Risk assessment / risk communication

- Frumkin H [Ed.] (2010) Environmental Health: From Global to Local, 2nd Ed. Chapter 29 "Risk Assessment" pp.1037-62, Chapter 31 "Risk Communication" pp. 1099-1140.
- Risk Assessment
  - Hazard identification + dose-response assessment + exposure assessment + risk characterization
  - Dose-response <- animal experiment + statistical model
  - De minimis risk: risk management concept
  - Interdisciplinary new techniques: CVM, CRA, etc.
- Risk Communication (no time to explain today)
  - Two-way exchange of information about environmental, health, and safety threats
  - Core public health function to inform the public, achieve behavioral change, provide warnings of disasters and emergencies
  - Applicable to emergency situation
  - Practiced by governmental agencies, NGO, private sector
  - Based on an understanding of the determinants of risk perception
- Reference web pages for risk communication
  - http://fshn.ifas.ufl.edu/seafood/sst/27thAnn/SP05.pdf
  - http://www.ecdc.europa.eu/en/publications/publications/risk-communication-literary-review-jan-2013.pdf

What is risk assessment?

- The process of identifying and evaluating adverse events that could occur in defined scenarios
  - Scenarios must be defined, including many events
  - Major assessors: (1) What can happen? (2) How likely is it to happen? (3) What are the consequences if it does happen?
  - In environmental health settings: risk assessors focus on "health impacts" <- exposure to a particular agent / working in, living in, or visiting a particular environment
    - For instance, assessment of drinking water with chemical or microbial contaminants, or of eating fish contaminated with mercury or PCBs
  - Environmental health risk assessment: quantitative framework for evaluating and combining evidence from toxicology, epidemiology and other disciplines -> decision making
- Risk assessment does not generate new evidence, but synthesize existing scientific information to address specific regulatory or policy issues.

Process

- Example: chloroform (as a by-product of water chlorination to sterilize) ingestion at average concentration of 1 to 90 µg/L in USA drinking water systems. Water chlorination is very effective to eliminate cholera and other waterborne diseases. Exposure to chloroform may increase cancer.
- In 1970s, the impossibility of "zero-risk" has been realized. -> determination of acceptable limits for concentrations of pollutants in air, water, soil, biota and in emissions.
- In 1983, NRC report "Risk Assessment in the Federal Government" (a.k.a. Red Book) divided it into 4 elements
  - hazard identification
  - dose-response assessment
  - exposure assessment
  - risk characterization

Hazard identification

- Identifying and selecting environmental agents and health effects for assessment
  - causal inference for particular health outcomes <- strength of toxicological/epidemiological evidences
  - single agent / single health effect -> straightforward
  - broad inquiry for multiple agents / multiple health effects -> selection of key agents / most important health effects
    - In 1970s, widespread concern with the potential contribution of environmental pollution rising cancer rates -> assessments focused on cancer
    - High level chloroform in drinking water can cause cancer in lab. animals (EPA, 2001). The slight increases of bladder, rectal, colon cancer were observed in humans who drink chlorinated drinking water <- many epidemiological studies, but unclear whether it was caused by chloroform or not.
    - fish with low level chemical contaminants is another example
- IARC (International Agency for Research on Cancer) published more than 90 monographs and classified agents into several weight of evidence categories (Group 1, Group 2A, Group 2B, Group 3, Group 4)

Dose-response Assessment

- Attempts to describe the quantitative relationship between exposure and disease
  - Direct evidence -> mathematical dose-response model is unnecessary: Rare case
  - Usually no direct evidence -> relying on mathematical models
  - Mathematical models may also be used to adjust effect estimates for differences in species, gender, race, ... (confounders)
- The most famous dose-response model for cancer "Linearized Multistage Model": Assuming every molecule of exposure adds more risk to cancer
  - "Threshold model" assumes that nobody exposed at a level below a critical threshold dose will develop cancer as the result of exposure

Example of dose-response assessment

- Carcinogenic effects of chloroform on male rats
  - Haas1994 <- data.frame(dose = c(0, 19, 38, 81, 160), tested = c(301, 313, 148, 48, 50), kidneytumor = c(4, 4, 4, 3, 7), proportion = c(0.013, 0.013, 0.027, 0.063, 0.140))
  - plot(proportion ~ dose, data=Haas1994, type="b")
  - fit <- glm(cbind(kidneytumor, tested-kidneytumor)~dose, data=Haas1994, family=binomial)
  - # Logistic regression
  - summary(fit)
  - exp(coef(fit)[2])
- Then we can get the estimate of odds ratio as 1.016, whereas the Haas (1994) estimated 0.00011 (/mg/kg/day) cancer risk added for lifetime based on 2 stage model.

Exposure assessment

- Estimation/measurement of the following aspects of human exposures to the agent of concern (NRC, 1994)
  - magnitude
  - duration
  - timing
- Often quite difficult, especially in the case of time-varying behavior such as the frequency and amounts of water consumption, origins of soil and dust unintentionally to ingest or to inhale
- Full profile of each individual's exposures over time is ideal, but usually unavailable. Usually using time-averaged exposure rates, especially media contact rates
  - Chloroform in drinking water (> 90µg/L): drinking water ingestion + skin absorption and inhalation in bathing, ...
  - EPA assume that an adult drinks 2L water: if the one's body weight is 70kg, the exposure is 2 x 90 / 70 = 2.6 µg/kg/day.

Risk characterization: The final step

- Combining the information from the other 3 steps to estimate the level of response for the identified health effects at the specific level of exposure
- Terms to estimate
  - relative risk: P(d)/P(0)
  - additional risk (absolute risk): P(d)-P(0)
  - attributable risk (excess risk): (P(d)-P(0))/(1-P(0))
- Chloroform: 0.0026 mg/kg/day x 0.00011 (/mg/kg/day) = 3 in 100 million.
- The Red Book emphasize the uncertainties with this step.
  - Qualitative uncertainties: carcinogenicity of low exposure
  - Quantitative uncertainties: the shape of dose-response model. Including the control (zero dose) data makes the estimate interpolated, not extrapolated

Risk management

- Chloroform in drinking water causes 3 in 100 million kidney cancer.
  - 38% in women and 46% in men were killed by cancer in USA
  - "3 in 100 million" is a drop in the bucket, so that nobody would care such a drop
- What should a risk manager do?
  - "de minimis risk" concept
  - risk-benefit analysis
  - cost-benefit analysis
    - contingency valuation method (CVM) or comparative risk assessment (CRA) should also be applied
  - decision analysis or alternative analysis
  - paying attention to the "precautionary principle"
- "Grey Book" (2008) ~ "Science and decisions: Advancing risk assessment" by U.S. EPA's landmark report.