Challenges of Communicating Risks

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July 11, 2005

Webster's Defines "Risk"

- A dangerous element or factor
- Possibility of loss or injury
- The degree of probability of such loss

Understanding Risk

- Concept embodies 2 distinct notions
  - An unwanted outcome
  - Uncertainty about its occurrence
- To articulate requires combining
  - Objective information
  - Subjective interpretation

Objectives

- Discuss 5 basic elements of risk
- Review general approaches to communicating risk
- Review factors influencing risk interpretation and perception

- *Focus on risk, but could easily apply same concepts to benefit, which most people like much better!*

5 Key Elements of Risk

- Identification
- Permanence
- Timing
- Probability
- Value (subjective badness)

Elements of Risk: Identification

- Identification of risk to the patient is first task of physician, regulator, company
  - Kalet (1994) audiotaped 160 patient visits to 19 community-based physicians
    - Risk NOT routinely discussed
  - Patients scheduled for angioplasty interviewed day before procedure
    - 46% recalled one or more possible risks
    - 25% had not yet had discussion with doctor
    - 67% wanted major role in determining acceptability of risk

Elements of Risk: Permanence

- Is the outcome temporary or permanent?
- Not always clear
  - Low birth weight is a temporary state, but may have longer term consequences
  - Incontinence or impotence after radical prostatectomy

Elements of Risk: Timing

- When will the untoward outcome occur?
  - Immediate
    - MI, bleeding, anaphylaxis
  - Delayed
    - Liver toxicity, cancer, potential interaction with future meds
- How does this risk look in light of potential benefit NOW?

Elements of Risk: Probability

- How likely is the unwanted outcome?
- Often not clear
- Usually only population derived numbers are available.
  - Patient cares about n=1
  - Hard to apply clinical trial or population data to the individual patient

Elements of Risk: Value

- How much does an untoward outcome matter to the patient?
  - Patients differ greatly on how they rate adverse outcomes
  - May be influenced by degree of discomfort or impairment underlying need for treatment
    - Impotence may seem minor when staring at a cancer diagnosis, but to others it is a critical choice in deciding treatment

Getting all of this to patients

- Which risks should be highlighted?
- How should risks be communicated, regardless of venue or who is communicating?

Challenges in Risk Communication

- Breadth of users and needs
  - Doctors, patients, counselors
  - Prescribing, comparing drugs
- Reasonable person standard
  - What would a reasonable person want to know?
- Expertise in communication often lacking among scientists & regulators

Challenges of Risk Communication

- Framing Effect
- Qualitative information versus quantitative
- Finding the best quantitative expressions
- Common interpretation errors

Framing Effect

- How risk and benefit are presented can influence patient decision making
- McNeil (New Eng J Med, 1982)
  - Patients are more likely to choose surgery over radiation for lung cancer when surgery outcomes are framed as “probability of survival” versus “probability of death”

Qualitative versus Quantitative

- How should outcome data be presented?
- Qualitative expressions are often more "accessible" to consumers or patients
  - Lack accepted anchoring at specific levels of frequency
    - *The risk of aplastic anemia is 3 per 100,000 patient years*
    - *The risk of aplastic anemia is low*

Best quantitative expression?

- Percentage
- Relative risk
- Attributable risk
- Number needed to treat or harm
- Range of confidence interval

Best quantitative expression?
(continued)

- Important when comparing drugs and attempting label consistency
- Public does not have clear understanding of meaning of terms
- Physicians do not distinguish well between different quantitative terms

Patient Preferences

- Mazur (J Gen Intern Med 1991) studies patient preferences
  - Like numeric only 32%
  - Like words only 35%
  - Either words or numbers 22%
  - Like to have both 8%

Physician Action

- Forrow et al (Am J Med 1992)
  - Almost half (49%) of physicians were more likely to treat high cholesterol when outcomes of treatment were expressed as relative risk reduction instead of absolute risk reduction.

