

Guide to Evidence-Based Risk and Benefit Communication

Baruch Fischhoff
Carnegie Mellon University

White Oak, MD
August 16, 2011

Risk Communication Advisory Committee

Formal roles (under FDAAA of 2007)
permanent committee
specific charges (recalls, DTC ...)
general consultation resource

Informal roles

channel to science
research seminars
recommendations

Evidence-Based Communication

FDA RCAC Meetings

Feb 2008 Briefings, food recalls

May 2008 DTC advertising

Aug 2008 Science of communication

Feb 2009 Consumer medication information

April 2009 FDA Strategic Plan

Aug 2009 Food recalls (2)

Nov 2009 Tobacco, ClinicalTrials.gov, emerging events

Feb 2010 Communication guidelines, updates/warnings

April 2010 Science forum

Nov 2010 Food recalls (3), in-home medical devices

May 2011 Social media

FDA RCAC Meetings

Feb 2008 Briefings, food recalls

May 2008 DTC advertising

Aug 2008 **Science of communication**

Feb 2009 Consumer medication information

April 2009 FDA Strategic Plan

Aug 2009 Food recalls (2)

Nov 2009 Tobacco, ClinicalTrials.gov, emerging events

Feb 2010 Communication guidelines, updates/warnings

April 2010 **Science forum**

Nov 2010 Food recalls (3), in-home medical devices

May 2011 Social media

Formal Recommendations

Consumer medication information (Feb 09)
Strategic risk communication plan (Apr 09)
Emerging events (Aug 09)

<http://www.fda.gov/oc/advisory/OCRCACACpg.html>

FDA RCAC Meetings

Feb 2008 Briefings, food recalls

May 2008 DTC advertising

Aug 2008 Science of communication

Feb 2009 **Consumer medication information**

April 2009 **FDA Strategic Plan**

Aug 2009 Food recalls (2)

Nov 2009 Tobacco, ClinicalTrials.gov, **emerging events**

Feb 2010 Communication guidelines, updates/warnings

April 2010 Science forum

Nov 2010 Food recalls (3), in-home medical devices

May 2011 Social media

FDA RCAC Meetings

Feb 2008 Briefings, food recalls

May 2008 DTC advertising

Aug 2008 Science of communication

Feb 2009 Usefulness of CMI

April 2009 FDA Strategic Plan

Aug 2009 Food recalls (2)

Nov 2009 Tobacco, ClinicalTrials.gov, emerging events

Feb 2010 Communication guidelines, updates/warnings

April 2010 Science forum

Nov 2010 Food recalls (3), in-home medical devices

Goals

Make communication science accessible
Facilitate evidence-based approaches
Enhance human capital of agency staff

From Evidence to Practice

What does the science say?

What does the science mean?

(best guesses for communication)

How can you tell how well you've done?

(how good are your best guesses?)

Topics (1)

Strategy

Goals

Evaluation

Adequacy

Defining “risk” and “benefit”

Language/framing

Kinds of Information

Quantitative

Qualitative

Warnings and disclosures

Persuasion

Topics (2)

Audiences

Low literacy (readability)

Emotion

Life-span (young, old)

Underserved

Professionals

Media

Decision aids

Mass media

Design (packages, devices)

Training/organization

Thanks!

Nancy Derr
Jan Elieker
Elena Ketelhut
Erica Munoz
and others
and FDA

Thanks!

Nancy Derr
Jan Elieker
Elena Ketelhut
Erica Munoz
and others
and FDA
and Lee Zwanziger

Chapter 3

Evaluation

Research is always needed because

We can't trust our intuitions.

Basic behavioral research is indeterminate.

Faulty Intuitions

common knowledge effect

false consensus effect

fundamental attribution error

self-serving biases

myths (panic, adolescents' unique sense
of invulnerability, ...)

poor feedback (absent, distorted,
delayed)

...

Basic Research Is Indeterminate

Decision making follows simple principles.

Basic Research Is Indeterminate

Decision making follows simple principles.

