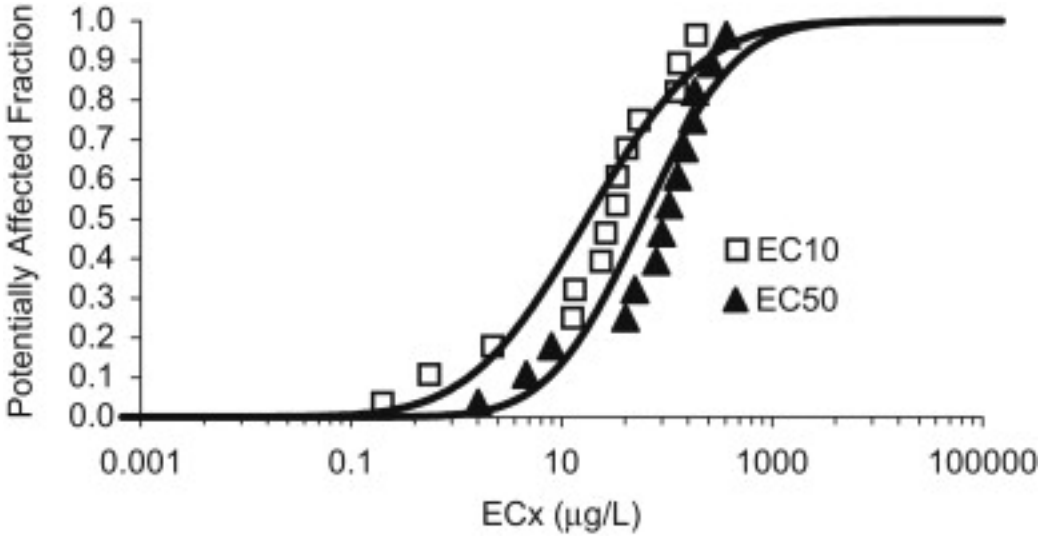
Issues: endpoints? Survival, reproduction, growth

Ecological validity of lab studies for field exposures?

Species impacted at particular stressor concentrations?

Species sensitivity distributions (http://www.epa.gov/ceampubl/fchain/webice/iceSSD.html)
= cumulative probability distributions of toxicity values for multiple species.

Impact on fungicide on freshwater invertebrates and algae (van Wijngaarden et al. (2010) Ecotoxicology and Environmental Safety 73: 109-122



Statistical aspects of this story …

A separate regression model was fit to each species – the fitted model was inverted to estimate the concentration association with a specified impact level (issue: what impact level should be specified)

Species level data is collected and display in a cumulative distribution

Uncertainty sources? Number of species included to construct this curve? Model to estimate action level? (Model fit on the previous page?)

EXAMPLE: HIGHWAY SAFETY

Decision to be made:
Set blood alcohol level to reduce risk of fatal crashes

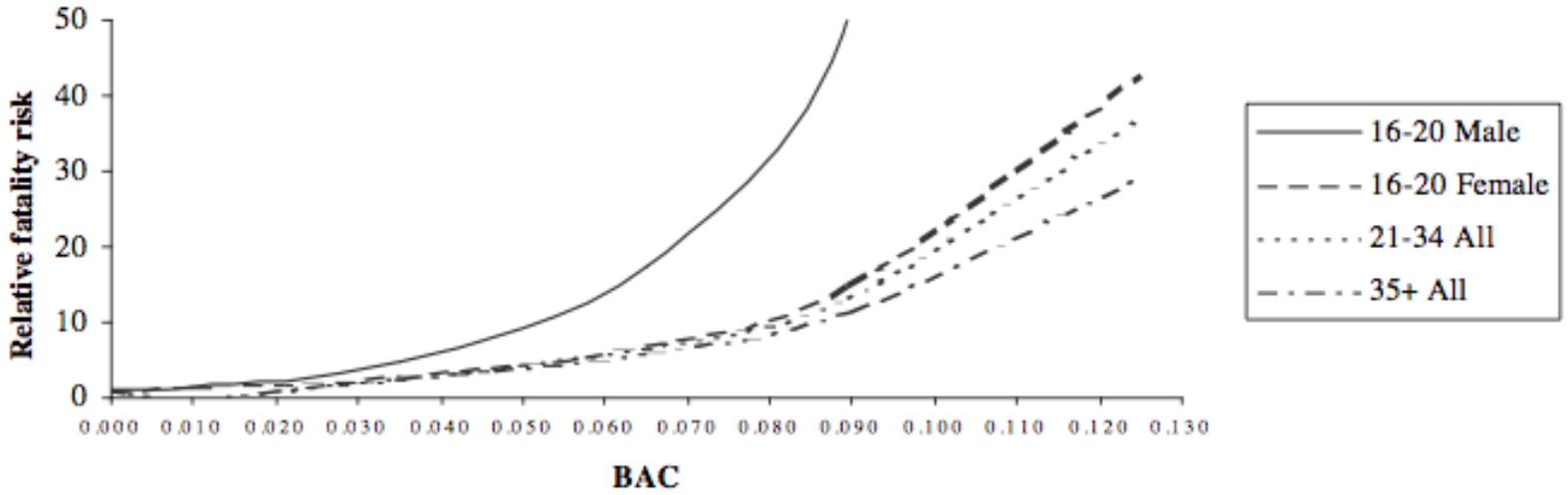
(photo: www.wisegeek.org)