Interpretation of Facts

- No matter how well the facts about a risk are laid out, their interpretation may not be correct
  - Anchoring bias
  - Availability bias
  - Compression
  - Miscalibration

Interpretation Errors

- Anchoring bias
  - Estimation of risk based on risk of related events or procedures familiar to the patient (e.g., my father had that happen)
- Availability bias
  - Patient overestimates risk that has had much public notoriety (e.g., breast cancer, birth defects)

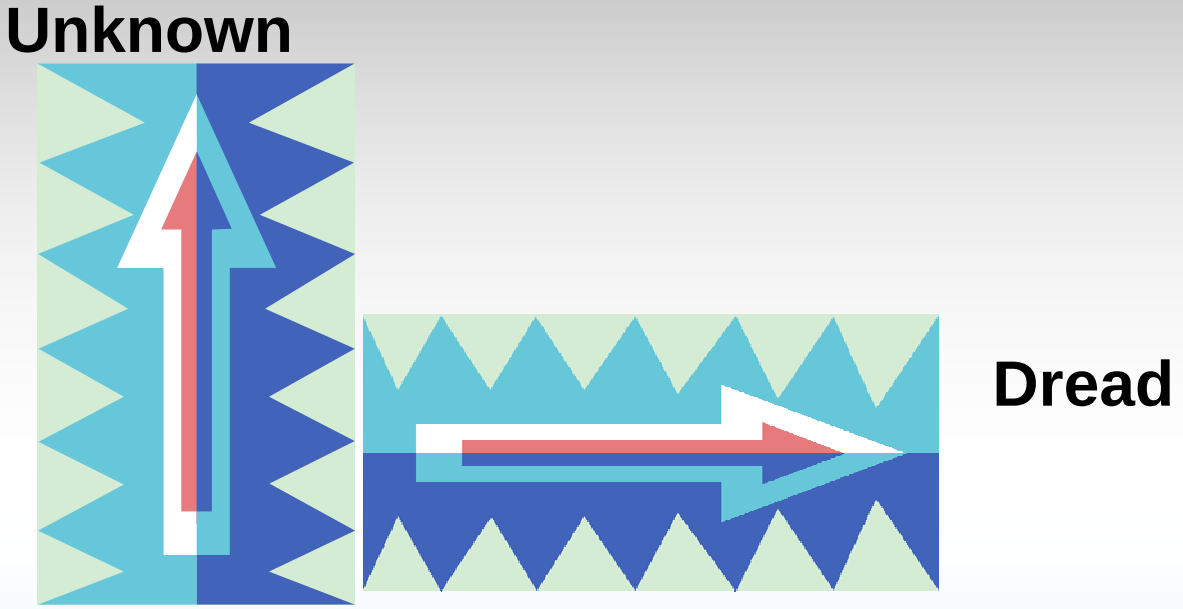
Interpretation Errors continued

- Compression
  - Overestimating small risks and underestimating big risks, often depending on perceptions
- Miscalculation
  - Simply overestimating or underestimating because of misinterpretation of the facts or numbers

Risk Perception:
Numbers, Interpretation and Feeling

- Paul Slovic, PhD (Science 1987)
- Axes of Risk Perception are related to outcome of exposure to an individual risk
  - Axis of Dread
    - Lack of control; catastrophic potential; fatality
  - Axis of Unknown
    - Some new, unanticipated outcome; delayed manifestation of harm

Axes of Risk Perception Intersect



Perception varies by who you are

Slovic, 1980s and 1990s

Scientific Experts

- Judge risk according to numbers or numeric estimations

Patients

- Judge risk according to the degree to which they dread the untoward outcome

Physicians

- More like patients than scientific experts

Summary

- Determining of risk is hard, but communication is often more difficult
- No one best method for communication
- Interpretation errors must be anticipated and guarded against
- Perception critical to understanding impact of any risk on population

Challenge for FDA

- How to provide information to effectively communicate nature, degree and probability of a potential untoward event:
  - To meet a variety of audiences and needs
  - Concisely
  - Understandably
  - In an accessible format
  - In a way that articulates uncertainties
  - All in the light of dread over possible outcomes