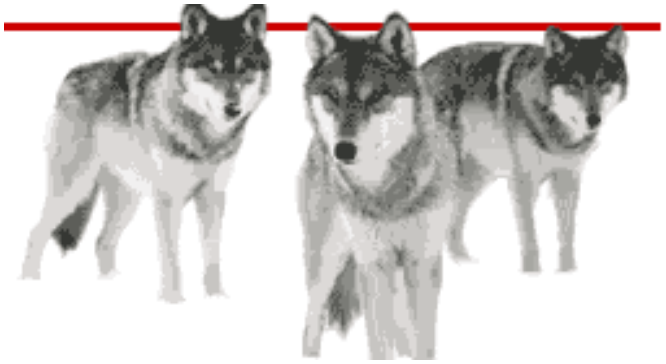

On Testing the Effectiveness of Risk Communications

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Introduction

- Medicines help, but also can harm
- Concerns for safety and health
- FDA reg: "safe and effective”
- Labeling is part of product
- Info is needed because hazards are not obvious

- **Assessment of labeling**
  - **Not just for defects, but does it enable safe use**
    - **Regulations**
    - **FDA advisements**
    - **Guidelines on warning design**
      - **(e.g., ANSI Z535, 1998)**
    - **User testing**

- **FDA Code of Federal Regulations 21 CFR 330.10 Paragraph A4(v):**
  - **Labeling shall be clear and truthful in all respects and may not be false or misleading in any particular. It shall state the intended uses and results of the product; adequate directions for proper use; and warning against unsafe use, side effects, and adverse reactions *in such terms as to render them likely to be read and understood by the ordinary individual including individuals of low comprehension under customary conditions of purchase and use.***

- **Complicated process because people are involved**
- **Different characteristics**
  - **e.g., age, literacy, education, & culture**
- **Different moods, illnesses, distraction**
- **Different tasks, situations, environs**

- **Test target users**
  - **Not commonly done**
- **Marketing**
  - **Different goal: Sell more product**
  - **Techniques, e.g., focus groups**
- **Consumer input is critical**

- Might already have indications that risk communications are not working
- Need to verify that info given is understood as intended
- Can people find the information they need quickly and easily

- NEED Quantitative Measurement

- **Usability testing**
  - **from Human Factors / Cognitive Ergonomics / Human-Computer Interaction**
  - **Initially, design early prototypes based on FDA regs & label design guidelines**
  - **Iterative Design and Test**
    - **Repeat: Redesign (fix label based on feedback) & retest:**
    - **Fast prototyping: quick evaluation / quick evolution**
    - **Sequence of small numbers of participants**
    - **Finally, test with large sample to support near-final choices**

- **Communication-Human Information Processing (C-HIP) Model**
  - Source (Manufacturer, FDA, other)
  - Channel (Different senses, modalities and media)
  - Receiver (Target/User: Health professional vs. end user)
- **Within the Receiver**
  - Attention getting (e.g., prominence)
  - Attention holding (e.g., legibility)
  - Comprehension / Knowledge / Beliefs (formation of a valid mental model)
  - Motivation / Behavior (Does behavior change?)

- **Different kinds of testing**
- **Different methods for different levels**
  - **Prominence:** e.g., reduced time to find information
  - **Legibility:** Can they read it?
  - **Completeness:** e.g., expert assessment, prioritization, expanded surface area
  - **Understandability:** Are questions answered correctly?
  - **Change attitudes and beliefs:** e.g., risk/hazard rating scales
  - **Motivate correct behavior** (display appropriate actions)
- **Monitor post-sale: adverse effects**
  - **Modify label**

- **Example tests**
  - **Ask participant a question and then measure time to find information**
    - **Fast, accurate answers indicate better labeling**
  - **Have participants do an incidental exposure task with the product**
    - **e.g., tell them to take pills from bottle and place in daily organizer in some manner (or any other task in which they handle the product but are not told before hand that they would be asked questions about the label later). Afterwards, without the bottle present, ask them questions about the label (e.g., what they remember). This provides data on what people glean from incidental exposure to the label**

- **Benefit of testing**
  - Increased safety
  - Fewer lawsuits
  - Testing is less expensive than litigation
  - Data to support validity of label
  - Face validity
  - Labels look good compared to other labels
  - Enhance jury's belief that the plaintiff had a good opportunity to acquire information
- **Doing the minimum is probably not good enough**