Data sources:

geographically stratified multi-stage cluster sample (BAC info)
Census of all motor vehicles crashes that occur on a public trafficway in US (FARS)

Relative risk of fatal crash involvement by BAC, age and gender
NHTSA sponsored project – www.nhtsa.gov/people/injury/research/809-050pdf.pdf

Figure 1. Relative fatality risk for drinking drivers by age and sex in single-vehicle crashes[6]



Statistical aspects of the story …

1. Complex survey sample with appropriate weighting
2. Matching records in multiple data sources
3. Imputation of missing data (BAC)
4. Modeling of risk

5. Other predictor variables? Location? Time of day? Time of year?

6. Next steps? How do you manage this? When and where do you set up drunk driving lanes? (spatial analysis to identify hot spots?)

EXAMPLE: Maintaining fiscal health of institutions

Decision to be made:

Make the loan or not

(source: blog.pennlive.com)

Credit risk = primary financial risk in banking systems

Banks performance reflects how it selects and manages credit risk ("capital depletion through loan losses has been the proximate cause of most institution failures")

Employ credit risk ratings to:

- determine credit approval
- amount credit extended – borrower's ability to meet future debt obligations

Ref: http://www.occ.gov/publications/publications-by-type/comptrollers-handbook/rcr.pdf

Statistical aspects of the story …

1. Bank's internal risk rating systems are examined to determine if ratings are accurate
2. Sample of loans reviewed and bank ratings are compared to external evaluators
3. Examiners most concerned when banking underestimates risk

EXAMPLE: Promoting food safety

Decision to be made: Issue seafood consumption advisory?

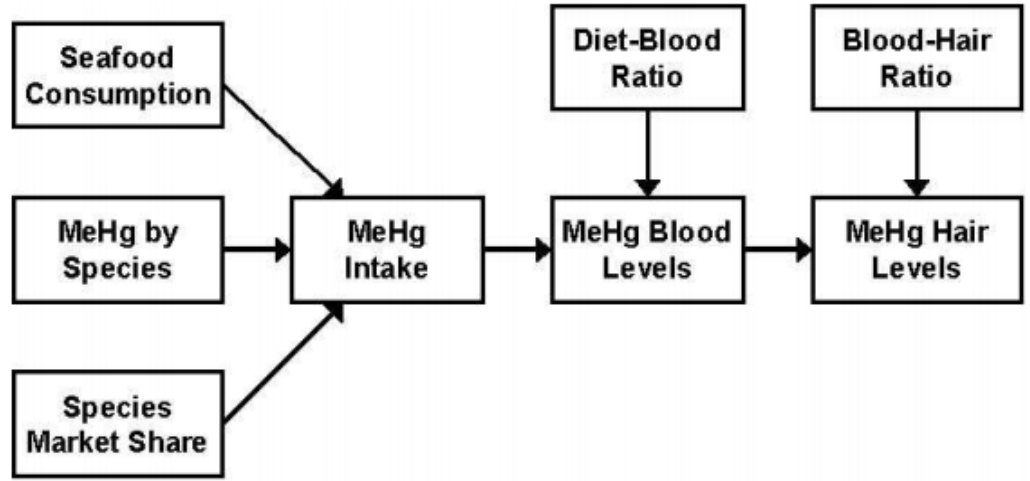
(photo: www.lakeplacid.com)