However,

- the set of principles is large,

- the contextual triggers are subtle, and

- the interactions are complex

As a result, decision-specific research is needed.

Some Principles of Judgment

People are good at tracking what they see,
but not at detecting sample bias.

People have limited ability to evaluate the
extent of their own knowledge.

People have difficulty imagining themselves
in other visceral states.

People have difficulty projecting non-
linear trends.

People confuse ignorance and stupidity.

Some Principles of Choice

People dislike uncertainty,
but can live with it.

People consider the return on their
investment in making decisions.

People are insensitive to opportunity costs.

People are prisoners to sunk costs,
hating to recognize losses.

People may not know what they want,
especially with novel questions.

**As a result,
empirical research is essential.**

Without scientifically sound data collection, one can only guess what people believe and want in any specific situation

Forms of Evaluation Research

Formative: alternative strategies

Process: fidelity of implementation

Outcome: impacts

Table. Outcome evaluation research designs

Design type	Factors to consider
Randomized controlled trials	Highest quality design for outcome evaluation
	Can definitively establish causality
	Can assess mediators to demonstrate process
Observation of environmental changes	Useful when external validity is especially important
	Gradual, long-term changes
	Inclusion of yoked control population raises confidence in results
Limited comparisons (pre- versus post-communication)	Can be done with very small budget
	Partial support of causality, if other factors are well controlled
	Better than nothing, if measures are well designed

Chapter 4

Adequacy

A communication is adequate, if...

- it has the information the people need for effective decision making
- people can access that information
- people can comprehend what they access

A materiality standard for communication content

A communication is adequate if it contains any information that might affect a significant fraction of users' choices.

A proximity standard for information accessibility

A communication is adequate if it puts most users within X degrees of separation from the needed information, given their normal search patterns.

A comprehensibility standard for user understanding

A communication is adequate if most users can extract enough information to make sound choices.

Policy Judgments

A communication is adequate if it contains any information that might **affect** a **significant fraction** of **users'** choices.

A communication is adequate if it puts **most** users within **X degrees of separation** from the needed information, given their normal search patterns

A communication is adequate if most users can extract enough information to make **sound choices**.

Chapter 6

Defining “Risk” and “Benefit”

What Does the Science Say?

People exaggerate how well they know what matters to others.

People may not know what they want.

Values are sometimes embedded in how choices are defined.

Defining “Risk of Death”

probability of premature death

vs.

expected life-year lost

Defining “Risk of Death”

probability of premature death

vs.

expected life-year lost

The choice of measure depends on whether a death is a death or one values deaths of young people more.

Other Possible Bases for Distinguishing among Deaths

Are the risks distributed equitably?

Are the risks assumed voluntarily?

Are the risks catastrophic?

Are the risks well understood?

Are the risks controllable?

Are the risks dreaded?

Are the risks borne by future generations?

...

What Practical Advice Does the Science Support?

Use standard definitions, based on
normative research – examining choices
facing audience, informed by subject
matter research
descriptive research – examining existing
beliefs and values
prescriptive research – evaluating
interventions

Evaluation

No expense: face validity

Low expense: think-aloud interviews

comprehensibility

bias

completeness

Modest expense: construct validity

Chapter 8

Qualitative Information

Qualitative Information:

What do we know about how risks and benefits created and controlled?

Allows understanding and evaluating quantitative claims.

Affords warranted self-efficacy.

Demonstrates experts' respect for lay audiences.

What Does the Science Say?

Qualitative information varies in importance.
People rely on mental models.
Some processes are unintuitive.
Some terms trigger inappropriate models.

What Practical Advice Does the Science Support?

Step 1. Identify main factors affecting risks and benefits in a formal model.

Step 2. Characterize existing beliefs in terms comparable to model.

Step 3. Draft, test, retest communications closing critical gaps.

Evaluation

No expense: ask a few people to read drafts
Low expense: analyze cognitive interviews
Modest expense: create structured survey,
apply before and after

Goals

Make communication science accessible
Facilitate evidence-based approaches
Enhance human capital of agency staff