EXAMPLE: Promoting food safety

Decision to be made: Issue seafood consumption advisory? -

http://www.fda.gov/downloads/Food/FoodSafety/Product-SpecificInformation/Seafood/FoodbornePathogensContaminants/Methylmercury/UCM114740.pdf

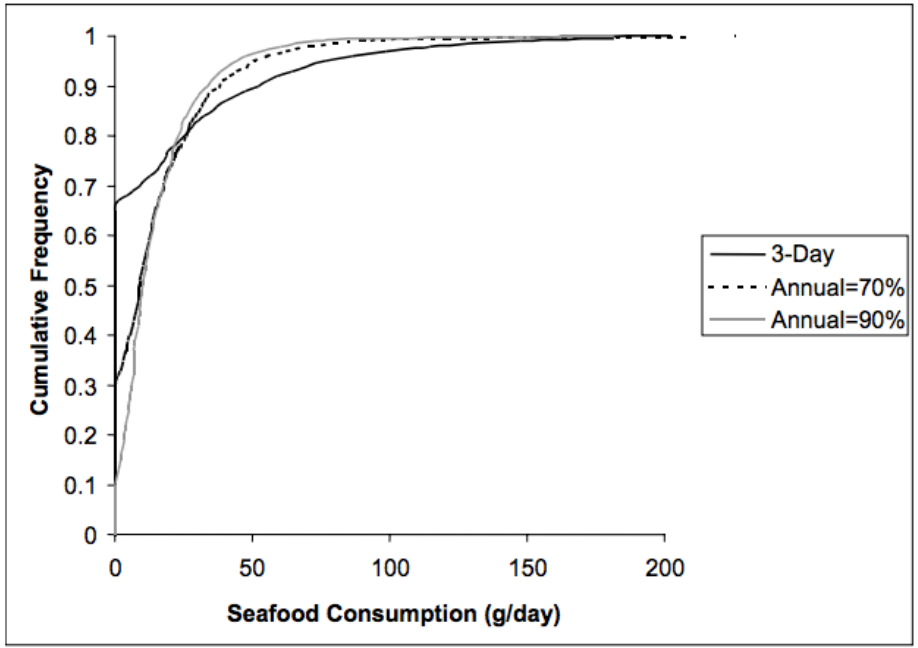
Figure 1 : Strucure of the Exposure Assessment



Simulation for characterizing ‘uncertainty distribution’

- 70%-90% consume seafood
- Per capita intake held constant

Figure 2: Adjustment for Short-term to Long-term Population Seafood Consumption



The dashed line reflects the results of a three day dietary consumption survey in which the number of adult women consuming seafood was about 33% of the total population. The other two lines represent uncertainty bounds where the number of persons consuming seafood at any time over a one year period is between 70 and 90%, with daily percapita intake held constant.

Statistical aspects of the story …

1. Distribution of the amount of mercury in each food item
2. Distribution in the amount of seafood consumed in the population
3. Derived distributions of blood mercury level compared to NHANES data
4. Guidance for industry: estimating dietary intake of substances in food
   http://www.fda.gov/food/guidancecomplianceregulatoryinformation/guidancedocuments/foodingredientsandpackaging/ucm074725.htm

Figure 2 shows the distribution of inputs for a typical Monte Carlo Simulation.

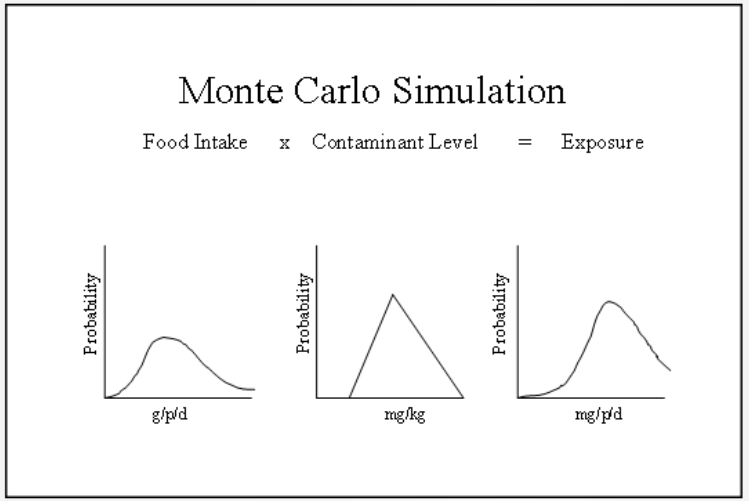


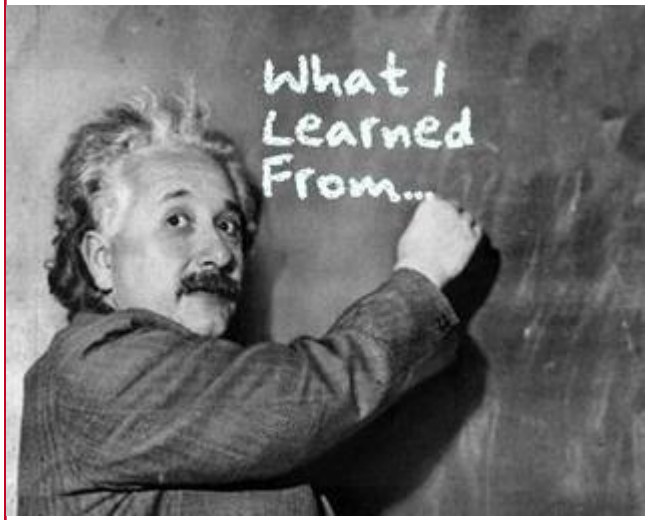
Figure 2. Monte Carlo Simulation

Checklist / questions when thinking about risks associated with particular hazards

(elements from Cohn and Cope *News and Numbers* +)

Image: blog.sparkhire.com

1. How was the hazard identified?
2. Who is exposed, how often and too how much?
    a) Sensitive subgroups?
3. What is the risk of adverse outcome associated with this hazard?
4. How was this risk determined?
    a) Risk estimates based on studying what populations? Applicability of risk-hazard model?
    b) Uncertainties?
5. What are the options for controlling this hazard? How do these options impact risk?



To recap …

1. Comparing competing options for action is important for supporting decision making/
2. Risk (probability of some adverse outcome) is a frequently used metric
3. Uncertainty – property of a decision maker
4. Variability – property of a system
5. Critical to determine the implication of uncertainty and variability on risk estimates that are reported to you (ask for ranges)

References

V. Cohn and L. Cope (2001) *News and Numbers: A Guide to Reporting Statistical Claims and Controversies in Health and Other Fi*elds. 2nd Ed. Wiley-Blackwell. (newer edition with D. Cohn Runkle published in 2011)

Bailer A.J. and Bailar J.C. (2009) Risk Assessment. In J.C. Bailar and D.C. Hoaglin (Eds): *Medical Uses of Statistics*, 3rd Edition.

NAS/NRC reports

✓Risk Assessment in the Federal Government: Managing the Process (1983)
✓Issues in Risk Assessment (1993)
✓Science and Judgment in Risk Assessment (1994)
✓Scientific Review of the Proposed Risk Assessment Bulletin from the Office of Management and Budget (2007)
✓Science and Decisions: Advancing Risk Assessment (2009)

Cool web sites that you might be interested in exploring …

http://understandinguncertainty.org/files/090409-CARR-communication.pdf
http://plus.maths.org/content/113-chance-death
http://plus.maths.org/content/os/issue55/features/risk/index

http://understandinguncertainty.org/files/animations/Micromorts/Micromorts.html
http://understandinguncertainty.org/node/622

http://www.deathriskrankings.com/tutorial2.aspx

Thank you for your interest

(and for your work in Washington!)

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APPENDIX: How topics from previous "Stats for Staffers" connect with today's session [see http://www.amstat.org/policy/statsforstaffers.cfm for slides from previous SfS sessions]

1. "How sound are the data" – Mary Foulkes
   * Stat = discipline of drawing conclusion from data/science of uncertainty/basis of policy making** {** == relates to today's talk }
   * relative risk vs. absolute risks (value of screening mammography) **
   * Types of study design
   * Types of errors**
2. "Seeing through statistical studies" – Jessica Utts
   * Relationships (real or by chance) **
   * risk, relative risk and increased risk **
   * Confusion of the inverse – **

     Pr(disease GIVEN positive test) vs. Pr(positive test GIVEN disease)

Stats for Staffers (continued)

3. "Connecting the dots: statistics, causality and policy" – Frank Yoon
   * Stat = discipline that concerns itself with the study of the nature of data
   * Associations = described by stat models
   * Evaluating evidence **
4. "Regression analysis" – Michael Costello
   * Describing relationship between predictor variables and some response **
5. "Survey and polls: what contributes to quality and cost" – Michael Larsen
   * Steps in survey
   * Sampling variability / non-sampling errors **